Rationalisation of primary hip replacement using evidence from linked national databases

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RATIONALISATION OF PRIMARY HIP REPLACEMENT USING EVIDENCE FROM LINKED NATIONAL DATABASES

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Summary

End-stage osteoarthritis of the hip can be treated effectively with hip replacement. Many implant brands are available with multiple component options including different methods of fixation, femoral head size and articulating surface materials. The costs of these implant components vary dramatically. Surgical outcome can be assessed variously by functional and quality of life scores, risk of failure over time requiring revision surgery, post-operative mortality and complications (such as wound infections), and readmission to hospital. Patient expectation, perception of success and the satisfaction with surgery are also important metrics. Surgeon and patient characteristics may influence these outcomes.

Health systems under considerable financial pressure are confronted with an aging population with increasing need for joint replacement surgery. In response, efficient, rationalised provision of services is required. The most cost-effective procedures combine the best implant survival rates (and hence the fewest revisions) and patient outcomes with the lowest mortality, complications and costs.

To establish the benefits and relative performance of different hip implants, large patient numbers and long term follow-up are required, limiting the use of experimental studies. Joint registries and other large collections of data play a pivotal role in providing evidence of efficacy, although careful statistical analysis is required to ensure findings are robust. Through a series of examples, this thesis illustrates the potential of such analyses to appropriately inform patient care and explores the issues surrounding the use of these large datasets.

Despite a global trend favouring cementless implants, hard bearings and larger head sizes, a cemented hip replacement with a taper slip stem, a metal-on-polyethylene bearing and a 28mm head offers equivalent or better outcomes for the vast majority of patients. Cost data from the NHS suggest these implants are also the cheapest to purchase. Young females have marginally better functional outcomes following cementless or hybrid replacement, but clinically this may not be important, and costs are higher. Standardisation of hip replacement type across all patients is likely to improve outcome, reduce error and enhance training.

The posterior approach provides a marginally better functional outcome compared with the direct lateral approach. Patients with a high BMI have greater risks of complications with only slightly poorer improvement in function. Implant characteristics appear to have little or no influence on patient outcomes. Interpretation of outcome measures is complex, requiring a greater understanding of the interactions between surgical and patient factors.

This thesis provides evidence to inform decision-making by surgeons, professional bodies and healthcare providers when offering hip replacement to patients with osteoarthritis.

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Statement of copyright

Acknowledgements

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Figures and tables from the NJR 9th Annual Report have been reproduced with permission from the NJR Research Committee.

Conflicts of interest

The NJR for England and Wales is funded through a levy raised on the sale of hip and knee replacement implants. The NJR Steering Committee sets the cost of the levy and is responsible for data collection. This work was funded by a fellowship from the NJR. The author has conformed to the NJR's standard protocol for data access and publication. The views expressed represent those of the author and do not necessarily reflect those of the NJR Steering committee or HQIP who do not vouch for how the information is presented.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this body of work.

Ethics

Explicit patient consent was taken for both the NJR and patient reported outcome measures (PROMs) at the time of data collection. Further ethical approval was not required for this study.

1. Introduction

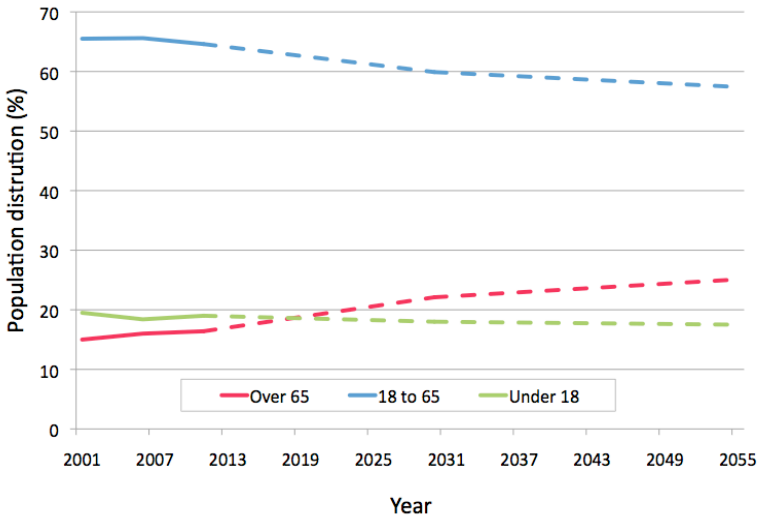
Overview

In this introductory chapter, osteoarthritis of the hip and the treatment options are described. In particular, the different surgical implant options available to the hip replacement surgeon are introduced, together with current patterns of use in the United Kingdom (UK), as well as evidence supporting current use. The recently introduced national patient reported outcome measures (PROMs), which provide joint specific and quality of life scores for patients undergoing surgery, are described. Finally, statistical methods for analyzing and comparing large datasets are introduced and explained since the use of appropriate methods is crucial for the analysis of large datasets.

Osteoarthritis

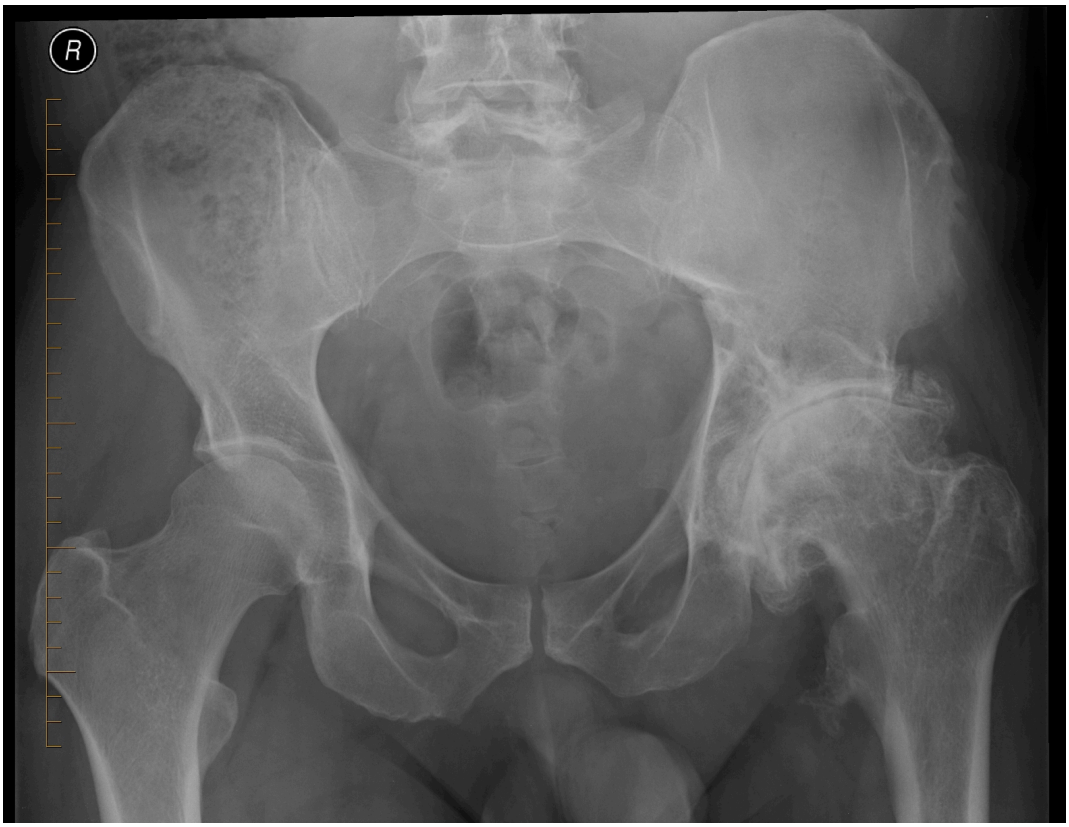
Arthritis (from Greek arthro-, joint + -itis, inflammation) is a joint disorder that involves inflammation of one or more joints [1]. There are many different forms; the most common is osteoarthritis (OA, degenerative joint disease), which occurs predominantly with increasing age, but can also be precipitated by physically demanding occupations (e.g. farming), developmental disorders (e.g. development dysplasia of the hip), trauma to the joint (e.g. meniscal tear in the knee) or rarely a previous joint infection. The vast majority of patients with OA are aged over 50 years. OA affects about 8 million people in the United Kingdom [1] and nearly 27 million people in the United States, where it is the leading cause of chronic disability [2]. Projections for a shift in age distribution within the population over the next 50 years suggest this burden is likely to increase dramatically (**Figure 1.1**) [3]. Other forms of arthritis include rheumatoid arthritis, psoriatic arthritis and septic arthritis (joint infection).

Figure 1.1. Projected population distribution by age, England and Wales (2001 to 2056)



Osteoarthritis can affect both large and small joints, but typically affects the weight bearing joints such as those in the spine, the hip and knee. This mechanical damage begins with the loss of the protective cartilage and eventually leads to joint erosion by the two opposing bones grinding against each other and creating hard (sclerotic) bone interspersed with areas of weakness (bone cysts). Radiographic investigation of a patient with hip joint OA reveals four classical signs; joint space narrowing, subchondral sclerosis, bone cysts and osteophyte (abnormal bone growth) formation around the joint periphery (**Figure 1.2**).

Figure 1.2. Antero-posterior pelvic radiograph showing left hip OA (normal right hip)



Hip OA is characterized by intermittent pain usually felt in the groin while walking, often progressing to constant severe pain, disturbance of sleep and decreasing quality of life. Other symptoms include joint stiffness and a reduction in mobility. Simple daily activities can become difficult or impossible without assistance, and the condition ultimately leaves the patient disabled. Pain from OA occurs as a result of movement at the exposed bone-bone interface, peri-articular soft tissue damage, and weakened muscles attempting movement against stiff, painful joints. Patients may also experience pain at rest and night pain, impacting upon sleep patterns. A patient with OA expends more energy for a given exercise when compared with a person without OA, resulting in early fatigue. As a result of decreased movement secondary to pain, local muscle bulk is reduced and ligaments degenerate.

In the UK, around 9% of females and 6% of males over 65 years old consult their general practitioner at least annually with OA and around 20% of the population over 65 years have radiographic evidence of hip OA [1].

Treatment options for osteoarthritis of the hip

In the early 20th century there were few treatment options for hip OA. Analgesia was primitive and little was known of the benefits of physiotherapy. The most commonly performed surgical treatments for severe, disabling disease were excision arthroplasty – removal of the head of the femur bone to create space for

scar tissue to form – and interpositional arthroplasty – where soft tissue, such as muscle or tendon, were interposed between the bony surfaces of the joint in order to keep them apart. Arthrodesis, or fusion of the joint, was also performed in some patients.

Sir John Charnley pioneered modern hip replacement over 50 years ago in the UK [4]. Total hip replacement (THR) involved replacing both the acetabulum (hip socket) and the head and neck of the femur with an artificial 'ball and socket' joint in an attempt to relieve pain, to restore range of motion and to improve walking ability, leading to improved muscle strength. In the subsequent decades many different brands of THR have been used, and patient expectations have increased with improved education. Patients are encouraged to return to their desired recreational activities, including relatively low demand (e.g. golf) and low impact (e.g. swimming, cycling) sports, and the majority of patients (60%) achieve this [5]. In younger patients, some authors have suggested hip resurfacing may allow participation in more demanding activities, like downhill skiing (51%), high-impact activities (12%) and contact sports (22%) [6].

Initial management of hip arthritis involves non-operative treatments such as lifestyle changes (increasing exercise levels, weight loss), physiotherapy and progressively stronger analgesia. If pain becomes debilitating, hip replacement surgery can be used to improve the quality of life and is the mainstay of modern surgical treatment, with over 70,000 performed annually in the UK [1].

Hip replacement and resurfacing

There are many implant options available in contemporary hip surgery – design philosophy, fixation type, bearing surface materials and head size – which may affect patient outcome and implant survival. The chosen implant must perform well whilst balancing patient factors (age, sex, socio-economic status, general health, level of function and expectation) with surgeon constraints (experience, training, skills and knowledge). For the surgeon, it is crucial that he or she has a thorough understanding of current evidence and uncertainties in order to inform the most appropriate decision for a particular patient. Patients have a right to information about surgical options and to expect evidence-based care.

Design philosophy

A THR comprises femoral and acetabular components. The femoral component is made up a stem (fixed within the upper or 'proximal' part of the femoral canal), a neck, and the spherical head ('ball' of the joint). This can be either a one-piece design (monoblock) or modular, with different sized stem, neck and head components fitting together to create a patient-specific implant. The most commonly implanted femoral components have stem and head modularity. The surface finish of the components depends on the method of fixation and design philosophy.

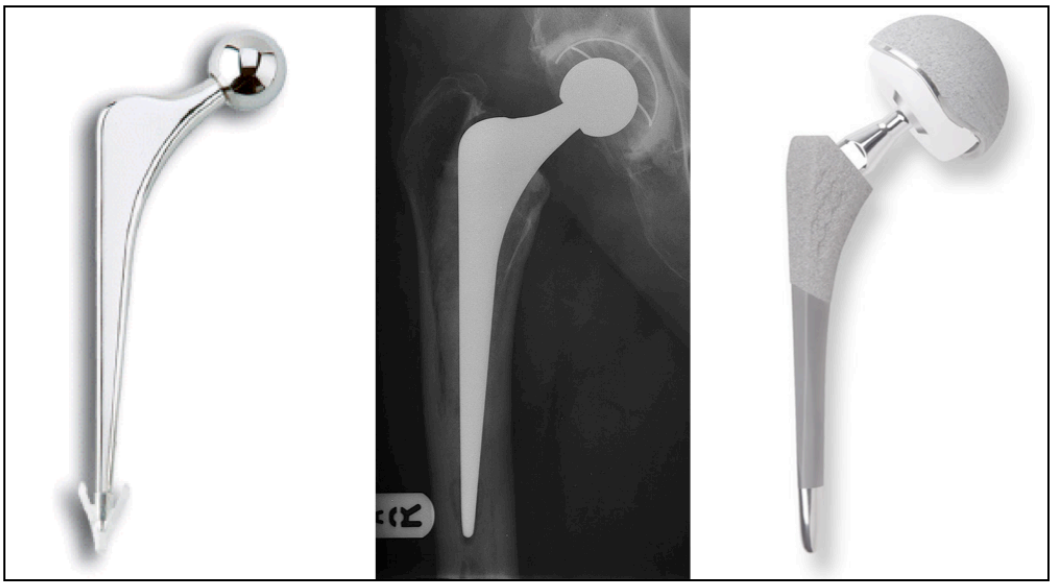
One of two principles are employed when cement is used for fixation; a polished, tapered stem (**Figure 1.3**, left image) designed to subside a few millimetres and

settle firmly in the cement mantle; or a composite beam design (which often has a roughened surface), and is designed to bind to the cement, offering rigid fixation immediately with no necessity to settle [7].

Cementless components are designed to 'press-fit' into a space created within the bone (which provides immediate rigid fixation), and have a rough, porous surface coating allowing bony in-growth to supplement stability (**Figure 1.3**, right image).

Both composite beam cemented and cementless stems may have a collar at the neck, which is designed to rest on the inner (medial) cortex of the bone (the 'calcar') to help prevent undesirable subsidence over time.

Figure 1.3. Image of a polished cemented femoral stem and head of a THR (left), radiograph of a cemented THR (middle) and image of a rough, porous coated 'cementless' THR (femoral and acetabular components shown, right)
(Images reproduced with permission from Stryker Corporation)



The cup of the hip replacement may be secured into the pelvis with or without cement. Polyethylene monoblock cups are cemented into the acetabulum (the 'socket' of the joint), with different outer sizes to match the patient's acetabular size. Cementless cups employ a press-fit method of fixation, and comprise a metal shell (usually with porous coating on the outer surface, and the option of supplementing fixation with screws into the underlying acetabular bone) and a liner (one of three material types – polyethylene, metal or ceramic), which articulates with the femoral head.

Hip resurfacing

Modern resurfacing devices were introduced in the 1990s as a potential answer to the high failure rates seen in young, active patient following standard hip replacement. A solid metal shell is employed in the acetabulum using press-fit and porous coat technology; however, as these are monoblock cups,

supplementary screws cannot be used. This socket articulates with a large spherical metal 'cap' positioned on a prepared femoral neck (most brands employing cement to hold this part of the implant in place), in order to replicate the size and shape of the patient's femoral head (**Figure 1.4**). All resurfacings have a metal-on-metal (MoM) bearing surface.

By providing a more anatomical solution, hip resurfacing was thought to reduce the risk of dislocation and improve functional outcome. When launched, benefits were perceived to be lower bearing surface wear, bone preservation (femoral neck retained, **Figure 1.5**) and greater function, resulting in an implant that could allow high levels of activity whilst prolonging the need for revision surgery. As femoral neck bone was preserved, the revision procedure was thought to be easier and less destructive [8]. The implant was marketed for younger, more active patients where longevity is essential.

Figure 1.4. Image of a resurfacing device (left) and anteroposterior pelvic radiograph of patient with bilateral hip resurfacings (right)
(Images reproduced with permission from Smith & Nephew)

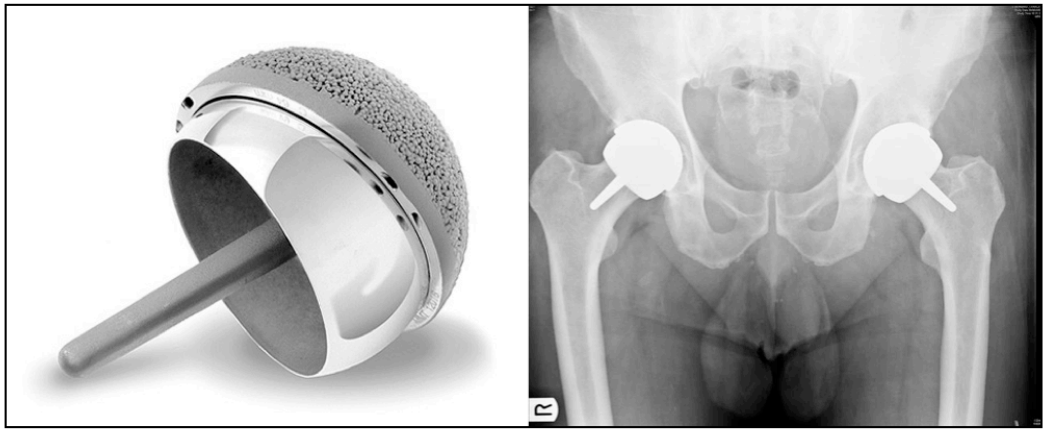
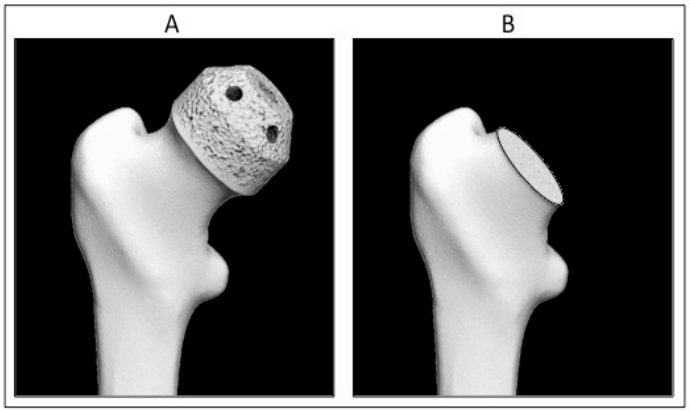


Figure 1.5. Comparison of femoral bone resection during (A) resurfacing and (B) standard hip replacement



Hip resurfacing has proven to be one of the most contentious issues in current orthopaedic practice, despite its evolution over many decades. Early resurfacing designs were flawed and had high failure rates [9, 10]. Modern resurfacing is based upon learning experiences from the Mckee-Farrar hip replacement, the successful pioneer of MoM bearing total hip replacement (THR), which provided good long-term implant survival in some patients [11]. These past design experiences, together with new innovations (improved manufacturing tolerances), led to the development of the first of the new generation of resurfacing implants, the Birmingham Hip Resurfacing (BHR, Smith and Nephew, Memphis, TN, USA). Encouraging early to mid-term results [12] for this implant prompted many manufacturers to exploit the concept and bring versions to market, each with subtly differing interpretations of the fundamental design characteristics. Excellent ten-year results for the BHR have been reported from the designers' series and from independent units [13-15]. At the peak of usage (2007) over 6000 hip resurfacings (all brands) were implanted in England and Wales annually [16]. However, there is a risk of femoral neck fracture, which does not exist after THR. There are also reports of excessive bearing surface wear leading to high circulating cobalt and chromium metal ion levels in the blood, local soft tissue reactions possibly attributable to wear-related cellular cytotoxicity or hypersensitivity reactions (known as aseptic lymphocyte-dominated vasculitis-associated lesion, or ALVAL), inflammatory fluid collections (cysts and pseudotumours), soft tissue stripping, bone destruction, pain and disability [17-20]. Increased risk of cancers as a consequence of the high circulating cobalt and chromium blood metal ion levels has not been proven in the short-term but, as several cancers have long latency periods, concerns remain and longer-term data is required [21].

In 2010 the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK issued an alert warning of problems with MoM implants and the need for regular follow-up [22]. These recommendations include annual clinical and radiological review, blood tests (for metal ion levels in the blood) and, if symptomatic, Magnetic Resonance Imaging (MRI) of the pelvis to examine for fluid collections and soft tissue destruction. The Articular Surface Replacement (ASR) implant (DePuy, Leeds, UK) has now been withdrawn from the UK market amid concerns of high failure rates [16, 23, 24]. Although specific design characteristics associated with the ASR may be important, other brands are also thought to perform poorly [25]. Potentially, a range of surgical, patient and implant factors may contribute to the high failure rates – implant position, component size, and female gender have all been implicated [26, 27]. An analysis using NJR data found that resurfacing resulted in similar implant survival when compared to standard THR in men with large femoral heads, but inferior survival in other patient groups, particularly women [28]. Moreover, a randomised clinical trial comparing resurfacing with THR found no additional functional benefit at 12 months following surgery [29]. Despite this evidence, resurfacing implants were used in 15% of males under 60 years in England and Wales in 2011 [30].

The place of hip resurfacing in current orthopaedic practice needs to be defined more clearly. Uncertainties include the risk of revision and functional benefits relative to THR (after adjusting for other factors), the choice of resurfacing prosthesis and the patient groups most likely to benefit.

Implant fixation

There are two approaches to producing a solid construct between the implant and the bone: cemented or cementless fixation. In cemented THRs, a synthetic polymer (polymethylmethacrylate, PMMA) is used as a filler material to hold the implants in place. The dough-like PMMA ('cement') is produced after mixing constituent parts, which is then inserted into the bone cavity immediately prior to implant insertion. This gradually hardens (after around 10 minutes, depending on preparation), occupying the space between the prosthesis and the bone, preventing movement. Cemented THRs were introduced into mainstream orthopaedics in the 1960s. Primary cemented THR today is a successful operation with good medium- to long-term implant survival across all joint registries and meta-analyses of findings globally, especially in older patients [30-42].

During the late 1970s concerns were raised regarding early stem loosening, particularly in younger patients [43-47]. These concerns stimulated the development of the first cementless stems [48]. Unfortunately, several stems became associated with poor results as attempts to produce an optimum surface coating faltered [49-54]. Despite this, some cementless designs show good long-term survival [55-57].

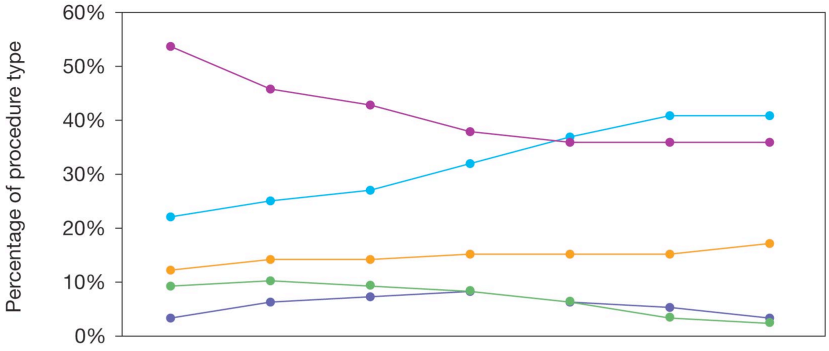
Survival analyses of cemented THRs have previously reported higher revision rates on the acetabular side [58], leading to design changes and the use of different materials in an attempt to reduce wear debris and improve long-term survival. Cementless acetabular components appear to perform well in the mid-term [30, 59], and offer the surgeon a greater range of options, such as hard-bearings and larger head sizes.

These benefits, together with contemporary data supporting the use of cemented stems, have encouraged surgeons to consider 'hybrid' THRs in younger patients [60], where the stem is cemented and the cup is cementless. When these implants were examined in patients less than 70 years using NJR data, 5-year revision rates were equivalent to cemented implants, and superior to cementless implants [61]. In addition, Australian registry data for patients aged 50 to 64 years have demonstrated superior results with hybrid implants compared to both fully cemented and fully cementless fixation [24]. In 2010, 16% of 68 907 THRs in England and Wales employed hybrid fixation [16]. Reverse hybrid, where cement is employed on the acetabular side only, is also used.

Despite their success, the use of cemented THR is declining. Cementless implants are now used in the majority of THRs in the United Kingdom (UK), Australia and the US [30, 38, 62]. In 2005, 54% of 56 350 THRs in England and Wales were cemented. However, during 2010 this had fallen to 36% of 68 907 procedures (**Figure 1.6**) [16]. There is no robust evidence for this shift in practice in older

patients, in whom the majority of hip replacements are performed. In younger patients the best type of fixation is not known, given the potentially poorer long-term results with cemented implants [43], and the lack of benefit (in terms of implant survival) of cementless and resurfacing designs [16].

Figure 1.6. Types of primary hip replacement (England and Wales, 2005 to 2011)
(Source: NJR 9th Annual report)



Year	2005	2006	2007	2008	2009	2010	2011
Cemented	54%	46%	43%	38%	36%	36%	36%
Cementless	22%	25%	27%	32%	37%	41%	41%
Hybrid	12%	14%	14%	15%	15%	15%	17%
Resurfacing	9%	10%	9%	8%	6%	3%	2%
Large head metal-on-metal (≥36mm)	3%	6%	7%	8%	6%	5%	3%
Number of procedures	56,369	59,807	66,906	70,248	70,628	72,452	71,672

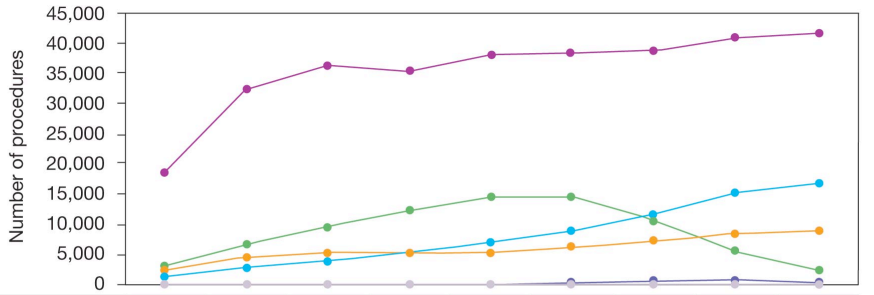
Advances in technology and engineering capability over the past 30 years have led to a proliferation of implant options available within brands. These include larger, more anatomical femoral head sizes in an attempt to reduce dislocation risk, and 'hard-on-hard' articulations, where highly engineered MoM or ceramic-on-ceramic (CoC) bearings are employed in an effort to minimise long-term wear and subsequent failure [63-65].

Bearing surface and femoral head size

Several different bearing couples have been employed for hip replacement. Charnley perfected the use of a metal (cobalt-chrome) femoral head component and a plastic (polyethylene) cup (metal-on-polyethylene, MoP). Historically MoM bearings suffered from the difficulty in machining matching pairs of components resulting in high failure rates due to excessive wear. However, during the last 25 years, MoM has become more popular, both in the emerging hip resurfacing field and in standard THRs, allowing the use of larger head sizes (32 and 36mm, compared to the traditional 28mm or smaller) because of the potential resilience to wear of metal liners (and hence their ability to be thinner). MoM resurfacing technology has also been employed in THR, with the use of larger resurfacing heads (over 36mm) on a standard stem ('large-head metal-on-metal THR', LHMoM). However, failure of these LHMoM THRs has been high [30]. Other combinations, such as ceramic-on-polyethylene (CoP) and CoC are also in use,

and are thought to offer good implant longevity because of their low wear characteristics. Manufacturing of polyethylene with cross-linked bonds ('highly cross-linked polyethylene', XLPE) improves impact and tensile strength, scratch resistance, and resistance to brittle fractures. XLPE has been introduced as an alternative to conventional polyethylene (cPE) for younger patients who require their implant to function with minimal wear for many years [66]. This also allows the use of larger diameter femoral heads for the same acetabular size (stronger PE generates less wear and so thinner walls are possible). Analyses of NJR data have so far failed to separate the performance of polyethylene types, although results of XLPE are routinely reported separately in other registries. Bearings used in England and Wales are shown in **Figure 1.7**. Despite the hope that hard bearings might offer greater longevity, mid-term revision rates are higher with CoC bearings when compared with MoP [67]. As yet unproven bearings, such as ceramic-on-metal (CoM) which may reduce wear still further [68], have also been used in the last five years.

Figure 1.7. Bearings used in hip replacement (England and Wales, 2003 to 2011)
(Source: NJR 9th Annual report)

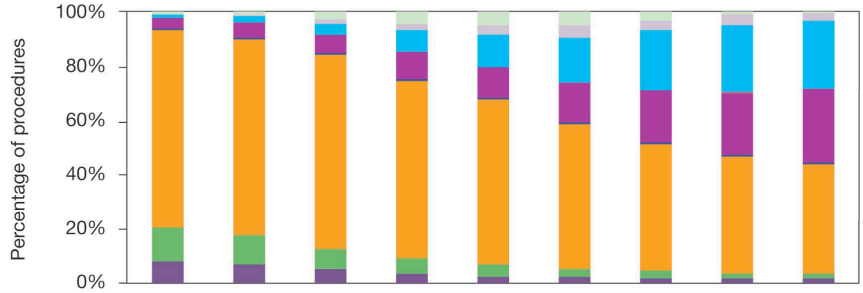


Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of procedures with hip articulation details	25,341	46,534	55,659	58,130	65,174	68,557	69,168	70,865	70,111

The ideal femoral head size is a compromise between stability and wear. A 28mm head was thought to offer the ideal compromise, and this remains the most commonly implanted, although there is a trend towards increasing size; the NJR has shown the proportion of hip replacements performed with a size greater than 28mm has risen from 7% in 2003 to 56% in 2011 (**Figure 1.8**) [30]. Larger head sizes may decrease the risk of dislocation and increase range of movement [64, 69-76], whilst hard bearings may reduce wear [77-81]. Use of a larger head size is an attractive option in younger patients who require stability at higher levels of function, and in older patients in order to reduce dislocation risk. However, larger diameter bearings may fail earlier because of either increased wear at the bearing surface (as a result of a larger surface area and increased torque) or at the head-neck interface ('taper' or 'trunion' wear) [82, 83]. Failure may also be bearing dependent; as head size increases, MoM THR implants have poorer survival, whilst CoC implants have better survival [84]. Larger femoral sizes utilising

hard bearing technology offered no functional improvement over 28mm MoP in a small randomised trial [85], and larger head sizes have not been shown to offer gait benefits [86].

Figure 1.8. Head sizes used in hip replacement (England and Wales, 2003 to 2011)
(Source: NJR 9th Annual report)



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used with head size detail	18,887	36,120	45,032	48,362	56,093	61,384	63,610	67,322	67,625

22.25mm 26mm 28mm 30mm 32mm 34mm
36mm 38-44mm 46+mm

A systematic review of the published literature addressing bearing surfaces used in THR found that patient outcome scores in cohort studies were as good or significantly better with traditional bearings (MoP) compared with MoM (in 3404 procedures), and there was a significantly greater risk of revision with MoM compared with MoP in registry data, after adjustment for a number of variables (including over 720 000 procedures from the Australian, New Zealand and England and Wales registries) [40]. There are now many long-term cohort studies (supported by worldwide registry data) suggesting a cemented hip replacement with a metal-on-polyethylene (MoP) articulating surface has good survival [30, 31, 33, 35, 36, 38, 39, 41, 42].

Areas of limited evidence

In the UK, a cemented MoP THR may be the best option for the majority of patients – particularly those who are older and have lower demands – due to the good implant survival achieved compared with other implant types [30]. However, differences in functional benefit have yet to be established. Moreover, mortality and complication risks may vary across types. There is also limited evidence for the benefits of the many different options available to the hip surgeon. Clinical benefits of the following have yet to be fully explored:

- Different fixation methods in THR
- Hip resurfacing
- Large femoral head sizes
- Newer bearing surfaces

- Different surgical approaches

Understanding the influence of each of these factors upon performance and outcome is made complicated by the multifactorial aspects of each hip replacement, with surgical team, procedure and patient variables all being potentially important.

Implant failure and revision procedures

Early Implant failure (in the first weeks and months) is a result of either infection, a mechanical problem (such as recurrent dislocation, where the ball persistently escapes from the socket) or fracture of the bone around the prosthesis. In the mid- to long-term (10 years +) bearing surface wear, reactions to wear debris particles (causing increased bone absorption, soft tissue destruction, implant loosening and pain) or persistent low-grade infection can result in failure. In most cases patients will require a further surgical procedure (a revision) to replace part or all of the prosthesis in order to improve symptoms and quality of life.

Joint registries

The purpose of a joint registry is to provide high quality demographic information on the practice of joint-replacement surgery, explore the factors that influence outcomes, and establish a mechanism of audit for hospitals and individual surgeons [87]. Initially established to monitor the increasing number of joint prosthesis manufacturers, national joint replacement data in Scandinavian populations has now been used to quantify implant failure rates for several decades [88, 89]. As data is collated from across many surgical units, registries can provide an early warning system for poorly performing implants, but can also identify surgeons and units with significantly elevated revision rates – 'outliers'. The potential value of national registries continues to increase in the context of ageing populations, increasing numbers of joint replacements, rising national health expenditure and the need to demonstrate cost effective surgical intervention. Many countries have subsequently developed national registries with the primary aim of reducing implant revision rates, thereby reducing morbidity, mortality and costs associated with further surgical intervention. The Australian Orthopaedic Association predicted that the knowledge gained from their national registry could reduce revision rates by 1%, saving $10 million annually [87].

National joint registries are now established in Australia, New Zealand, Finland, Norway, Sweden and across the UK. Joint replacement surgeons in the US are under pressure to increase transparency in their practice: consulting fees from industry, a demographic shift to younger patients, and the lack of evidence for the benefit of using newer prostheses are driving this change. Defining attributes of the most suitable patient, the safest surgical unit and the most appropriate implant are important steps to promote better outcomes in the future – both in terms of implant longevity and avoiding patient morbidity. In addition, registries

may need to satisfy the data requirements of payers, purchasers, policymakers as well as patient needs for information [90]. Reasonably priced implants with the lowest revision rates together with the highest satisfaction, function and general health scores are likely to be the most cost-effective options.

There are a multitude of variables that can potentially influence outcome. A major difficulty is determining the best implant choice for an individual patient. Large population-based databases can provide the platform and capability to analyse these variables and provide quality evidence for the most appropriate implant choice and the best surgical technique.

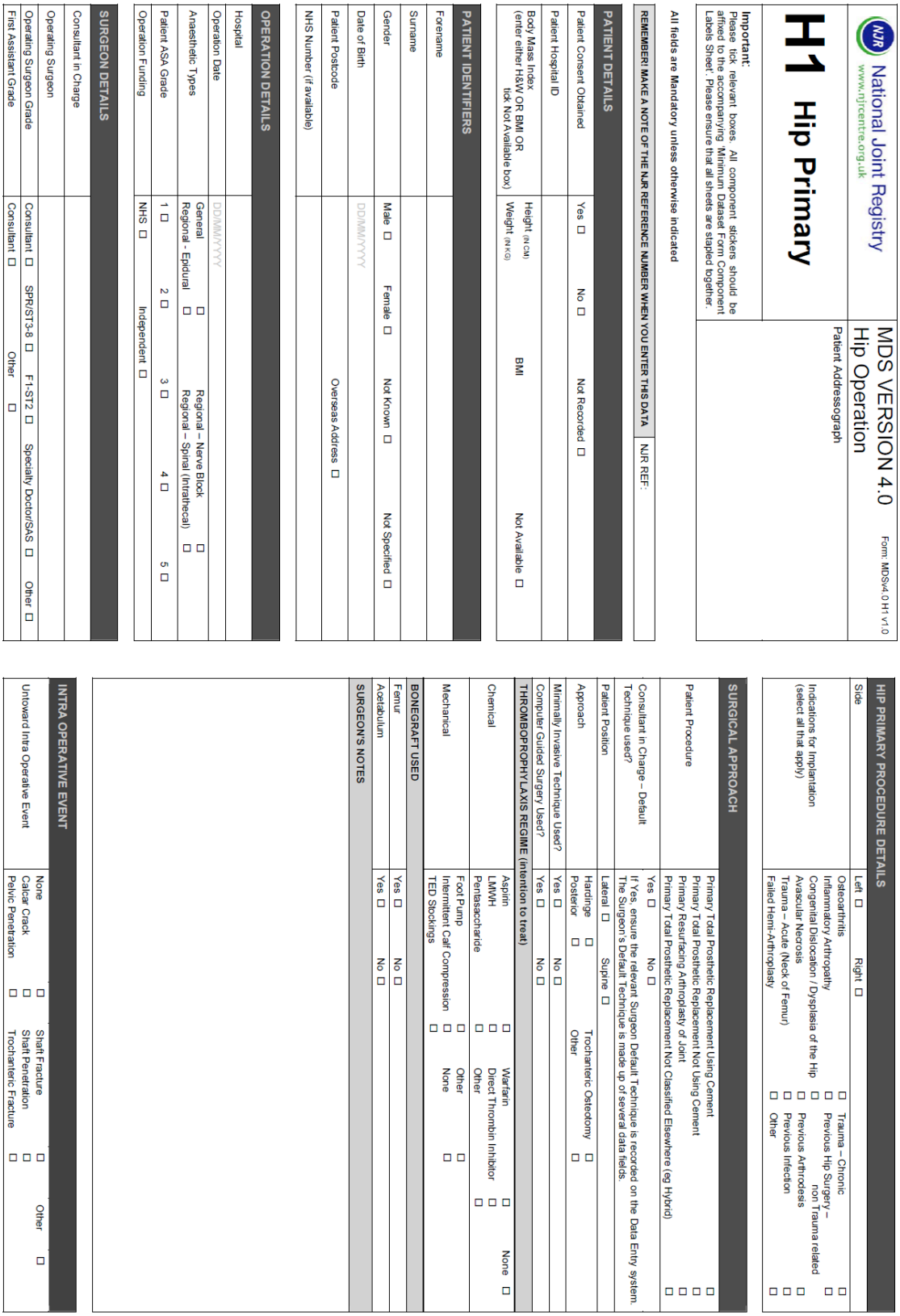
National Joint Registry for England and Wales

The National Joint Registry (NJR) for England and Wales was established by the Department of Health in 2002. It is currently operated by the Healthcare Quality Improvement Programme (HQIP) and is the largest joint registry in the world, with over one million hip, knee and ankle implants registered. Northgate Information Solutions (UK) Ltd currently holds the contract to collect, store and analyse the NJR data. Bristol University are contracted to produce the annual report and specialist topics.

A £20 levy (2010/2011) – which is an additional payment placed on the sale of every acetabular, talar and knee femoral components sold in England and Wales – covers the costs associated with the ongoing operation and development of the NJR. Patient, surgeon and implant data are submitted on operations performed across the NHS and the independent sector via the minimum dataset (MDS) collection forms (**Figure 1.9**). Whilst NHS hospitals in England and Wales have always been 'expected' to submit data to the NJR, the process has been mandatory for independent sector units since the inception of the registry. However, the Standard NHS Contract for Acute Services now states that all providers shall participate in audits relevant to the service they provide, such as the NJR. Therefore, submission of complete data to the NJR is now mandatory for all NHS Trusts and Foundation Trusts within England. The Welsh Government has also agreed that the NJR is mandatory for all NHS Wales hospitals. By linking patient records within the registry (by NHS patient number) revision of previously implanted primaries can be identified and a cause of failure assigned. The data has been used to describe demographic trends over time, such as an increase in the mean body mass index of TKR patients [30], or identify outlier implants or surgeons. The NJR currently provides level 2 registry data – MDS and additional information, such as venous thromboembolic prophylaxis.

Mortality data is also available, based on Office of National Statistics (ONS) information; this is thought to be robust as death registration is compulsory within five days and burial or cremation cannot be performed without appropriate documentation.

Figure 1.9. Minimum Data Set used to collect data for primary hip replacements in the NJR for England and Wales



National Joint Registry
www.njrcentre.org.uk

MDS VERSION 4.0
Hip Operation

Form: MDSv4.0 H1 v1.0

Patient Addressograph

H1 Hip Primary

Important:
Please tick relevant boxes. All component stickers should be affixed to the accompanying 'Minimum Dataset Form Component Labels Sheet'. Please ensure that all sheets are stapled together.

All fields are Mandatory unless otherwise indicated

REMEMBER! MAKE A NOTE OF THE NJR REFERENCE NUMBER WHEN YOU ENTER THIS DATA	NJR REF:

PATIENT DETAILS				
Patient Consent Obtained	Yes ☐	No ☐	Not Recorded ☐	
Patient Hospital ID				
Body Mass Index (enter either H&W OR BMI OR tick Not Available box)	Height (IN CM)			
	Weight (IN KG)	BMI		Not Available ☐

PATIENT IDENTIFIERS				
Forename				
Surname				
Gender	Male ☐	Female ☐	Not Known ☐	Not Specified ☐
Date of Birth	DD/MM/YYYY			
Patient Postcode		Overseas Address ☐		
NHS Number (if available)				

OPERATION DETAILS						
Hospital						
Operation Date	DD/MM/YYYY					
Anaesthetic Types	General		☐	Regional – Nerve Block		☐
	Regional - Epidural		☐	Regional – Spinal (Intrathecal)		☐
Patient ASA Grade	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	
Operation Funding	NHS ☐	Independent ☐				

SURGEON DETAILS							
Consultant in Charge							
Operating Surgeon							
Operating Surgeon Grade	Consultant ☐	SPR/ST3-8 ☐	F1-ST2 ☐	Specialty Doctor/SAS ☐	Other ☐		
First Assistant Grade	Consultant ☐		Other ☐				

HIP PRIMARY PROCEDURE DETAILS							
Side	Left ☐	Right ☐					
Indications for Implantation (select all that apply)	Osteoarthritis		☐	Trauma – Chronic			☐
	Inflammatory Arthropathy		☐	Previous Hip Surgery – non Trauma related			☐
	Congenital Dislocation / Dysplasia of the Hip		☐	Previous Arthrodesis			☐
	Avascular Necrosis		☐	Previous Infection			☐
	Trauma – Acute (Neck of Femur)		☐	Other			☐
	Failed Hemi-Arthroplasty						

SURGICAL APPROACH							
Patient Procedure	Primary Total Prosthetic Replacement Using Cement						☐
	Primary Total Prosthetic Replacement Not Using Cement						☐
	Primary Resurfacing Arthroplasty of Joint						☐
	Primary Total Prosthetic Replacement Not Classified Elsewhere (eg Hybrid)						☐
Consultant in Charge – Default Technique used?	Yes ☐	No ☐					
	If Yes, ensure the relevant Surgeon Default Technique is recorded on the Data Entry system. The Surgeon's Default Technique is made up of several data fields.						
Patient Position	Lateral ☐	Supine ☐					
Approach	Hardinge	☐		Trochanteric Osteotomy			☐
	Posterior	☐		Other			☐
Minimally Invasive Technique Used?	Yes ☐	No ☐					
Computer Guided Surgery Used?	Yes ☐	No ☐					
THROMBOPROPHYLAXIS REGIME (intention to treat)							
Chemical	Aspirin		☐	Warfarin			☐
	LMWH		☐	Direct Thrombin Inhibitor			☐
	Pentasaccharide		☐	Other			☐
Mechanical	Foot Pump		☐	Other			☐
	Intermittent Calf Compression		☐	None			☐
	TED Stockings		☐				
							None ☐
BONEGRAFT USED	Yes ☐	No ☐					
Femur							
Acetabulum	Yes ☐	No ☐					
SURGEON'S NOTES							

INTRA OPERATIVE EVENT							
Untoward Intra Operative Event	None		☐	Shaft Fracture		☐	Other ☐
	Calcar Crack		☐	Shaft Penetration		☐	
	Pelvic Penetration		☐	Trochanteric Fracture		☐	

Strengths of registry data

Registries offer unique opportunities for research as they capture the diversity of national practice and provide considerable opportunities to analyse complexity in very large numbers of patients in pragmatic circumstances. Accurate attribution of causes of failure using registry data is more challenging than within a randomized controlled design because of the need to adjust for many potential influences, requiring more complex statistical methods. However, such analyses are able to explore the interplay of all the influences affecting rare outcomes over a long period of time. Experimental designs, ideally suited to explore the influence of one or possibly two factors at a time, would be prohibitively costly.

Limitations of registry data

Despite the myriad of implant options and materials used, many registries analyse implants using simple discriminators, such as fixation type or bearing surface, when in reality no two brands of implants are alike; assumptions of similarity may be misplaced and subsequent findings confounded. Most registries report revision or death as the only endpoints. Revision is a crude measure of failure, since non-revision doesn't differentiate between patients with a well-performing implant and those living with significant symptoms, while patients with failing replacements may not request further surgery, or they may be deemed unsuitable because their specific risk of complications or death following revision surgery may be unacceptably high. Subsequent procedures performed around a hip replacement, such as acetabular liner change, fixation of a periprosthetic fracture, washout for infection and closed reduction of a dislocated hip, are potential 'failures' which carry morbidity, but are not recorded by the NJR if both the acetabular and femoral components are retained. Consequently revision, as a surrogate for implant failure, has been cited as a major limitation of registry data [91].

Data quality has been a major criticism of registry data in the past. Reporting of primary procedures has improved over time and is now mandatory, but revisions are still of concern; it is not clear whether all revisions are reported nor whether linkage to the corresponding primary can be carried out in all cases. In addition, registries may fail to collect specific information which may have significant bearing upon outcomes such as the severity of joint disease at time of surgery, general health and certain demographic details (such as socioeconomic status and race). These limitations may mean registries can identify problems but may not necessarily identify the underlying cause, or worse, misattribute the cause.

The introduction of the patient reported outcome measures (PROMs) programme may help with these problems by providing validated subjective and objective measures of patient health and disability, both prior to and at specific intervals following surgery [92].

Ultimately, using observational data to estimate the contribution of a range of factors to overall performance (such as implant type and surgical technique) cannot preclude bias. Obvious limitations include the potential for omitted

variables or using the wrong functional form. Furthermore, with large numbers it is possible to incorrectly attribute cause with great precision. Exploration of the assumptions behind models through robust checks and a range of specification tests can help to reduce, but not entirely remove the potential for bias. More weight can be given to findings that are consistent over a range of modeling approaches and assumptions.

Compliance, Consent and Linkage

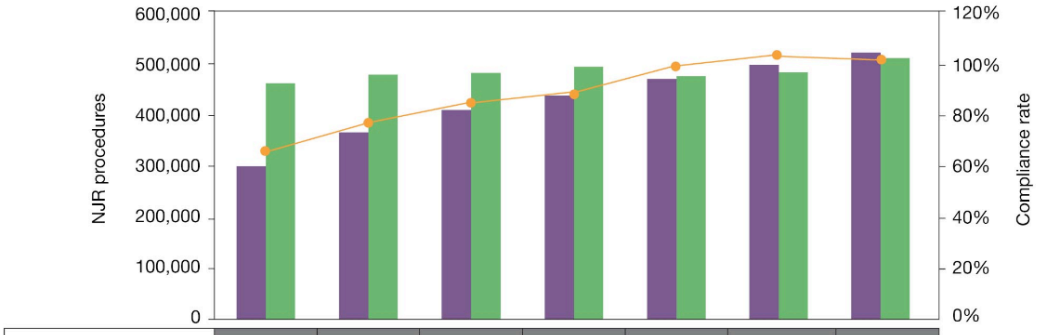
In the financial year 2011/12, only one unit (of 411) failed to submit any records to the NJR. However, there is variation in the quality of submissions, and not all units achieve the 95% target for compliance. Three key indicators are used to measure the completeness and quality of the data submitted to the NJR Centre:

Compliance

This is the proportion of procedure records submitted to the NJR compared with the levy returns for the number of implants sold. It is impossible to establish a one-to-one link between a single levy and the use of the implant, since the link is subject to a number of factors, such as variation in the procurement cycle throughout the year (leading to a compliance rate of over 100% at times). For individual NHS Trusts, compliance can also be measured against data held in the Hospital Episodes Statistics (HES) service and the Patient Episode Database Wales (PEDW) service, although there are also variations in coding practice. However, this process cannot be used to check compliance of privately funded procedures, as no HES or PEDW data exist for these.

The compliance rate across all units for the past eight years, compared to the number of levies, is illustrated in **Figure 1.10**. The compliance rate has shown a steady upwardly trend since 2003; for the four years 2008 to 2012 the rate was 102% (more procedures were submitted to the NJR than implant levies). By comparison, the compliance rate for English NHS Trusts and Welsh Health Boards, assessing using HES and PEDW, for the 2011 was 93%. The overall compliance rate from 1 April 2003 to 31 March 2012 was 85.7% (by levy estimate).

Figure 1.10. NJR compliance 2003/04 to 2011/12, based on levies from implant sales
(Source: procedures entered into the NJR 1st April 2003 to 31st March 2012 and levy submissions to NJR by implant suppliers and manufacturers, NJR 9th Annual Report)

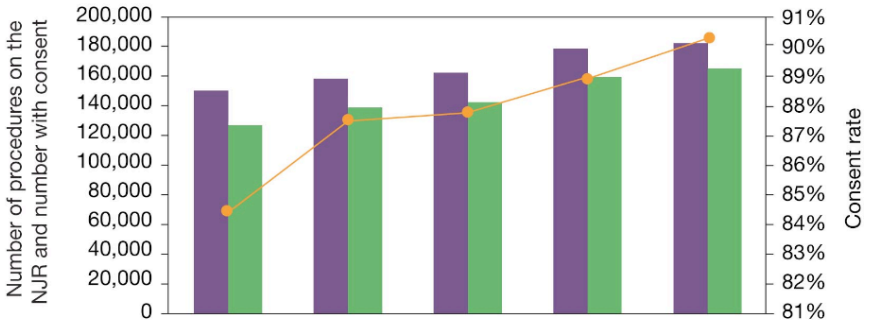


Year	2003/04 - 2005/06	2004/05 - 2006/07	2005/06 - 2007/08	2006/07 - 2008/09	2007/08 - 2009/10	2008/09 - 2010/11	2009/10 - 2011/12
NJR procedures	297,602	364,120	407,708	435,275	467,908	495,665	519,510
Levy	459,797	478,207	480,531	492,504	473,052	481,279	509,297
Compliance rate (%)	64.7%	76.1%	84.8%	88.4%	98.9%	103.0%	102.0%

Consent

This is the number of records submitted with patient consent compared with the total number of procedures recorded. Patients must 'opt in' to have their personal data held by the NJR (in contrast with some other registries – such as the Australian registry – where consent is assumed). Consent is essential for linkage between primary and revision procedures on the same joint. **Figure 1.11** shows the rise in the consent rate over the past five years, with 90.4% in 2011/12.

Figure 1.11. NJR consent rates 2007/08 to 2011/12
(Source: procedures entered into the NJR 1st April 2007 to 31st March 2012, NJR 9th Annual Report)



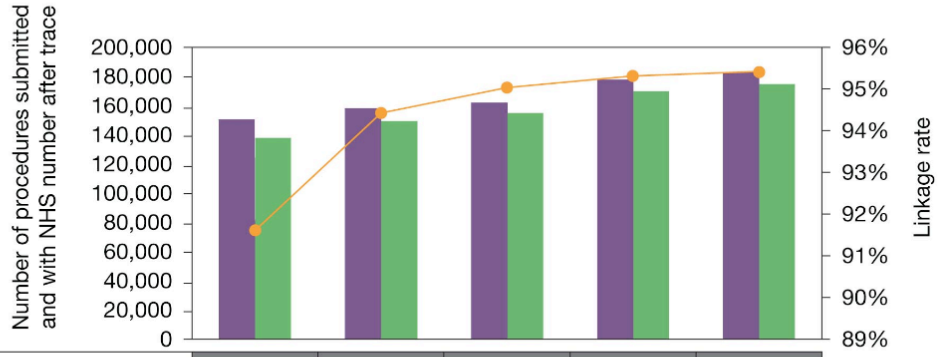
Year	2007/08	2008/09	2009/10	2010/11	2011/12
Number of procedures	150,710	158,710	162,766	178,204	182,631
Number of procedures with consent	127,214	139,012	142,965	158,483	165,166
Consent rate (%)	84.4%	87.6%	87.8%	88.9%	90.4%

Linkability

This is the number of records submitted with the patient's NHS number compared with the total number of procedures. The NHS number is required to link all primary and revision procedures relating to a single patient. The linkability rate refers to the proportion of operations submitted with both patient consent and the NHS number recorded. Low rates of linkability adversely affect the ability of the NJR to monitor clinical and implant performance.

The percentage of linkable records submitted to the NJR from 2007/08 to 2011/12 is shown in **Figure 1.12**. The linkability rate for 2011/12 was 95.5%, the highest for any year.

Figure 1.12. NJR linkability rates 2007/08 to 2011/12
(Source: procedures entered into the NJR 1st April 2007 to 31st March 2012, NJR 9th Annual Report)



Year	2007/08	2008/09	2009/10	2010/11	2011/12
Number of procedures	150,710	158,710	162,766	178,204	182,631
Number with NHS number traced	138,175	149,963	154,747	169,995	174,437
Linkage rate (%)	91.7%	94.5%	95.1%	95.4%	95.5%

Although performance against these indicators has continued to improve year on year, the accuracy of the data collected has never been assessed on a large scale. The problems linking primary with revision hip replacement, together with an inability to capture all revision data has led to criticisms of registry data, with a general belief that the NJR under reports revision rates.

National Institute for Health and Care Excellence (NICE) and The Orthopaedic Data Evaluation Panel (ODEP)

The National Institute for Health and Clinical Excellence (NICE) provides clinical guidelines for UK health professionals [93]. In April 2000, NICE published Technology Appraisal Guidance (TAG) No. 2 – 'Guidance on the selection of prostheses for Primary Total Hip Replacements' [94], subsequently revised in 2011.

NICE recommend the use of a prosthesis that meets the standard as set by the ten-year 'benchmark' with a revision rate of 10% or less at ten years. The institute also recommends the use of prostheses with a minimum of a three-year data if their revisions rate performance is consistent with the ten-year

benchmark, based on adequate numbers (i.e. 3% at three years). However, as demonstrated by a revision rate of 13.7% at 5 years and 36.4% at 9 years for the DePuy Articular Surface Replacement (ASR, DePuy International Ltd, Leeds, United Kingdom), an acceptable three-year revision rate does not always translate to a 5- or 10-year benchmark [30]. NICE recommends the use of cemented prostheses as there is "currently more evidence of [their] long-term viability", and states that there is "no cost effective data, based on revision rate of ten years or more follow-up, to support the use of generally more costly cementless and hybrid hip prostheses." It also states that there is "no reliable evidence to support the proposition that the potential ease of revision of a hip prosthesis would outweigh its poorer revision rate" [94].

The ODEP (Orthopaedic Data Evaluation Panel) rating provides a further guide to implant longevity based on the quality and quantity of published data, and varies depending upon implant [95]. This information can guide practice, and ODEP provides a useful rating system to assist surgeons. Implants are rated as an A*, A, B or C based on quality of evidence, and as 3, 5, 7 or 10 depending on the length of follow up in years. Any hip brand with an ODEP rating has been assessed by ODEP and shows performance within the guidelines set by NICE. Products without an ODEP rating are listed in the NJR as being "unclassified" and therefore a potential risk to patients. Based on the latest NJR report, the 10A benchmark is achieved in 85% of all cemented stems implanted (this represents 13 of 57 brands used) and 40% of all cemented cups implanted (10 of 48), compared to 72% of cementless stems (16 of 85) and only 3% of cementless cups (7 of 71). Only one resurfacing brand of the ten used (57%) has a 10A rating [30]. The ratings for the most common combinations, together with market share, are shown in **Table 1.1**.

Table 1.1. Orthopaedic Device Evaluation Panel (ODEP) rating (2013) and 7-year estimated revision rate for the combination of implants with the largest market share (within type), in England and Wales

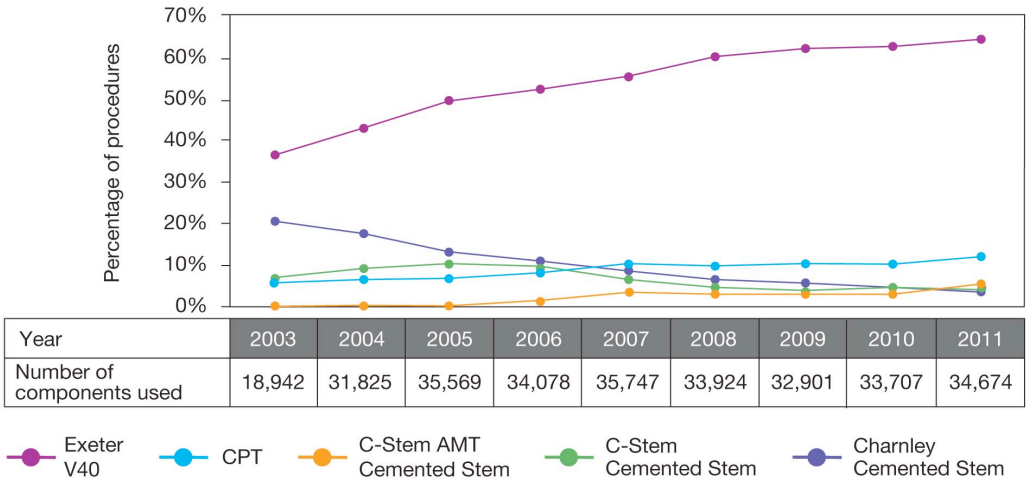
Type	Prosthesis combination	ODEP rating	Market share (2011, %)	7-year revision (%, 95% CI)
Cemented	Stryker Exeter V40 stem	10A	64	1.79 (1.55 to 2.05)
	Stryker Contemporary cup	7A	35	
Hybrid	Stryker Exeter V40 stem	10A	64	2.01 (1.69 to 2.39)
	Stryker Trident cup	7A	19	
Cementless	DePuy Corail stem	10A	48	4.12 (4.51 to 5.85)
	DePuy Pinnacle cup	10C	33	
Resurfacing	BHR	10A	60	5.09 (4.64 to 5.57)

Revision rate data courtesy of the National Joint Registry, England and Wales 9th Annual Report
CI – confidence intervals

The Stryker Exeter Contemporary is the most commonly implanted cemented hip set in England and Wales (**Figures 1.13, 1.14**). The most commonly used cementless combination is the DePuy Corail Pinnacle (**Figures 1.15, 1.16**), and the market leading resurfacing brand is the BHR (**Figure 1.17**). When used in a hybrid

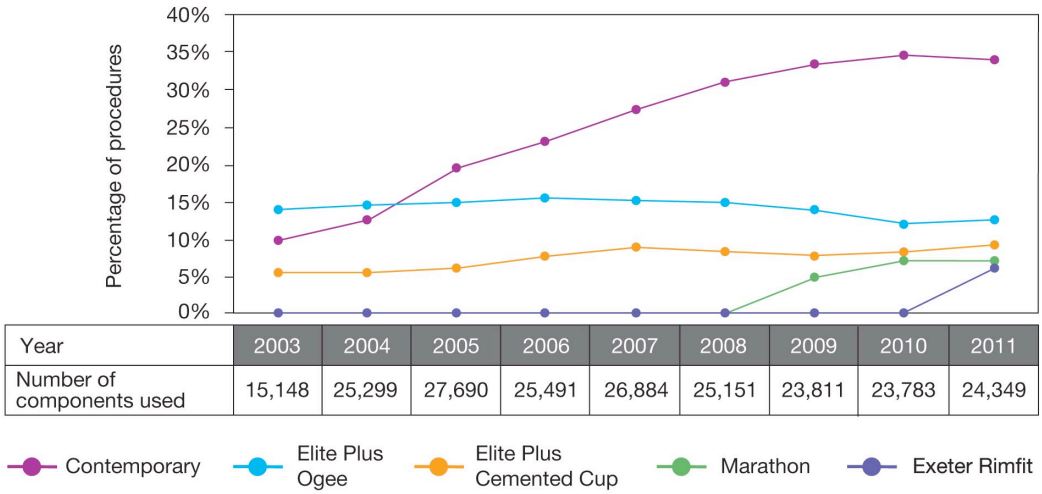
combination, the Stryker Trident cup is used most commonly with a cemented stem (Exeter) (**Figures 1.13, 1.16**).

Figure 1.13. Top five cemented hip stem brands, trends 2003 to 2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



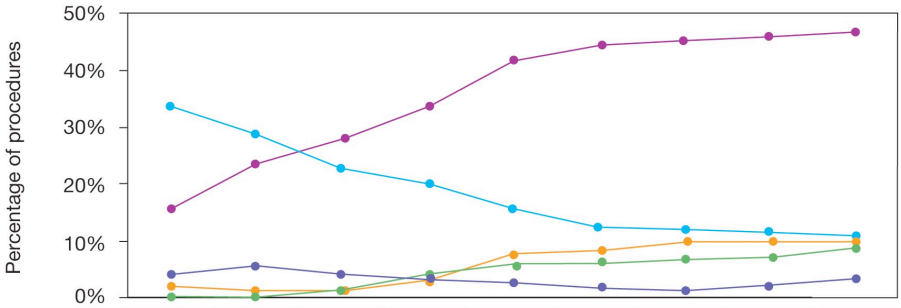
Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	18,942	31,825	35,569	34,078	35,747	33,924	32,901	33,707	34,674

Figure 1.14. Top five cemented hip cup brands, trends 2003 to 2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	15,148	25,299	27,690	25,491	26,884	25,151	23,811	23,783	24,349

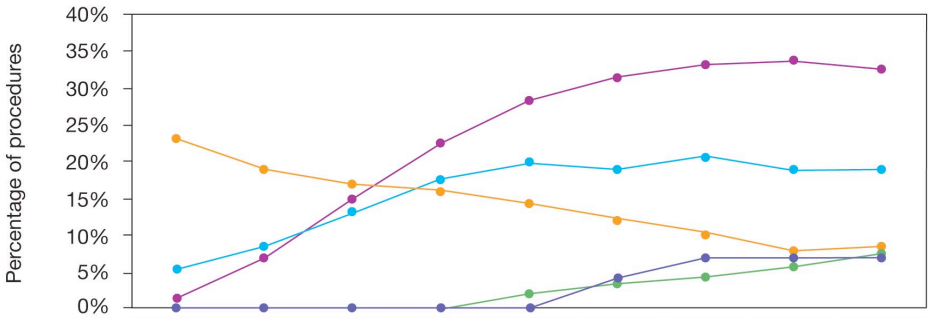
Figure 1.15. Top five cementless hip stem brands, trends 2003 to 2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	4,461	10,766	15,134	18,457	23,439	29,200	32,129	34,550	33,724

Corail · Furlong HAC Stem · Accolade · Taperloc Cementless Stem · Versys Cementless Stem

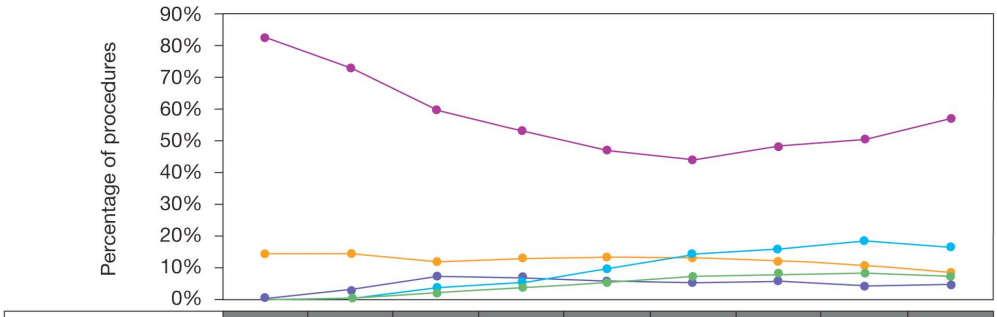
Figure 1.16. Top five cementless hip cup brands, trends 2003 to 2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	7,905	16,412	21,145	24,068	28,577	34,155	39,227	44,097	44,223

Pinnacle · Trident · Trilogy · Exceed ABT · CSF Plus

Figure 1.17. Top five resurfacing head brands, trends 2003 to 2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Year	2003	2004	2005	2006	2007	2008	2009	2010	2011
Number of components used	2,640	5,023	6,214	6,483	6,678	5,780	4,350	2,680	1,801

BHR Resurfacing Head; Adept Resurfacing Head; Cormet 2000 Resurfacing Head; Recap Resurfacing Head; Durom Resurfacing Head

Patient reported outcome measures (PROMs)

The NJR, in collaboration with the Department of Health (DoH), commissioned the first collection of Patient Reported Outcomes Measures (PROMS) in England and Wales in 2008, introducing patient-centred outcomes to supplement the measures traditionally used to assess the success of joint replacement (risk of revision and mortality) [96]. PROMs include a joint specific score, general health measures and self-reported complication data collected before and around six months after selected NHS funded elective procedures.

Use of PROMs is intended to help the NHS measure and improve the quality of its care and use patients' perspectives to inform decision-making. This reflects key themes in current NHS reforms to empower patients in decisions about their care. A limited amount of PROMs data for hip and knee replacement is currently published at HES online [97]. However, these analyses are unsophisticated, combining all patients and all implant types together. For the orthopaedic community the opportunity exists to amalgamate patient outcome measures with clinical outcome data from the NJR, allowing a more sophisticated and comprehensive analysis of surgical and patient variables. This will supplement the information already available from NJR annual reports. PROMs data are currently stored separately from NJR data, by the Information Centre (IC), thus linkage of the datasets is required.

While post-operative PROMs data collection is currently limited to six months, there are plans to extend collection to one, three and five years for a subset of patients. General health status is measured using the EuroQol tool (EQ-5D-3L index and a visual analogue scale, EQ-VAS) [98]. The EuroQol is a simple, generic measure of health used for clinical and economic appraisal and provides two separate measures of general health. The EQ-5D-3L index is derived by combining patients' responses to questions on five different dimensions of health

(mobility/self-care/usual activities/pain & discomfort/anxiety & depression) and 3 levels, using weightings based on population norms. This produces a single EQ-5D index value (referenced to 0 to 1, where 1 represents perfect health and 0 represents death, but negative values are possible for states perceived as being worse than death). The EQ-VAS (0 to 100) provides an additional visual analogue assessment of patient well-being. Condition specific measures relate to the procedure under investigation and hence can only be compared within that procedure. PROMs for hip replacements within the NHS are measured using the Oxford Hip Score (OHS, 0 lowest to 48 highest) [99]. The OHS has previously been shown to be a reliable, valid and responsive outcome measure and can be used for the clinical assessment of populations following hip replacement [100].

In addition to the EuroQol and OHS measures, PROMs also collect other relevant information. As part of the pre-operative questionnaire patients are asked about co-morbidities, living arrangements and self-reported disability, which can be used to understand the differences in health status between patients presenting for different surgical procedures. The post-operative questionnaire includes information on complications (wound problems, bleeding problems, urinary tract infections and allergic reactions), reoperations and readmissions as well as specific questions relating to satisfaction and the patients perception of how successful their surgery has been. Complication questions are derived from the patient's experience of surgery, which have previously been used to audit complications after day case surgery [101]. Asking the patient "How would you describe the results of your operation?" assesses satisfaction. Responses are recorded on a five-point Likert-type scale with the options: Excellent/Very Good/Good/Fair/Poor. Success after surgery is similarly assessed with the question "Overall, how are your hip problems now, compared to before your operation?" with the corresponding options: Much better/A little better/Much the same/A little worse/Much worse.

Limitations of PROMs data

There are several limitations associated with this patient-reported data. The PROMs project is still in its infancy limiting the impact of findings, until consistent quality and completeness can be demonstrated. Data comes in two separate databases that have to be linked, verified, cleaned and recoded prior to analysis. As with many questionnaire-based projects there is a problem with missing or non-returned questionnaires. Once the datasets are linked, there are a number of cases for which the date for operation stated on the NJR database is markedly different to that recorded by patients on the post-operative questionnaire. Preliminary analysis of the linked NJR-PROMs dataset for hip and knee replacements suggests the number of records lost for these reasons may be around 30%.

There are a number of methodological limitations when working with PROMs. Interpretation occurs in the context of differing patient expectations of the outcome following hip replacement, which may vary depending for example on age, geography, socioeconomic status and temporality. Care must therefore be

taken when analysing variables such as patient satisfaction – dissatisfaction may simply reflect varying expectation, as opposed to poor outcome. While collapsing the EQ-5D index into a single score is appropriate for analysis and comparison purposes, it results in the loss of information about the domains in which any differences in health-related quality of life occur. Although the EQ5D used by the PROMs project is based on a three level ('3L') response to specific questions, there is a version with five levels, which may be more sensitive. Inferring benefit based on two PROMs observations makes the timing of the second observation crucial when transient changes can be expected for a period of time following surgery. PROMs are based on the assumption that any change in health reflects only the operation under scrutiny without consideration of other extraneous factors, and many patients have concurrent arthritis in other lower limb joints – until all of these issues have been treated effectively, function will remain poor and outcome measures affected. In addition, absence of improvement does not necessarily indicate an unsuccessful outcome when treating a degenerative condition. In some cases it may be necessary to slow the rate of disease progression and degradation in quality of life, rather than necessarily provide improvement. Moreover, the limited high-end sensitivity of these outcome scores enables a great number of patients to achieve the highest score available (the 'ceiling effect', where data is clustered at or just below the highest score); in reality there may be a benefit of one treatment or another, but analyses may not identify this difference. Finally, self-reporting excludes certain patient groups (e.g. with dementia or severe cognitive impairment) from analysis, and may skew the responses towards older patients, who are more geographically stable and who may have more time and a greater inclination to respond. These factors present potential sources of variation within PROMs records. Whilst a question regarding the occurrence of complications provides an objective endpoint, outcome scores are subjective. The implication of this is that, while supportive, they may not be adequate to inform policy decisions in isolation.

These concerns accepted, PROMs data represent a significant step forward in terms of the assessment of patient outcomes, and the influence of a range of surgical parameters may be possible given the very large numbers of patients involved. Use of PROMs represents a move away from revision rate as the predominant method by which registries assess outcome following surgery. The ability to link PROMs data to the NJR will, for the first time, allow researchers to look at the patient experience of surgery, and the factors that influence this.

Surgical practice

A number of surgically related factors may influence outcome following hip replacement. The surgeon may be of training grade or may have limited experience of a particular operation. Although hip replacement is one of the key operations in which UK trainees are required to achieve a specific standard prior to completion of training, hip resurfacing or cementless procedures are often perceived as more complex (because of the different technical challenges and the

use in predominantly younger people) and so surgical training with these types of implants may be more limited.

The most appropriate surgical approach for primary hip replacement continues to stimulate debate. The two most commonly used techniques are the posterior approach, where the joint capsule is approached through the external rotator muscles on the posterior aspect of the femoral neck [102], and the lateral approach, where the abductor muscles are divided mid-tendon and reflected from the anterior aspect of the femoral neck [103]. Post-operative limping secondary to abductor muscle weakness occurs in 4 to 20% of procedures performed through a lateral approach [104]. Proponents of the posterior approach cite the benefits of less tissue damage, more rapid functional recovery and lower incidence of limp, and recommend this in younger patients. However, dislocation rates following a posterior approach may be higher due to the inherent weakness of the posterior capsular and soft tissue structures following surgery.

The NJR 9th Annual Report states that 60% (42 566 of 71 642) of primary hip replacements are currently implanted via the posterior approach compared to 35% (25,244) through the lateral approach [30]. Other approaches account for the remaining 5% (3882). Functional outcome, complications and early revision may differ depending on surgical approach. A single unit study demonstrated a functional benefit of the posterior approach at one to three years following THR [105], whereas a multi-centre study found no differences in improvement of OHS and dislocation or revision rates between surgical approaches at five years [106]. However, these analyses are limited by modest numbers of procedures and the heterogeneity of implants used. NJR-PROMs linked data may permit informative analysis of surgical approach.

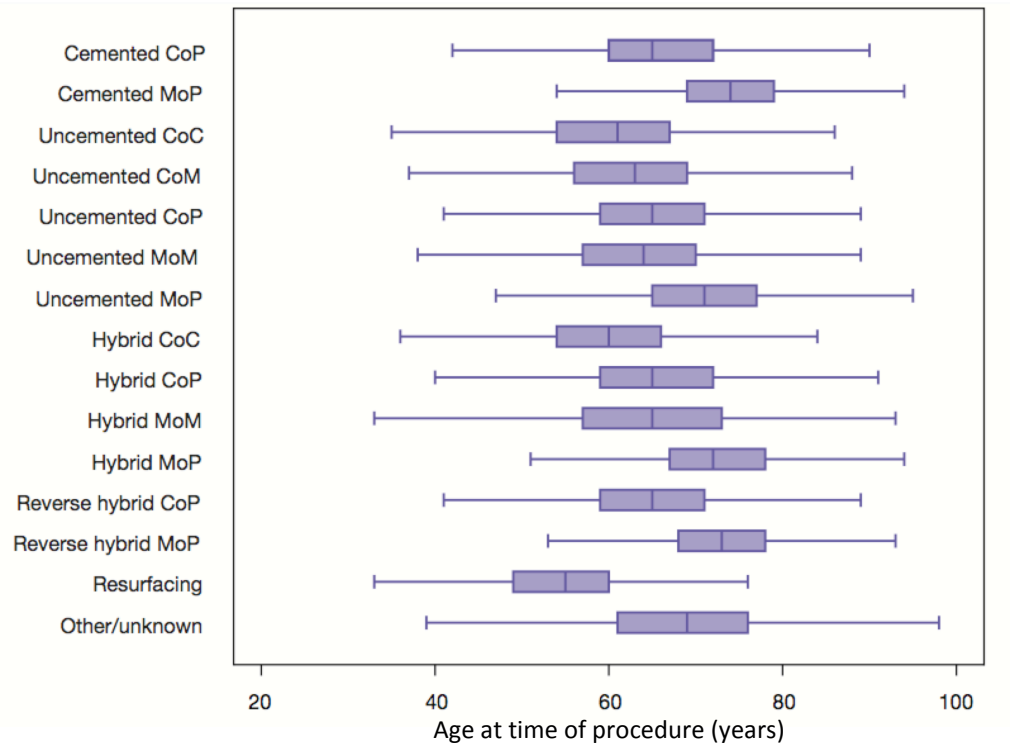
Specific surgical unit initiatives, such as pre-operative patient education (which may help to manage patient expectations) and post-operative pain management strategies may have effects on functional outcome, but these are unmeasured in these analyses.

Patient factors

The average age of a patient undergoing hip replacement is 67 years. Whilst the majority of patients have a generally sedentary lifestyle, younger patients can present particular challenges. They are more active, with greater life expectancy and may have higher functional expectations. Many still work and want to pursue active lifestyles. Though a threshold below which a patient is deemed young is difficult to establish, clinically the use of 60 years is thought reasonable. Of the primary hip replacements performed in 2011 with patient data available, 20.3% (13 871 of 68 331, 7249 females and 6622 males) were implanted in patients under 60 years. The majority of these replacements used cementless (either fully cementless [60.4%, 8372 of 13871] or hybrid [14.9%, 2064]) fixation or utilised a resurfacing (8.4%, 1159), although the evidence supporting this practice remains elusive. Despite a goal to reduce revision rates in these young patients in whom it is desirable for a replacement to last as long as possible, new

modes of failure have contributed to poorer outcome and greater reoperation rates. Therefore, whilst age of a patient is simply a surrogate for general health status and activity level, it remains an important consideration for selecting the most appropriate implant and may determine the success of surgery. Different types of implant have differing age range profiles (**Figure 1.18**), which is an important consideration when attempting to compare outcomes across types in specific age groups.

Figure 1.18. Age profile of hip replacement patients by type and bearing surface in 2011 *(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)*



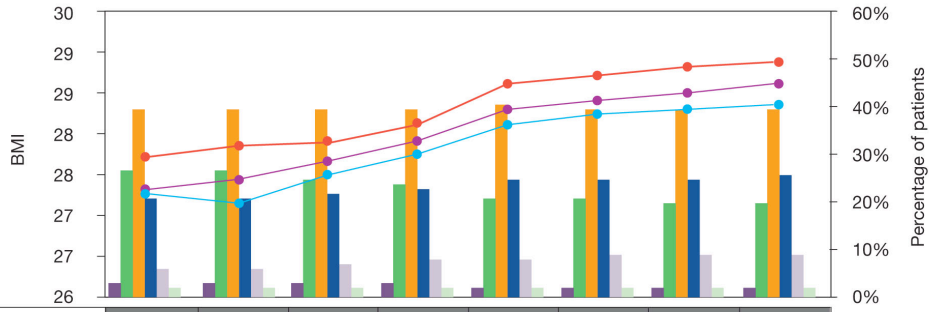
Note: On the plot, the box indicates the interquartile range (the 25th-75th percentile) so half of all patients have an age in the box. The line across the box is the median age. The whiskers show the upper and lower adjacent values (these are set at the highest or lowest value in the data within a maximum of 1.5 times the interquartile range). Outliers (unusual values outside these whiskers) are not shown on the plot. The box illustrates the likely ages of patients in each group whereas the lengths of the whiskers relative to the length of the box give an idea of how stretched out the rest of the values are. Key: CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, CoP – ceramic-on-polyethylene, MoM – metal-on-metal, MoP – metal-on-polyethylene.

Body mass index (BMI) and rates of obesity within the population are increasing across the developed world [107], resulting in poorer general health and greater risk of lower limb OA [108, 109]. The NJR has noted a year-on-year increase in THRs performed overall and in obese patients, with 38% having a BMI over 30kg/m^2 in 2011 compared with less than 30% in 2004 (**Figure 1.19**) [30].

Hip replacement in obese patients is more technically demanding (due to instrumentation issues), takes longer to perform [110], is associated with higher surgical and medical complications in the early post-operative period [111, 112], and outcomes such as function and implant longevity may be poorer [113, 114]. Thus, it has been suggested that raised BMI might be used to ration primary THR in a public funded health service, in effect denying patients access to surgical intervention [115]. Restrictions might apply to BMIs >35kg/m^2, although lower cut-off limits have been proposed [116]. However, the evidence for denying access to a

hip surgeon for patients with a high BMI is limited and ethically questionable (116, 117).

Figure 1.19. Body mass index for primary hip replacement, trends 2004-2011
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Year	2004	2005	2006	2007	2008	2009	2010	2011
Average BMI -all patients	27.35	27.46	27.67	27.90	28.31	28.42	28.51	28.59
Average BMI -female	27.28	27.15	27.53	27.76	28.12	28.22	28.31	28.39
Average BMI -male	27.71	27.86	27.94	28.17	28.61	28.72	28.83	28.90
BMI 15-19	3%	3%	3%	3%	2%	2%	2%	2%
BMI 20-24	27%	27%	25%	24%	21%	21%	20%	20%
BMI 25-29	40%	40%	40%	40%	41%	40%	40%	40%
BMI 30-34	21%	21%	22%	23%	25%	25%	25%	26%
BMI 35-39	6%	6%	7%	8%	8%	9%	9%	9%
BMI 40-44	2%	2%	2%	2%	2%	2%	2%	2%
BMI 45+	<1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
Number of procedures	5,906	8,985	10,448	14,190	33,769	39,359	43,413	39,619

It is known that a patient's health status and pre-existing medical problems influence mortality in the immediate period after surgery. To a certain degree this may also influence functional outcome. Depression, anxiety and other mental health disorders may affect outcome following hip surgery, as shown following knee surgery [117]. The influence of ethnicity and socioeconomic status is currently unknown.

Cross database linkage

In order to realise the full potential of the various sources of data, effective cross database linkage is required. The NJR already links datasets in order to describe revision rates (with Hospital Episodes Statistics databases, for example to capture revisions not recorded in the NJR and post-operative complications as sequelae of using different thromboprophylactic agents in hip replacement) [118]. Linkage across the NJR and PROMs datasets in this thesis will allow in depth analyses of specific implant groups. This linkage methodology could be applied to other national datasets, such as the Health Protection Agency Surgical Site Infection Surveillance Service and the National Hip Fracture Database [119, 120].

Economic implications

Health care costs in most countries are growing rapidly. Management of OA of the hip is a significant global health burden. Hip replacement is an established and successful treatment of end-stage OA, with typically excellent quality of life improvement and cost-effectiveness [121, 122]. Over 270 000 hip replacements are performed in the US annually, and over 70 000 across the UK [30, 123]. Costs to perform these replacements are expected to triple over the next five years in the US, whilst annual volume is expected to double within ten [40]. These cost increases may be unsustainable in the current economic climate [124].

The majority of patients have joint specific (95%, OHS) and general health (87%, EQ-5D index; 63%, EQ-VAS) improvements following hip replacement [97]. An estimated quality-adjusted life years (QALYs) gain of 6.5 per patient provides a cost per QALY of £1372, based on Scottish hip replacement tariffs for a primary procedure, with built-in costs for subsequent revision procedures (at the current national revision rates) [122].

Specific analyses of registry data linked with patient reported outcomes can reduce healthcare costs by helping to identify the most cost-effective strategy; Fordham et al stated that the most cost-effective implants are those with the best survival rates (and hence the fewest revisions), with the best patient outcomes and the least cost [121].

Medical device costs within a healthcare system are notoriously difficult to establish; list prices are higher than actual costs and providers often receive volume discounts. Currently, most Trusts in England and Wales agree local contracts based on surgeon preference, manufacturer support, ancillary equipment benefits and costs.

Future direction

There is significant room for further, more penetrating analyses of currently available national data. Analyses provided by HES online are basic and lack clinical relevance [97]. Due to the complexity of the NJR dataset, the annual reports have so far been unable to provide in-depth analysis. Risk adjustment, cross database linkage, and audit to ensure validity of data is essential in order to gain maximum benefit from these data sources. With appreciation of the potential limitations, these databases can be used effectively to describe changes over time with changing patterns of interventions and provide comparisons within large patient cohorts that would not be possible prospectively. They can also identify areas that require further investigation, and could contribute towards the design and data collection of future experimental trials. Whilst there are limitations to the current national databases, they remain an excellent resource and, when handled appropriately, may produce accurate comparative outcome data.

Statistical modelling

Types of data

There are several levels of evidence available to surgeons and health care providers in order to make the most appropriate decisions for treatment. Case series can provide some useful information, such as tips to minimise errors, radiographic information and accurate reasons for implant revisions. However, these are limited by a range of potential biases, operations are usually performed by only one or a few surgeons, limiting the generalisability of the results, and surgeons may have specific financial and professional interests (for example, an inventor's series). In addition, due to the lag period between implantation and failure, relevant and interesting results are rarely reported in a timely fashion.

Randomised trials (or a collection of trials analysed as a systematic review) are the gold standard for evaluating treatment benefits. However, in order to compare the rare event of revision across implants, a long follow-up period and a large study population are necessary; experimental designs would therefore be prohibitively expensive and impractical and could not cope with the multiplicity of factors. Thus, prospectively collected population based observational studies (such as those produced from joint registries) provide an adequate compromise.

The potential for bias when basing inferences on non-randomised comparisons has been well recognised. A 'review of reviews' comparing the results of experimental and observational studies concluded that there are differences between the results of studies with a randomised and non-randomised design, but without there being a consistent pattern indicating systematic bias [125].

In randomised trials, the random selection process should provide reasonable balance in each variable influencing outcome (known and unknown), allowing for an unbiased estimation of treatment effect. However, in observational studies, the type of treatment may be selected based (to some degree) on these variables, meaning different treatment groups may have an imbalance of prognosis. For example, the decision to choose cemented THR may depend on older age or lower activity level. To explore causality, statistical analyses must attempt to adjust for selection and other biases, although this is not a perfect science.

Regression models

To explore multiple determinants of the outcomes of hip replacement requires multiple regression where variation in an outcome variable (such as implant failure) is explained using a number of explanatory variables (such as the type of implant, patient age, gender and co-morbidity). Where explanatory variables strongly predict outcomes this might suggest cause and effect, where for example cause precedes effect and the relationship is clinically plausible. In this way, multiple and potentially interacting influences can be determined and variables that have no independent influence can be excluded. The type of regression model used reflects the dependent variable being evaluated e.g. linear

regression for a continuous variable, logistic regression for binary, and survival analysis for time sensitive event data.

A limitation of the multivariable approach is the assumption that the range of covariates overlaps substantially. This may not be true if, for example, younger patients tend to get one prosthesis and older ones another, or femoral heads tend to larger sizes with hard bearings (MoM and CoC) and smaller with standard MoP bearings. It is also important to recognise the extent to which the overall variation of outcome measures is explained, if this is low then there may remain unknown reasons for variation, potentially limiting the value of the results obtained.

Conducting regression analyses under different conditions and assumptions helps establish model reliability. These include modeling by alternative stepwise procedures (the order in which explanatory variables are added to a model), varying significance thresholds for selection within models and testing interactions between independent variables. Exploring a number of influences upon outcome is best characterized as hypothesis generation. With increasing multiple testing of variables and models the chance of finding spurious associations by chance is greatly increased. The use of a low threshold of statistical significance reduces the risk of chance findings. As the influence of continuous variables may not be truly linear, it is also important to test these as discrete variables with clinically relevant partitions.

Propensity score matching (PSM) provides an alternative method to limit confounding effects of multiple explanatory variables, and attribute variations in outcome to treatment differences alone [126]. The idea is to identify and compare otherwise similar groups of patients receiving different treatments. Like traditional regression, it requires reasonable overlap between the comparison treatment groups and large sample sizes. Logistic regression is used to estimate a propensity score, which represents the probability of one treatment or another. Proximity searching identifies closely matched patients receiving different treatments and then multivariable analysis is carried out on these matched groups.

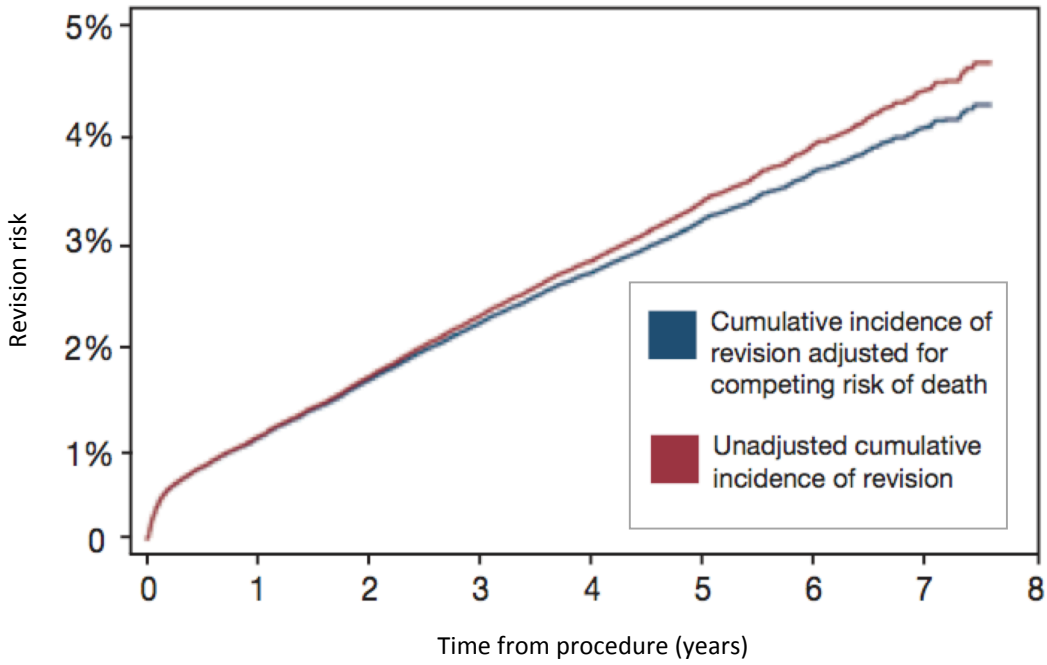
There are some limitations with this technique. As with logistic regression, PSM cannot match for unobserved variables [127]. A consequence of omitted variables is that over-attribution to measured variables may occur, with misleading policy implications. Finally, the ability to generalise the findings of this method depends upon the proportion of matched and unmatched patients drawn from the different treatment groups.

Survival models

Survival analysis is a special class of regression dealing with time to event data and censoring. Within a period of observation patients may or may not experience an event (for example implant revision). If an event occurs for a patient during observation, then the time to the event is known (in our example the survival time of an implant from insertion to replacement). If an event doesn't occur for a patient during observation their record is censored at the time the observation ends (as it is not known whether or not they will experience an event at a later date). Censoring is a common feature as it would take many years to determine whether or not implant failure occurred before death. Subsequently multiple regression is conducted as before but with variation explained in the specially defined time-to-event variable. Within a survival model a hazard function is estimated which reflects the risk of failure over time for baseline values of variables. The effect of the variables on the hazard function can then be determined. This is commonly done using a proportional hazards model, which provides the relative risk (or multiplicative risk) of failure for each variable (which may be discrete or continuous). Interactions between variables must be explored and this approach assumes constant proportionality over time (which should be tested for), with several potential solutions when non-proportionality is apparent.

There is a particular complication for analyses of implant revision in that patients are at a competing risk of death – revision is no longer possible once death has occurred. This becomes apparent as a problem since (at least theoretically) an implant may have an artificially higher revision rate, when death is recorded as censoring rather than an event. Adjusting for competing risks may be important when there are differences in baseline patient demographics between groups. However, the importance may be limited when the death rate is low compared to the revision rate. Both competing risk models and traditional Cox Proportional Hazards models adjust for patient and surgical factors, which may predominantly influence implant survival and risk of death. Although it is important to consider competing risks, according to the Nordic Arthroplasty Register Association (NARA) the size of bias in Kaplan-Meier survival estimates (a simple form of survival analysis) as a result of ignoring competing risks was small in registry data [128]. The NJR have previously compared cumulative incidence of revision with and without adjustment for death after all primary hip replacements registered on the dataset (**Figure 1.20**). In the death-adjusted analysis, patients who have died are no longer able to contribute to the survival curve resulting in a smaller population to sample from and to assess implant survival. Therefore, risk of revision is lower when adjusting for death. In the example produced by the NJR, an absolute difference emerged at 3 to 4 years, but this difference was small even at 8 years (0.4%) despite analysis of almost 0.5 million hip replacements. Analysis of relative differences between treatments could be expected to be an order of magnitude smaller.

Figure 1.20. Cumulative incidence of revision following primary hip replacement, adjusted for the competing risk of death
(Source: National Joint Registry for England and Wales 9th Annual Report, 2012)



Another competing risk may be a patient's poor general health, precluding revision. Patients failing to undergo revision instead contribute as censored at the end of the observation period. The resolution would be to record hip replacement failure rather than revision as the outcome, although this data is difficult to obtain and would require significant changes to the data collection infrastructure within the NJR.

Introductory Chapter Summary

Surgical procedures for hip replacement have evolved over the past century. Interpreting the performance of these procedures is complex due to the large numbers of patient, clinical and prosthesis influences. Given this complexity, analysis of large observational datasets provides the best opportunity to identify clinically important determinants of treatment failure and potentially guide policy.

The following chapter introduces the methods used to estimate the performance of a THR for osteoarthritis of the hip.

2. Methodology

Overview

In this chapter, the study design and methods are reported. Issues surrounding data access and approval processes are discussed, and the patient populations are described in detail, including the variables analysed and the reasons for their inclusion. Preliminary processing of the data such as cleaning, handling of missing data and linkage between databases are explained.

The statistical techniques introduced in the first chapter are described in greater detail, including tests of baseline differences between groups, simple and multivariable regression analyses, and comparisons between methods of statistical modeling. The management of variable categories and the methods employed to test variable selection within the models are explained.

Specific methodological detail is provided for each of four analyses. Firstly, survival analysis will evaluate four separate hip replacement populations (cemented, hybrid, cementless and resurfacing) in order to determine specific predictors of implant failure; this identifies optimum component sets within each type of replacement, to help with comparisons across types. Secondly, PROMs data will be used to evaluate the influence of BMI, surgical approach, head size and bearing on functional outcome. Thirdly, methods of statistical modeling will be compared to inform current controversies about appropriate methods. Finally, implant types will be compared using stratified implant survival data, perioperative mortality figures, complications and PROMs, together with implant costs for specific component sets, based on National Health Service procurement data. These analyses will be reported by age group and gender in order to determine the most suitable and cost-effective implant for individual patients.

Data

Access and data security

Applications were made to HQIP and the IC to access the entire NJR and PROMs datasets respectively. Access to NJR data was originally granted in June 2011 via a secure personal laptop (installed with encryption software), allowing local storage. Northumbria Healthcare NHS Foundation Trust provided Caldicott approval. The NHS Information Centre granted data controller status. As the IC stipulated that PROMs data could not be stored locally, a secure server was provided by Northgate Information Solutions Ltd (NIS), allowing access to and linking of datasets via an encrypted NIS-owned laptop (January 2012). All statistical analyses were performed and stored on the server. The output from final statistical analyses was the only data approved for extraction.

In order to access NJR and PROMs data, the following approvals were granted: HES application form 1b/appendices A1-3 (Office of National Statistics [ONS] mortality data), B/C (Security approval), E (PROMS access), NJR non-disclosure agreement, NIS access control policy P0804106, NIS allocation of IT equipment P0807103, NIS information technology acceptable usage policy P08051103, NIS software use P08052103, NIS virus protection P08053104, NIS network security P08054103, IC standard terms and conditions for the use and reuse of public sector information, and IC PROMs data reuse agreement (extracts) (NIC-114678-MPR47).

Approval from HQIP to access NJR data was based on adherence to their security policy and a work plan documenting the proposed analyses, agreed by the NJR research committee. Caldicott approval was subsequently taken over by HQIP in January 2012. Data access was permitted for research fellows only; raw data and statistical analyses were performed solely by the author, with advice and guidance from University statistical support and supervisors where required.

Populations studied and data available

The NJR has assimilated data on patients, surgeons and implants performed in the public (NHS) and private sectors in England and Wales. Patient demographic details, surgeon characteristics, and implant information were available for the period between 1st April 2003 and 31st December 2010. Linkage to revision hip procedures performed on the same hip following a recorded primary replacement (over the same period) allows identification of an implant failure. Similarly, notification of a death to the ONS in a patient registered on the NJR is captured at any time after surgery. Therefore, patient outcome data (revisions and/or deaths) are also available within the NJR data.

All patients undergoing hip replacement between 1st April 2008 and 31st December 2010 were also invited to complete PROMs pre-operatively and at six months following the procedure. Patients' general health, comorbidities and disability before surgery, together with hip specific and general health scores recorded pre- and post-operatively, and complications following surgery are

recorded. Data on patients' satisfaction with the procedure and their perception of success are also available. The data available for analysis are summarized in **Table 2.0.1**.

Table 2.0.1. Data available for analysis

Data	NJR	PROMs
Patient	Unique identifiers Age Sex ASA BMI Pathology	Unique identifiers Age Sex Preoperative health Preoperative disability Preoperative OHS Preoperative Eq5d index Preoperative VAS Comorbidities
Surgical	Date of operation Surgeon identifier Surgeon grade Unit identifier Surgical approach Patient position VTE prophylaxis	Date of operation
Implant	Femoral stem brand Stem specification Cup brand Cup specification Head size Head bearing Cement specification	
Outcome	Revision Death	Postoperative OHS Postoperative Eq5d index Postoperative VAS Success Satisfaction Complications

NJR – National Joint Registry, PROMs – patient reported outcome measures, ASA – American Society of Anaesthiologists, BMI – body mass index, OHS – Oxford Hip Score, VAS – visual analogue score, VTE – venous thromboembolic

Data were extracted for all hip procedures performed with the primary diagnosis of osteoarthritis. This accounted for 93% of all hip replacements performed in England and Wales in 2011 [30]. Procedures performed using the commonest brand of cemented, cementless or hybrid procedures were used for analyses in order to manage variation. These most commonly used brands also have the lowest revision risk within their category, according to analyses previously performed by the NJR. All hip resurfacings were included in preliminary analyses, but final analyses used only the most commonly used brand (also the lowest revision risk). The inclusion of only the most common indication for surgery and only the most commonly used brands of each type of hip increased the power of our analyses (i.e. increased ability to detect differences by reducing variation) whilst also allowing in-depth component assessment within brands. Although the

inclusion of all brands would increase patient numbers and provide more generalisable conclusions, performance can vary considerably between brands and configurations of each type of replacement; this is a limitation of most registry analyses to date. The primary interest was to identify the best performing hip prostheses, and understand which specific component sets within categories were outperforming others.

Data cleaning and management of missing data

Raw data was provided as separate NJR and PROMs csv format dataset files (originally manipulated by NIS using the SQL database language). Due to the size of the NJR dataset after tabulating (over 400,000 rows and 100 columns), the data were divided into a manageable size for manipulation in Microsoft Excel 2010 version 14 (10 files of 40,000 records). Columns of data that were not required (such as prosthesis description at revision surgery) were deleted. The data of interest (procedures using the specific brand combinations of the commonest used prostheses in each category, and all resurfacings) were then extracted as separate data files.

Extensive reformatting of the data was performed in order to separate implant variables (*stem* – offset, size, collar type; *head* – material, size, neck length; *cup* - shell size, surface finish, and presence of screw holes, liner material, offset, and presence of augment, cement brand and presence of antibiotic) from within multiple component strings. An example of this is shown in **Table 2.0.2**. Excel functionality allowed a combination of multiple and individual episode manipulation to complete this task. Where this was not possible, implant identification reference codes were used (based on manufacturers catalogue data) or manual imputation, based on other implant data (for example, a missing head size could be imputed manually if the cup internal diameter was recorded).

Patient outcome, as recorded at the censor date of 31st December 2010, was defined as either unrevised, revised, or dead (with the date of death or revision provided). Where revision was registered, data was available for the reason for revision. Operations with missing or obviously incorrect patient, implant or surgeon data were excluded from the analysis unless missing data could be manually imputed from other sources. An exception to this was BMI, which was poorly recorded across NJR data (50% available overall, but recording chronologically improved to 80% in 2010). Clinically impossible values (for example, 2 or 160) were assumed to be errors. Therefore, BMI was considered accurate if between 15 and 60; all other values were deleted. Automatic imputation for missing data was considered but ultimately discounted, due to the uncertainty associated with these methods. Data deletion was not considered a problem given the large study populations. The nature of missing data was assumed to be random. However, poor data collection or input in particular areas may result in clustering of incorrect or absent data. In addition, for a patient's BMI very high or very low values may be more commonly recorded than normal values. These situations could potentially introduce bias into conclusions drawn from analyses of this data.

There were a number of exclusion criteria for the PROMs data: procedures with missing questionnaires or missing data fields (as two separate scores are required to calculate change in PROMs); undated questionnaires; those dated more than 12 months prior to or following the operation, or dated within 6 months of the procedure (to limit the effects of shorter follow up upon functional recovery); or non-identical duplicates. For identical duplicates the first record was retained for analysis. Where the presence of a co-morbidity or complication was sought in the questionnaire but left blank by the patient, it was assumed to be absent.

Table 2.0.2. Example of a cleaned extract from the acetabular and head component description string in National Joint Registry raw data file

NJR raw data		Cleaned data					
Cup details	Head details	Type of cup	Details	Head size	Head material	Head offset	Bearing
ELITE PLUS LPW (LONG POSTERIOR WALL) CUP 28/43mm	28mm ELITE PLUS MODULAR HEAD +3	Cemented polyethylene	Posterior lip	28	SS	Plus	MoP
DC FIT M/BACK ASSEMBLY CUP 56MM DUAL	EUROCONE CoCR MODULAR HEAD SHT NK 28MM	Cementless	NA	28	CoCr	Minus	MoP
ELITE PLUS LPW (LONG POSTERIOR WALL) CUP 28/40mm	28mm ELITE PLUS MODULAR HEAD +3	Cemented polyethylene	Posterior lip	28	SS	Plus	MoP
DURALOC OPTION CUP 54mm	HIP BA BIO 28MM 12/14+1.5	Cementless	NA	28	Ceramic	Plus	CoP
Cobalt Chrome 'BHR' Acetabular Cup 56mm	Cobalt Chrome 'BHR' Femoral Head 50mm	Resurfacing	NA	50	CoCr	NA	MoM
REFL I POR ACET SHELL 50MMOD L	ORTHINOX V40 HEAD 28MM	Cementless	NA	28	SS	Standard	MoP
Cobalt Chrome 'BHR' Acetabular Cup 54mm	Cobalt Chrome 'BHR' Femoral Head 46mm	Resurfacing	NA	46	CoCr	NA	MoM
EXETER DURATION CUP LP 22.2X40MM	ORTHINOX V40 HEAD 22MM	Cemented polyethylene	Low profile	22	SS	Standard	MoP
Cobalt Chrome 'BHR' Acetabular Cup 56mm	Cobalt Chrome 'BHR' Femoral Head 50mm	Resurfacing	NA	50	CoCr	NA	MoM
CHARNLEY OGEE CUP 22.225/40mm	ORTHINOX V40 HEAD 22MM	Cemented polyethylene	NA	22	SS	Standard	MoP
Cobalt Chrome 'BHR' Acetabular Cup 60mm	Cobalt Chrome 'BHR' Femoral Head 54mm	Resurfacing	NA	54	CoCr	NA	MoM
CONTEMPORARY HOODED CUP 26X54MM	ORTHINOX V40 HEAD 26MM	Cemented polyethylene	Hooded	26	SS	Standard	MoP

NA – not applicable, SS – stainless steel, CoCr – cobalt chromium, MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, MoM – metal-on-metal

Bilateral observations

Many statistical methods are based on the assumption of independent observations. However, patients can undergo bilateral replacements; patient-specific physiological and behavioural factors can play an important role in the

success of these replacements, and so bilateral observations are not truly independent. In addition, timing of the surgeries is important; a patient with bilateral hip arthritis may undergo sequential (i.e. one hip replacement followed by the second during the same theatre episode) or staged bilateral replacements, with weeks or months between the procedures (to allow recovery and adequate rehabilitation following the first replacement and to reduce the risk burden of a sequential procedure). Patients may also have bilateral procedures many years apart, perhaps having the first replacement at a time when the contralateral hip was asymptomatic.

There are several ways to deal with this data issue, such as observing only the first replacement, or analysing the correlated observations. However, analyses of registry data tend to ignore bilaterality, assuming that the revision risks of uni- and bilateral joint replacements are identical. Data collection is also an issue, as a sequential bilateral procedure can be recorded as either bilateral on one MDS form, or separately as two unilateral procedures. The NJR annual report describes 368 (0.4%) bilateral procedures during 2012, although it is acknowledged that the true figure may be higher [30]. As there is no consensus on this and the number of bilateral events appears small, a decision was made to treat all observations as independent; therefore in these analyses, no adjustment is carried out for bilaterality [129].

Revision data

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) on the NJR dataset, a complete record of the revision procedure (including side of operation) is submitted from the treating hospital and linked to the original index procedure by matching unique patient identifiers. A number of causes of revision can be recorded for each operation. In order to summarise this data effectively, infection then peri-prosthetic fracture were selected as the primary reason when recorded. For resurfacing procedures, soft tissue reaction to metal debris and metallosis (including other free text terms such as 'ALVAL') were grouped together. Pain was only taken as a cause when no other reason was provided. Information regarding radiographic appearance at the time of the primary procedure and immediately prior to revision is not available within the NJR dataset currently.

Dataset linkage

By linking the PROMs and NJR datasets at patient level, general health scores, hip specific scores, and complication data can be combined with the corresponding demographic and operative details held within the NJR.

In order to link the two datasets a number of linkage criteria were used. Firstly, to ensure correct matching, two unique identifiers (NJR and procedure numbers) recorded in both datasets were used. Secondly, the operation date recorded by the patient in the PROMs data had to be within +/-30 days of the operation date recorded on the NJR record, to ensure the patient was scoring the same

procedure. Linkage was carried out in Microsoft Excel 2010 using the *vlookup* functionality.

To ensure the PROMs-NJR linked data was representative of the general population undergoing hip arthroplasty the demographic details of each linked cohort was compared to those for all patients undergoing that particular type of hip replacement (linked and unlinked).

Statistical analyses

Variables

Variable categories previously thought to have a influence on revision risk (patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), stem size, cup shell type and coating, bearing surface materials and head size) were included in these analyses, with American Society of Anaesthesiology (ASA) grade taken to be a surrogate for co-morbidity score [57, 130-133]. The influence of stem design (two designs of cementless Corail stem are available), component brand (resurfacing analysis), offset, cement type (when used), surgical approach and primary surgeon characteristics were also examined. Variables used in the revision analyses are summarised in **Table 2.0.3**.

For the PROMs analyses pre-existing comorbidities, general health and disability, and pre-operative scores (available within the PROMs dataset) were modelled together with the NJR dataset variables (**Table 2.0.4**). However, it was felt that implant covariates with no significant influence on any of the original implant models were unlikely to significantly influence the combined analysis models, and these were therefore disregarded.

Management of variables

Continuous variables, such as age, stem size, and consultant volume were analysed as both continuous and categorical data (to ensure non-linear influences were not missed). Grouping continuous data into categories may also be of the greater clinical relevance when making group comparisons. As available head sizes differ across bearing surfaces, these were partitioned into groups in order to ensure the influence of sizes and bearings was represented within the models. In systems with modularity, bearing surface categories were initially partitioned based on head and liner combination, including presence of posterior lip and type (standard or highly cross-linked) for polyethylene liners. To examine femoral offset (the distance from the centre of rotation of the femoral head to a line bisecting the long axis of the femur) as an influence on implant survival, one of two methods was used: firstly, for the implants using the Exeter stem, offset can be adjusted depending on the stem and head used – these were analysed as separate entities within the cemented and hybrid analyses; secondly, for the cementless implants (Corail stem/Pinnacle cup), offset can be adjusted using the stem design, the head or the polyethylene liner – a combination of these values (based on manufacturers figures) was used to calculate combined offset.

Table 2.0.3. Variables used in NJR revision analyses of each of the separate implant types

Category	Type	Covariate
Patient factors		
Age (years)	Ordinal	≤60, 61-75, ≥76[abc] ≤45, 46-55, 56-65, ≥66[d]
Gender	Binary	Female, Male
ASA grade	Ordinal	≤2, ≥3[abc] 1, 2, ≥3[d]
Body mass index	Ordinal	<30kg/m^2, ≥30kg/m$^{2\ abc}$ <19kg/m^2, 19<25kg/m^2, 25<30kg/m^2, ≥30kg/m$^{2\ d}$
Implant factors		
Stem size[c]	Ordinal	8-10, 11-13, ≥14
Stem design[c]	Nominal	Collared, collarless
Stem offset[ab]	Ordinal	35mm, 37.5mm, 44mm, 50mm
Stem taper[ab]	Ordinal	1, 2, 3, ≥4[a] ≤2, ≥3[b]
Head size	Ordinal	<28mm, 28mm, 32mm[a] 28mm, 32mm, ≥36mm[b] 28/32mm, 36mm[c] ≤44mm, 45-47mm, 48-50mm, ≥51mm[d]
Offset[abc]	Ordinal	Standard, 'Plus' head, 'Minus' head[ab] Low, medium, high, minus[c]
Shell design[bc]	Nominal	Solid-back, Multi-/cluster-hole[b] Solid-back, Solid HA-coated, Cluster-hole, Cluster-hole HA-coated[c]
Cup design[a]	Nominal	Flanged, Hooded
Bearing[abc]	Nominal	MoPE, CoPE[a] MoPE, CoPE, MoXLPE, CoXLPE, CoC[b] MoPE, CoPE, MoXLPE, CoXLPE, CoC, CoM, MoM[c]
Cement type[ab]	Nominal	High viscosity antibiotic impregnated Palacos HV, CMW HV Low viscosity antibiotic impregnated Simplex LV, Other (Palacos LV, CMW LV) High viscosity, no antibiotic Palacos HV, CMW HV Low viscosity, no antibiotic Simplex LV, Other (CMW LV, Palacos LV)
Brand[d]	Nominal	Birmingham Hip Resurfacing, Articular Surface Replacement, Adept, Cormet, Conserve Plus, Durom, Mitch, Recap
Surgeon factors		
Surgical approach	Nominal	Posterior, Anterolateral, Other
Primary surgeon	Binary	Consultant, Other
Consultant implant volume	Ordinal	Low (≤50 cases throughout study period), Medium (51-200), High (≥201)[bd] Low (≤50), Medium (51-300), High (≥301)[ac]

ASA – American Society of Anaesthesiologists, kg – kilogram, m – metre, mm – millimeter, Metal-on-standard polyethylene (MoPE), Metal-on-highly-cross-linked (MoXLPE), Ceramic-on-standard polyethylene (CoPE), Ceramic-on-highly-cross-linked (CoXLPE), Ceramic-on-ceramic (CoC), Ceramic-on-metal (CoM), Metal-on-metal (MoM) a – cemented analysis, b – hybrid analysis, c – cementless analysis, d – resurfacing analysis

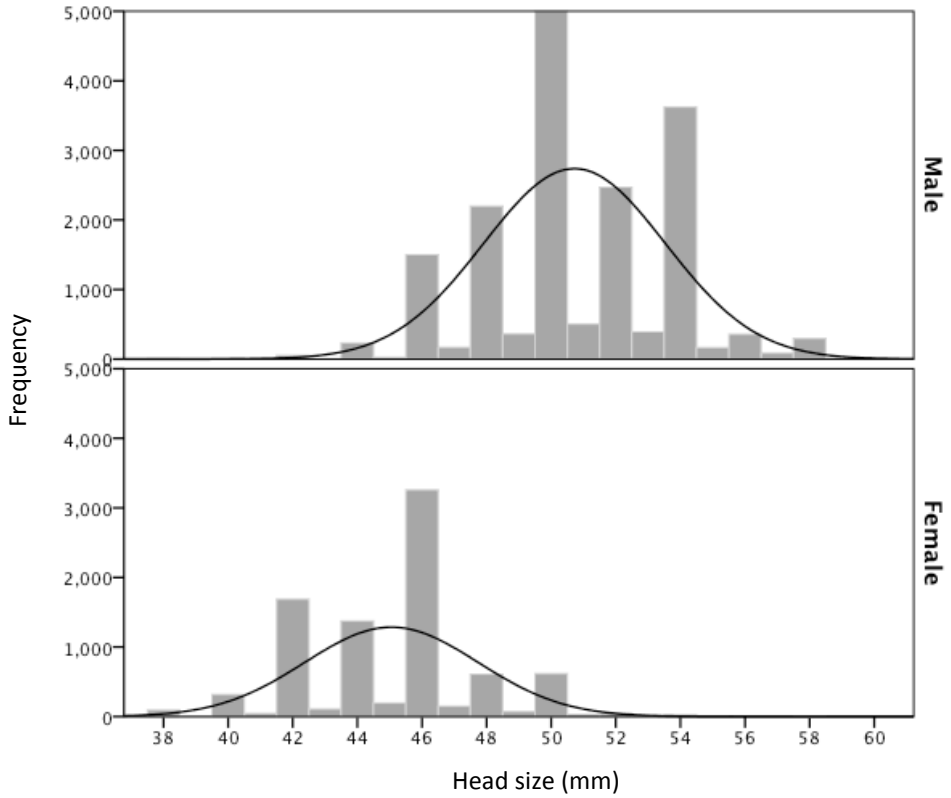
Table 2.0.4. Variables used in the NJR-PROMs linked analyses

	Source	Description
Patient factors		
Age (years)	NJR/PROMs	
Sex	NJR/PROMs	
American Society of Anaesthesiology (ASA) grade	NJR	Grades 1 to 4
Body mass index (BMI) (kg/m^2)	NJR	Only BMI within 15 kg/m^2 to 60 kg/m^2 included
Comorbidities	PROMs	Recorded by patients as part of the pre-operative PROMs questionnaire. Nine co-morbidities: i) ischaemic heart disease, ii) respiratory disease, iii) diabetes, iv) hypertension, v) kidney disease, vi) liver disease, vii) circulatory problems, viii) cancer, ix) depression
Pre-operative general health	PROMs	Indicates the patient's perception of their own general health with five options: i) excellent, ii) very good, iii) good, iv) fair, v) poor
Pre-operative disability	PROMs	Indicates whether the patient considers themselves to have a disability
Pre-operative Oxford Hip Score (OHS)	PROMs	Derived from adding the points (0 to 4) together from the response to hip symptom-specific questions on a scale of 0 to 48 (0 worst, 48 best)
Pre-operative EQ5D Visual Analogue Score	PROMs	Indicates how well the patient feels on the day of completing the questionnaire on a scale of 0-100 (0 worst, 100 best)
Pre-operative EQ5D index	PROMs	Single summary score derived from EQ5D profile (based on response to 5 questions) by applying a formula with appropriate operation specific weightings
Surgical factors		
Lead surgeon grade	NJR	Consultant or other
Approach	NJR	Posterior or direct lateral
Patient position	NJR	Lateral or supine
Anaesthesia	NJR	i) Regional only, ii) general only, iii) general and regional
Chemical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) aspirin only, ii) LMWH only, iii) other, iv) none
Mechanical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) Compression stockings (CS) only, ii) combination CS/mechanical pump, iii) foot pump only, iv) intermittent calf pump only, v) other, and vi) none
Time from operation to post-operative PROMs completion	PROMs	Calculated from the date of operation as recorded on the NJR database to the date of post-operative PROMs as recorded on the questionnaire

NJR – National Joint Registry, PROMs – patient reported outcome measures, LMWH – low molecular weight heparin

As resurfacing component size is patient anatomy dependent, females tended to have smaller components than males (**Figure 2.0.1**). In order to ensure all bearings were represented in each gender, four size categories were selected to use in the analyses (≤44mm, 45 to 47mm, 48 to 50mm, ≥51mm).

Figure 2.0.1. Distribution of resurfacing femoral component size, by gender



To explore the influence of variables the most common category within each variable was generally used as the reference or baseline value: for example, 28mm heads were used as the baseline against which all other head sizes were compared in the cemented analysis. Similarly, for bearings, the most commonly used standard (polyethylene acetabular liner) bearing was used (MoP). Exceptions to this were age (where the youngest group was used as the baseline), combined offset (where the standard/smaller 'plus' offsets were used), consultant volume (where the highest volume group was used) and, in the hybrid analysis, bearing (where the type most commonly used in 2010 was the baseline). Where variable management differs from this within specific analyses, this is discussed.

Analysing baseline characteristics

Tests of normality were performed on continuous data variables. For comparisons of two groups of normally distributed data, a two-tailed independent sample t-test with assumed equal variance was used. For non-parametric data, the two-sample Wilcoxon rank-sum (Mann-Whitney) test was used. Where there were more than two groups, analysis of variance (ANOVA)

was performed on parametric data and the Krushal-Wallis test on non-parametric data. For discrete data variables, Fisher and Chi-squared tests (categorical data) and ordinal logistic regression (ordinal data) were used.

Risk of implant revision and survival models

A revision procedure was considered a 'failure event', where time between the primary hip replacement and a revision procedure measured the implant survival. Survival times for patients who had not undergone revision were censored at the study census date (31st December 2010). Kaplan-Meier survival charts were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates using the pair-wise over strata method. Variable categories with significant influences are presented, with life tables to describe numbers within each category entering each year of the study.

Cox proportional hazard models were used to assess the extent to which the timing of revision could be explained in terms of the measured patient, surgeon and implant variables (multivariable analysis). The Cox model assumes that there is an underlying unspecified baseline hazard that stays constant over time and that is influenced proportionately by variables that mitigate or enhance the risk of failure. Additionally it assumes non-informative censoring, where (for example) the event studied (implant failure) is unrelated to censoring (due to end of follow-up or death). For the cemented analysis, two separate models were constructed: all causes of revision; and, revisions where dislocation was recorded as a reason (other reasons for revision were treated as an alternative outcome – in effect, excluding these from the analysis). For the remaining analyses, all cause revision was solely modeled. Results are presented as Hazard Ratios (HRs) with 99% confidence intervals (CI): ratios greater than one indicate that risk is higher when compared with the reference variable category. Due to the statistical methods employed, and the large population size, only covariates fitting models with $p<0.01$ were considered significant influences, to reduce the risk of a Type 1 error. An exception to this was made for the hybrid analysis (small population size), where statistical thresholds were lowered (95% CIs and $p<0.05$) to accommodate a greater level of uncertainty for modelled survival estimates.

In order to improve the power of final statistical models to detect parameter differences, where no statistical differences were found within subcategories (for example, different polyethylene liners) during preliminary modelling, these were combined. The reliability of the models was explored by alternative stepwise procedures using the likelihood ratio test. Variables found not to be statistically significant were excluded from the model, based on statistical entry ($p<0.05$) and rejection ($p>0.10$) criteria. The same variables were fitted forward and reverse stepwise to ensure findings were not qualitatively affected in the final model, with any inconsistency reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring 2-way interactions between variables and for the constant proportionality over time assumption. In addition, baseline entry and rejection

criteria for the model were reduced to $p<0.01$ and $p>0.05$ respectively to test covariate selection within the model. Simple (unadjusted) results are displayed for univariable analysis of each variable, and for multivariable analyses for variables found to have significant influence on each model.

Other factors, such as the influence of surgical unit, post-operative pain and pre-operative educational initiatives to manage expectations may have effects on functional outcome, but these are unmeasured in this analysis. It is possible to introduce measures into statistical models to attempt to account for these, (in effect, a way of inserting unmeasured variation, known as statistical 'frailty') but this may be unreliable. Thus, variation associated with these factors remains unmeasured.

Adjusting for competing risks (such as death) in implant survival analyses may be important when there are differences in baseline patient demographics between groups. Patients who have died will be treated as 'censored' by the model if this approach is not taken, thus in theory still contributing to the survival curve. There are therefore clear advantages of a Competing Risks survival model (CRM) over the Kaplan-Meier survival analysis. However, the benefits are less clear when CRM is compared with multivariable survival modelling (such as Cox Proportional Hazards), as this allows adjustment for patient factors (such as age, comorbidities and gender), which may affect both implant survival and risk of death.

Life tables were produced to report unadjusted revision rates (using the normal approximation) within each of the analyses. Survival was not reported beyond the time when the number of patients remaining was less than 5% of each original cohort.

PROMs, complications and regression models

PROMs questionnaires are completed prior to surgery and at around 6 months following surgery. Several outcomes are of interest: post-operative OHS, EQ-5D index and EQ-VAS, post-operative complications, and a patient's perception of success of and their satisfaction with the procedure. However, analysis of these dependent variables is problematic. Both the OHS and the EQ-5D index have an attainable maximum score, so although pre-operative scores are generally normally distributed (**Figure 2.0.2**), post-operative scores are negatively skewed with many patients attaining the highest score (**Figure 2.0.3**). Change scores (the difference between pre- and post-operative scores), being approximately normally distributed, are analytically preferable to post-operative scores and were used in analyses (**Figure 2.0.4**). This is similar to the approach taken by the authors of the PROMs feasibility pilot [134].

Figure 2.0.2. Pre-operative Oxford Hip Scores (0 to 48)

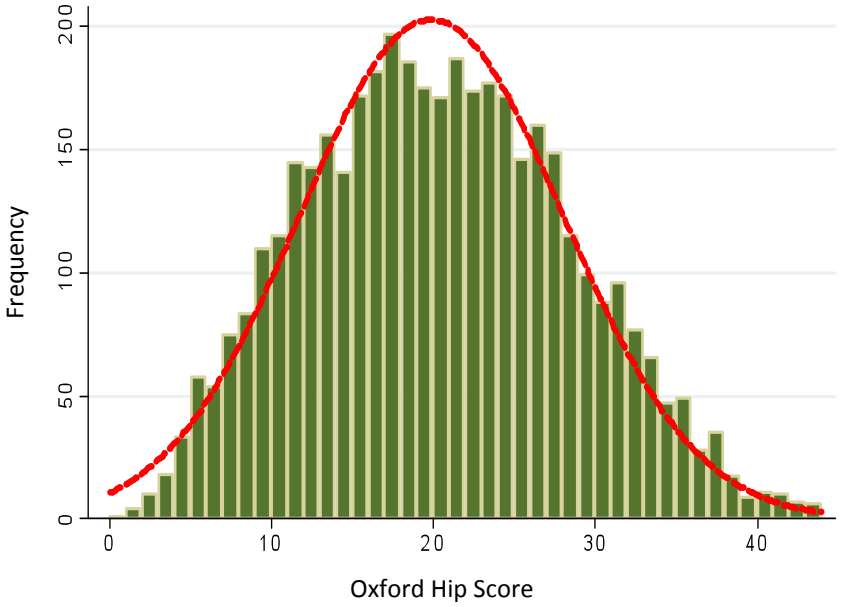


Figure 2.0.3. Post-operative Oxford Hip Scores (0 to 48)

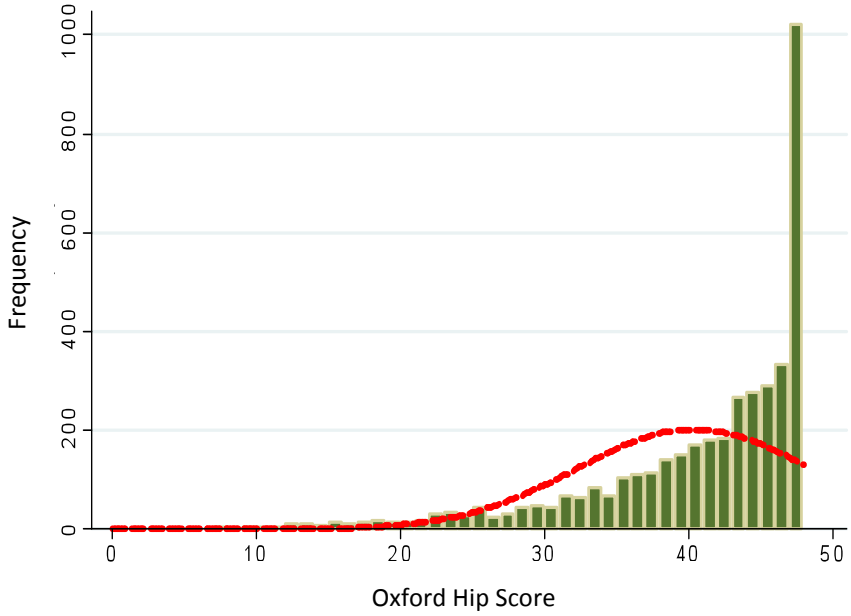
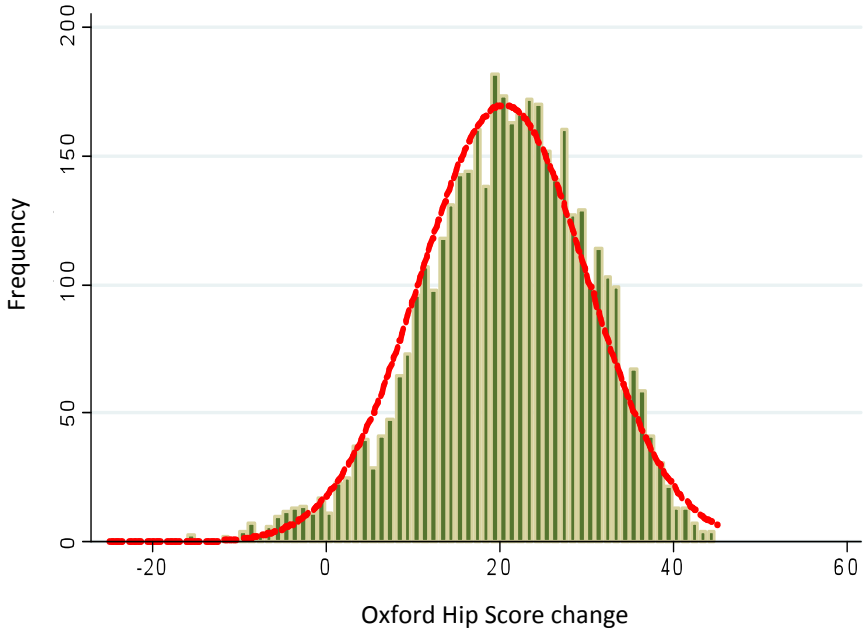


Figure 2.0.4. Change in Oxford Hip Scores (pre- to post-operative)



To permit meaningful comparison between groups it is important to account for differences in patient and surgical characteristics, as these variables could potentially confound any comparative analysis. Variables explaining the variance of PROMs outcomes were sought using linear regression (change in OHS/EQ-5D index) and logistic regression (rate of complications) modeling. The models included all patient characteristics and clinical factors collected routinely by the NJR and the pre-operative PROMs questionnaire. One exception to this was in the modeling of perioperative death (at 30 and 90 days following the index procedure), which used the entire NJR dataset and did not require linkage to the PROMs pre-operative fields. Univariable analysis was performed initially to identify variables potentially influencing each outcome; these were then subsequently included in multivariable models. To help limit the effects of multiple testing and ensure a parsimonious model only the most important variables were included within the final models (significant at $p<0.05$).

Statistical models for the change scores were evaluated using the 'margins' function, providing predicted values (including 99% CIs and p-values) compared with the reference category. For complication risks, results were presented as odds ratios (ORs) with 99% CIs, with ratios greater than one indicating that risk was higher when compared with the reference category.

Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Pre-operative scores were included, as recommended by the designers of the OHS [100]. Although BMI is an important variable there were concerns about missing data and the possibility of recording bias. Inclusion of BMI is discussed specifically within each analysis.

Sample sizes in excess of 150/group are reported as the threshold to identify meaningful differences, according to the PROMs feasibility pilot [134]. However the clinical importance of findings should always be considered alongside statistical significance, as with large patient numbers unimportant differences might become significant.

The reliability of the multivariable statistical models was explored in a number of ways. Covariates found not to be statistically significant were excluded from the model, based on statistical entry ($p<0.05$) criteria. The same covariates were fitted forward and reverse stepwise manually to ensure findings were not qualitatively affected in the final model, with any inconsistency reported. The final models were re-evaluated as a directly entered model (non-stepwise), and were assessed by exploring 2-way interactions between covariates.

The purpose of the analyses was hypothesis generating (exploring factors influencing hip replacement performance) rather than hypothesis testing. Consequently there was no adjustment for multiple testing. The choice of level of statistical significance in final models was set as the cohort sizes allowed (generally $p<0.01$), to identify strongly associated factors. Although causality was not being demonstrated formally, factors identified and reported met the conditions of temporality, strength of exposure, dose response (where continuous variables) and biological/clinical plausibility [135].

Unadjusted values for the PROMs success and satisfaction have been provided for information, without adjustment for baseline differences. Previous analyses have demonstrated that the variables available within the NJR and PROMs databases are insufficient to explain differences in the VAS, patient satisfaction and success of the procedure (i.e. unexplained variation remains considerable) [134].

Statistical software

Preliminary survival models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, New York). Subsequent PROMs and survival analyses were performed in STATA/SE 12.0 for Windows (StataCorp LP, Texas, United States).

Cost analysis

Implant costs were provided by NHS Wales (all seven Trusts) and NHS Supply Chain (buyers on behalf of 30 Trusts within the English NHS). The modal costs (and a range of costs, representing highest and lowest amounts paid) for specific components during 2012 were produced at source. These costs represent actual prices paid, after discounts, and include Value Added Tax (VAT, at 20%) and the NJR levy fee (£20, which is included in the amount paid for each implant). Costs for specific implant combinations have been calculated, including ancillary materials required to implant, such as acetabular screws (for cementless cup fixation) where used, cement (using costs of the commonest cement used for each implant type), femoral cement restrictors and all equipment required to mix and perform pressurised cementation. For the purposes of this analysis, it is assumed that theatre utilisation and length of stay are similar for all types of replacement. Although there may be small variations in surgical time according to procedural selection there is no evidence that these differences would amount to differing numbers of patients within surgical lists.

Part 1. Preliminary survival analysis of commonest brands

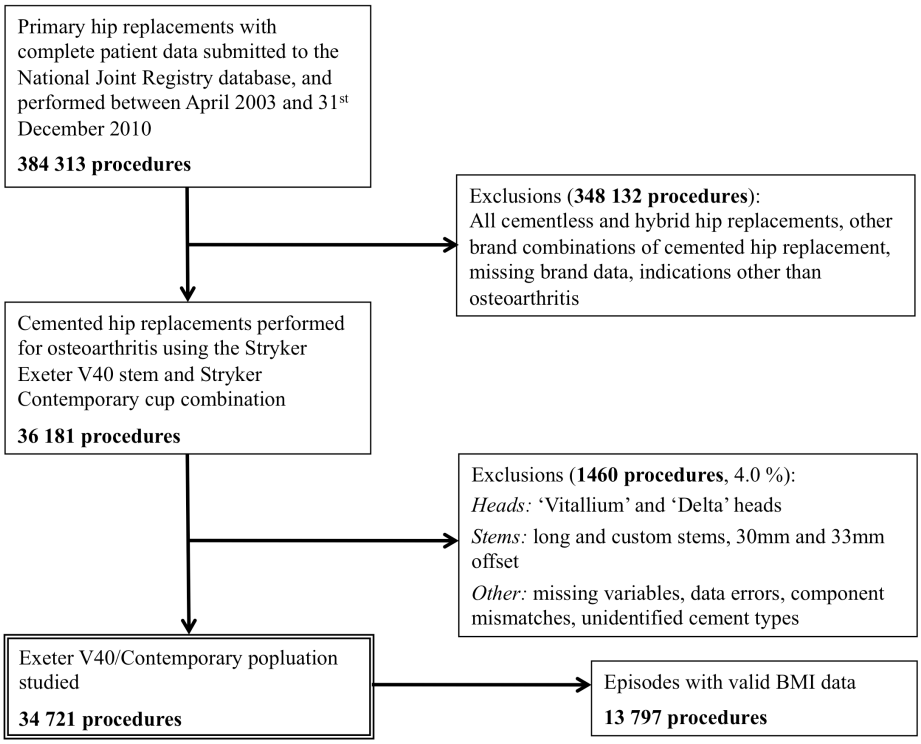
Analyses were conducted using patient-level NJR data to identify significant implant, patient and surgical influences on implant survival for the most commonly used cemented, hybrid, cementless and resurfacing brands, using Cox Proportional Hazards models.

Cemented analysis

The commonest brand combination of cemented THR used in England and Wales since 2003 features the Stryker Exeter V40 hip and Contemporary socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 23.2% of all cemented THRs (37 995 of 163 981) [30]. The Exeter V40 femoral stem is a polished, double tapered, collarless stainless steel design with a 'V40' taper and a hollow distal centraliser to allow subsidence of the implant by compressive loading throughout the cement mantle. It is available in a range of taper sizes (0 to 5), offsets (30mm to 56mm) and lengths (short: 104 to 134mm, standard: 158mm, and long stem options: 200mm to 260mm). The monobloc Contemporary cup is manufactured from standard (non cross-linked) Ultra High Molecular Weight Polyethylene (UHMWPE, branded as 'Duration' by Stryker) and incorporates four PMMA spacer beads on the outer surface. It is available in flanged and hooded varieties, and a range of acetabular (40mm to 60mm) and internal diameter sizes (22mm to 32mm). Femoral heads are available in stainless steel ('Orthinox': 22 to 32mm), cobalt-chrome ('Vitallium': 28 and 32mm) and ceramic ('Alumina' and 'Delta' zirconia-alumina: 28 and 32mm).

Three brands of cement have been used: 'Palacos' (three manufacturers: Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corporation, Kenilworth, New Jersey, USA; Biomet Inc., Warsaw, Indiana, USA), 'CMW' (DePuy Orthopaedics Inc., Warsaw, Indiana, USA) and 'Simplex' (Stryker Corporation, Kalamazoo, Michigan, USA). Palacos and CMW are available as high and low viscosity, and all brands have plain or antibiotic impregnated versions. As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in **Figure 2.1.1**.

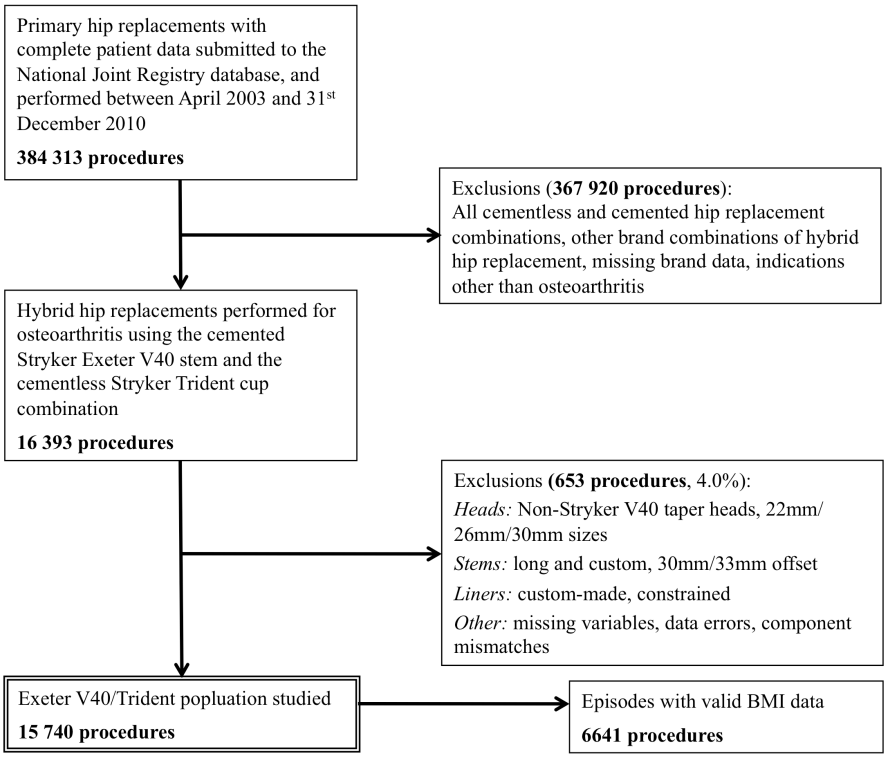
Figure 2.1.1. Flow chart describing the inclusion criteria for the cemented analysis



Hybrid analysis

The commonest brand combination of hybrid THR used in England and Wales since 2003 features the Stryker Exeter V40 hip and Trident socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 33.0% of all hybrid THRs (18 358 of 55 551) [30]. The Trident Acetabular System is an uncemented modular cup manufactured from hydroxyapatite (HA) coated porous titanium (non-HA coated Trident cups are not available in the United Kingdom). Liner options include standard polyethylene (PE), highly cross-linked (XL) PE (first generation: 'Crossfire', and second generation: 'X3'), alumina ceramic, and constrained. The shells are available as a press-fit no-hole ('Solid-back') type, or in multi-hole ('5-hole', 'Cluster-hole (3-hole)' and 'Multi-hole') form, allowing supplementary fixation with acetabular screws. Two types of shell geometry are manufactured: 'Hemispherical' and 'Peripheral self-locking' (PSL, or rim-fitting). Femoral heads are available in stainless steel ('Orthinox': 22, 26, 28, 30, 32, and 36mm), cobalt-chrome ('Vitallium': 28, 32, 36, 40, and 44mm) and ceramic ('Alumina' 28, 32, and 36mm). The same three brands of cement (as described earlier) were used with these components. As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in **Figure 2.1.2**.

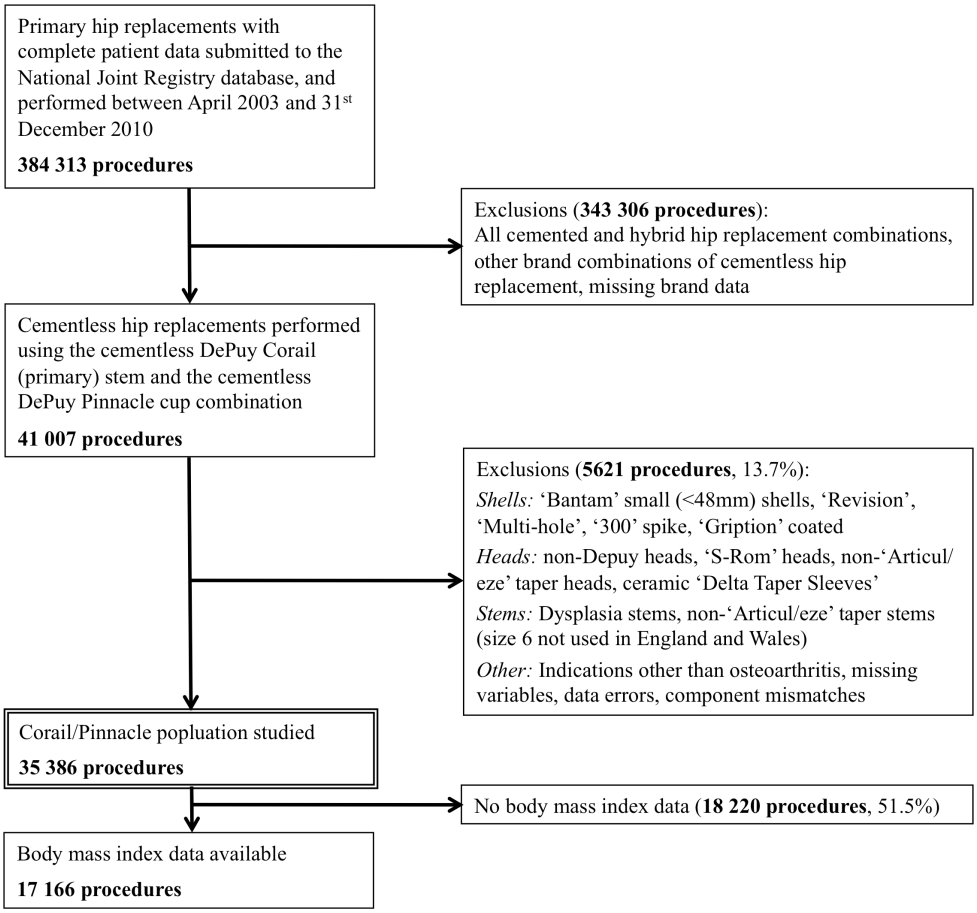
Figure 2.1.2. Flow chart describing the inclusion criteria for the hybrid analysis



Cementless analysis

The commonest brand combination of cementless THR is the Corail stem/Pinnacle cup (DePuy Ltd, Leeds, United Kingdom), accounting for 31.2% of all cementless THRs (40 879 of 130 920) [30]. The Corail femoral stem is a fully hydroxyapatite (HA) coated non-porous forged titanium alloy stem and comprises a proximal trapezoid cross section and quadrangular cross section distally, with a polished, low profile neck and a 12/14 taper ('Articul/eze'). It is available in a range of sizes (6 to 20), neck offsets (standard, 'Lateralised Coxa Vara', and 'High Offset') and can be used with or without a collar. The Pinnacle cup system comprises a 180° titanium shell with coating options including 'Porocoat' (titanium sintered beads), 'Duofix' (Porocoat with an HA coating) and 'Gription' (high friction porous surface). The shell accepts polyethylene ('Enduron' standard polyethylene or 'Marathon' highly cross-linked polyethylene), ceramic ('Biolox Delta') and metal liners ('Ultamet'). It is available in acetabular sizes 38 to 66mm and the shell comes in four varieties: solid backed '100', spiked solid back '300', the 3-hole 'Sector', and a 'Multi-hole'. A summary of inclusion criteria is shown in **Figure 2.1.3**. A sub-group analysis was performed on patients with complete BMI records.

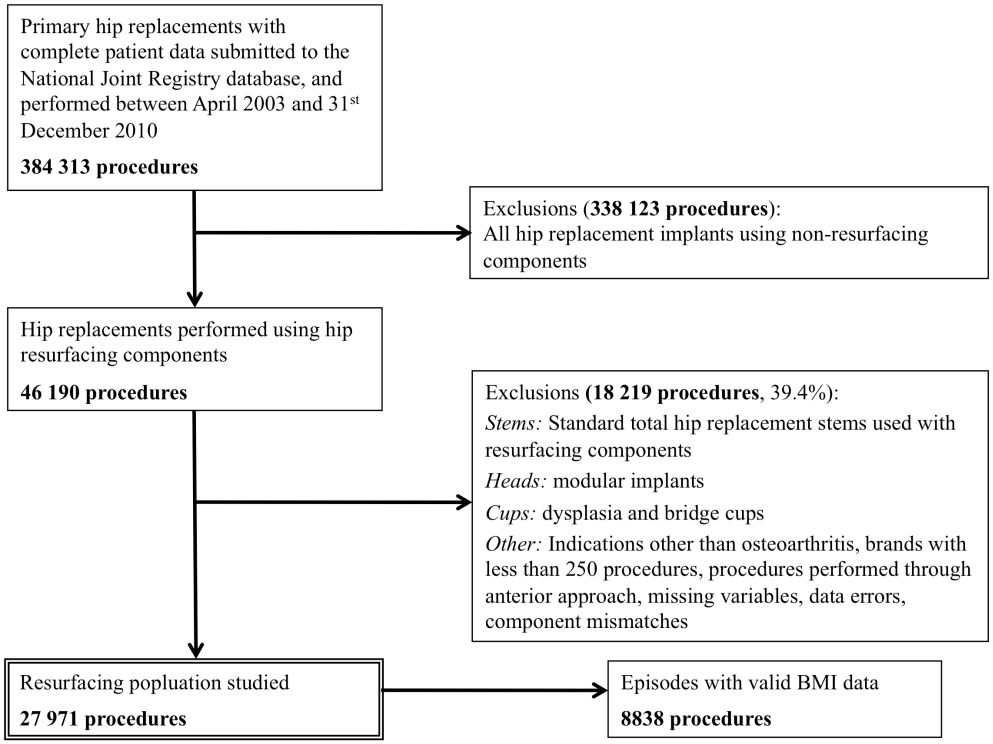
Figure 2.1.3. Flow chart describing the inclusion criteria for the cementless analysis



Resurfacing analysis

Data were extracted for all hip resurfacing procedures performed and submitted to the NJR until December 2010. Resurfacing bearing components using a femoral stem, modular resurfacing implants and complex resurfacings (e.g. using dysplasia or bridge acetabular components) were excluded. The anterior approach was used for fewer than 100 procedures and was therefore excluded. A summary of inclusion criteria is shown in **Figure 2.1.4**.

Figure 2.1.4. Flow chart describing the inclusion criteria for the resurfacing analysis



Part 2. Patient reported outcome measures (PROMs) analyses

Overall PROMs analysis

PROMs data were analysed for patients undergoing the commonest cemented, cementless, hybrid and resurfacing procedures between 2008 and 2010, after linking with NJR data fields. The intention was to determine the factors that significantly influenced OHS and EQ-5D scores (using multivariable linear regression). Since a strong interaction between gender and other factors was identified, separate models were developed for male and female patients. The variables available for the analyses are shown in **Table 2.0.4**.

The influences of four factors on PROMs were specifically of interest: BMI, surgical approach, head size and bearing type.

Influence of body mass index

Patients with a high BMI may be denied access to hip replacement in some parts of the UK. There is a perception that these patients do not experience the same functional benefits as those with a normal BMI. Analyses of patient-level NJR/PROMs-linked data compared general and joint specific outcome scores and self-reported complications at a minimum 6 months following primary hip replacement in patients with different BMIs.

The single most commonly used brand of cemented (Exeter/Contemporary) and cementless (Corail/Pinnacle) hip replacement were analysed in order to remove the substantial variation between implants, while providing widely applicable results. Procedures with missing or outlying BMI (<19kg/m^2 or >65kg/m^2) data were excluded. The study population is summarised in **Figure 2.2.1**.

For this analysis the outcomes of interest were improvements in change scores (OHS and EQ-5D index) and rates of self-reported post-operative complications (bleeding, wound problems, readmission and reoperation). Sample sizes for all the BMI groups were in excess of the minimum numbers identified in the PROMs feasibility pilot to identify meaningful differences (more than 150/group).

The variables available for the analyses are shown in **Table 2.0.4**. To align with its clinical application, BMI was grouped into three categories: 19.0kg/m^2-29.9kg/m^2 (normal and overweight – reference group), 30.0kg/m^2-34.9kg/m^2 (Obese class I), 35.0kg/m^2+ (Obese class II and III). BMI was also assessed as a continuous variable to ensure BMI categorisation did not qualitatively alter findings. Analyses of cemented and cementless procedures were performed independently as no attempt was made to adjust for baseline differences of patients with different types of implants.

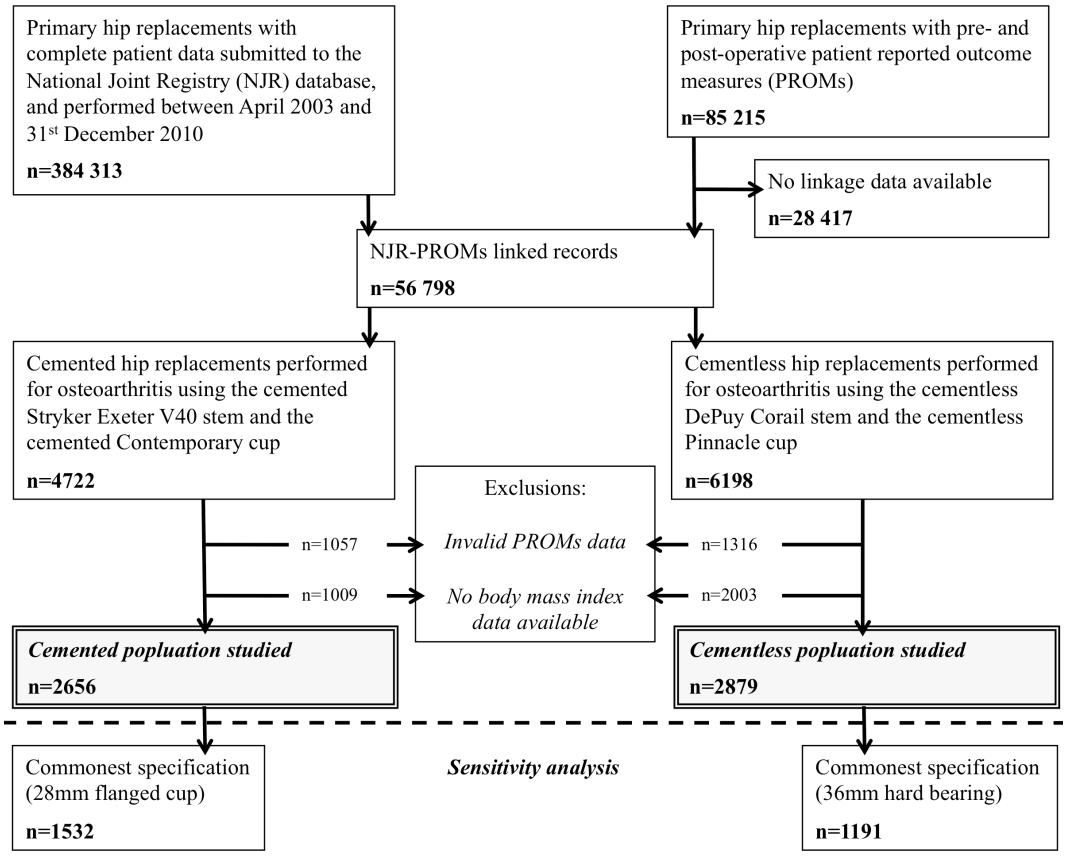
Analysis of Covariance (ANCOVA) was used to test differences in OHS and EQ5D index change scores across BMI groups. Multivariable logistic regression was used to analyse differences in the risk of each of the complications across BMI groups.

In order to provide 'real-world' clinical scenarios, predicted changes in OHS were produced for the cemented model using the margins function in STATA. This

demonstrated the differences in procedure-specific improvement when sex, differences in pre-existing health status and disability, and level of pre-operative OHS were specified within the model, in addition to BMI.

To test the models generated, a sensitivity analysis was performed using only the most commonly implanted component sets within the cemented (28mm flanged cup, representing 70% of all Exeter V40-Contemporary THRs implanted in 2010) and cementless groups (36mm hard bearing, representing 51% of all Corail Pinnacle THRs implanted in 2010).

Figure 2.2.1. Flow chart describing the inclusion criteria for the PROMs analysis of body mass index



Influence of surgical approach

The majority of hip replacements are performed through either a posterior or a lateral approach. Both techniques have benefits and drawbacks. Functional outcome following each has previously not been reported on a national level. Therefore, analyses were conducted using patient-level NJR and NJR/PROMs-linked primary hip replacement data to compare outcome scores and early revision risk following these two commonly performed approaches.

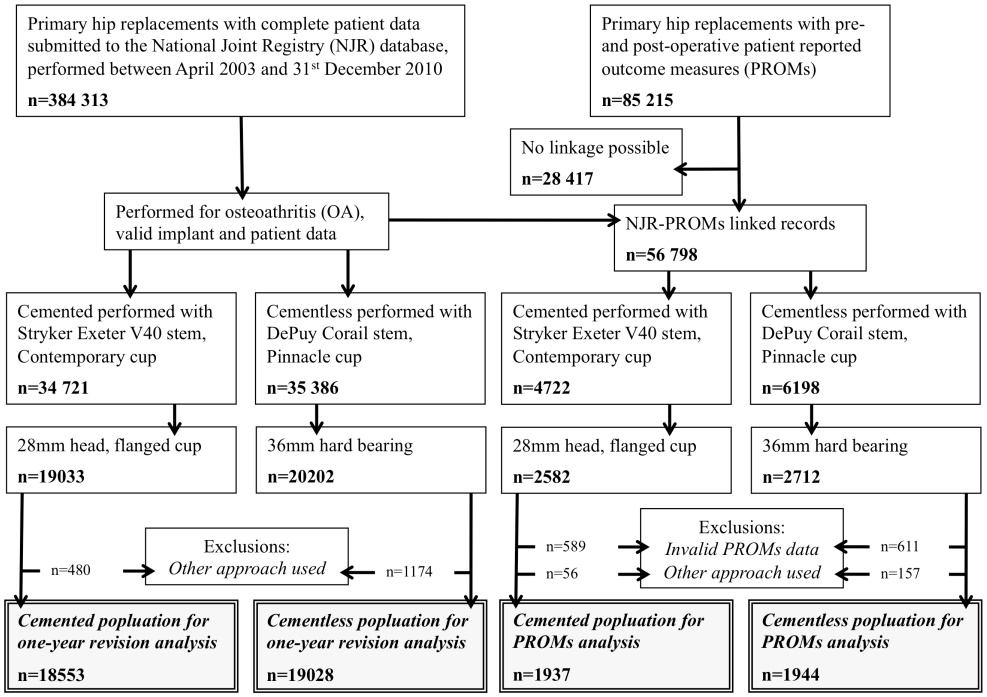
Specific component combinations of the commonest cemented and cementless brands were analysed in order to limit variations within types of implant. Femoral head size and type of Contemporary cup (hooded or flanged) are independent influences on revision risk (see results from **part 1 – cemented analysis**) in the cemented Exeter V40/Contemporary cohort. For this analysis all procedures performed with a 28mm head and a flanged cup design (representing 70% of all Exeter V40/Contemporary THRs implanted in 2010) were examined. For the cementless Corail stem/Pinnacle cup combination, procedures that employ a 36mm hard bearing (ceramic-on-ceramic [CoC] and metal-on-metal [MoM]) were examined. These represent almost half of components implanted (48%), and provide a suitable contrast with the cemented implants. This ensures the results from this study can be applied generally across different surgeons' practice. Sample sizes for the two groups were in excess of the minimum numbers identified in the PROMs feasibility pilot. The study population is summarised in **Figure 2.2.2.**

The variables available for the analyses are shown in **Table 2.0.4**. Analyses of cemented and cementless procedures were performed independently; no attempt was made to adjust for baseline differences between types of implants.

Multivariable linear regression was used to identify the influence of surgical approach upon OHS and EQ5D index change scores. Similarly, multivariable logistic regression was used to analyse differences in the risk of each of the self-reported complications available within the PROMs data, and revision risk at one-year (using data from the unlinked NJR cohort). As BMI is known to have an influence on PROMs, it was included in models where its influence was significant. For the revision analysis, NJR data unlinked to PROMs was preferred due to the larger population size.

In order to provide 'real-world' clinical scenarios, predicted changes in OHS were produced for both the cemented and cementless models. These demonstrated the difference in hip specific improvement when sex, pre-existing health status, disability, and comorbidities were specified within the model, in addition to surgical approach.

Figure 2.2.2. Flow chart describing the inclusion criteria for the surgical approach PROMs analysis



Influence of head size and bearing analysis

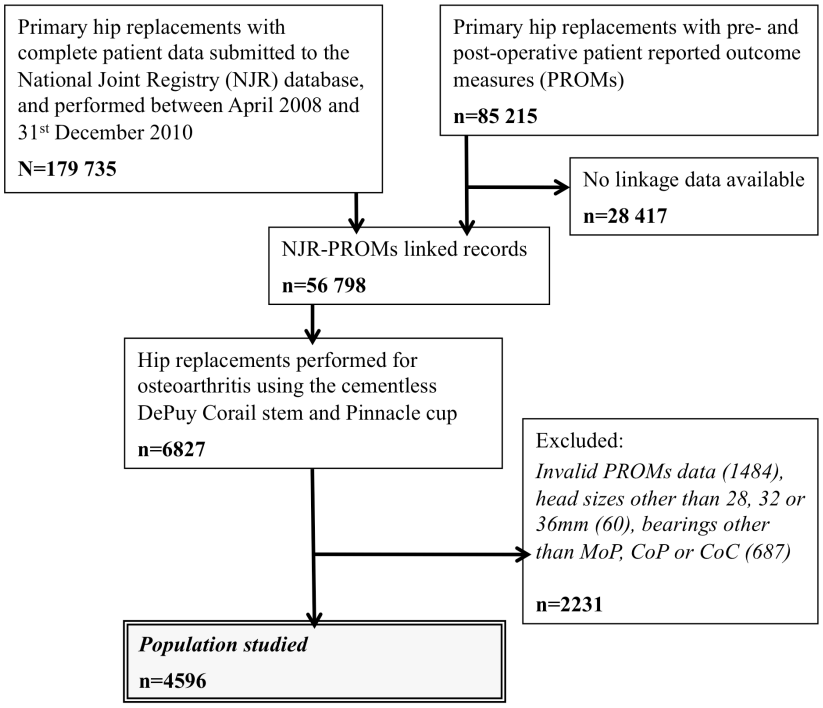
The use of larger head sizes and hard bearings for hip replacement has increased dramatically over the last decade. Functional benefit of these options has yet to be proven. Analyses were conducted using patient-level NJR/PROMs-linked data to compare outcome scores and self-reported complications across different head sizes and bearings following primary hip replacement.

Data from the single most commonly used brand of hip replacement performed in England and Wales between 2003 and 2010 (Corail stem/Pinnacle cup) was used for analysis [30]. Procedures performed with head sizes smaller than 28mm and larger than 36mm, and rarely used bearings (ceramic-on-metal and metal-on-ceramic) were excluded. Metal-on-metal bearings were also excluded as few are now implanted. The study population is summarised in **Figure 2.2.3**.

The variables available for the analyses are shown in **Table 2.0.4**. Head sizes analysed were 28mm, 32mm and 36mm. Bearings were MoP, CoP and CoC. For this analysis the outcomes of interest were the OHS and EQ5D index change scores and self-reported post-operative complications (bleeding, wound problems, readmission and reoperation). Sample sizes for all the head size and bearing groups were in excess of the minimum numbers identified in the PROMs feasibility pilot.

ANCOVA was used for testing differences in OHS and EQ-5D index change scores across head size and bearing groups. Multivariable logistic regression was used to analyse differences in the risk of each of the complications across groups.

Figure 2.2.3. Flow chart describing the inclusion criteria for the head size and bearing PROMs analysis



MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic

Part 3. Comparison of survival modelling

Alternative survival models are discussed and compared. The commonly used method is Cox proportional hazards, but it has been proposed that competing risk of death is an important component of implant survival analysis and may be more accurate. This claim is explored.

Survival modelling

The findings for the Cox proportional hazards model and the Fine and Gray competing risks model [136] are compared when analysing the revision risk of two implant types (cemented versus cementless). In principle a competing risks model is preferable when censoring is informative, violating the Cox regression assumption of non-informative censoring. Death affects (prevents) the chance of revision and is thus a competing risk, but it may only influence models substantially if of the same order of magnitude as revision risks (for absolute risks of revision) or if influencing implants differentially (for relative risks of revision). In order to compare implants of similar type and to reduce confounding, we chose standard implants from the most commonly used brands (Stryker Exeter V40 stem with a flanged Contemporary cup and DePuy Corail stem sizes 11+ with a Pinnacle cup/polyethylene liner using a 28mm head). These specific implant combinations were found to offer the best survival within each system (see **Part 1**); thus, the best cemented implant was compared with the best cementless implant.

NJR variables available for analysis are described in **Table 2.0.3**. As BMI data was only available in 11708 (44%) procedures, the survival models are built with BMI data included and excluded and the results for each analysis are discussed.

Part 4. Multi-outcome analyses of revision risk-stratified implants

Findings from previous analyses are brought together, comparing the performance of different implant types within age and gender categories, complemented by cost analyses.

Younger patient population (under 60 years at time of surgery)

Whilst it is difficult to define age limits for a 'younger' population requiring hip replacement, an arbitrary definition of less than 60 years is thought appropriate. Analyses were conducted using patient-level NJR and PROMs data, comparing implant survival and patient reported outcomes across different primary hip replacements in patients under 60 years old. Additionally, material costs were analysed using NHS procurement data in order to quantify the financial impact of using specific types of replacement.

The single most commonly used brands of each type of hip replacement performed in England and Wales were chosen for the analysis, in order to remove brand heterogeneity within groups (cemented [taper slip design]: Exeter V40 stem / Contemporary cup [23% of cemented implants]; cementless: Corail stem / Pinnacle cup [31% of cementless]; hybrid: Exeter V40 stem / Trident cup [33% of hybrids]; and resurfacing, BHR [55% of resurfacings]) [30]. These implants were each separately stratified into two groups based on revision risk of component options as described in **part 1**. The 'best' performing and the remaining ('other') component sets are summarised in **Table 2.4.1.** Therefore, implants were compared across eight groups. The study population is summarised in **Figure 2.4.1**.

Table 2.4.1. Eight implant groups for multi-outcome analysis across implant types

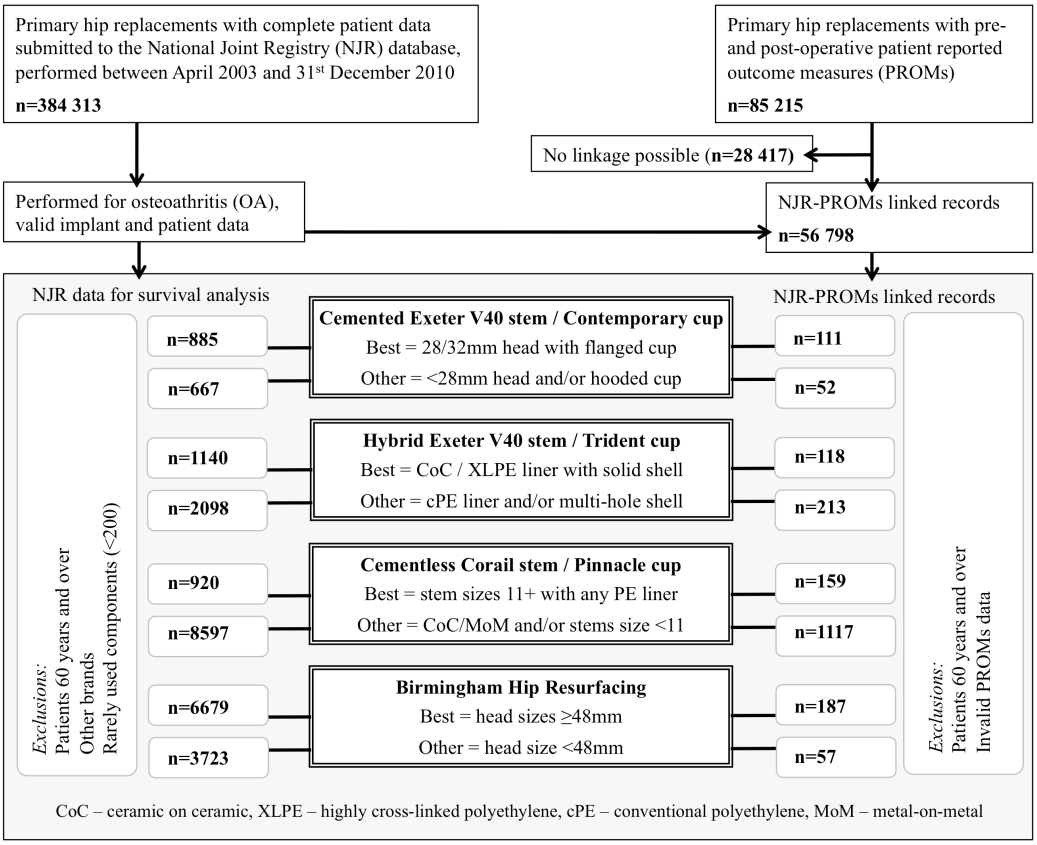
	Best	**Other**
Cemented *Exeter V40/Contemporary*	28mm or 32mm head and flanged cup	All hooded cups or all with head sizes <28mm
Hybrid *Exeter V40/Trident*	MoXLPE or CoXLPE or CoC and solid-back shell	All multi-hole shells or standard polyethylene bearings
Cementless *Corail/Pinnacle*	Stem sizes ≥11 and MoP or CoP bearings	All small stems (<10) or CoC or MoM
Resurfacing *Birmingham Hip Resurfacing*	≥48mm head size	<48mm head size

MoXLPE – metal-on-highly cross-linked polyethylene, CoXLPE – ceramic-on- highly cross-linked polyethylene, CoC – ceramic-on-ceramic, MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, MoM – metal-on-metal

ANCOVA was used to explore differences in OHS and EQ5D index change scores on the NJR/PROMs linked data. Competing risks models are used to explore adjusted differences in survival across the implant groups, where patient death prior to either revision or censoring was the competing risk (entire NJR dataset). Statistical tests report differences between the reference (cemented Exeter with a Contemporary flanged PE cup and 28 or 32mm metal or ceramic head) implant and the seven other groups. In this section, significance is taken as $p<0.05$ and

estimates are reported with 95% CIs: (ratios greater than one indicate that risk is higher when compared with the reference cemented category). For the purpose of identification, parameter estimates with probabilities <5% are considered significant, with further consideration of the clinical importance of magnitude of estimates.

Figure 2.4.1. Flow chart describing the inclusion criteria for the multi-outcome analysis of patients under 60 years



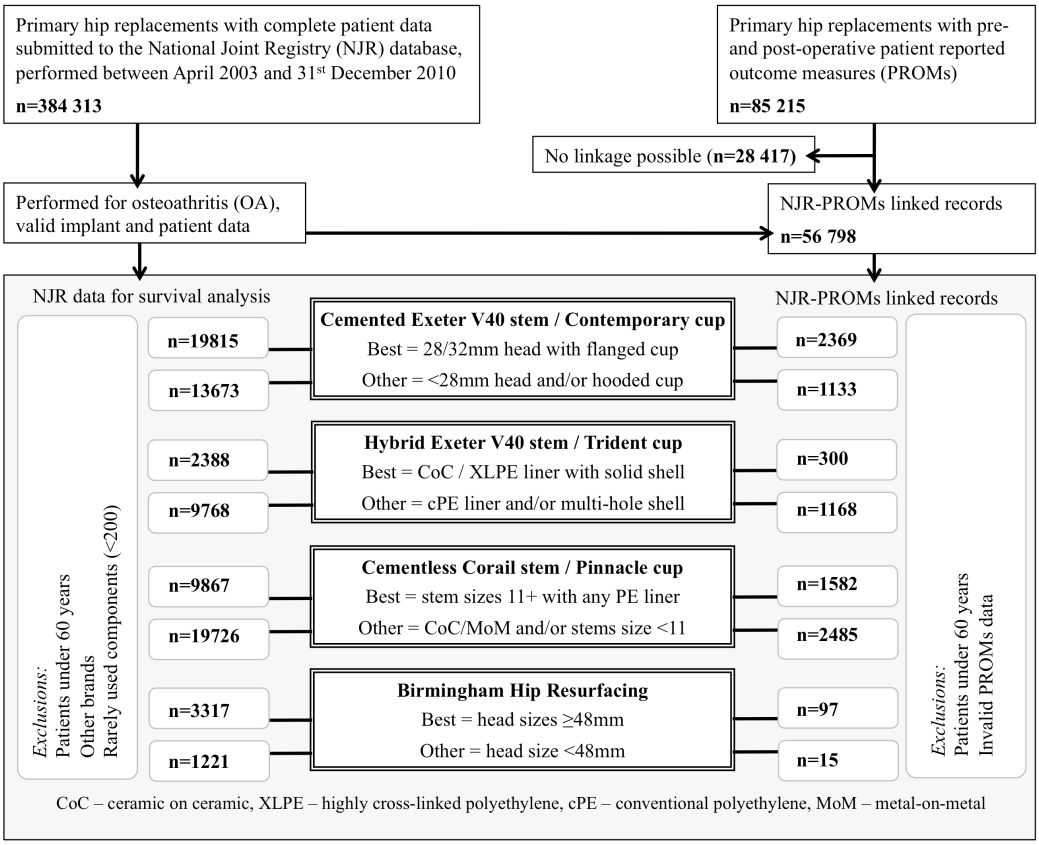
Normal hip replacement population (≥60 years at time of surgery)

As before, analyses were conducted using patient-level NJR and PROMs data to compare implant survival, patient reported outcomes and complications, and perioperative mortality across different hip replacements in a normal hip replacement population (patients 60 years and over), with additional material cost data from National Health Service (NHS) procurement.

Implant inclusion was identical to the above section (**younger patient population**): implants were compared across the same eight configurations of hip replacement. The study population is summarised in **Figure 2.4.2**.

Competing risks models were used to test adjusted differences in survival across the implant groups. Cumulative incidence charts for type of implant are provided, by gender. ANCOVA was used for testing differences in OHS and EQ5D index change scores. Multivariable logistic regression was used to analyse differences in the risk of complications (wound complications, readmission and reoperation) and perioperative mortality (at 30 and 90 days). Statistical probabilities are reported for differences between the reference (cemented Exeter with a Contemporary flanged PE cup and 28 or 32mm metal or ceramic head) implant and the seven others, with a significance threshold of $p<0.05$.

Figure 2.4.2. Flow chart describing the inclusion criteria for the multi-outcome analysis of patient aged 60 years and over



Methodology chapter summary

Statistical methods used within a range of analyses of a national registry of hip replacement data have been described. Identifying the factors that significantly influence performance is complex because of the multitude of procedural and patient variables. Preparation of data is made more complex by the challenges of correctly linking national datasets. Additionally some statistical controversies have been introduced that will be explored.

The following chapter presents the results of each of the four analyses described in this chapter, finally bringing together a number of clinical outcomes together with implant cost data to identify the best performing and cost-effective implants for patients undergoing primary hip replacement for osteoarthritis. The importance of alternative statistical methods is explored.

3. Results

Overview

The large number of different brands and designs of hip replacement makes it difficult to differentiate the benefits and drawbacks of specific configurations, resulting in some uncertainty and variation in the findings of national registry implant analyses. Within this thesis, the commonest brands of replacement type are analysed, providing greater clarity about subsequent configuration decisions.

Assessing the performance of hip replacement procedures begins by identifying the optimal configuration (component set) for each of the four types of available hip procedures (cemented, hybrid, cementless and resurfacing), in terms of implant survival. Optimal hip replacement configurations for each type are then compared in subsequent analyses.

The performance of optimal and non-optimal configurations is further explored using PROMs measures with particular attention to the influence of BMI, surgical approach, head size and bearing on functional outcome. Then the importance of alternative statistical methods is explored when comparing optimal cemented and non-cemented procedures.

Finally, the findings from the combined analysis of implant types are presented, including stratified implant survival data, perioperative mortality figures, complications, PROMs and material costs. Following interpretation a flowchart is produced to help inform the management of patients with OA who require hip replacement.

Part 1. Individual brand implant survival analyses

Cemented hip replacement

Despite globally-reported excellent mid- to long-term results, the use of cemented THR is declining in England and Wales. These implants offer very low revision rates. However, opponents argue they work poorly in younger patients, restrict functional outcome, offer only a limited number of articulating bearing options and take longer to perform. Performance and risk factors associated with failure of the commonest cemented implant (Stryker Exeter V40 stem with Contemporary acetabular cup) used in England and Wales are described.

Of 34 721 primary procedures recorded between 2003 and 2010, the majority were performed in females (22 790, 65.6%), with ASA ≤2 (28 747, 82.8%) and 75 years of age or less (18 598, 53.5%); the mean age at implantation was 74 years old. There were 13 797 (39.7%) procedures with complete BMI data, of these the majority were less than 30kg/m^2 (8929, 64.7%). The majority of stems used 44mm offset (18 161, 52.3%) and the most commonly used taper was size 1 (10 925, 31.5%). The commonest cup design was flanged (24 212, 69.7%) and the commonest head was stainless steel (32 724, 94.2%), 28mm (27 218, 78.4%) with standard offset (22 446, 64.6%). The majority of procedures were performed with high viscosity antibiotic impregnated cement (21 674, 62.4%), and the commonest brand was Palacos HV (20 664, 59.5%). In most cases the senior surgeon (consultant) performed the procedure (25 962, 74.8%) through a lateral approach (17 065, 49.1%). The majority of cases were carried out by a medium- or high-volume surgeon (≥51 cases over study period: 25 688, 74.0%). Patients were under the care of 973 different consultants in 271 different surgical units. Demographics are shown in **Table 3.1.1**.

The proportion of flanged cups used increased from 56.2% (470) in 2003 to 71.8% (4339) in 2010. Over the period of study the use of <28mm heads declined from 56.4% (472) in 2003 to 5.1% (309) in 2010, whilst the use of 28mm heads increased from 43.6% (365) to 79.7% (4812). Thirty-two millimetre heads were used in small numbers from 2004; by 2010 they accounted for 15.2% (919) of the head sizes used (**Table 3.1.2**). In this study, 54.0% (18 746) of procedures were performed with a 28mm head and flanged cup combination.

Table 3.1.1. Demographics of 34 721 Exeter V40/Contemporary cemented hip replacements (England and Wales, 2003-2010)

Age, mean years (SD, range)	73.9 (8.0, 23-100)	
≤60, n (%)	1603	(4.6)
61-75	16 965	(48.9)
≥76	16 153	(46.5)
Gender		
Female	22 790	(65.6)
Male	11 931	(34.4)
ASA grade		
½	28 747	(82.8)
≥3	5974	(17.2)
BMI, mean kg/m^2 (SD)	28.2	(5.1)*
<30kg/m^2, n (%)	8929	(25.7)
≥30kg/m^2	4868	(14.0)
No data	20 924	(60.3)
Stem offset		
35mm	1690	(4.9)
37.5mm	13 449	(38.7)
44mm	18 161	(52.3)
50mm	1421	(4.1)
Stem taper		
0	10 656	(30.7)
1	10 925	(31.5)
2	8770	(25.3)
3	3227	(9.3)
≥4	1143	(3.3)
Head size		
<28mm	5036	(14.5)
22mm	*104*	*(0.3)*
26mm	*4932*	*(14.2)*
28mm	27 218	(78.4)
32mm	2467	(7.1)
Head offset		
Standard (0)	22 446	(64.6)
Plus (+2mm to +12mm)	5686	(16.4)
Minus (-2mm to – 4mm)	6589	(19.0)
Cup design		
Flanged	24 212	(69.7)
Hooded	10 509	(30.3)
Bearing		
Metal-on-polyethylene	32724	(94.2)
Ceramic-on-polyethylene	1997	(5.8)
Cement		
High viscosity antibiotic impregnated	21 674	(62.4)
Palacos HV	*20 664*	*(59.5)*
CMW HV	*1011*	*(2.9)*
Low viscosity antibiotic impregnated	8561	(24.7)
Simplex LV	*8280*	*(23.8)*
Other (Palacos LV, CMW LV)	*281*	*(0.8)*
High viscosity, no antibiotic	1426	(4.1)
Palacos HV	*831*	*(2.4)*
CMW HV	*595*	*(1.7)*
Low viscosity, no antibiotic	1570	(4.5)
Simplex LV	*1567*	*(4.5)*
Other (CMW LV, Palacos LV)	*3*	*(0.0)*
Missing	1490	(4.3)
Surgical approach		
Lateral	17 065	(49.1)
Posterior	15 386	(44.3)
Other	1067	(3.1)
Missing data	1203	(3.5)
Primary surgeon		
Consultant	25 962	(74.8)
Other	8759	(25.2)
Number of consultants (n)	973	
Consultant volume		
Low (≤50 cases over study period)	9033	(26.0)
Medium (51-250)	15 978	(46.0)
High (≥251)	9710	(28.0)
Number of surgical units (n)	271	

BMI – body mass index, SD – standard deviation, * - based on 13 797 procedures, HV – high viscosity, LV – low viscosity

Table 3.1.2. Proportion of cup designs and head sizes used by year, Exeter V40/Contemprorary cemented hip replacement (England and Wales, 2003-2010)

Year	Cup design				Head size					
	Flanged		Hooded		<28mm		28mm		32mm	
2003, n (%)	470	(56.2)	367	(43.8)	472	(56.4)	365	(43.6)	0	(0.0)
2004	1038	(63.4)	599	(36.6)	745	(45.5)	884	(54.0)	8	(0.5)
2005	2273	(64.6)	1243	(35.4)	839	(23.9)	2642	(75.1)	35	(1.0)
2006	3045	(69.9)	1327	(30.4)	779	(17.8)	3507	(80.2)	86	(2.0)
2007	4168	(71.0)	1702	(29.0)	788	(13.4)	4916	(83.7)	166	(2.8)
2008	4402	(69.8)	1904	(30.2)	599	(9.5)	5270	(83.6)	437	(6.9)
2009	4477	(72.9)	1666	(27.1)	505	(8.2)	4822	(78.5)	816	(13.3)
2010	4339	(71.8)	1701	(28.2)	309	(5.1)	4812	(79.7)	919	(15.2)
Total	*24 212*	*(69.7)*	*10 509*	*(30.3)*	*5036*	*(14.5)*	*27 218*	*(78.4)*	*2467*	*(7.1)*

Reasons for revision

Two hundred and seventy-nine patients had undergone a revision procedure by the census date (31st December 2010): the most common reason reported was dislocation (98 revisions, 35.1% of all revisions) followed by infection in 25.8%, aseptic component loosening/lysis (21.9%), malalignment (11.8%) and peri-prosthetic fracture (7.9%). Revision data are summarized in **Table 3.1.3**.

Table 3.1.3. Reasons recorded for revision of 279 Exeter V40/Contemporary cemented hip replacements (England and Wales, 2003-2010)

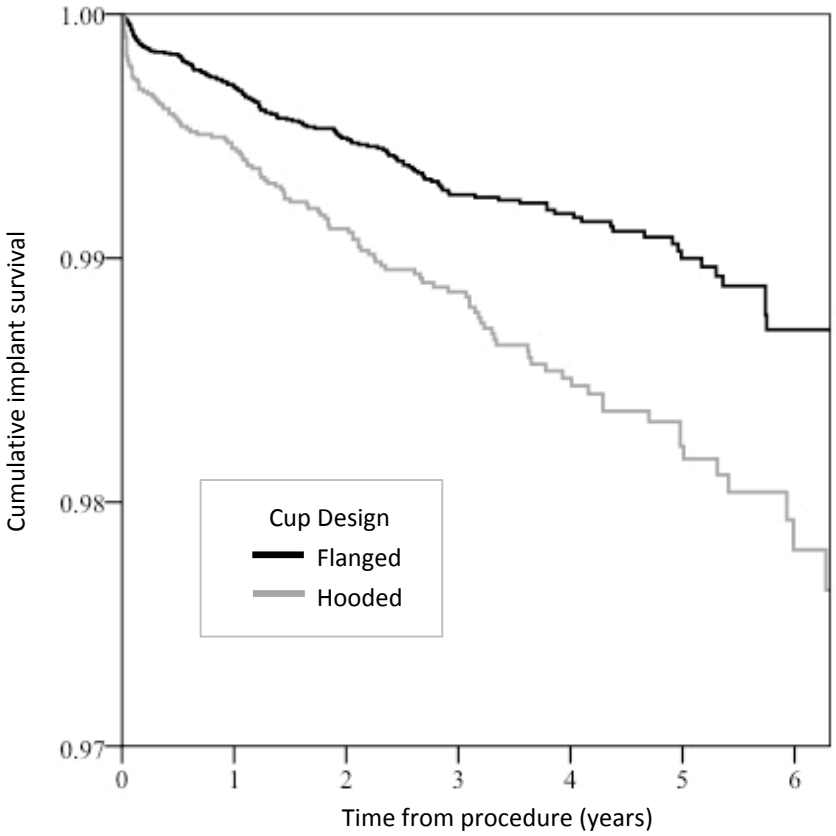
Dislocation, n (%)	98	(35.1)
Infection	72	(25.8)
All aseptic component loosening/lysis	61	(21.9)
Stem only	*19*	*(6.8)*
Cup only	*41*	*(14.7)*
Both	*1*	*(0.4)*
All malalignments	33	(11.8)
Stem only	*5*	*(1.8)*
Cup only	*23*	*(8.2)*
Both	*5*	*(1.8)*
Periprosthetic fracture	22	(7.9)
Stem only	*20*	*(7.2)*
Cup only	*2*	*(0.7)*
Unexplained pain	9	(3.2)
Polyethylene cup wear	8	(2.9)
All implant fractures	4	(1.4)
Stem only	*2*	*(0.7)*
Cup only	*2*	*(0.7)*
Other	28	(6.3)

All-cause revision model

In simple (univariable) regression analysis of 'all revisions', only cup design influenced implant revision risk (p<0.001) (**Figure 3.1.1**), although there was a trend towards significance in femoral head sizes <28mm (p=0.022) (**Figure 3.1.2**, **Table 3.1.4**). Brand of cement was not found to be a significant influence for survival: these covariates were therefore merged into common cement type

categories. After risk adjustment, hooded cup design (HR=1.88, p<0.001) and head sizes <28mm (HR=1.50, p=0.005) were independent influences associated with revision. Risk of revision for 32mm head sizes (HR=0.84, p=0.595) and ceramic heads (HR=1.10, p=0.720) was not significantly different to 28mm and stainless steel heads respectively. Cement viscosity and impregnation with antibiotic did not influence risk of revision (**Table 3.1.4**). Revision risk was independent of patient variables (gender, age, ASA grade, BMI), stem characteristics, head offset, surgical approach and consultant experience.

Figure 3.1.1. Kaplan-Meier unadjusted cumulative implant survival of Exeter V40/Contemporary hip replacements by cup design (England and Wales, 2003-2010)

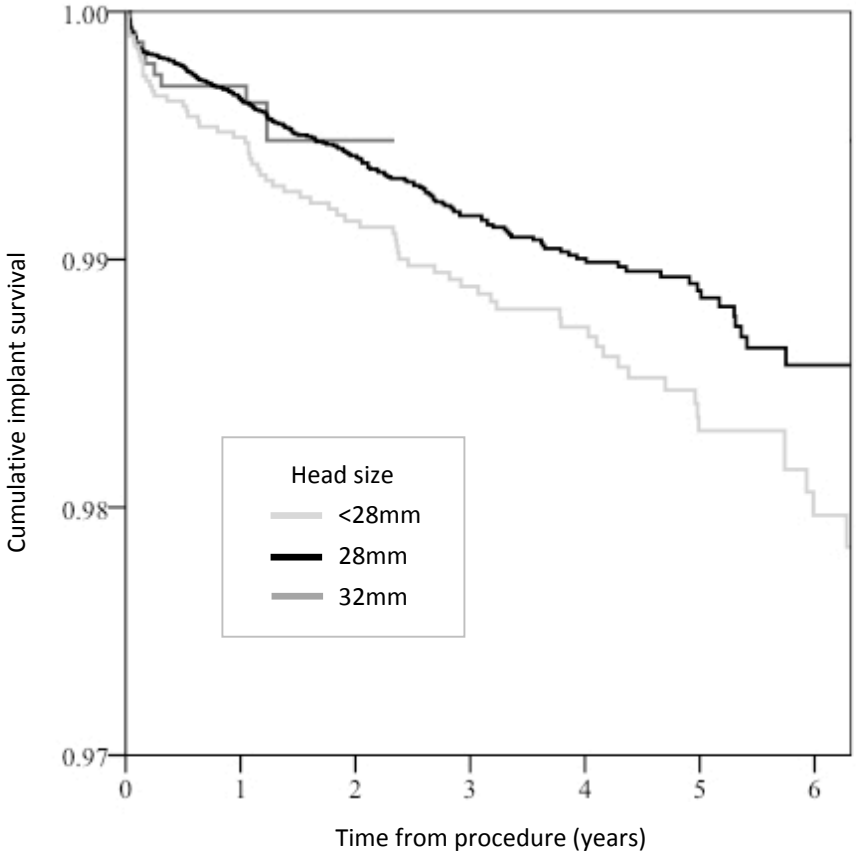


Log rank (Mantel-Cox)	Flanged	Hooded
Flanged (p-value)	-	<0.001
Hooded	<0.001	-

Life table showing numbers at risk in each year

Design	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Flanged	24212	19491	14795	10276	6176	3282	1281	375
Hooded	10509	8582	6793	4846	3176	1913	790	283

Figure 3.1.2. Kaplan-Meier unadjusted cumulative implant survival of Exeter V40/Contemporary hip replacements, by head size (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	<28mm	28mm	32mm
<28mm (p-value)	-	0.022	0.101
28mm	0.022	-	0.615
32mm	0.101	0.615	-

Life table showing numbers at risk in each year

Size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
<28mm	5036	4619	4032	3365	2547	1783	1034	378
28mm	27218	21946	16873	11482	6691	3374	1031	280
32mm	2467	1508	683	275	114	38	6	0

Table 3.1.4. Independent predictors of all revisions following 34 721 Exeter/Contemporary hip replacements: simple and multivariable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Female	1					
Male	1.22	0.89 to 1.67	0.112			
Age						
Category			0.086			
≤60	1					
61-75	0.81	0.43 to 1.51	0.373			
≥76	0.64	0.34 to 1.22	0.075			
ASA grade						
½	1					
≥3	0.97	0.63 to 1.50	0.869			
Body mass index						
<30kg/m^2	1					
≥30kg/m^2	1.61	0.66 to 2.05	0.500			
Stem offset						
Category			0.580			
35mm	1.11	0.53 to 2.34	0.719			
37.5mm	1.16	0.84 to 1.60	0.237			
44mm	1					
50mm	0.83	0.34 to 2.02	0.598			
Stem taper						
Category			0.586			
0	1.07	0.73 to 1.57	0.655			
1	1					
2	0.82	0.54 to 1.25	0.231			
3	0.90	0.51 to 1.59	0.630			
≥4	0.90	0.37 to 2.21	0.764			
Head size						
Category			0.055			0.009
<28mm	1.38	0.96 to 1.99	0.022	1.50	1.03 to 2.17	0.005
28mm	1			1		
32mm	0.84	0.36 to 1.94	0.595	0.76	0.33 to 1.75	0.391
Head offset						
Category			0.452			
Standard	1					
Plus	1.13	0.74 to 1.73	0.445			
Minus	1.19	0.81 to 1.76	0.249			
Bearing						
Metal-on-poly.	1					
Ceramic-on-poly.	1.10	0.57 to 2.13	0.720			
Cup design						
Flanged	1			1		
Hooded	1.79	1.32 to 2.45	<0.001	1.88	1.38 to 2.57	<0.001
Cement						
Category			0.807			
HV antibiotic	1					
LV antibiotic	1.09	0.77 to 1.54	0.546			
HV, no antibiotic	0.83	0.35 to 1.89	0.530			
LV, no antibiotic	0.93	0.44 to 1.96	0.809			
Surgical approach						
Category			0.226			
Anterolateral	1					
Posterior	0.84	0.60 to 1.17	0.172			
Other	1.33	1.33 to 3.23	0.410			
Operator						
Consultant	1					
Other	0.96	0.67 to 1.38	0.779			
Consultant volume						
Category			0.137			
Low (≤50)	1.39	0.91 to 2.11	0.046			
Medium (51-300)	1.18	0.81 to 1.74	0.257			
High (≥301)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HV – high viscosity, LV – low viscosity

Table 3.1.5. Independent predictors of revision for dislocation: simple and multivariable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Female	1					
Male	1.14	0.65 to 2.02	0.541			
Age						
Category			0.371			
≤60	1					
61-75	2.61	0.41 to 16.69	0.183			
≥76	2.29	0.36 to 14.81	0.252			
ASA grade						
½	1					
≥3	1.23	0.63 to 2.42	0.422			
Body mass index						
<30kg/m^2	1					
≥30kg/m^2	0.54	0.21 to 1.44	0.107			
Stem offset						
Category			0.305			
35mm	1.91	0.67 to 5.46	0.112			
37.5mm	1.36	0.78 to 2.39	0.153			
44mm	1					
50mm	1.21	0.32 to 4.65	0.715			
Stem taper						
Category			0.607			
0	1.23	0.64 to 2.37	0.421			
1	1					
2	0.85	0.40 to 1.79	0.566			
3	1.00	0.38 to 2.68	0.991			
≥4	1.61	0.46 to 5.60	0.327			
Head size						
Category			0.349			
<28mm	1.43	0.76 to 2.68	0.147			
28mm	1					
32mm	1.11	0.33 to 3.66	0.830			
Head offset						
Category			0.014			0.010
Standard	1			1		
Plus	2.02	1.09 to 3.75	0.003	2.05	1.10 to 3.80	0.003
Minus	1.20	0.59 to 2.42	0.512	1.09	0.54 to 2.20	0.762
Bearing						
Metal-on-poly.	1					
Ceramic-on-poly.	1.18	0.40 to 3.49	0.701			
Cup design						
Flanged	1			1		
Hooded	2.30	1.36 to 3.90	<0.001	2.34	1.38 to 3.96	<0.001
Cement						
Category			0.420			
HV antibiotic	1					
LV antibiotic	1.18	0.66 to 2.11	0.468			
HV, no antibiotic	0.24	0.02 to 3.25	0.159			
LV, no antibiotic	0.86	0.23 to 3.27	0.773			
Surgical approach						
Category			0.141			
Anterolateral	1					
Posterior	1.53	0.87 to 2.66	0.051			
Other	1.54	0.33 to 7.26	0.470			
Operator						
Consultant	1					
Other	0.86	0.46 to 1.63	0.546			
Consultant volume						
Category			0.266			
Low (≤50)	1.58	0.76 to 3.31	0.110			
Medium (51-300)	1.39	0.70 to 2.73	0.216			
High (≥301)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HV – high viscosity, LV – low viscosity

Revision for dislocation model

Revisions performed due to dislocation were then analysed. Using simple (univariable) regression analysis, cup design (p<0.001) and 'plus' head offsets (p=0.003) influenced implant revision risk (**Table 3.1.5**). After risk adjustment, cup design (HR=2.34, p<0.001) and plus head offset (HR=2.05, p=0.003) remained significant influences upon the risk of revision.

Revision rates

The overall seven-year revision rate was 1.70% for the entire study population (**Table 3.1.6**). Seven-year revision rates were lowest with 28mm heads and flanged cups (1.16%). A head size <28mm used together with a hooded cup resulted in a 7-year revision rate of 3.49%. Although 32mm heads have only been used since 2006, early (3-year) revision for hip replacements with flanged cups (0.53%) was similar to 28mm heads and flanged cups (0.67%).

Table 3.1.6. Revision rates following Exeter V40/Contemporary hip replacement, by head size and cup design (England and Wales, 2003-2010)

	Revision rates by head size			Overall rates
	<28mm	28mm	32mm	
1-year				
All	0.52% (0.25 to 0.78)	0.36% (0.26 to 0.46)	0.35% (0.01 to 0.69)	0.38% (0.29 to 0.47)
Flanged	*0.41% (0.15 to 0.68)*	*0.27% (0.17 to 0.38)*	*0.35% (0.00 to 0.80)*	*0.30% (0.21 to 0.40)*
Hooded	*0.92% (0.13 to 1.71)*	*0.55% (0.34 to 0.77)*	*0.35% (0.00 to 0.88)*	*0.57% (0.38 to 0.77)*
3-year				
All	1.13% (0.72 to 1.54)	0.84% (0.67 to 1.01)	0.62% (0.09 to 1.15)	0.88% (0.73 to 1.04)
Flanged	*1.07% (0.62 to 1.52)*	*0.67% (0.49 to 0.86)*	*0.53% (0.00 to 1.17)*	*0.75% (0.58 to 0.92)*
Hooded	*1.38% (0.40 to 2.35)*	*1.20% (0.85 to 1.56)*	*0.73% (0.00 to 1.58)*	*1.18% (0.87 to 1.50)*
5-year				
All	1.71% (1.13 to 2.28)	1.13% (0.90 to 1.37)	0.62% (0.09 to 1.15)	1.26% (1.03 to 1.48)
Flanged	*1.42% (0.84 to 2.01)*	*0.85% (0.60 to 1.10)*	- -	*0.99% (0.75 to 1.23)*
Hooded	*2.63% (1.13 to 4.12)*	*1.71% (1.21 to 2.21)*	*0.73% (0.00 to 1.58)*	*1.82% (1.35 to 2.30)*
7-year				
All	2.12% (1.36 to 2.89)	1.60% (1.05 to 2.15)	- -	1.70% (1.28 to 2.12)
Flanged	*1.62% (0.93 to 2.31)*	*1.16% (0.69 to 1.63)*	- -	*1.25% (0.89 to 1.62)*
Hooded	*3.49% (1.50 to 5.48)*	*2.37% (1.25 to 3.48)*	- -	*2.55% (1.63 to 3.46)*
Total				
All	5036	27218	2467	34 721
Flanged	*4024*	*18 746*	*1442*	*24 212*
Hooded	*1012*	*8472*	*1025*	*10 509*

(99% confidence intervals)

Statistical considerations

When age was considered as a continuous variable, in the adjusted model there was a trend towards significance (HR=0.98, p=0.013), but this did not affect selection within the model nor the influence of the significant covariates (hooded cup: HR=1.89, head size <28mm: HR=1.47). The final model was therefore reported with age as a categorical covariate. Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance

thresholds led to the same final models for all-cause revision and revision for dislocation.

Summary

Significantly greater revision rates were independently associated with a hooded cup design and small femoral head sizes (<28mm). Other potentially modifiable factors, including surgical approach, femoral head material and type of cement used, did not significantly influence revision. It would seem reasonable to recommend antibiotic impregnated cement, as revision risk is equivalent and there may be a benefit in terms of reduced infection risk. In addition, patient covariates available for analysis also failed to influence revision risk. Notably BMI was not associated with greater rates of revision.

The estimated revision rate at 7 years for the optimal configuration of a 28mm head and flanged cup was 1.16%, reflecting care received by 54% of this patient group. This demonstrates that pre-existing NJR analyses, where brand implant data is grouped together, fails to identify the subtle benefits of specific component configurations within brands. Additionally, this analysis does not support the historical evidence describing higher implant failure in younger patients.

Hybrid hip replacement

Hybrid implants have the potential to offer the best of cemented and cementless implants: a well-proven cemented stem coupled with a cup that offers the surgeon different bearing and head size options which may ultimately offer benefits over standard configurations. For this reason, hybrids are commonly used in younger patients with low wearing, large diameter bearings. Performance and risk factors associated with failure of the commonest hybrid implants used in England and Wales (Stryker Exeter V40 femoral stem and Trident modular cup system) are reported.

Of 15 740 primary procedures, the majority were performed in females (9573, 60.8%), with ASA ≤2 (13 693, 87.0%) and 75 years of age or less (11 764, 74.7%); the mean age at implantation was 68 years old. There were 6641 (42.2%) procedures with complete BMI data: of these the majority were less than 30kg/m^2 (4638, 69.8%). The most commonly used stem was 44mm offset (8627, 54.8%) and taper sizes ≤2 (14 255, 90.6%) accounted for the majority. A standard neck offset (63.4%, 9986) and a 32mm diameter (45.4%, 7153) were the most commonly used heads. The commonest cup design was a PSL multi-hole (10 497, 66.7%) and only 33.3% (5243) relied on press-fit fixation with a solid-back shell. Over the entire study, the commonest bearing was ceramic-on-ceramic (CoC, 6144, 39.0%). However, during 2010 this was metal-on-XLPE (MoXLPE). Palacos HV antibiotic impregnated (52.5%, 8264) was most commonly used to cement the stem. The procedure was performed through a posterior approach in 67.5% of cases (10 620). In most cases the consultant performed the procedure (12 886, 81.9%). Medium- or high-volume Exeter/Trident hybrid arthroplasty surgeons (≥51 cases over study period) accounted for 70.8% (11 147) of procedures. Patients were under the care of 575 different consultants in 239 different surgical units. Bearing use by year is shown in **Table 3.1.7** and demographics in **Table 3.1.8**.

Table 3.1.7. Bearings used for Exeter V40/Trident hybrid hip replacements, by year (England and Wales, 2003-2010)

Year	Bearing				
	MoXLP	MoSP	CoSP	CoXLP	CoC
2003, n (%)	0 (0)	26 (35.1)	5 (6.8)	0 (0)	43 (58.1)
2004	1 (0.3)	140 (37.2)	28 (7.4)	0 (0)	207 (55.1)
2005	6 (0.5)	453 (40.3)	62 (5.5)	1 (0.1)	603 (53.6)
2006	25 (1.4)	785 (44.7)	88 (5.0)	10 (0.6)	847 (48.3)
2007	383 (14.8)	956 (36.9)	56 (2.2)	65 (2.5)	1130 (43.6)
2008	782 (27.3)	671 (23.4)	40 (1.4)	242 (8.4)	1132 (39.5)
2009	1292 (25.8)	666 (18.4)	45 (1.2)	425 (11.8)	1182 (32.7)
2010	1340 (40.1)	568 (17.0)	30 (0.9)	405 (12.1)	1000 (29.9)
Total	*3829 (24.3)*	*4265 (27.1)*	*354 (2.2)*	*1148 (7.3)*	*6144 (39.0)*

MoXLP – metal-on-highly cross-linked polyethylene, MoSP – metal-on-standard polyethylene, CoSP – ceramic-on-standard polyethylene, CoXLP – ceramic-on-highly cross-linked polyethylene, CoC – ceramic-on-ceramic

Table 3.1.8. Demographics of 15 740 Exeter V40/Trident hybrid hip replacements (England and Wales, 2003-2010)

Age, mean years (SD, range)	67.5 (10.7, 15-102)	
≤60, n (%)	3535	(22.5)
61-75	8229	(52.3)
≥76	3976	(25.3)
Gender		
Female	9573	(60.8)
Male	6167	(39.2)
ASA grade		
½	13 693	(87.0)
≥3	2047	(13.0)
Body mass index, mean kg/m^2 (SD)	28.4	(5.3)*
<30kg/m^2, n (%)	4638	(29.5)
≥30kg/m^2	2003	(12.7)
No data	9099	(57.8)
Stem offset		
35.5mm	1186	(7.5)
37.5mm	5135	(32.6)
44mm	8627	(54.8)
50mm	792	(5.0)
Stem taper		
≤2	14 255	(90.6)
≥3	1485	(9.4)
Head size		
28mm	4764	(30.3)
32mm	7153	(45.4)
≥36mm	3823	(24.3)
Neck offset		
Standard (0)	9986	(63.4)
Plus (+4mm to +8mm)	2534	(16.1)
Minus (-2.7mm to – 5mm)	3220	(20.5)
Shell design		
Solid back	5243	(33.3)
PSL	3882	(24.7)
Hemispherical	1361	(8.6)
Multi-hole	10 497	(66.7)
PSL	6934	(44.1)
Hemispherical	3563	(22.6)
Bearing		
Metal-on-standard polyethylene (PE)	4265	(27.1)
Metal-on-highly cross-linked (XL) PE	3829	(24.3)
Stainless steel-on-XLPE	1661	(10.6)
Cobalt-chrome-on-XLPE	2168	(13.8)
Ceramic-on-standard PE	354	(2.2)
Ceramic-on-XLPE	1148	(7.3)
Ceramic-on-ceramic	6144	(39.0)
Cement		
Palacos high viscosity antibiotic impregnated	8264	(52.5)
Simplex P antibiotic impregnated	5530	(35.1)
Other	1484	(9.4)
Missing	462	(2.9)
Surgical approach		
Posterior	10 620	(67.5)
Lateral/anterolateral	4662	(29.6)
Other	319	(2.0)
Missing data	139	(0.9)
Year of procedure		
2003	74	(0.5)
2004	376	(2.4)
2005	1125	(7.1)
2006	1755	(11.1)
2007	2590	(16.5)
2008	2867	(18.2)
2009	3610	(22.9)
2010	3343	(21.2)
Primary surgeon		
Consultant	12 886	(81.9)
Other	2854	(18.1)
Number of consultants (n)	575	
Consultant Exeter/Trident volume		
Low (≤50 cases over study period)	4593	(29.2)
Medium (51-200)	6969	(44.3)
High (≥201)	4178	(26.5)
Number of surgical units (n)	239	

SD – standard deviation, * - based on 6641 procedures

Reasons for revision

One hundred and forty-one patients had undergone a revision procedure by the census date. The most common reason was infection (27.0% of all revisions), then dislocation in 25.5%, followed by aseptic component loosening/lysis (23.4%), malalignment (12.8%) and peri-prosthetic fracture (12.1%). Revision for liner dissociation occurred in seven patients (5.0%), five of which were ceramic liners (3.5%). Revision data are summarised in **Table 3.1.9**.

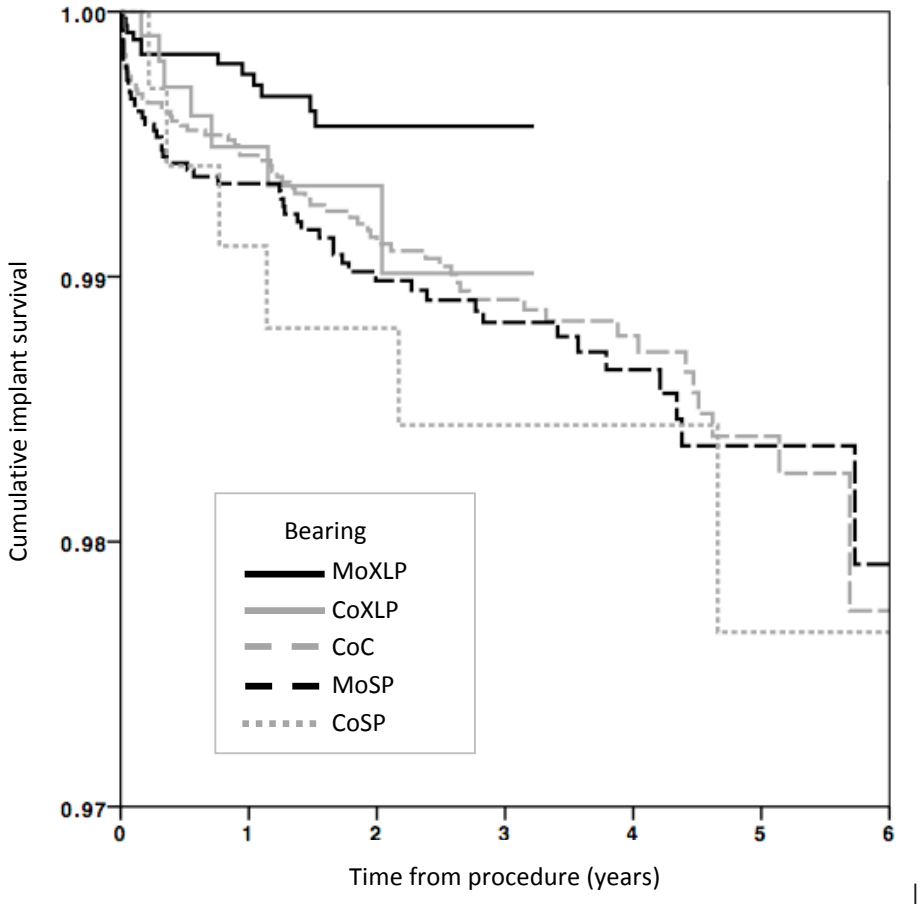
Table 3.1.9. Reasons recorded for 141 revisions following Exeter V40/Trident hip replacements (England and Wales, 2003-2010)

Infection, n (%)	38	(27.0)
Dislocation	36	(25.5)
All aseptic component loosening/lysis	33	(23.4)
Stem only	*4*	*(2.8)*
Cup only	*23*	*(16.3)*
Both	*6*	*(4.3)*
All malalignments	18	(12.8)
Stem only	*3*	*(2.1)*
Cup only	*14*	*(9.9)*
Both	*1*	*(0.7)*
Periprosthetic fracture	17	(12.1)
Stem only	*13*	*(9.2)*
Cup only	*4*	*(2.8)*
Dissociation of liner	7	(5.0)
All implant fractures	6	(4.3)
Stem only	*4*	*(2.8)*
Cup only	*2*	*(1.4)*
Unexplained pain	8	(5.7)
Liner wear	5	(3.5)
Other	5	(3.5)

Associations with implant revision

(As discussed within the methods chapter, the hybrid analysis uses a lower statistical threshold for association ($p<0.05$) reflecting smaller patient numbers). In simple (univariable) analysis, age (p=0.033), bearing (p=0.050, **Figure 3.1.3**), shell type (p=0.024, **Figure 3.1.4**), and surgical approach (p=0.036) influenced implant revision risk (**Table 3.1.10**). Bearing categories were close to or on the threshold of statistical significance. Brand of cement, shell geometry and type of femoral head metal (stainless steel or cobalt-chrome) were not found to be significant influences for survival: these covariates were therefore merged into common categories. First- ('Crossfire') and second-generation ('X3') XLPE liners were combined into one group, as the 'Crossfire' liner was used rarely.

Figure 3.1.3. Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident, by bearing (England and Wales, 2003-2010)



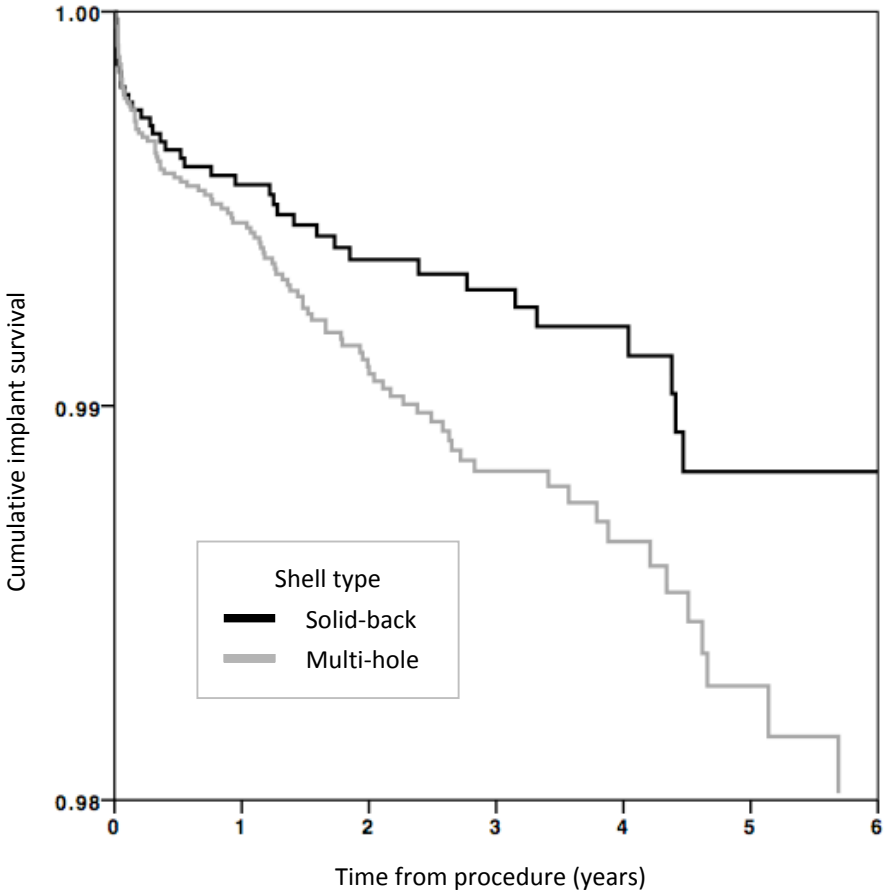
Log rank (Mantel-Cox)	MoXLP	MoSP	CoSP	CoXLP	CoC
MoXLP (p-value)	-	0.003	0.015	0.149	0.010
MoSP	0.003	-	0.368	0.521	0.706
CoSP	0.015	0.368	-	0.399	0.296
CoXLP	0.149	0.521	0.399	-	0.798
CoC	0.010	0.706	0.296	0.798	-

Life table showing numbers at risk in each year

Bearing	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoXLP	3829	2452	1146	395	30	7
MoSP	4265	3618	2911	2196	1276	554
CoSP	354	320	274	232	175	91
CoXLP	1148	728	305	72	8	1
CoC	6144	5100	3885	2753	1637	814

MoXLP – metal-on-highly cross-linked polyethylene, MoSP – metal-on-standard polyethylene, CoSP – ceramic-on-standard polyethylene, CoXLP – ceramic-on-highly cross-linked polyethylene, CoC – ceramic-on-ceramic

Figure 3.1.4. Kaplan Meier: unadjusted cumulative implant survival of Exeter V40/Trident, by shell type (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	Solid	Multi-hole
Solid-back shell (p-value)	-	0.023
Multi-hole shell	0.023	-

Life table showing numbers at risk each year

Shell type	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Solid-back	5243	4187	3098	2413	1343	597
Multi-hole	10497	8031	5423	3235	1783	870

Table 3.1.10. Independent predictors of revision following 15 740 Exeter V40/Trident hybrid hip replacements: simple and multivariable Cox regressions (England and Wales, 2003-2010)

	Simple analysis			Multivariable analysis		
	HR	95% CI	P value	HR	95% CI	P value
Gender						
Female	1					
Male	1.04	0.74 to 1.45	0.829			
Age						
Category			0.033			0.037
≤60 years	1			1		
61-75	0.79	0.54 to 1.14	0.201	0.75	0.50 to 1.11	0.148
≥76	0.50	0.30 to 0.84	0.009	0.46	0.25 to 0.83	0.010
ASA grade						
½	1					
≥3	1.08	0.66 to 1.77	0.766			
Stem offset						
Category			0.613			
35.5mm	0.73	0.34 to 1.59	0.429			
37.5mm	1.01	0.70 to 1.46	0.943			
44mm	1					
50mm	1.38	0.74 to 2.60	0.316			
Stem taper						
≤2	1					
≥3	0.63	0.32 to 1.24	0.180			
Head size						
Category			0.152			
28mm	1.28	0.89 to 1.84	0.176			
32mm	1					
≥36mm	0.82	0.51 to 1.33	0.421			
Neck offset						
Category			0.139			
Standard	1					
Plus	1.38	0.89 to 2.15	0.152			
Minus	1.41	0.95 to 2.10	0.085			
Bearing						
Category			0.050			0.035
Metal-on-XLPE	1			1		
Metal-on-standard PE	2.46	1.30 to 4.65	0.006	2.64	1.39 to 4.99	0.003
Ceramic-on-standard	3.51	1.37 to 9.00	0.009	3.07	1.18 to 8.00	0.022
PE	1.98	0.78 to 5.04	0.150	1.86	0.72 to 4.77	0.198
Ceramic-on-XLPE	2.29	1.23 to 4.26	0.009	1.93	1.00 to 3.69	0.049
Ceramic-on-ceramic						
Shell						
Solid back	1			1		
Multi-hole	1.54	1.06 to 2.24	0.024	1.70	1.16 to 2.48	0.006
Cement						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67 to 1.41	0.876			
Other	1.55	0.95 to 2.52	0.082			
Surgical approach						
Category			0.036			
Posterior	1					
Antero-lateral	1.53	1.09 to 2.15	0.015			
Other	0.51	0.07 to 3.63	0.497			
Year of procedure	1.06	0.94 to 1.19	0.341			
Operator						
Consultant	1					
Other	1.28	0.85 to 1.91	0.237			
Consultant Exeter/Trident volume						
Category			0.273			
Low (≤50)	1.14	0.71 to 1.83	0.597			
Medium (51-200)	1.40	0.91 to 2.13	0.130			
High (≥201)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene

After risk adjustment, procedures performed using standard PE liners (metal-on-PE bearings: HR=2.64, p=0.003, ceramic-on-PE: HR=3.07, p=0.022) and CoC bearings (HR=1.93, p=0.049) were associated with significantly higher revision rates when compared with procedures using a MoXLPE bearing. Procedures employing multi-hole acetabular shells (HR=1.70, p=0.006) had a greater risk of revision compared with solid-back shells. Older age (≥76 years) was associated with a lower revision risk (HR=0.46, p=0.010) compared to patients ≤60 years (**Table 3.1.10**). After risk adjusting, surgical approach was not selected for the final model.

When covariates were tested for multiplicative relationships a significant interaction between age group and shell type was found (p=0.022). Bearing category remained significant (p=0.048) but age group and shell type as individual covariates no longer met the inclusion criteria for the model. This suggests a lower risk of revision in patients ≥76 years while no significant difference was found for shell type in patients ≤60. (**Table 3.1.11**). In this model, CoC bearings were not associated with significantly higher revision, although the suggestion remains (HR=1.86, p=0.061). Revision risk was independent of gender, ASA grade, stem characteristics, head size, neck offset, cement type, operator grade and consultant experience.

Table 3.1.11. Revision following 15 740 Exeter/Trident hybrid hip replacements: Multivariable Cox regressions with multiplicative interaction of age and shell type (England and Wales, 2003-2010)

	Multivariable analysis		
	HR	95% CI	P value
Age			
Category			0.330
≤60 years	1		
61-75	0.79	0.49 to 1.25	0.307
≥76	0.62	0.33 to 1.17	0.141
Bearing			
Category			0.048
Metal-on-XLPE	1		
Metal-on-standard PE	2.52	1.33 to 4.78	0.005
Ceramic-on-standard PE	2.99	1.50 to 7.78	0.025
Ceramic-on-XLPE	1.74	0.68 to 4.45	0.252
Ceramic-on-ceramic	1.86	0.97 to 3.56	0.061
Shell			
Solid back	1		
Multi-hole	1.37	0.91 to 2.07	0.135
*Age*shell*			
Category			0.022
≤60 years	1		
61-75	0.80	0.33 to 1.94	0.628
≥76	0.23	0.08 to 0.70	0.010

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene

Revision rates

The overall five-year revision rate was 1.56% (95% CI 1.23 to 1.89) for the entire study population. In patients ≤75 years, the five-year revision rates for solid-back shells was 1.21% (95% CI 0.67 to 1.76) compared with 2.07% (95% CI 1.52 to 2.62) for multi-holes (**Table 3.1.12**). Three-year revision rates for bearing and shell type indicate the use of a MoXLPE bearing with a solid-back shell may ultimately have the lowest revision rate, although there are currently no statistically significant differences between groups.

Table 3.1.12. Revision rates following Exeter/Trident hybrid hip replacement by bearing and shell type in patients ≤75 years (England and Wales, 2003-2010)

	Revision rates by bearing				Overall revision
	MoXLP	MoSP	CoXLP	CoC	
1-year					
All	0.33%	0.73%	0.65%	0.54%	0.57%
	(0.07 to 0.60)	(0.39 to 1.08)	(0.08 to 1.21)	(0.35 to 0.74)	(0.43 to 0.71)
Solid shell	*0.24%*	*0.79%*	-	*0.25%*	*0.40%*
	(0.00 to 0.72)	*(0.21 to 1.37)*		*(0.03 to 0.46)*	*(0.20 to 0.59)*
Multi-hole	*0.36%*	*0.70%*	*0.67%*	*0.73%*	*0.67%*
	(0.05 to 0.68)	*(0.27 to 1.13)*	*(0.00 to 1.42)*	*(0.44 to 1.02)*	*(0.47 to 0.86)*
3-year					
All	0.72%	1.36%	1.49%	1.10%	1.14%
	(0.26 to 1.18)	(0.87 to 1.86)	(0.10 to 2.87)	(0.79 to 1.41)	(0.92 to 1.37)
Solid shell	*0.24%*	*1.35%*	-	*0.42%*	*0.64%*
	(0.00 to 0.72)	*(0.55 to 2.16)*		*(0.13 to 0.71)*	*(0.37 to 0.91)*
Multi-hole	*0.86%*	*1.37%*	*2.15%*	*1.57%*	*1.46%*
	(0.28 to 1.44)	*(0.74 to 2.00)*	*(0.00 to 4.51)*	*(1.08 to 2.06)*	*(1.13 to 1.79)*
5-year					
All	-	2.01%	-	1.66%	1.74%
		(1.25 to 2.78)		(1.15 to 2.16)	(1.35 to 2.13)
Solid shell	-	*1.78%*	-	*1.13%*	*1.21%*
		(0.63 to 2.92)		*(0.43 to 1.83)*	*(0.67 to 1.76)*
Multi-hole	-	*2.17%*	-	*1.99%*	*2.07%*
		(1.14 to 3.19)		*(1.30 to 2.67)*	*(1.52 to 2.62)*
Total number					
All	2193	2476	937	5831	11 764
Solid shell	*504*	*957*	*375*	*2202*	*4180*
Multi-hole	*1689*	*1519*	*562*	*3629*	*7584*

Inadequate numbers of CoSP for analysis. (95% confidence intervals).
For sub-analysis of data, where numbers were inadequate no figures are reported.

Statistical considerations

Age as a continuous covariate was a significant influence in univariable analysis (HR=0.98, 95% CI 0.96 to 1.00, p=0.016). We created separate multivariable models to test age selection (as continuous or categorical data). As a continuous covariate, the model did not select age, nor did this influence the other significant covariates (multi-hole shell and bearing). The final model was therefore reported with age as a categorical variable.

Table 3.1.13. Independent predictors of revision following Exeter V40/Trident hybrid hip replacements, based on 6637 replacements with body mass index data: simple and multivariable Cox regressions (England and Wales, 2003-2010)

	Simple analysis			Multivariable analysis*		
	HR	95% CI	P value	HR	95% CI	P value
Gender						
Female	1					
Male	1.04	0.74 to 1.45	0.829			
Age						
Category			0.033			
≤60	1					
61-75	0.79	0.54 to 1.14	0.201			
≥76	0.50	0.30 to 0.84	0.009			
ASA grade						
½	1					
≥3	1.08	0.66 to 1.77	0.766			
Body mass index						
<30kg/m^2	1			1		
≥30kg/m^2	2.03	1.15 to 3.58	0.015	2.00	1.13 to 3.54	0.017
Stem offset						
Category			0.613			
35.5mm	0.73	0.34 to 1.59	0.429			
37.5mm	1.01	0.70 to 1.46	0.943			
44mm	1					
50mm	1.38	0.74 to 2.60	0.316			
Stem taper						
≤2	1					
≥3	0.63	0.32 to 1.24	0.180			
Head size						
Category			0.152			
28mm	1.28	0.89 to 1.84	0.176			
32mm	1					
≥36mm	0.82	0.51 to 1.33	0.421			
Neck offset						
Category			0.139			
Standard	1					
Plus	1.38	0.89 to 2.15	0.152			
Minus	1.41	0.95 to 2.10	0.085			
Bearing						
Category			0.050			0.159
Metal-on-XLPE	1			1		
Metal-on-standard PE	2.46	1.30 to 4.65	0.006	1.97	0.71 to 5.45	0.194
Ceramic-on-standard PE	3.51	1.37 to 9.00	0.009	5.44	1.08 to 27.4	0.040
Ceramic-on-XLPE	1.98	0.78 to 5.04	0.150	3.16	1.02 to 9.81	0.046
Ceramic-on-ceramic	2.29	1.23 to 4.26	0.009	2.50	1.02 to 6.15	0.046
Shell						
Solid back	1					
Multi-hole	1.54	1.06 to 2.24	0.024			
Cement						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67 to 1.41	0.876			
Other	1.55	0.95 to 2.52	0.082			
Surgical approach						
Category			0.036			
Posterior	1					
Anterolateral	1.53	1.09 to 2.15	0.015			
Other	0.51	0.07 to 3.63	0.497			
Year of procedure	1.06	0.94 to 1.19	0.341			
Operator						
Consultant	1					
Other	1.28	0.85 to 1.91	0.237			
Consultant Exeter/Trident volume						
Category			0.273			
Low (≤50)	1.14	0.71 to 1.83	0.597			
Medium (51-200)	1.40	0.91 to 2.13	0.130			
High (≥201)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, XLPE – highly cross-linked polyethylene, PE – polyethylene, *based on 6637 procedures with body mass index data

High BMI (≥30kg/m^2) was associated with an increased risk of revision compared to BMI <30kg/m^2 within univariable analysis (≥30kg/m^2: HR=2.03, 95% CI 1.15 to 3.58, p=0.015). This inclusion of BMI in the preliminary multivariable modelling resulted in the loss of 58% of records from the analysis, and while the survival of individual bearings were not qualitatively affected by this, shell type and age were not selected suggesting this to be a less informative model (**Table 3.1.13**). This substantial data loss was accompanied by stepwise selection instability, and thus BMI was removed from the final analysis.

Tests for time-dependency of covariates were not statistically significant. Forward and reverse stepwise model construction led to the same final model.

Summary

Cementless cup specification of a hybrid hip replacement influenced revision risk. A metal-on-highly cross-linked polyethylene liner within a solid shell provided the lowest risk of revision (3-year estimated risk of only 0.24%). Significantly greater revision rates were associated with conventional polyethylene bearings and multi-hole shells. This is the first analysis to identify the clinical benefit of highly cross-linked polyethylene from a single manufacturer.

However, although the surgeon can choose the bearing, the decision to use a solid-back shell can only be taken if there is adequate purchase within the acetabulum. If this is suboptimal a multi-hole shell with supplementary screw fixation must be used. Other implant factors, such as femoral head size, were not found to significantly influence revision.

Patient age showed an interaction with shell type; older patients experienced lower revision risk with a multi-hole shell, suggesting supplementary screw fixation may provide a better solution in poorer bone quality.

Cementless hip replacement

The popularity of cementless has now surpassed cemented THR in England and Wales, and these are used almost exclusively in several other health systems. Regardless of this, registry data and meta-analyses suggest these implants have a higher revision risk than cemented. Cementless fixation may ultimately offer greater longevity, and cup modularity allows a surgeon to choose from a range of different bearing and head size options to meet the needs of individual patients. However, modularity is complex and costly. The functional benefit of larger head sizes and increased survival of hard bearings has yet to be proven. The performance and risk factors associated with failure of the commonest cementless implant (DePuy Corail femoral stem / Pinnacle cup) are reported.

Of 35 386 primary procedures, the majority were performed in females (20 166, 57.0%), of ASA ≤2 (31 286, 88.4%) aged 75 years or less (28 497, 80.5%); the mean age at implantation was 66 years old. There were 17 166 (48.5%) procedures with complete BMI data; of the procedures with data, the majority were with BMI less than 30kg/m^2 (10 553, 57.9%). The majority of stems used were mid-range sizes (11-13: 20 774, 58.7%) and collarless (24 404, 69.0%). The commonest cup shell was a HA-coated cluster-hole (16 071, 45.4%). The commonest single type of bearing was CoC (10 540, 29.8%); MoM accounted for 27.5% (9736) of implants, and MoP accounted for (9242, 26.1%). The majority of polyethylene bearings were highly cross-linked without a posterior lip (5876 of 13 923 PE bearings [42.2%], representing 16.6% of all bearings) and most were 28mm (10 162, 28.7%) (**Table 3.1.14**). Just over half of all head sizes were 36mm or larger (19 344, 54.7%) and the combined offset was between zero and 10mm in the majority (27 677, 78.2%). In total, 21 463 hard bearings were used, of which 18 005 (50.9%) were 36mm (**Table 3.1.14**). In 79% of these procedures the consultant had completed more than 50 Corail Pinnacle THRs over the study period (27 901 procedures). Patients were under the care of 854 different consultants in 301 different surgical units and, in most cases, the consultant performed the operation (29 954, 84.6%). Demographics are shown in **Table 3.1.15**. There were 1690 (4.8%) procedures with greater than five completed years of follow-up.

Table 3.1.14. Breakdown of Corail/Pinnacle cementless hip replacement used, by bearing and head size (England and Wales, 2003-2010)

	Usage, n (%)					*Overall*
	MoP	CoP	CoC	CoM	MoM	
28mm	7242 (20.5)	2920 (8.3)	2042 (5.8)	43 (0.1)	359 (1.0)	*12606 (35.6)*
32mm	1520 (4.3)	1212 (3.4)	704 (2.0)	0	0	*3436 (9.7)*
36mm	472 (1.3)	544 (1.5)	7794 (22.0)	1144 (3.2)	9067 (25.6)	*19021 (53.8)*
40mm	7 (0.0)	3 (0.0)	0	0	269 (0.8)	*279 (0.8)*
44mm	1 (0.0)	2 (0.0)	0	0	41 (0.1)	*44 (0.1)*
Total	*9242 (26.1)*	*4681 (13.2)*	*10540 (29.8)*	*1187 (3.4)*	*9736 (27.5)*	*35386*

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal, BMI – body mass index

Table 3.1.15. Demographics of 35 386 Corail/Pinnacle cementless hip replacement patients (England and Wales, 2003-2010)

Age, mean years (SD)	66.3	(10.0)
≤60, n (%)	8835	(25.0)
61-75	19 662	(55.6)
≥76	6889	(19.5)
Gender		
Female	20 166	(57.0)
Male	15 220	(43.0)
ASA grade		
½	31 286	(88.4)
≥3	4100	(11.6)
Body mass index, mean kg/m^2 (SD)	28.8	(5.3)*
<30kg/m^2, n (%)	10 553	(29.8)
≥30kg/m^2	6613	(18.7)
No data	18 228	(51.5)
Stem size		
8-10	10 168	(28.7)
11-13	20 774	(58.7)
≥14	4444	(12.6)
Stem design		
Collarless	24 404	(69.0)
Collared	10 982	(31.0)
Cup shell type		
Solid HA coated	7496	(21.2)
Solid, non-HA	2805	(7.9)
Cluster-hole HA	16 071	(45.4)
Cluster-hole, non-HA	9014	(25.5)
Bearing		
Metal-on-polyethylene (all)	9242	(26.1)
Standard polyethylene	*3892*	*(11.0)*
Standard lipped polyethylene	*453*	*(1.3)*
XL polyethylene	*4198*	*(11.9)*
XL lipped polyethylene	*699*	*(2.0)*
Ceramic-on-polyethylene (all)	4681	(13.2)
Standard polyethylene	*1742*	*(4.9)*
Standard lipped polyethylene	*406*	*(1.1)*
XL polyethylene	*1678*	*(4.7)*
XL lipped polyethylene	*855*	*(2.4)*
Ceramic-on-ceramic	10 540	(29.8)
Ceramic-on-metal	1187	(3.4)
Metal-on-metal	9736	(27.5)
Head size		
28/32mm	16 042	(45.3)
≥36mm	19 344	(54.7)
Combined offset category		
Low (0-4mm)	11 770	(33.2)
Medium (5-10mm)	15 907	(45.0)
High (≥11mm)	5977	(16.9)
Minus	1732	(4.9)
Primary surgeon		
Consultant	29 954	(84.6)
Other	5432	(15.4)
Number of consultants (n)		854
Consultant volume		
Mean volume (range), SD	242 (1 to 1208), 275	
Low (≤50 cases over study period)	7485	(21.2)
Medium (51-300)	17 902	(50.6)
High (≥301)	9999	(28.3)
Number of surgical units (n)		301

ASA – American Society of Anaesthesiologists, SD – standard deviation, * - based on 17 166 patients, HA – hydroxyapatite, XL – highly cross-linked

Reasons for revision

Four hundred and forty-eight patients had undergone a revision procedure by the census date. The most common reason was dislocation (24.1% of all revisions). Other reasons include aseptic component loosening/lysis accounted for 21.0%, infection (15.4%), malalignment (11.4%) and peri-prosthetic fracture (10.5%). Revision data are summarized in **Table 3.1.16**.

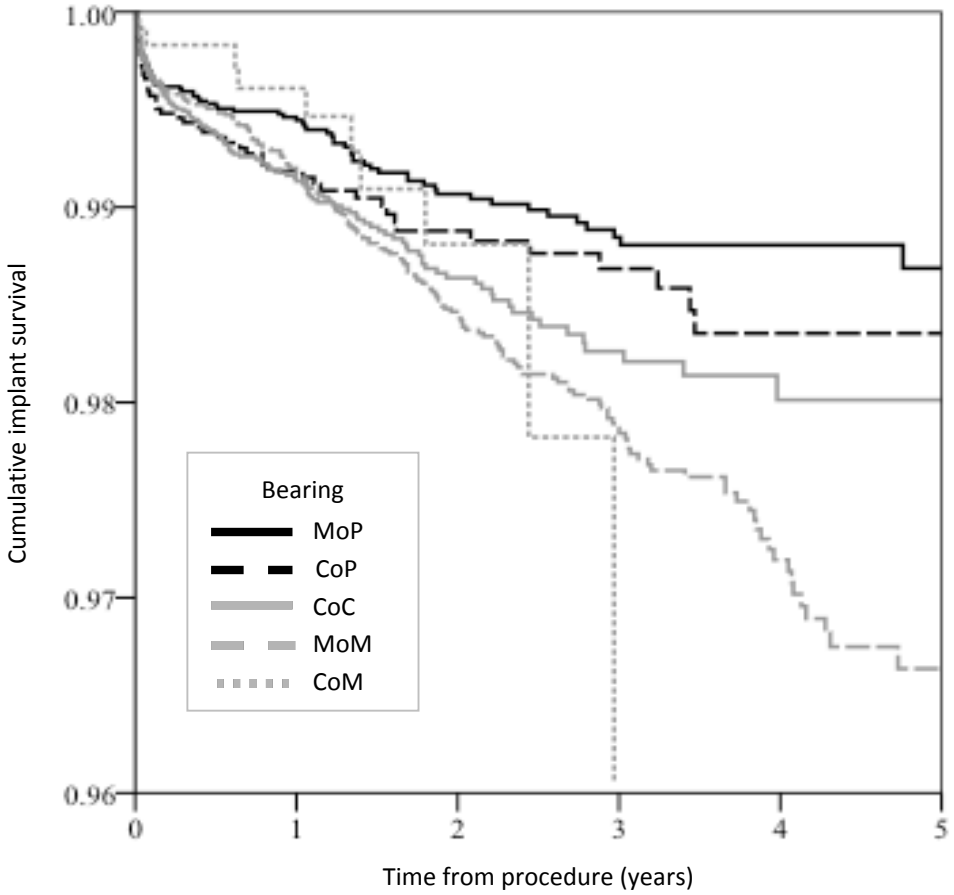
Table 3.1.16. Reason recorded for revision of 448 Corail/Pinnacle cementless hip replacements (England and Wales, 2003-2010)

Dislocation, n (%)	108	(24.1)
All aseptic component loosening/lysis	94	(21.0)
Stem only	*64*	*(14.3)*
Cup only	*20*	*(4.5)*
Both	*10*	*(2.2)*
Infection	69	(15.4)
All malalignments	51	(11.4)
Stem only	*20*	*(4.5)*
Cup only	*28*	*(6.3)*
Both	*3*	*(0.7)*
Periprosthetic stem fracture	47	(10.5)
Soft tissue reaction / 'Metallosis'	31	(6.9)
Unexplained pain	22	(4.9)
All implant fractures	20	(4.5)
Stem only	*7*	*(1.6)*
Cup only	*13*	*(2.9)*
Dissociation of liner	10	(2.2)
Liner wear	5	(1.1)
'Stem subsidence'	3	(0.7)
Other	28	(6.3)

Implant revision model

In simple (univariable) analysis, the following categories influenced implant revision risk: BMI (p=0.001), bearing (p<0.001) (**Figure 3.1.5**), femoral stem size (p<0.001) (**Figure 3.1.6**) and head size (p=0.001) (**Table 3.1.17**). There was a trend towards ASA grade influencing revision risk (p=0.014). Type of polyethylene (standard and highly cross-linked) and presence of a posterior lip were not found to be significant influences on implant survival: these covariates were therefore merged into one common polyethylene liner category to improve model precision. BMI was a significant influence but was unavailable in 51.5% of procedures and, as imputation may be unreliable with large amounts of missing data, the final adjusted model was presented in two ways: firstly, by removing BMI from the model and presenting adjusted results for the entire population, and secondly, using only those procedures (17 166) where a valid BMI was available.

Figure 3.1.5. Kaplan Meier: unadjusted cumulative implant survival of Corail/Pinnacle cementless hip replacements, by bearing (England and Wales, 2003-2010)



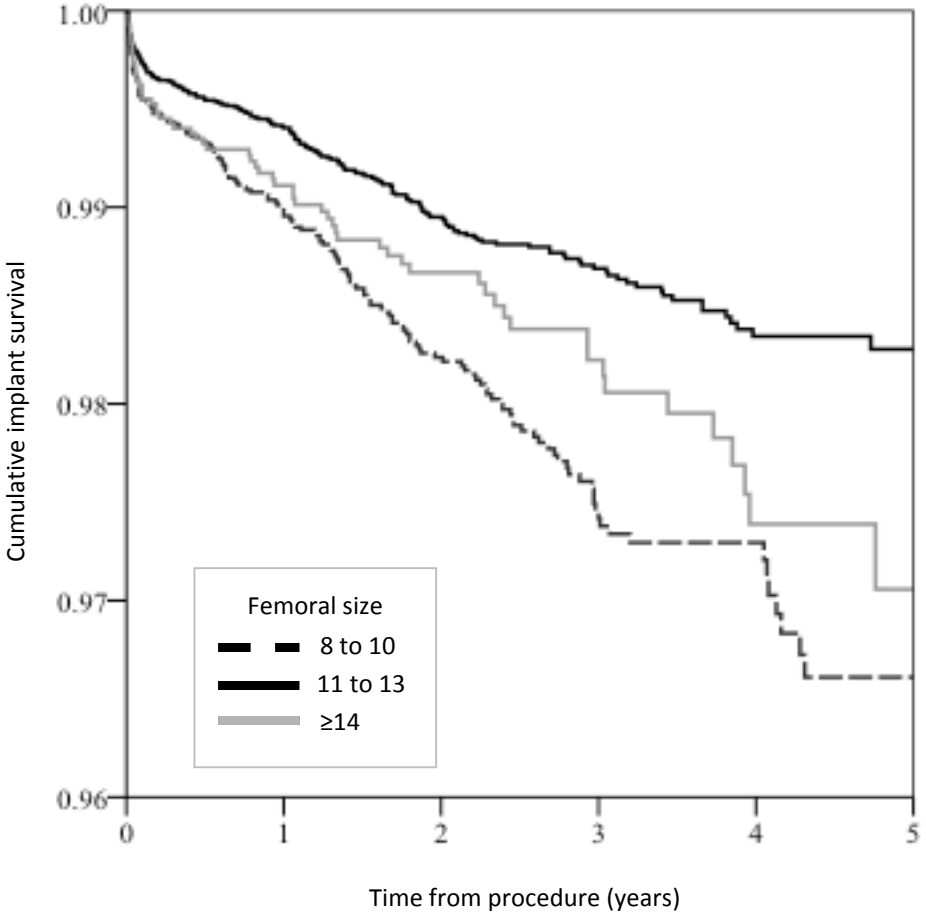
Log rank (Mantel-Cox)	MoP	CoP	CoC	CoM	MoM
MoP (p-value)	-	0.160	0.006	0.321	<0.001
CoP	0.160	-	0.398	0.800	0.024
CoC	0.006	0.398	-	0.819	0.101
CoM	0.321	0.800	0.819	-	0.685
MoM	<0.001	0.024	0.101	0.685	-

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal

Life table showing numbers at risk in each year

Bearing	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoP	9242	6211	4066	2513	1489	640
CoP	4681	3077	1938	1148	520	167
CoC	10540	6587	3816	1877	772	289
MoM	9736	8689	6370	3781	1733	592
CoM	1187	711	238	28	8	2

Figure 3.1.6. Kaplan Meier: unadjusted cumulative implant survival of Corail/Pinnacle cementless hip replacements, by femoral stem size (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	8 to 10	11 to 13	≥14
Sizes 8 to 10 (p-value)	-	<0.001	0.132
Sizes 11 to 13	<0.001	-	0.011
Sizes ≥14	0.132	0.011	-

Life table showing numbers at risk each year

Femoral size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
8 to 10	10229	7221	4616	2532	1133	431
11 to 13	20897	14976	9771	5613	2769	1043
≥14	4260	3078	2041	1202	620	216

Table 3.1.17. Independent predictors of revision following entire series of 35 386 Corail/Pinnacle cementless hip replacements: simple and multi-variable Cox regressions (BMI data excluded, England and Wales, 2003-2010)

Covariate	Simple analysis			Multi-variable analysis		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Female	1					
Male	1.03	0.81 to 1.32	0.725			
Age						
Category			0.796			
≤60	1					
61-75	0.94	0.70 to 1.25	0.553			
≥76	0.92	0.63 to 1.33	0.559			
ASA grade						
½	1			1		
≥3	1.38	0.98 to 1.94	0.014	1.39	0.99 to 1.96	0.013
Stem size						
Category			<0.001			<0.001
8-10	1.79	1.38 to 2.33	<0.001	1.82	1.40 to 2.37	<0.001
11-13	1			1		
≥14	1.44	0.99 to 2.09	0.012	1.43	0.98 to 2.07	0.014
Stem design						
Collarless	1					
Collared	1.05	0.80 to 1.37	0.670			
Cup shell type						
Category			0.354			
Solid, HA coated	0.82	0.59 to 1.15	0.128			
Solid, non-HA	1.10	0.69 to 1.75	0.591			
Cluster, HA coated	1					
Cluster, non-HA	0.92	0.68 to 1.24	0.447			
Bearing						
Category			<0.001			<0.001
Metal-on-polyethylene	1			1		
Ceramic-on-poly.	1.32	0.82 to 2.11	0.135	1.33	0.83 to 2.12	0.123
Ceramic-on-ceramic	1.54	1.06 to 2.25	0.003	1.55	1.07 to 2.26	0.003
Ceramic-on-metal	1.47	0.64 to 3.37	0.237	1.45	0.63 to 3.33	0.253
Metal-on-metal	1.92	1.36 to 2.72	<0.001	1.93	1.36 to 2.73	<0.001
Head size						
28/32mm	1					
≥36mm	1.38	1.07 to 1.77	0.001			
Combined offset						
Category			0.352			
Low	1					
Medium	1.05	0.79 to 1.40	0.639			
High	1.23	0.86 to 1.76	0.136			
Minus	1.30	0.76 to 2.21	0.213			
Operator						
Consultant	1					
Other	0.84	0.59 to 1.20	0.206			
Consultant volume						
Category			0.230			
Low (≤50)	1.02	0.73 to 1.43	0.869			
Medium (51-300)	0.86	0.65 to 1.13	0.152			
High (≥301)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HA – hydroxyapatite,

Table 3.1.18. Independent predictors of revision following Corail/Pinnacle cementless hip replacements based on 17 166 patients with valid BMI data: simple and multi-variable Cox regressions (England and Wales, 2003-2010)

Covariate	Simple analysis			Multi-variable analysis		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Female	1					
Male	1.03	0.81 to 1.32	0.725			
Age						
Category			0.796			
≤60	1					
61-75	0.94	0.70 to 1.25	0.553			
≥76	0.92	0.63 to 1.33	0.559			
ASA grade						
½	1					
≥3	1.38	0.98 to 1.94	0.014			
Body mass index						
<30kg/m^2	1			1		
≥30kg/m^2	1.58	1.11 to 2.26	0.001	1.55	1.08 to 2.22	0.002
Stem size						
Category			<0.001			0.002
8-10	1.79	1.38 to 2.33	<0.001	1.70	1.16 to 2.51	<0.001
11-13	1			1		
≥14	1.44	0.99 to 2.09	0.012	1.44	0.83 to 2.49	0.092
Stem design						
Collarless	1					
Collared	1.05	0.80 to 1.37	0.670			
Cup shell type						
Category			0.354			
Solid, HA coated	0.82	0.59 to 1.15	0.128			
Solid, non-HA	1.10	0.69 to 1.75	0.591			
Cluster, HA coated	1					
Cluster, non-HA	0.92	0.68 to 1.24	0.447			
Bearing						
Category			<0.001			0.001
Metal-on-polyethylene	1			1		
Ceramic-on-poly.	1.32	0.82 to 2.11	0.135	1.36	0.69 to 2.68	0.242
Ceramic-on-ceramic	1.54	1.06 to 2.25	0.003	2.09	1.21 to 3.63	0.001
Ceramic-on-metal	1.47	0.64 to 3.37	0.237	1.31	0.45 to 3.83	0.514
Metal-on-metal	1.92	1.36 to 2.72	<0.001	2.19	1.29 to 3.72	<0.001
Head size						
28/32mm	1					
≥36mm	1.38	1.07 to 1.77	0.001			
Combined offset						
Category			0.352			
Low	1					
Medium	1.05	0.79 to 1.40	0.639			
High	1.23	0.86 to 1.76	0.136			
Minus	1.30	0.76 to 2.21	0.213			
Operator						
Consultant	1					
Other	0.84	0.59 to 1.20	0.206			
Consultant volume						
Category			0.230			
Low (≤50)	1.02	0.73 to 1.43	0.869			
Medium (51-300)	0.86	0.65 to 1.13	0.152			
High (≥301)	1					

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, HA – hydroxyapatite

After risk adjustment for the entire study population (excluding BMI from the model), MoM (HR=1.93, p<0.001) and CoC (HR=1.55, p=0.003) bearings, and small femoral stem sizes (8-10: HR=1.82, p<0.001) were independent influences associated with greater revision, when compared with MoP. There was a trend towards higher revision with a large stem (≥14, HR=1.43, p=0.014) and ASA ≥3 (HR=1.39, p=0.013). Risk of revision for CoP bearings was not significantly different to MoP (HR=1.33, p=0.123) (**Table 3.1.17**).

After risk adjustment with BMI included (17 166 patients), bearing (p=0.001) and stem size (p=0.002) categories remained significant influences on risk of revision. ASA grade was no longer selected in the final model. Despite the smaller numbers, the influence of individual bearing types on revision risk was similar to the entire population model (MoM: HR=2.19, p<0.001, CoC: HR=2.09, p=0.001), validating model estimates on the larger population, without adjustment for BMI. Small femoral stem sizes remained a significant influence (HR=1.82, p=<0.001) but the large size category was not selected in the final model (**Table 3.1.18**).

Risk of revision was independent of age, gender, stem design, cup shell type, head size, combined offset, operating surgeon grade and consultant volume.

Revision rates

The overall 5-year revision rate was 2.41% for the entire study population. By bearing surface, five-year revision rates were 1.36% for MoP, 1.76% for CoP, 2.05% for CoC and 3.47% for MoM (**Table 3.1.19**).

Table 3.1.19. Revision rates following entire series of Corail/Pinnacle cementless hip replacements by bearing, and overall England and Wales, 2003-2010)

	Revision rates by bearing (99% CI)					Overall revision rates
	MoP	CoP	CoC	CoM	MoM	
1-year	0.61% (0.38 to 0.83)	0.90% (0.51 to 1.29)	0.93% (0.66 to 1.20)	0.42% (0.00 to 0.96)	0.82% (0.58 to 1.06)	0.79% (0.66 to 0.93)
3-year	1.22% (0.84 to 1.60)	1.41% (0.85 to 1.97)	1.82% (1.35 to 2.29)	3.46% (0.01 to 6.91)	2.17% (1.72 to 2.61)	1.77% (1.53 to 2.01)
5-year	1.36% (0.90 to 1.83)	1.76% (0.99 to 2.53)	2.05% (1.47 to 2.62)	-	3.47% (2.63 to 4.31)	2.41% (2.02 to 2.79)
Total number	9242	4681	10540	1187	9736	35386

CI – confidence intervals, CoP – ceramic-on-polyethylene, MoP – metal-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal

For patients with a valid BMI, overall 1-, 3- and 5-year results were similar to the entire population. Although risk of 5-year revision with MoP and MoM bearings was higher in patients with BMI ≥30kg/m^2 (BMI <30kg/m^2: CoP 0.85%, MoM 3.70%, BMI ≥30kg/m^2: CoP 1.61%, MoM 5.01%) (**Table 3.1.20**).

Table 3.1.20. Revision rates following Corail/Pinnacle cementless hip replacements, by bearing in 17 166 patients with body mass index data, and overall (England and Wales, 2003-2010)

	Revision rates by bearing (99% CI)					Overall revision rates
	MoP	CoP	CoC	CoM	MoM	
1-year						
All	0.63%	0.86%	1.33%	0.29%	0.95%	0.92%
	(0.30 to 0.97)	(0.34 to 1.38)	(0.84 to 1.82)	(0.00 to 0.83)	(0.55 to 1.35)	(0.71 to 1.13)
BMI <30kg/m^2	*0.50%*	*0.84%*	*1.00%*	*0.23%*	*0.76%*	*0.73%*
	(0.13 to 0.88)	*(0.19 to 1.49)*	*(0.45 to 1.54)*	*(0.00 to 0.83)*	*(0.30 to 1.22)*	*(0.50 to 0.97)*
BMI ≥30kg/m^2	*0.86%*	*0.90%*	*1.84%*	*0.40%*	*1.25%*	*1.22%*
	(0.22 to 1.49)	*(0.03 to 1.77)*	*(0.94 to 2.75)*	*(0.00 to 1.42)*	*(0.52 to 1.99)*	*(0.83 to 1.60)*
3-year						
All	1.13%	1.59%	2.27%	3.29%	2.61%	2.03%
	(0.60 to 1.66)	(0.68 to 2.50)	(1.35 to 3.19)	(0.00 to 7.39)	(1.77 to 3.46)	(1.61 to 2.44)
BMI <30kg/m^2	*0.85%*	*1.58%*	*1.75%*	*2.82%*	*2.19%*	1.66%
	(0.25 to 1.45)	*(0.39 to 2.78)*	*(0.65 to 2.85)*	*(0.00 to 7.47)*	*(1.24 to 3.13)*	*(1.18 to 2.14)*
BMI ≥30kg/m^2	*1.61%*	*1.58%*	*3.06%*	*4.11%*	*3.34%*	*2.63%*
	(0.60 to 2.62)	*(0.25 to 2.92)*	*(1.47 to 4.65)*	*(0.0 to 11.9)*	*(1.73 to 4.95)*	*(1.85 to 3.40)*
5-year						
All	1.13%	1.59%	-	-	4.17%	2.68%
	(0.60 to 1.66)	(0.68 to 2.50)			(2.32 to 6.02)	(1.91 to 3.45)
BMI <30kg/m^2	*0.85%*	*1.58%*			*3.70%*	*2.25%*
	(0.25 to 1.45)	*(0.39 to 2.78)*			*1.60 to 5.80)*	*(1.37 to 3.13)*
BMI ≥30kg/m^2	*1.61%*	*1.58%*			*5.01%*	*3.41%*
	(0.60 to 2.62)	*(0.25 to 2.92)*			*(1.38 to 8.64)*	*(1.92 to 4.89)*
Total number	4763	2612	4827	836	4128	17 166

CI – confidence intervals, BMI – body mass index, MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal

Statistical considerations

When treated as continuous covariates neither age (HR=1.00, 99% CI 0.99 to 1.01, p=0.543) nor consultant volume (HR=1.00, 99% CI 0.99 to 1.00, p=0.232) were significant influences within univariable analysis.

Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final model when BMI was included. When BMI was removed from the analysis, forward stepwise construction (but not backward) failed to select ASA grade when thresholds for inclusion were reduced.

Spearman's rank correlation coefficient between ASA grade and BMI for 17 166 patients (with recorded BMI) was 0.177 (2-tailed significance of p<0.001), indicating a weakly positive correlation and possible explanation for the role of these covariates in the entire and BMI-subset models.

Summary

Registry data demonstrates higher revision rates in cementless implants compared with cemented. However, this analysis reveals subtle differences in revision risk depending on implant configuration and patient factors, with an estimated revision rate at 5 years in patients with a BMI <30kg/m^2 and when using a metal-on-polyethylene bearing of only 0.9%.

However, cementless implants featuring hard bearings (MoM, CoC) were associated with significantly greater revision rates; these bearings represent over 60% of all configurations implanted, and explain the poorer results overall when this data are analysed as a single brand by national registries. Smaller femoral stem sizes (sizes 8-10) and higher BMI were also significant positive predictors of revision. Other implant factors, including head size, did not significantly influence revision in this analysis.

Hip resurfacing

Modern metal-on-metal hip resurfacing arthroplasty has been widely performed in the United Kingdom for over a decade. However, there are contradictory reports of the benefits with excellent medium to long-term results for some brands and high failure rates and local soft tissue reactions for others. Only a few manufactures offer this type of implant, and the only bearing is metal-on-metal, with the range of sizes offered reflecting the anatomical differences between patients. Thus, unlike previous hip replacement analyses discussed earlier in this chapter, different implant configurations within brands are not possible, and design differences between brands may influence survival. The following analysis includes all the commonly used brands, and explores the performance and risk factors associated with hip resurfacing.

There were a total of 27 971 hip resurfacings performed and recorded between 2003 and 2010 in England and Wales. The majority were male patients (19 335, 69.1%), almost all were ASA ≤2 (27 148, 97.1%) and the mean age was 55 years old. The posterior approach was favoured in over 70% of cases, and the BHR was the most commonly implanted prosthesis (15 459, 55.3%). Small or very small femoral components (≤47mm) were used in 33% (9223). Patients were under the care of 722 different consultants in 376 different surgical units and, in the majority of cases, the consultant performed the operation (93.5%, 26 166 operations). This is more technically demanding procedure than a standard hip replacement and yet 25.7% (7202) of the procedures were under the care of a consultant who had recorded 50 or less resurfacing procedures over the course of the study. Demographics are shown in **Table 3.1.21**.

One thousand and three (3.59%) of 27 971 patients underwent a revision procedure during the available period of follow-up. The most common reason was aseptic component loosening/lysis (26.3% of all revisions), followed by peri-prosthetic fracture (21.2%) and pain (18.2%) without a cause recorded. Seventy-one patients (7.1%) had revision secondary to an adverse soft tissue reaction to metal debris. Revision data are summarised in **Table 3.1.22.** Ninety-day mortality rate was 0.08%. As of December 2010, 1.24% of patients had died.

Table 3.1.21. Demographics of 27 971 hip resurfacing patients (England and Wales, 2003-2010)

Age, mean years (SD)	55.1	(8.48)
≤45, n (%)	3383	(12.1)
46-55	9540	(34.1)
56-65	12 215	(43.7)
≥66	2833	(10.1)
Gender		
Male	19 335	(69.1)
Female	8636	(30.9)
ASA grade		
1	13 767	(49.2)
2	13 381	(47.8)
≥3	823	(2.9)
Body mass index, mean kg/m^2 (SD)	28.3	(4.60)*
Underweight (<20kg/m^2), n (%)	95	(0.3)
Normal (20<25kg/m^2)	1634	(5.8)
Overweight (25<30kg/m^2)	4088	(14.6)
Obese (≥30kg/m^2)	3021	(10.8)
No data	19 131	(68.4)
Approach		
Posterior	20 048	(71.7)
Antero-lateral	5578	(19.9)
No data	2345	(8.4)
Brand		
BHR	15 459	(55.3)
ASR	2631	(9.4)
Adept	2466	(8.8)
Conserve	1173	(4.2)
Cormet	3193	(11.4)
Durom	1381	(4.9)
Mitch	339	(1.2)
Recap	1329	(4.8)
Head size category		
Very small (≤44mm)	3928	(14.0)
Small (45-47mm)	5295	(18.9)
Medium (48-50mm)	10 720	(38.3)
Large (≥51mm)	8028	(28.7)
Operator		
Consultant	26 166	(93.5)
Other	1805	(6.5)
Number of consultants (n)	722	
Consultant volume		
Low (≤50 cases over study period)	7202	(25.7)
Medium (51-200)	11 910	(42.6)
High (≥201)	8859	(31.7)
Number of surgical units (n)	376	

SD – standard deviation, * - based on 8838 patients

Table 3.1.22. Reason recorded for revision of 1003 hip resurfacings (England and Wales, 2003-2010)

Aseptic component loosening/lysis, n (%)	264	(26.3)
Femoral	*112*	
Acetabular	*132*	
Both	*20*	
Periprosthetic fracture	213	(21.2)
Femoral neck	*203*	
Acetabulum	*6*	
Both	*4*	
Unexplained pain	183	(18.2)
Technical errors	90	(9.0)
Component mismatch	*9*	
Component malalignment	*81*	
Adverse soft tissue reaction to metal debris*	71	(7.1)
Infection	71	(7.1)
Dislocation / subluxation	45	(4.5)
Component fracture	37	(3.7)
Acetabular wear	10	(1.0)
Other	11	(1.1)
Avascular necrosis of femoral head	*9*	
Heterotrophic ossification	*1*	
Leg length discrepancy	*1*	
No cause described	60	(6.0)

*Including free text terms: metallosis, aseptic lymphocyte-dominated vasculitis associated lesion (ALVAL)

Patient specific predictors of implant failure in the unadjusted data were female gender and ASA grades 2 and above. After risk adjustment using the Cox proportional hazards model, female gender (HR=1.30, p=0.007) and ASA grade ≥3 (HR=1.74, p<0.001) remained significant (**Table 3.1.23**).

There were 19133 (68.4%) missing BMI entries and 2345 (8.4%) missing surgical approach entries. Patient age, BMI, surgical approach and grade of operator did not significantly influence the risk of implant revision.

When the unadjusted data were analysed for brand ASR, Cormet, Conserve and Durom had significantly higher revision rates compared with the BHR (**Figure 3.1.7**). Some brands lacked longer-term data to permit adequate comparison at this point in time (Adept, Recap). After risk adjustment, the same five brands were found to have a greater revision hazard than the BHR (**Table 3.1.23**).

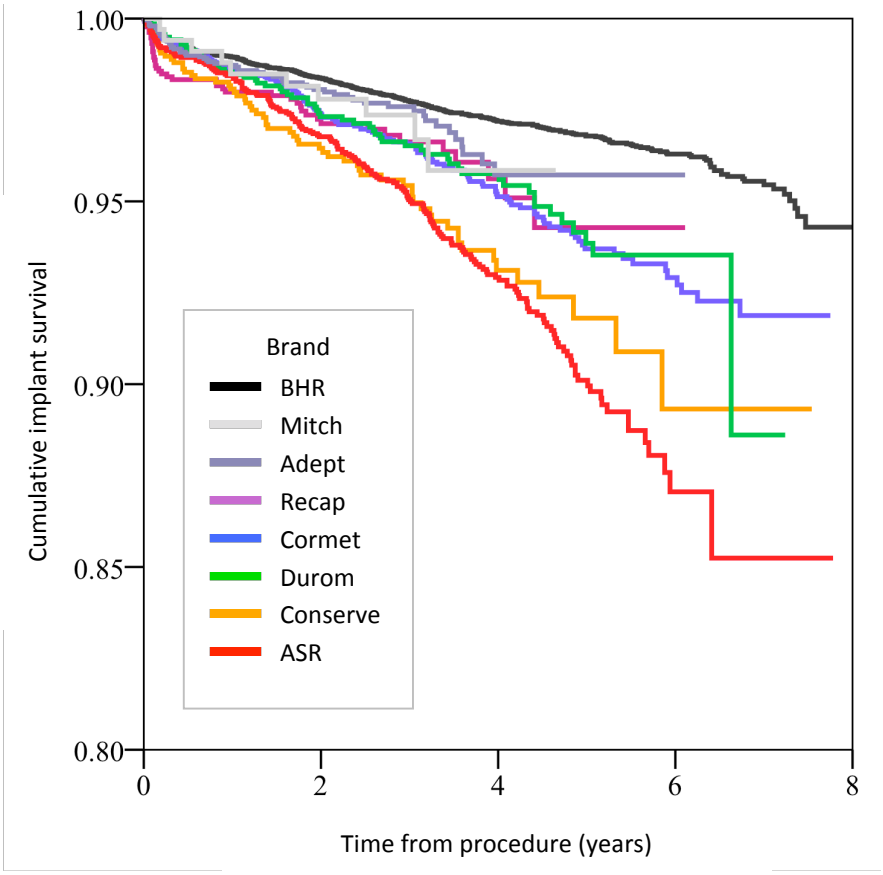
Table 3.1.23. Independent predictors of revision following 27 971 hip resurfacings (England and Wales, 2003-2010)

Covariate	Unadjusted analysis			Adjusted analysis		
	HR	99% CI	P value	HR	99% CI	P value
Gender						
Male	1			1		
Female	2.04	1.74 to 1.41	<0.001	1.30	1.01 to 1.67	0.007
Age						
Category			0.368			
≤45	1					
46-55	0.91	0.70 to 1.19	0.375			
56-65	0.85	0.66 to 1.09	0.091			
≥66	0.91	0.64 to 1.27	0.452			
ASA grade						
Category			<0.001			0.001
1	1			1		
2	1.19	1.00 to 1.40	0.008	1.14	0.96 to 1.35	0.045
≥3	1.74	1.16 to 2.60	<0.001	1.74	1.17 to 2.61	<0.001
Body mass index						
Category			0.050			
Underweight	2.07	0.70 to 6.11	0.082			
Normal	1.46	0.97 to 2.19	0.016			
Overweight	1					
Obese	1.19	0.83 to 1.73	0.213			
Approach						
Posterior	1					
Antero-lateral	1.26	1.04 to 1.53	0.002			
Brand						
Category			<0.001			<0.001
BHR	1			1		
ASR	2.80	2.24 to 3.51	<0.001	2.82	2.24 to 3.54	<0.001
Adept	1.32	0.92 to 1.90	0.047	1.26	0.87 to 1.81	0.107
Conserve	2.45	1.73 to 3.47	<0.001	2.03	1.42 to 2.91	<0.001
Cormet	1.74	1.36 to 2.23	<0.001	1.43	1.10 to 1.86	0.001
Durom	1.72	1.20 to 2.45	<0.001	1.67	1.16 to 2.39	<0.001
Mitch	1.50	0.65 to 3.38	0.222	1.40	0.61 to 3.20	0.298
Recap	1.73	1.14 to 2.64	0.001	1.58	1.03 to 2.42	0.007
Head size category						
Category			<0.001			<0.001
Very small (≤44mm)	2.46	1.95 to 3.11	<0.001	2.14	1.53 to 3.00	<0.001
Small (45-47mm)	1.60	1.27 to 2.03	<0.001	1.48	1.09 to 2.00	0.001
Medium (48-50mm)	0.87	0.68 to 1.01	0.118	0.99	0.77 to 1.26	0.907
Large (≥51mm)	1			1		
Operator						
Consultant						
Other	1.07	0.76 to 1.49	0.624			
Consultant volume						
Category			<0.001			0.001
Low (≤50)	1.52	1.22 to 1.88	<0.001	1.36	1.09 to 1.71	<0.001
Medium (51-200)	1.24	1.01 to 1.51	0.007	1.14	0.92 to 1.41	0.110
High (≥201)	1			1		

Age of patient, body mass index, operator and surgical approach were not entered into the final model.

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, BHR – Birmingham Hip Replacement, ASR – Articular Surface Replacement

Figure 3.1.7. Kaplan-Meier: unadjusted cumulative implant survival, by hip resurfacing brand (England and Wales, 2003-2010)



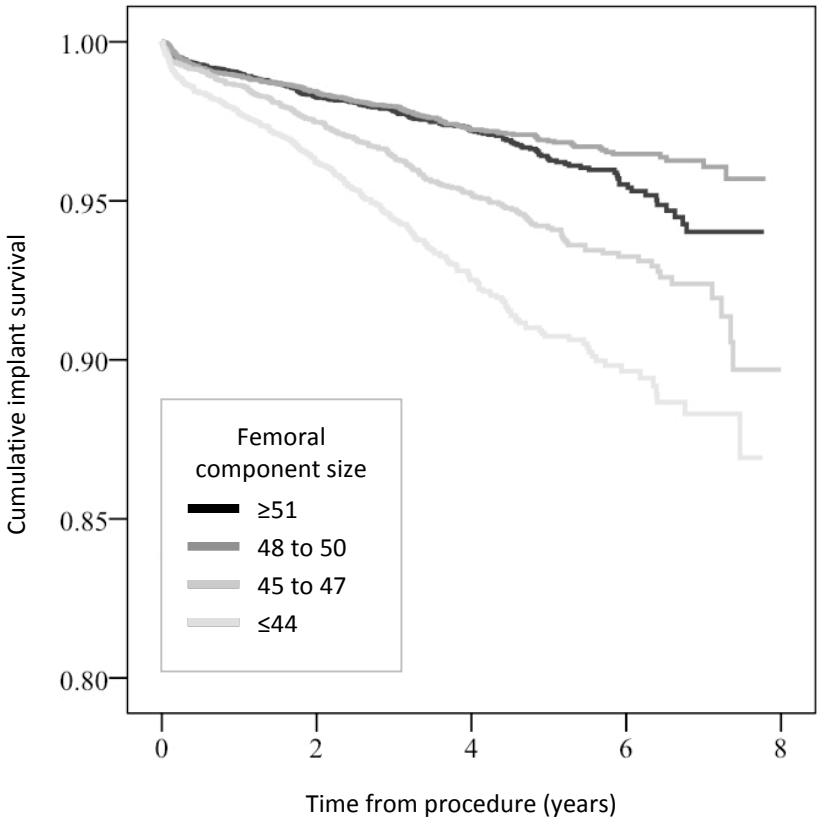
Log rank (Mantel-Cox)	BHR	ASR	Adept	Conserve	Cormet	Durom	Mitch	Recap
BHR (p-value)	-	<0.001	0.130	<0.001	<0.001	<0.001	0.316	0.003
ASR	<0.001	-	<0.001	0.546	<0.001	0.001	0.117	0.027
Adept	0.130	<0.001	-	0.001	0.098	0.200	0.773	0.192
Conserve	<0.001	0.546	0.001	-	0.023	0.041	0.147	0.083
Cormet	<0.001	<0.001	0.098	0.023	-	0.858	0.648	1.000
Durom	<0.001	0.001	0.200	0.041	0.858	-	0.742	0.926
Mitch	0.316	0.117	0.773	0.147	0.648	0.742	-	0.702
Recap	0.003	0.027	0.192	0.083	1.000	0.926	0.702	-

BHR – Birmingham Hip Resurfacing, ASR – Articular Surface Replacement

Life table showing numbers at risk in each year

Brand	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
BHR	15459	14172	12314	10069	7545	5092	2821	989
ASR	2631	2554	2314	1819	1201	586	135	1
Adept	2466	2049	1481	842	296	107	4	0
Conserve	1173	1037	850	610	332	127	52	10
Cormet	3193	3029	2590	1996	1334	883	463	159
Durom	1381	1318	1117	862	595	311	82	10
Mitch	339	314	272	151	39	0	0	0
Recap	1329	1120	818	488	189	44	2	0

Figure 3.1.8. Kaplan-Meier: unadjusted cumulative implant survival, by femoral head size (England and Wales, 2003-2010)



Log rank (Mantel-Cox)	≤44	45 to 47	48 to 50	≥51
≤44 (p-value)	-	<0.001	<0.001	<0.001
45 to 47	<0.001	-	<0.001	<0.001
48 to 50	<0.001	<0.001	-	0.116
≥51	<0.001	<0.001	0.116	-

Life table showing numbers at risk in each year

Size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
≤44	3928	3697	3178	2444	1613	966	474	167
45 to 47	5295	4075	4368	3522	2492	1534	786	245
48 to 50	10720	9674	8124	6166	4186	2644	1362	488
≥51	8028	7247	6086	4705	3240	2006	937	269

Femoral sizes smaller than 48mm were found to be significant predictors of revision in both the unadjusted and the adjusted data (**Figure 3.1.8, Table 3.1.23**). Small femoral head sizes had significantly higher revision hazards than large heads (≤44mm: HR=2.14, p<0.001, 45-47mm: HR=1.48, p=0.001). There were no significant differences between the medium and the larger head sizes.

Surgeons who performed 200 or fewer resurfacings during the study period were associated with having higher revision rates in the unadjusted data. However, after risk adjustment, only patients operated on by low volume surgeons (50 or fewer resurfacings) had a higher revision hazard (HR=1.36, p<0.001) when compared with high volume surgeons (**Table 3.1.23**).

Tests for interaction (multiplicative) between covariates and time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final model.

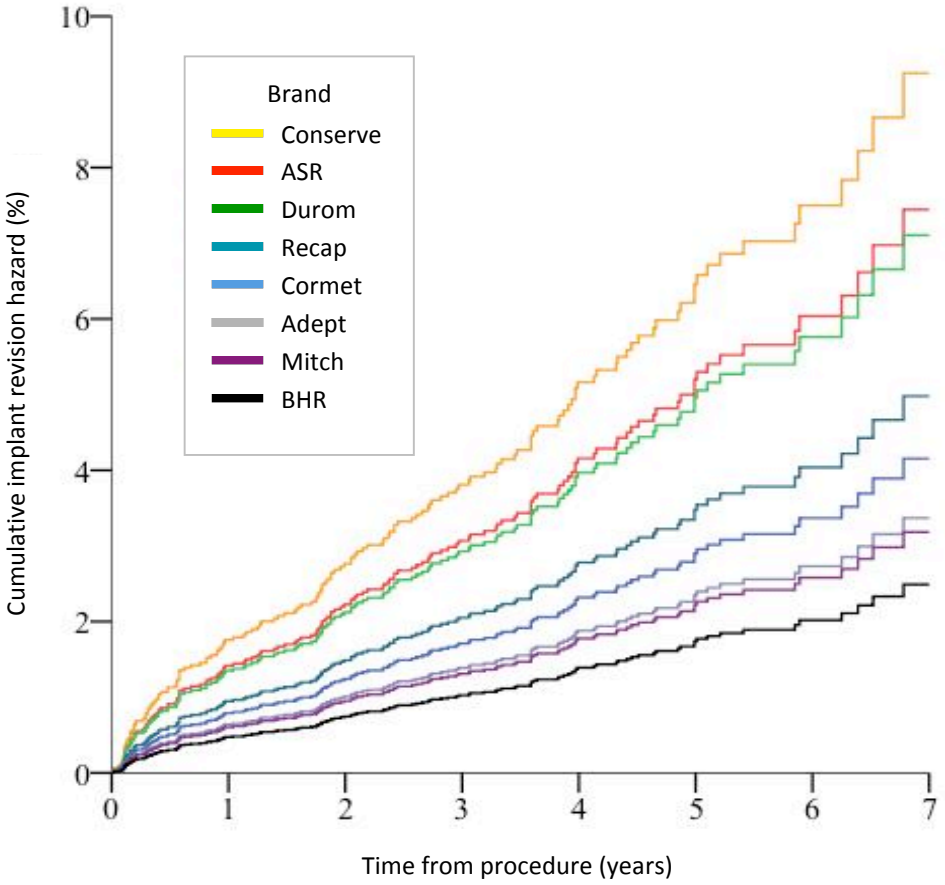
When data for younger (<60 years), fitter (ASA grades 1 and 2) male patients were analysed by brand, following resurfacings performed with head sizes ≥48mm by medium- to high-volume consultants, BHR patients (4873) had a significantly lower 5-year estimated revision rate (1.59%) when compared to the poorest performing brand (ASR [715 patients]: 5.67%) and the entire resurfacing cohort (8172 patients: 2.47%) (**Table 3.1.24** and **Figure 3.1.9**). The estimated revision rate for the whole study population at five years was 4.76% (**Table 3.1.24**).

Table 3.1.24. Estimated revision rates following resurfacing by brand under optimal conditions (males <60 years, ASA ≤2, femoral head size ≥48mm, mid- to high-volume consultant), compared to the entire study population (England and Wales, 2003-2010)

	Revision rates under optimal conditions (95% CI)							Overall revision rates (entire population)
	BHR	ASR	Adept	Cormet	Durom	Recap	*Total*	
1 year	0.65% (0.43-0.88)	0.99% (0.26-1.72)	0.70% (0.09-1.31)	0.26% (0.00-0.62)	1.03% (0.03-2.03)	0.96% (0.00-2.04)	*0.71% (0.52-0.89)*	1.29% (1.15-1.42)
3-year	1.18% (0.85-1.51)	2.78% (1.51-4.04)	1.06% (0.27-1.85)	1.21% (0.37-2.04)	2.85% (1.10-4.61)	2.41% (0.44-4.38)	*1.51% (1.22-1.80)*	2.93% (2.72-3.25)
5-year	1.59% (1.17-2.00)	5.67% (3.48-7.85)	2.20% (0.45-3.96)	2.79% (1.27-4.31)	5.27% (2.33-8.22)	-	*2.47% (2.04-2.91)*	4.76% (4.44-5.08)
7-year	2.21% (1.51-2.91)	6.42% (3.80-9.04)	-	5.31% (1.94-8.69)	-	-	*3.34% (2.62-4.06)*	6.29% (5.76-6.81)
Total number	4873	715	787	783	395	348	*8172*	27971

Conserve and Mitch brands had less than 200 operations overall so were excluded from this table
CI – confidence intervals, BHR – Birmingham Hip Replacement, ASR – Articular Surface Replacement

Figure 3.1.9. Estimated cumulative revision risk following resurfacing by brand under optimal conditions (males under 60 years, ASA ≤2, femoral head size ≥48mm, mid- to high-volume consultant) (England and Wales, 2003-2010)



ASA – American Society of Anaesthesiologists grade, ASR – Articular Surface Replacement, BHR – Birmingham Hip Resurfacing

Summary

The revision risk was lowest with the most commonly used brand (BHR). Significantly greater revision rates were independently associated with some brands (ASR, Durom, Conserve, Cormet) while others lacked adequate longer-term data (Adept, Recap). Additionally female gender, smaller implant sizes (<48mm), ASA and lower consultant volume were independently associated with higher failure rates. Increasing age and BMI were not associated with a greater revision risk. Under optimal conditions, where the patient is a healthy young male, the implant is a large BHR (≥48mm femoral head size) and the surgeon is experienced using resurfacing implants, estimated revision rate at 7 years is 2.21%.

Part 1 summary

Analyses of hip replacement data in this section have revealed differing implant survival associated with specific component sets. Some patient and surgical characteristics also have an influence. Much of this detail is lost within national registry analyses, which attempt to assess all implants across broadly similar groups and provide revision risk for the entirety of a brand.

The approach adopted allows more refined comparative analyses of different types of implants within specific patient groups. For each of the four THR procedures, implant configurations are separated into the 'best' and 'others' in terms of implant survival.

*The variation of performance within brands shows dramatic variation (**Table 3.1.25**), although this detail is lost when assessed by aggregating performance as can occur within national registry analyses. Taking the best performing implant within brand, a summary of the findings of part 1 are summarised in **Table 3.1.26.***

Table 3.1.25. Comparison of NJR annual report analyses with findings from preliminary analysis section

Cemented hip replacement	7-year revision risk (%)
Exeter V40 Contemporary (entire group, NJR 9th AR)	*1.8*
Exeter V40 26mm head Contemporary Hooded cup	3.5
Exeter V40 28mm head Contemporary Flanged cup	1.2
Cementless hip replacement	**5-year revision risk (%)**
Corail Pinnacle (entire group, NJR 9th AR)	*2.7*
Corail Pinnacle MoM, BMI>30kg/m^2	5.0
Corail Pinnacle MoP, BMI<30kg/m^2	0.9

NJR – National Joint Registry, AP – annual report, MoM – metal-on-metal, MoP – metal-on-polyethylene

Table 3.1.26. Summary of findings in the individual implant type analyses

	Modifiable influences	Non-modifiable influences	**Best**	**Other**
Cemented *Exeter Contemporary*	Cup design Head size	-	≥28mm head Flanged cup	All hooded cups Head sizes <28mm
Hybrid *Exeter Trident*	Bearing	Shell fixation	XLPE liner (or CoC*) Solid-shell cups	All multi-hole shells CPE bearings
Cementless *Corail Pinnacle*	Bearing	Stem size BMI	Stem sizes ≥11 MoP/CoP bearings	Small stems (<11) Hard bearings
Resurfacing	Surgeon experience	ASA grade Gender Head size	BHR (Mitch/Adept) ≥48mm head size	All other brands <48mm head size

* - borderline significance, XLPE – highly cross-linked polyethylene liner used with either metal or ceramic head, CoC – ceramic-on-ceramic, MoP – metal-on-polyethylene, PE – polyethylene, CoP – ceramic-on-polyethylene, BMI – body mass index, ASA – America Society of Anaesthesiologists, BHR – Birmingham Hip Resurfacing

Part 2. Patient reported outcome measures analyses

PROMs dataset for commonest hip replacement types

Patient reported outcome measures (PROMs) have been collected on NHS hip replacement patients since 2008. This consists of a pre-operative joint-specific (Oxford Hip Score) and general health assessment (EuroQol EQ5D and Visual Analogue Score), with reevaluation at around 6 months following surgery. The change (or improvement) score from pre- to post-operatively is calculated in order to assess a patient's outcome. Patients are also asked to rate their success and satisfaction with the procedure, together with reporting of any complications following surgery. This data is stored separately from NJR data but was linked with the use of unique patient identifiers. This section describes the PROMs data available for the patient populations described in part 1.

There were 56 798 valid NJR/PROMs linked episodes. Of these, 10 703 involved the commonest brand of each type of hip replacement (cemented – Exeter V40 / Contemporary, hybrid – Exeter V40 / Trident, cementless – Corail Pinnacle, resurfacing – BHR). Around 18% of the procedures were performed in patients under 60 years (1909).

When unadjusted OHS change were analysed separately for the best and other configurations of the four types of replacement (i.e. eight types), improvement was qualitatively similar, with a mean improvement of 20 points (**Figure 3.2.1**). Analysis by gender showed similar unadjusted improvements in OHS and EQ5D index, with greater benefits seen following cementless and resurfacing procedures (**Figures 3.2.2 and 3.2.3**).

Figure 3.2.1. Box plot showing OHS change at 6 months following different hip replacement configurations (unadjusted data, England and Wales, 2008-2010)

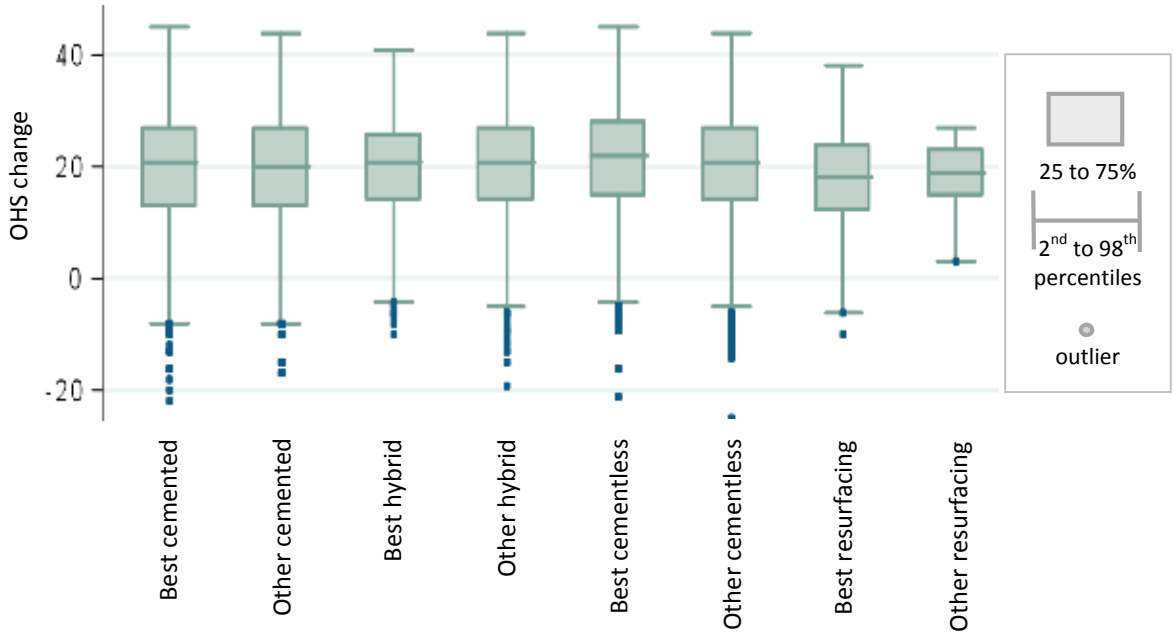


Figure 3.2.2. Box plot showing OHS change at 6 months following hip replacement with one of eight implant types in patients under 60 years, by gender (unadjusted data, England and Wales, 2008-2010)

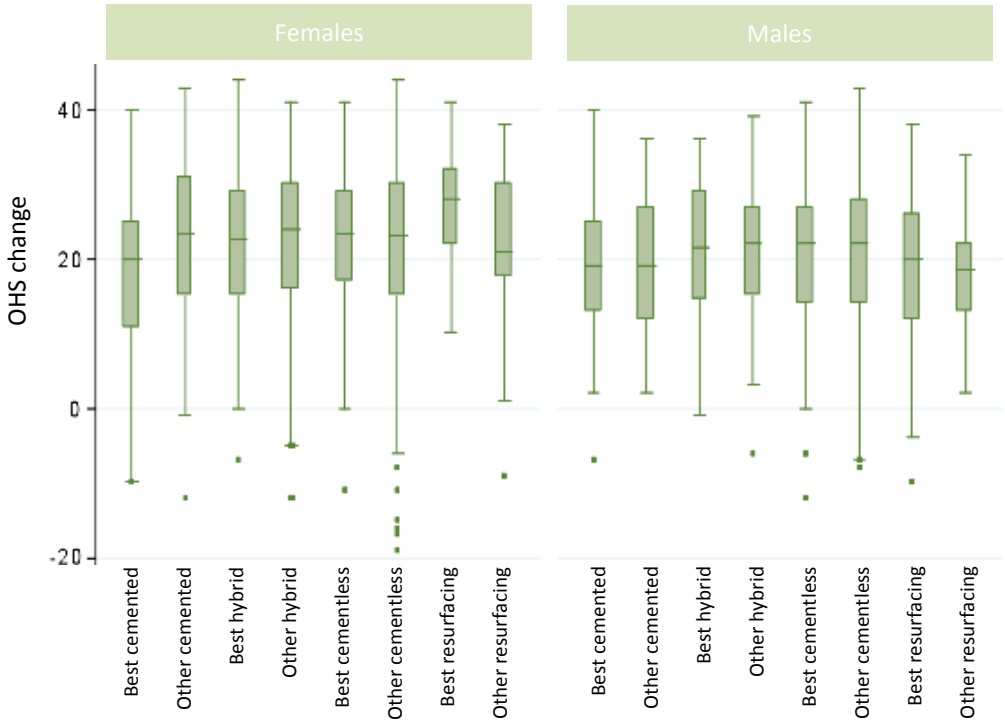
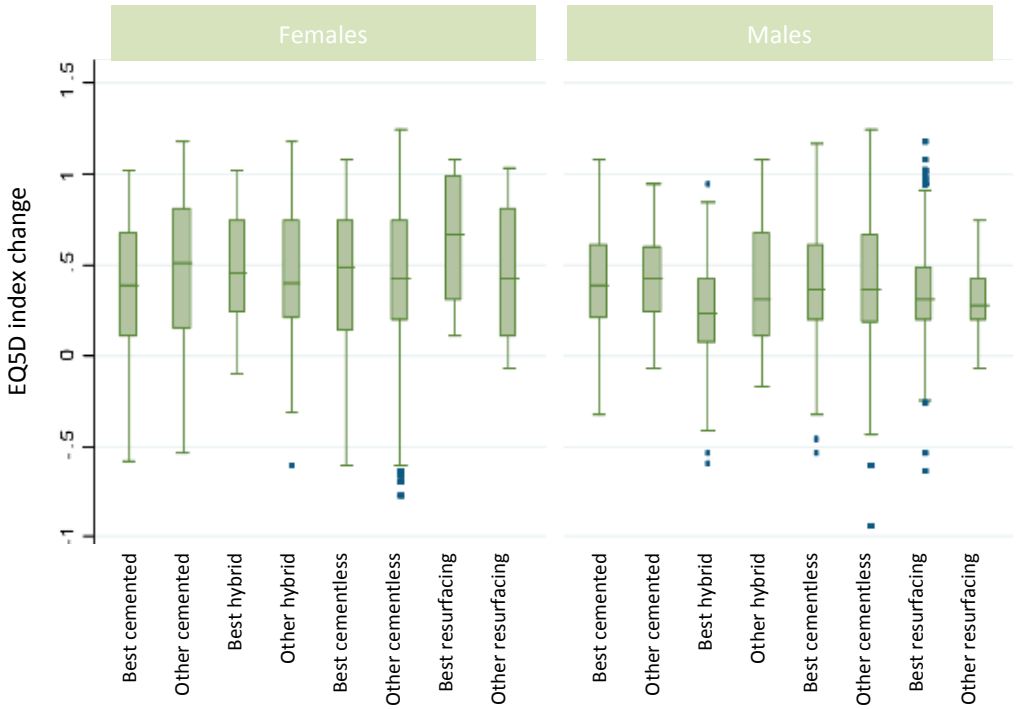


Figure 3.2.3. Box plot showing EQ-5D index change at 6 months following hip replacement with one of eight implant types in patients under 60 years, by gender (unadjusted data, England and Wales, 2008-2010)



After risk adjusting separately for males and females a number of highly significant patient influences were found for predicting change scores (**Tables 3.2.1 to 3.2.4**). For all analyses this included preoperative OHS/EQ5D index, general health score, and presence of disability, depression and circulatory problems prior to surgery. BMI also had an influence on OHS change (**Tables 3.2.1 and 3.2.2**). Surgical influences included surgical approach (where posterior conferred greater benefit) and regional anaesthesia (females only, **Tables 3.2.1 and 3.2.3**). Hip replacement type influenced change in OHS in females only (p<0.001), with cementless and hybrid implants appearing to offer benefit (**Table 3.2.1**).

Table 3.2.1. Significant influences on OHS change at 6 months in females (England and Wales, NJR/PROMs linked data 2008-2010)

Covariate			Associated with greater improvement in OHS
Patient	Pre-op OHS	<0.001	Lower pre-operative OHS
	Pre-op disability	<0.001	Disability absent
	Pre-op general health	<0.001	Higher pre-operative general health
	Depression	<0.001	Depression absent
	Previous stroke	<0.001	Stroke absent
	BMI	<0.001	Lower BMI
	Circulatory problems	0.004	Circulatory problems absent
	Liver disease	0.008	Liver disease absent
	Pre-op EQ5D index	0.025	Higher pre-operative EQ5D index
	Age	0.047	Younger patients
Surgical	Approach	<0.001	Posterior approach
	Hip type	<0.001	Hybrid / cementless
	Anaesthesia type	0.013	Regional

Multivariable linear regression model (n=6196, R squared=0.44)
OHS – Oxford Hip Score, NJR – National Joint Registry, PROMs – patient reported outcome measures, BMI – body mass index

Table 3.2.2. Significant influences on OHS change at 6 months in males (England and Wales, NJR/PROMs linked data 2008-2010)

Covariate			Associated with greater improvement in OHS
Patient	Pre-op OHS	<0.001	Lower pre-operative OHS
	Pre-op disability	<0.001	Disability absent
	Pre-op general health	<0.001	Higher pre-operative general health
	Depression	<0.001	Depression absent
	BMI	<0.001	Lower BMI
	Circulatory problems	0.004	Circulatory problems absent
	ASA grade	0.008	Lower ASA
Surgical	Approach	<0.001	Posterior approach

Multivariable linear regression model (n=4507, R squared=0.41)
OHS – Oxford Hip Score, NJR – National Joint Registry, PROMs – patient reported outcome measures, BMI – body mass index

Table 3.2.3. Significant influences on EQ5D index change at 6 months in females (England and Wales, NJR/PROMs linked data 2008-2010)

Covariate			Associated with greater improvement in EQ5D index
Patient	Pre-op EQ5D index	<0.001	Lower pre-operative EQ5D index
	Pre-op general health	<0.001	Higher pre-operative general health
	Depression	<0.001	Depression absent
	Pre-op disability	<0.001	Disability absent
	BMI	0.001	Lower BMI
	Circulatory problems	0.004	Circulatory problems absent
	Pre-op OHS	0.010	Lower pre-operative OHS
Surgical	Approach	<0.001	Posterior approach
	Anaesthesia type	0.025	Regional

Multivariable linear regression model (n=6196, R squared=0.62)
OHS – Oxford Hip Score, NJR – National Joint Registry, PROMs – patient reported outcome measures, BMI – body mass index

Table 3.2.4. Significant influences on EQ5D index change at 6 months in males (England and Wales, NJR/PROMs linked data 2008-2010)

Covariate			Associated with greater improvement in EQ5D index
Patient	Pre-op EQ5D index	<0.001	Lower pre-operative EQ5D index
	Pre-op general health	<0.001	Higher pre-operative general health
	Circulatory problems	<0.001	Circulatory problems absent
	Pre-op disability	<0.001	Disability absent
	Depression	<0.001	Depression absent
	Pre-op OHS	<0.001	Lower pre-operative OHS
	Stroke	0.006	No previous stroke
	ASA	0.008	Lower ASA grade
	BMI	0.017	Lower BMI
Surgical	Approach	<0.001	Posterior approach

Multivariable linear regression model (n=4507, R squared=0.52)
OHS – Oxford Hip Score, NJR – National Joint Registry, PROMs – patient reported outcome measures, BMI – body mass index

Tests of goodness of fit of the statistical models showed that significant influences in the EQ5D index model explained between 52 to 62% of the variation, leaving around 40% of unexplained variation. For the OHS change models, only 41 to 44% of variation could be explained by the known variables. This suggests that other unmeasured variables contribute to changes in OHS/EQ5D index following hip replacement.

Summary

Some of the variation within models for change in OHS and EQ-5D index can be explained by the variables available for analysis. The most important predictors were the pre-operative OHS and EQ-5D scores. Patients with the poorest pre-operative scores generally had the greatest improvement, consistent with a greater capacity to benefit. Patient factors associated with higher change scores were: better pre-operative general health, lower BMI, absence of a self-perceived disability, and no history of depression, circulatory problems or stroke. In terms of surgical factors, only the type of surgical approach influenced change score in all models, favouring the posterior approach. Interestingly, use of regional anaesthesia improved both OHS and EQ-5D change scores in females, but not males; the underlying reason may relate to adequacy of pain control, although the gender split cannot be easily explained. Implant type appeared to have a limited role in improvements following surgery.

Several of the variables identified as significant in these preliminary analyses are explored in the subsequent sections of this chapter to help inform surgical practice.

Influence of BMI on PROMs

BMI can increase the risk of complications and revision following hip replacement. In some areas of the UK a rationing structure has been proposed whereby patients over a threshold BMI may be denied referral for arthroplasty. The effect of BMI on functional outcome is previously unreported. This analysis explores the impact of BMI on PROMs and complications following primary THR with the commonest cemented and cementless brands.

There were 8547 NJR-PROMs linked primary procedures using either the Exeter / Contemporary cemented hip system or the Corail / Pinnacle cementless system, of which 5535 (65%) had BMI data (2656 cemented and 2879 cementless replacements).

Cemented hip replacement baseline characteristics

There were 1640 patients (61.7%) with a BMI of 19 to 29.9kg/m^2, 695 (26.2%) 30 to 34.9kg/m^2 and 321 (12.1%) 35kg/m^2 and over (**Table 3.2.5**). Obese patients were more likely to be younger ($p<0.001$), female ($p=0.002$) and have a higher ASA grade ($p<0.001$). Similarly, diabetes ($p<0.001$) and hypertension ($p<0.001$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health ($p<0.001$) was poorer and self-reported disability ($p<0.001$) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: $p<0.001$, EuroQol VAS: $p<0.001$, EQ5D index: $p<0.001$); time from operation to post-operative questionnaire completion was similar across groups (209.0 to 209.6 days, $p=0.636$) (**Table 3.2.5**).

Cementless hip replacement baseline characteristics

There were 1738 patients (60.4%) with a BMI of 19 to 29.9kg/m^2, 713 (24.8%) 30 to 34.9kg/m^2 and 428 (14.9%) 35kg/m^2 and over (**Table 3.2.6**). Similarly to the cemented group, obese patients were more likely to be younger ($p<0.001$) and have a higher ASA grade ($p<0.001$), but did not vary in gender composition. Diabetes ($p<0.001$), hypertension ($p<0.001$) and depression ($p=0.006$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health ($p<0.001$) was poorer and self-reported disability ($p<0.001$) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: $p<0.001$, EuroQol VAS: $p<0.001$, EQ5D index: $p<0.001$); time from operation to post-operative questionnaire completion was similar across groups (207.6 to 210.0 days, $p=0.985$) (**Table 3.2.6**).

Table 3.2.5. Patient demographics and PROMs data for cemented Stryker Exeter V40 Contemporary hip replacement, by body mass index

	All patients	Body mass index			Differences between BMI groups*
		19 to 29.9kg/m^2 (Reference group)	30 to 34.9kg/m^2 (Obese class I)	35kg/m^2 + (Obese class II/III)	
Number (%)	2656	1640 (61.7)	695 (26.2)	321 (12.1)	
Patient factors					
Age, mean years (standard deviation [sd], range)	73.3 (7.7, 36.7 to 93.7)	74.3 (7.6, 36.7 to 93.7)	72.3 (7.4, 45.1 to 92.9)	70.7 (7.4, 46.4 to 92.1)	p<0.001
Females	1687 (63.5)	1025 (62.5)	430 (61.9)	232 (72.3)	p=0.002
ASA					
1	274 (10.3)	195 (11.9)	67 (9.6)	12 (3.7)	p=0.000
2	1912 (72.0)	1186 (72.3)	500 (71.9)	226 (70.4)	
3+	470 (17.7)	259 (15.8)	128 (18.4)	83 (25.9)	
Co-morbidities					
Heart disease	268 (10.1)	149 (9.1)	83 (11.9)	36 (11.2)	p=0.086
Stroke	32 (1.2)	16 (1.0)	12 (1.7)	4 (1.3)	p=0.314
Diabetes	270 (10.2)	120 (7.3)	102 (14.7)	48 (15.0)	p<0.001
Hypertension	1219 (45.9)	682 (41.6)	360 (51.8)	177 (55.1)	p<0.001
Circulation	220 (8.3)	117 (7.1)	68 (9.8)	35 (10.9)	p=0.020
Lung	187 (7.0)	119 (7.3)	40 (5.8)	28 (8.7)	p=0.196
Depression	132 (5.0)	71 (4.3)	41 (5.9)	20 (6.2)	p=0.151
Preoperative general health					
Excellent	94 (3.6)	65 (4.0)	23 (3.4)	6 (1.9)	p<0.001
Very good	767 (29.4)	517 (32.1)	184 (26.9)	66 (20.9)	
Good	1207 (46.3)	727 (45.2)	328 (47.9)	152 (48.1)	
Fair	470 (18.0)	259 (16.1)	126 (18.4)	85 (26.9)	
Poor	72 (2.8)	41 (2.6)	24 (3.5)	7 (2.2)	
Preoperative disability	1548 (58.3)	901 (58.9)	425 (66.4)	222 (75.3)	p<0.001
PROMs					
Oxford Hip scores					
Pre-operative, mean (sd, range)	18.2 (8.1, 0 to 48)	19.2 (8.1, 0 to 44)	17.4 (7.9, 0 to 48)	15.3 (7.4, 1 to 40)	p<0.001
Post-operative, mean (sd, range)	38.3 (8.9, 2 to 48)	39.4 (8.3, 6 to 48)	36.8 (9.4, 2 to 48)	35.7 (9.6, 4 to 48)	p<0.001
EQ5D visual analogue score					
Pre-operative, mean (sd, range)	67.1 (19.8, 0 to 100)	68.3 (19.2, 0 to 100)	67.2 (20.4, 0 to 100)	60.8 (20.7, 4 to 100)	p<0.001
Post-operative, mean (sd, range)	75.2 (17.8, 0 to 100)	76.6 (17.4, 0 to 100)	74.0 (18.1, 0 to 100)	70.7 (18.6, 0 to 100)	p<0.001
EQ5D index					
Pre-operative, mean (sd, range)	0.368 (0.313, -0.484 to 1)	0.392 (0.307, -0.429 to 1)	0.345 (0.322, -0.484 to 1)	0.305 (0.315, -0.349 to 0.796)	p<0.001
Post-operative, mean (sd, range)	0.779 (0.225, -0.239 to 1)	0.799 (0.217, -0.239 to 1)	0.756 (0.232, -0.239 to 1)	0.728 (0.235, -0.074 to 1)	p<0.001
Time from operation to PROMs completion, mean days (sd, range)	209.2 (29.1, 183 to 358)	209.1 (29.0, 183 to 358)	209.6 (29.4, 183 to 358)	209.0 (29.3, 184 to 337)	p=0.636

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures
* - analysis of variance test (continuous data variables) or Chi squared (categorical data variables)

Table 3.2.6. Patient demographics and PROMs data for cementless Corail Pinnacle hip replacement, by body mass index

	All patients	Body mass index			Differences between BMI groups*
		19 to 29.9kg/m^2 (Reference group)	30 to 34.9kg/m^2 (Obese class I)	35kg/m^2 + (Obese class II/III)	
Number (%)	2879	1738 (60.4)	713 (24.8)	428 (14.9)	
Patient factors					
Age, mean years (standard deviation [sd], range)	65.8 (9.5, 25.2 to 94.0)	66.7 (9.6, 26.2 to 94.0)	65.3 (9.2, 25.2 to 90.2)	62.9 (9.1, 28.7 to 88.2)	p<0.001
Females	1602 (55.6)	979 (56.3)	374 (52.5)	249 (58.2)	p=0.112
ASA					
1	554 (19.2)	417 (24.0)	106 (14.9)	31 (7.2)	p<0.001
2	2057 (71.5)	1202 (69.2)	541 (75.9)	226 (73.4)	
3+	268 (9.3)	119 (6.9)	66 (9.3)	83 (19.4)	
Co-morbidities					
Heart disease	226 (7.8)	130 (7.5)	51 (7.2)	45 (10.5)	p=0.082
Stroke	35 (1.2)	22 (1.3)	8 (1.1)	5 (1.2)	p=0.953
Diabetes	219 (7.6)	81 (4.7)	76 (10.7)	62 (14.5)	p<0.001
Hypertension	1123 (39.0)	582 (33.5)	300 (42.1)	241 (56.3)	p<0.001
Circulation	136 (4.7)	74 (4.3)	34 (4.8)	28 (6.5)	p=0.136
Lung	158 (5.5)	88 (5.1)	36 (5.0)	34 (7.4)	p=0.054
Depression	172 (6.0)	96 (5.5)	36 (5.0)	40 (9.3)	p=0.006
Preoperative general health					
Excellent	150 (5.4)	110 (6.6)	26 (3.8)	14 (3.4)	p<0.001
Very good	870 (31.5)	582 (35.0)	206 (30.0)	82 (19.8)	
Good	1210 (43.8)	698 (42.0)	321 (46.7)	191 (46.1)	
Fair	473 (17.1)	241 (14.5)	121 (17.6)	111 (26.8)	
Poor	61 (2.2)	31 (1.9)	14 (2.0)	16 (3.7)	
Preoperative disability	1405 (53.9)	783 (50.1)	350 (53.9)	272 (68.9)	p<0.001
PROMs					
Oxford Hip scores					
Pre-operative, mean (sd, range)	18.8 (8.1, 1 to 43)	19.9 (8.1, 2 to 43)	18.5 (7.8, 2 to 43)	15.1 (7.3, 1 to 39)	p<0.001
Post-operative, mean (sd, range)	40.1 (8.6, 0 to 48)	40.8 (8.1, 6 to 48)	40.0 (8.3, 8 to 48)	37.0 (10.1, 1 to 48)	p<0.001
EQ5D visual analogue score					
Pre-operative, mean (sd, range)	66.7 (20.9, 0 to 100)	68.5 (20.1, 0 to 100)	66.5 (21.0, 0 to 100)	60.1 (22.7, 4 to 100)	p<0.001
Post-operative, mean (sd, range)	77.1 (18.4, 0 to 100)	78.6 (17.3, 0 to 100)	77.3 (17.3, 0 to 100)	70.9 (20.6, 0 to 100)	p<0.001
EQ5D index					
Pre-operative, mean (sd, range)	0.381 (0.313, -0.349 to 1)	0.414 (0.306, -0.349 to 1)	0.379 (0.310, -0.239 to 1)	0.253 (0.316, -0.349 to 0.796)	p<0.001
Post-operative, mean (sd, range)	0.799 (0.246, -0.594 to 1)	0.823 (0.228, -0.594 to 1)	0.800 (0.231, -0.074 to 1)	0.705 (0.306, -0.319 to 1)	p<0.001
Time from operation to PROMs completion, mean days (sd, range)	208.5 (27.8, 183 to 363)	208.5 (27.8, 183 to 363)	207.6 (27.1, 183 to 363)	2010.0 (28.6, 183 to 362)	p=0.985

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures
* - analysis of variance test (continuous data variables) or Chi squared (categorical data variables)

Surgical factors

The majority of operations were performed through the posterior approach (cemented: 55.4%; cementless: 63.6%), with the patient in a lateral position (79.1%; 78.4%), by a consultant (64.0%; 77.0%), and using regional anaesthesia (78.8%; 80.4%). Low molecular weight Heparin (53.6%; 66.2%) and mechanical methods (80.3%; 89.9%) were used as venous thromboembolic prophylaxis in the majority of cases (**Table 3.2.7**).

Table 3.2.7. Surgical factors for populations studied

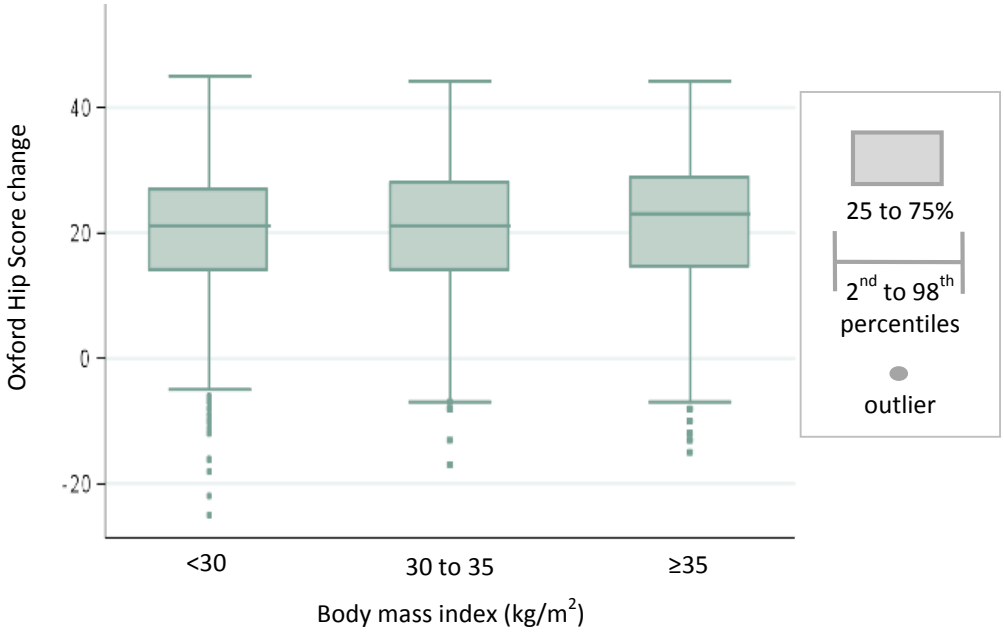
	Cemented (Exeter Contemporary)	**Cementless** (Corail Pinnacle)
Number	2656	2879
Approach		
Posterior	1471 (55.4)	1830 (63.6)
Direct lateral	1117 (42.1)	888 (30.8)
Other	68 (2.6)	161 (5.6)
Chemical VTE prophylaxis		
LMWH only	1218 (53.6)	1593 (66.2)
Aspirin only	233 (10.2)	208 (8.7)
Other	701 (30.8)	379 (15.8)
None	122 (5.4)	225 (9.4)
Mechanical VTE prophylaxis		
GCS	747 (28.1)	912 (37.9)
GCS/mechanical pump combination	663 (25.0)	662 (27.5)
Foot pump only	413 (15.6)	221 (9.2)
Mechanical calf pump only	280 (10.5)	350 (14.6)
Other	30 (1.1)	17 (0.7)
None	523 (19.7)	243 (10.1)
Anaesthesia		
Regional	1085 (47.7)	1369 (57.2)
General	481 (21.2)	470 (19.6)
Regional and general	708 (31.1)	554 (23.2)
Grade		
Consultant	1700 (64.0)	2216 (77.0)
Other	956 (36.0)	663 (23.0)
Position		
Lateral	2102 (79.1)	2256 (78.4)
Supine	172 (6.5)	149 (5.2)
Unknown	382 (14.4)	474 (16.5)

VTE – Venous thromboemolism, LMWH – Low molecular weight Heparin, GCS – Graduated compression stockings

Oxford Hip Score improvement

The unadjusted change in OHS for the entire group was similar across the BMI groups (**Figure 3.2.4**).

Figure 3.2.4. Box plot showing Oxford hip score change at 6 months following hip replacement in patients with different body mass indices (unadjusted data, England and Wales, 2008-2010)



For the cemented procedure, univariable analysis showed no differences in OHS improvement across the BMI groups. However, after adjusting for other influential variables, when compared with the reference BMI group (20.5), both obese class I (18.9, p<0.001) and class II/III patients (18.7, p<0.001) had a statistically significantly lower improvement in OHS (**Table 3.2.8**). However, these differences may not be considered clinically important.

Table 3.2.8. Patient reported outcome scores following primary cemented Stryker Exeter V40 Contemporary hip replacement, by BMI (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS						
19 to 29.9kg/m^2 (n=1640)	20.2	19.5 to 20.8	Reference	20.5	20.0 to 21.1	Reference
30 to 34.9kg/m^2 (n=695)	19.5	18.5 to 20.4	0.116	18.9	18.1 to 19.8	<0.001
35kg/m^2 + (n=321)	20.4	19.0 to 21.8	0.708	18.7	17.5 to 19.9	<0.001
Change EQ5D index						
19 to 29.9kg/m^2 (n=1640)	0.408	0.386 to 0.431	Reference	0.416	0.401 to 0.431	Reference
30 to 34.9kg/m^2 (n=695)	0.410	0.376 to 0.444	0.928	0.394	0.372 to 0.416	0.036
35kg/m^2 + (n=321)	0.418	0.367 to 0.468	0.669	0.387	0.353 to 0.420	0.043

OHS – Oxford Hip Score, BMI – Body mass index

For cementless procedure, there was no difference in OHS improvement between BMI groups in univariable analysis. After risk adjusting, when compared with the reference BMI group (21.5), obese class II/III patients (20.0, p<0.001) had a significantly lower improvement in OHS (**Table 3.2.9**). Again these differences may not be considered clinically important.

Table 3.2.9. Patient reported outcome scores following primary cementless DePuy Corail Pinnacle hip replacement, by BMI (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS						
19 to 29.9kg/m^2 (n=1738)	20.9	20.3 to 21.5	Reference	21.5	21.1 to 22.1	Reference
30 to 34.9kg/m^2 (n=713)	21.5	20.5 to 22.4	0.188	21.3	20.5 to 22.1	0.532
35kg/m^2 + (n=428)	21.9	20.7 to 23.1	0.065	20.0	18.9 to 21.0	<0.001
Change EQ5D index						
19 to 29.9kg/m^2 (n=1738)	0.408	0.386 to 0.429	Reference	0.425	0.410 to 0.441	Reference
30 to 34.9kg/m^2 (n=713)	0.420	0.386 to 0.454	0.422	0.419	0.395 to 0.442	0.527
35kg/m^2 + (n=428)	0.453	0.410 to 0.497	0.016	0.371	0.341 to 0.401	<0.001

OHS – Oxford Hip Score, BMI – Body mass index

'Real-world' scenarios may help to illustrate the range of variation in OHS improvement that can be expected, part of which is attributable to BMI. For example, when a male patient with a BMI between 19 and 29.9kg/m^2 reporting a pre-operative OHS of 10, no disability, very good preoperative health and minimal comorbidities undergoes a cemented THR, an improvement in OHS of 32 could be expected. However, a female patient with a BMI of 35kg/m^2+, self-reported fair health, presence of disability and co-morbidities and a pre-operative OHS of 25, is predicted to have an OHS improvement of only 9. Self-reported disability, pre-operative function and health scores, and comorbidities were greater influences on OHS change than BMI. A lower pre-operative OHS predicts a greater improvement, whilst presence of a disability and comorbidities, poorer health and higher BMI each in turn predict modestly reduced improvements in OHS (**Table 3.2.10**).

EQ5D improvement

For the cemented procedure, there were no differences in improvement of EQ5D score comparing BMI groups in univariable analysis. After risk adjusting, both obese class I (0.394, 99% CI 0.372 to 0.416, p=0.036) and class II/III patients (0.387, 99% CI 0.353 to 0.420, p=0.043) had lower improvement in EQ5D index when compared with the reference BMI group (0.416, 99% CI 0.401 to 0.431), but neither was significant at the threshold value (**Table 3.2.8**).

For the cementless procedure and univariable analysis, the EQ5D score improvement was actually numerically higher in obese class II/III patients (0.453, 99% CI 0.410 to 0.497, p=0.016) when compared with the reference group (0.408, 99% CI 0.386 to 0.429), but this failed to reach the significance threshold specified. However, after risk adjustment obese class II/III patients (0.371, 99% CI

0.341 to 0.401, p<0.001) had a significantly lower improvement in EQ5D index compared with the reference BMI group (0.425, 99% CI 0.410 to 0.441), although this difference may not be clinically important (**Table 3.2.9**).

Table 3.2.10. Predicted OHS improvement for specific self-reported patient factors, based on cemented hip replacement model

	Preoperative very good health				Preoperative fair health			
	No disability		Disability		No disability		Disability	
	Minimal* co-morbidity	Co-morbidity present ϕ	Minimal co-morbidity	Co-morbidity present	Minimal co-morbidity	Co-morbidity present	Minimal co-morbidity	Co-morbidity present
Females								
BMI 19 to 29.9kg/m^2								
Pre-op OHS 10	30.4	26.0	28.4	23.9	29.6	25.1	26.2	23.1
Pre-op OHS 15	26.4	21.9	24.3	19.9	25.5	21.1	22.1	19.1
Pre-op OHS 20	22.4	17.9	20.3	15.9	21.5	17.1	18.1	15.0
Pre-op OHS 25	18.3	13.9	16.3	11.9	17.5	13.1	14.1	11.0
BMI 30 to 34.9kg/m^2								
Pre-op OHS 10	28.9	24.5	26.9	22.4	28.1	23.6	24.7	21.6
Pre-op OHS 15	24.9	20.4	22.8	18.4	24.1	19.6	20.6	17.6
Pre-op OHS 20	20.9	16.4	18.8	14.4	20.0	15.6	16.6	13.5
Pre-op OHS 25	16.9	12.4	14.8	10.4	16.0	11.6	12.6	9.5
BMI 35kg/m^2 +								
Pre-op OHS 10	28.8	24.4	26.8	22.3	28.0	23.5	24.6	21.5
Pre-op OHS 15	24.8	20.4	22.8	18.3	24.0	19.5	20.6	17.5
Pre-op OHS 20	20.8	16.3	18.7	14.3	19.9	15.5	16.5	13.5
Pre-op OHS 25	16.8	12.3	14.7	10.3	15.9	11.5	12.5	9.4
Males								
BMI 19 to 29.9kg/m^2								
Pre-op OHS 10	32.2	27.8	30.2	25.7	31.4	26.9	28.0	24.9
Pre-op OHS 15	28.2	23.8	26.2	21.7	27.4	22.9	24.0	20.9
Pre-op OHS 20	24.2	19.8	22.1	17.7	23.4	18.9	19.9	16.9
Pre-op OHS 25	20.2	15.7	18.1	13.7	19.3	14.9	15.9	12.8
BMI 30 to 34.9kg/m^2								
Pre-op OHS 10	30.7	26.3	28.7	24.2	29.9	25.5	26.5	23.4
Pre-op OHS 15	26.7	22.3	24.7	20.2	25.9	21.4	22.5	19.4
Pre-op OHS 20	22.7	18.3	20.7	16.2	21.9	17.4	18.5	15.4
Pre-op OHS 25	18.7	14.2	16.6	12.2	17.8	13.4	14.4	11.4
BMI 35kg/m^2 +								
Pre-op OHS 10	30.7	26.2	28.6	24.2	29.8	25.4	26.4	23.3
Pre-op OHS 15	26.6	22.2	24.6	20.1	25.8	21.4	22.4	19.3
Pre-op OHS 20	22.6	18.2	20.6	16.1	21.8	17.3	18.4	15.3
Pre-op OHS 25	18.6	14.2	16.6	12.1	17.8	13.3	14.4	11.3

* Minimal co-morbidity – ASA 2, no depression, no circulatory problems
ϕ Co-morbidity present – ASA 3, depression, circulatory problems
BMI – Body mass index, ASA – American Society of Anaesthesiologists, Regional anaesthesia and posterior approach used in model

Risk of complications

In the cemented group there was a significantly increased risk of complications in obese class II/III patients compared to the reference group, adjusted for other variables: wound complications, OR=2.06, p<0.001; readmission, OR=1.99, p=0.001; and, reoperation, OR=2.73, p=0.003. Complications were less pronounced in obese class I patients with only wound complication rates being significant (OR=1.57, p=0.006). Bleeding risk was similar across all groups (**Table 3.2.11**).

Table 3.2.11. Patient reported complications following primary cemented Stryker Exeter V40 Contemporary hip replacement, by BMI (simple and multivariable analyses)

	%	n	Simple			Multivariable		
			OR	99% CI	P value	OR	99% CI	P value
Bleeding complications								
BMI 19 to 29.9kg/m^2 (n=1640)	3.7	(61)	1			1		
BMI 30 to 34.9kg/m^2 (n=695)	5.3	(37)	1.46	0.84 to 2.52	0.079	1.47	0.83 to 2.60	0.083
BMI 35kg/m^2 + (n=321)	4.4	(14)	1.18	0.54 to 2.58	0.584	1.16	0.52 to 2.57	0.633
Wound complications								
BMI 19 to 29.9kg/m^2 (n=1640)	7.2	(118)	1			1		
BMI 30 to 34.9kg/m^2 (n=695)	10.8	(75)	1.56	1.04 to 2.33	0.004	1.57	1.03 to 2.38	0.006
BMI 35kg/m^2 + (n=321)	15.0	(48)	2.27	1.41 to 3.64	<0.001	2.06	1.25 to 3.40	<0.001
Readmission								
BMI 19 to 29.9kg/m^2 (n=1640)	6.2	(102)	1			1		
BMI 30 to 34.9kg/m^2 (n=695)	8.8	(61)	1.45	0.94 to 2.24	0.027	1.45	0.94 to 2.24	0.028
BMI 35kg/m^2 + (n=321)	11.2	(36)	1.90	1.13 to 3.22	0.002	1.99	1.17 to 3.39	0.001
Reoperation								
BMI 19 to 29.9kg/m^2 (n=1640)	1.6	(26)	1			1		
BMI 30 to 34.9kg/m^2 (n=695)	2.7	(19)	1.74	0.79 to 3.83	0.068	1.67	0.76 to 3.68	0.095
BMI 35kg/m^2 + (n=321)	4.4	(14)	2.83	1.19 to 6.75	0.002	2.73	1.14 to 6.53	0.003

OR – Odds ratio, BMI – Body mass index, CI – confidence intervals

For the cementless group, wound complications were significantly higher in obese class II/III patients (OR=2.39, p<0.001) when compared to the reference group, after risk adjusting. Complication risk between the reference and other BMI groups for bleeding, readmission and reoperation were similar (**Table 3.2.12**).

Table 3.2.12. Patient reported complications following primary cementless DePuy Corail Pinnacle hip replacement, by body mass index (simple and multivariable analyses)

	%	n	Simple			Multivariable		
			OR	99% CI	P value	OR	99% CI	P value
Bleeding complications								
BMI 19 to 29.9kg/m^2 (n=1738)	5.1	(89)	1			1		
BMI 30 to 34.9kg/m^2 (n=713)	6.3	(45)	1.25	0.77 to 2.03	0.240	1.10	0.64 to 1.90	0.647
BMI 35kg/m^2 + (n=428)	5.8	(25)	1.15	0.63 to 2.10	0.550	1.15	0.59 to 2.25	0.595
Wound complications								
BMI 19 to 29.9kg/m^2 (n=1738)	6.6	(115)	1			1		
BMI 30 to 34.9kg/m^2 (n=713)	9.5	(68)	1.49	0.99 to 2.25	0.013	1.43	0.93 to 2.21	0.032
BMI 35kg/m^2 + (n=428)	14.5	(62)	2.39	1.55 to 3.68	<0.001	2.39	1.52 to 3.75	<0.001
Readmission								
BMI 19 to 29.9kg/m^2 (n=1738)	6.3	(110)	1			1		
BMI 30 to 34.9kg/m^2 (n=713)	5.5	(39)	0.86	0.52 to 1.40	0.419	0.87	0.50 to 1.50	0.503
BMI 35kg/m^2 + (n=428)	7.0	(30)	1.12	0.64 to 1.93	0.608	1.32	0.72 to 2.41	0.233
Reoperation								
BMI 19 to 29.9kg/m^2 (n=1738)	2.0	(35)	1			1		
BMI 30 to 34.9kg/m^2 (n=713)	1.4	(10)	0.69	0.27 to 1.76	0.309	0.69	0.27 to 1.76	0.309
BMI 35kg/m^2 + (n=428)	2.3	(10)	1.16	0.46 to 2.96	0.675	1.16	0.46 to 2.96	0.675

OR – Odds ratio, BMI – Body mass index, CI – confidence intervals

Statistical considerations

Tests for interaction (multiplicative) between covariates were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. Sensitivity analysis of the commonest component sets within cemented and cementless groups showed similar results for OHS and EQ5D index change, indicating that the findings of the entire cohort are applicable to a range of component choices within brands (**Tables 3.2.13**, **3.2.14**). Demographics and surgical data for these patients can be found in **Table 3.2.15**. Treating BMI as a continuous or categorical variable did not qualitatively affect the model.

Table 3.2.13. Patient reported outcome scores following primary cemented Stryker Exeter V40 Contemporary hip replacement, by BMI (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS (*)						
BMI 19 to 29.9kg/m^2 (n=924)	20.4	19.5 to 21.2	Reference	20.7	19.9 to 21.4	Reference
BMI 30 to 34.9kg/m^2 (n=417)	19.8	18.5 to 21.1	0.331	19.2	18.2 to 20.3	0.005
BMI 35kg/m^2 + (n=191)	20.0	18.1 to 21.9	0.643	18.6	17.0 to 20.1	0.002
Change EQ5D index (*)						
BMI 19 to 29.9kg/m^2 (n=924)	0.406	0.376 to 0.436	Reference	0.410	0.390 to 0.431	Reference
BMI 30 to 34.9kg/m^2 (n=417)	0.414	0.370 to 0.457	0.722	0.392	0.363 to 0.422	0.190
BMI 35kg/m^2 + (n=191)	0.408	0.343 to 0.474	0.945	0.377	0.334 to 0.421	0.082

*Commonest implant specification: Exeter V40 Contemporary flanged polyethylene cup (internal diameter 28mm). OHS – Oxford Hip Score, BMI – Body mass index

Table 3.2.14. Patient reported outcome scores following primary cementless DePuy Corail Pinnacle hip replacement, by body mass index (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS (*)						
BMI 19 to 29.9kg/m^2 (n=712)	21.2	20.3 to 22.2	Reference	21.7	20.9 to 22.6	Reference
BMI 30 to 34.9kg/m^2 (n=285)	20.7	19.2 to 22.3	0.481	21.0	19.7 to 22.3	0.218
BMI 35kg/m^2 + (n=194)	22.0	20.1 to 23.8	0.369	19.9	18.3 to 21.5	0.009
Change EQ5D index (*)						
BMI 19 to 29.9kg/m^2 (n=712)	0.413	0.379 to 0.448	Reference	0.440	0.416 to 0.465	Reference
BMI 30 to 34.9kg/m^2 (n=285)	0.404	0.350 to 0.459	0.722	0.406	0.367 to 0.445	0.059
BMI 35kg/m^2 + (n=194)	0.449	0.383 to 0.515	0.217	0.358	0.312 to 0.405	<0.001

*Commonest implant specification: Corail Pinnacle ceramic-on-ceramic or metal-on-metal with 36mm head
OHS – Oxford Hip Score, BMI – Body mass index

Summary

Patients experience a good improvement in outcome following THR irrespective of BMI. However, improvements were slightly smaller and complication rates higher in obese patients, after adjusting for other influences. A number of other patient variables also influence outcome scores in addition to BMI. In terms of improvement in health and function, it is apparent that a high BMI in isolation should not justify denying surgery within a public funded health service. However, hip replacement in obese patients is technically demanding. Obese patients should be counselled that improvement following hip replacement is likely to be less than that for an equivalent normal weight individual and risk of complications is greater.

Table 3.2.15. Demographics and surgical data for sensitivity analyses

	Cemented (Exeter Contemporary 28mm flanged polyethylene)		**Cementless** (Corail Pinnacle 36mm hard bearing)	
Number	1532		1191	
Patient factors				
Age, mean years (standard deviation [sd], range)	72.8 (7.7, 36.7 to 92.9)		63.0 (9.7, 25.2 to 89.0)	
Females	1036	(67.6)	540	(45.3)
ASA				
1	165	(10.8)	282	(23.7)
2	1106	(72.2)	814	(68.4)
3	252	(16.5)	94	(7.9)
4/5	9	(0.6)	1	(0.1)
Body mass index (kg/m^2)				
19 to 29.9	924	(60.3)	712	(59.8)
30 to 34.9	417	(27.2)	285	(23.9)
35+	191	(12.5)	194	(16.3)
Co-morbidities				
Heart disease	137	(8.9)	95	(8.0)
Stroke	19	(1.2)	12	(1.0)
Diabetes	164	(10.7)	78	(6.6)
Hypertension	706	(46.1)	438	(36.8)
Circulation	122	(8.0)	37	(4.0)
Lung	112	(7.3)	69	(5.8)
Liver	6	(0.4)	5	(0.4)
Kidney	21	(1.4)	13	(1.1)
Nervous	13	(0.9)	7	(0.6)
Cancer	88	(5.7)	39	(3.3)
Depression	76	(5.0)	82	(6.9)
Preoperative general health				
Excellent	57	(3.8)	62	(5.3)
Very good	467	(31.0)	375	(32.3)
Good	686	(45.5)	477	(41.1)
Fair	265	(17.6)	220	(19.0)
Poor	34	(2.3)	27	(2.3)
Preoperative disability	868	(56.7)	553	(46.4)
Preoperative OHS, mean score (sd, range)	18.4 (8.1, 0 to 44)		19.2 (8.1, 2 to 42)	
Pre-opEQ5D VAS, mean score (sd, range)	67.6 (19.7, 0 to 100)		66.2 (20.6, 0 to 100)	
Pre-op EQ5D index, mean (sd, range)	0.374 (0.311, -0.429 to 1)		0.387 (0.317, -0.349 to 1)	
Time from operation to PROMs completion, mean days (sd, range)	208.9 (29.1, 183 to 358)		209.6 (29.0, 183 to 362)	
Surgical factors				
Provider				
NHS	1313	(85.7)	1029	(86.4)
Other	3	(0.2)	4	(0.3)
Unknown	216	(14.1)	162	(13.6)
Approach				
Posterior	866	(56.5)	765	(64.2)
Direct lateral	628	(40.1)	337	(28.3)
Other	38	(2.5)	89	(7.5)
Chemical VTE prophylaxis				
LMWH only	623	(47.3)	625	(60.5)
Aspirin only	153	(11.6)	126	(12.2)
Other	438	(33.3)	193	(18.7)
None	102	(7.8)	89	(8.6)
Mechanical VTE prophylaxis				
GCS	431	(28.1)	400	(38.7)
GCS/mechanical pump combination	335	(21.9)	342	(33.1)
Foot pump only	253	(16.5)	64	(6.2)
Mechanical calf pump only	204	(12.3)	133	(12.9)
Other	23	(1.5)	12	(1.2)
None	286	(18.7)	82	(7.9)
Anaesthesia				
Regional	708	(53.8)	562	(54.5)
General	238	(18.1)	229	(22.2)
Regional and general	370	(28.1)	241	(23.4)
Grade				
Consultant	943	(61.6)	920	(77.3)
Other	589	(38.5)	271	(22.8)
Position				
Lateral	1211	(79.0)	964	(80.9)
Supine	105	(6.9)	69	(5.8)
Unknown	216	(14.1)	158	(13.3)

OHS – Oxford hip score, VAS – Visual analogue score, NHS – National Health Service, VTE – Venous thromboemolism, LMWH – Low molecular weight Heparin, GCS – Graduated compression stockings

Influence of surgical approach on PROMs

The best surgical approach to the hip is still unknown, with the majority of surgeons performing either a posterior or lateral procedure. Other approaches are rarely used and not considered in this analysis. Whilst the posterior approach may reduce risk of limp, the direct lateral may reduce risk of early dislocation. This analysis therefore aims to identify a benefit, if any, of either approach in the first 12 months after primary THR using fixed implant characteristics, in terms of PROMs and revision risk.

There were 37 593 primary procedures on the NJR database which met the inclusion criteria. Of these, 3881 could be linked to PROMs data; 1937 were cemented Exeter Contemporary with a flanged cup design and a 28mm head, and 1944 were cementless Corail Pinnacle with a hard bearing (MoM or CoC) with a 36mm head (**Table 3.2.16**). PROMs questionnaires were completed at a mean of 7 months following surgery (**Table 3.2.17**).

Cemented hip replacement baseline characteristics

The majority of procedures were performed through a posterior approach (57.9%, 1121) (**Table 3.2.17**). These patients were more likely to have a lower ASA grade (p=0.003), fewer comorbidities (p=0.002), better pre-operative general health (p=0.001) and less self reported disability (p=0.002).

Pre-operative and post-operative scores were significantly higher in hip replacements performed through a posterior approach (OHS: p<0.001 and <0.001, EuroQol VAS: p=0.003 and <0.001, EQ5D index: p<0.001 and <0.001); time from operation to post-operative questionnaire completion was equivalent to replacements performed through a lateral approach (**Table 3.2.17**). Levels of satisfaction (p<0.001) and perceived success (p<0.001) were higher with the posterior approach.

Cementless hip replacement baseline characteristics

The majority of procedures were performed through a posterior approach (65.1%, 1266) (**Table 3.2.16**). There were no significant differences in patient baseline characteristics across the two approach groups.

Post-operative scores were significantly higher in cementless hip replacements performed through a posterior approach (OHS: p=0.004, EuroQol VAS: p=0.015, EQ5D index: p=0.010); time from operation to post-operative questionnaire completion was equivalent to replacements performed through a lateral approach (**Table 3.2.17**). Levels of satisfaction (p<0.001) were higher with the posterior approach but there was no significant difference in perceived success (p=0.131).

The NJR-PROMs linked data subgroups were representative of the entire unlinked NJR populations (18 553 cemented and 19 040 cementless procedures) (**Table 3.2.18**).

Table 3.2.16. Demographics for NJR-PROMS linked populations, by surgical approach

	Cemented (Exeter V40/Contemporary flanged 28mm)			Cementless (Corail/Pinnacle MoM/CoC 36mm)		
	Posterior	Lateral	p value	Posterior	Lateral	p value
Number (%)	1121 (57.9)	816 (42.1)		1266 (65.1)	678 (34.9)	
Patient factors						
Age, mean years (standard deviation [sd], range)	72.6 (8.1, 36.7 to 93.5)	73.2 (7.2, 47.8 to 92.9)	0.945	63.2 (9.9, 25.2 to 96.2)	64.3 (8.9, 37.2 to 87.9)	0.994
Females, n (%)	765 (68.2)	523 (64.1)	0.056	585 (46.2)	284 (41.9)	0.068
ASA grade						
1	112 (10.1)	90 (11.0)	0.003	273 (21.6)	133 (19.6)	0.583
2	831 (74.8)	551 (67.5)		895 (70.7)	489 (72.1)	
3+	178 (15.1)	175 (21.5)		98 (7.7)	56 (8.3)	
BMI, mean kg/m^2 (sd, range)*	28.6 (4.9, 16 to 52)	28.9 (5.1, 18 to 59)	0.285	29.0 (5.3, 16 to 58)	29.7 (5.9, 18 to 65)	0.058
Co-morbidities						
Heart disease	87 (7.8)	94 (11.5)	0.005	98 (7.7)	62 (9.1)	0.283
Stroke	12 (1.1)	17 (2.1)	0.070	15 (1.2)	9 (1.3)	0.786
Diabetes	109 (9.7)	94 (11.5)	0.203	80 (6.3)	50 (7.4)	0.375
Hypertension	527 (47.0)	368 (45.1)	0.404	478 (37.8)	228 (33.6)	0.071
Circulation	90 (8.0)	67 (8.2)	0.885	45 (3.6)	34 (5.0)	0.120
Lung	63 (5.6)	67 (8.2)	0.024	79 (6.2)	50 (7.4)	0.338
Depression	49 (4.4)	53 (6.5)	0.039	81 (6.4)	62 (9.1)	0.027
Preoperative general health						
Excellent	56 (5.0)	25 (3.1)	0.001	73 (5.8)	38 (5.6)	0.818
Very good	361 (32.2)	211 (25.9)		408 (32.2)	201 (29.6)	
Good	506 (45.1)	393 (48.2)		514 (40.6)	288 (42.5)	
Fair	172 (15.3)	162 (19.9)		235 (18.6)	132 (19.5)	
Poor	26 (2.4)	25 (3.1)		36 (2.8)	19 (2.8)	
Preoperative disability	608 (54.2)	482 (59.1)	0.002	580 (45.8)	322 (47.5)	0.576
Surgical factors						
Chemical VTE prophylaxis						
LMWH only	470 (49.0)	355 (50.8)	<0.001	637 (57.8)	409 (71.3)	<0.001
Aspirin only	115 (12.0)	57 (8.2)		179 (16.2)	24 (4.2)	
Other	355 (37.0)	178 (25.5)		186 (16.9)	104 (18.1)	
None	19 (2.0)	109 (15.6)		101 (9.2)	37 (6.5)	
Mechanical VTE prophylaxis						
Compression stockings (CS)	260 (23.2)	261 (32.0)	<0.001	401 (36.4)	207 (36.1)	0.003
CS/mechanical pump combination	235 (20.1)	210 (25.7)		364 (33.0)	178 (31.0)	
Foot pump only	276 (24.6)	38 (4.7)		107 (9.7)	32 (5.6)	
Mechanical calf pump only	140 (12.5)	128 (15.7)		148 (13.4)	104 (18.1)	
Other	21 (1.9)	1 (0.1)		14 (1.3)	4 (0.7)	
None	189 (16.9)	178 (21.8)		69 (6.3)	49 (8.5)	
Anaesthesia						
Regional	502 (44.8)	379 (46.4)	0.607	625 (49.4)	341 (50.3)	0.433
General	195 (17.4)	129 (15.8)		246 (19.4)	119 (17.6)	
Regional and general	262 (23.4)	191 (19.0)		230 (18.2)	108 (15.9)	
Not recorded	162 (14.5)	117 (11.6)		165 (13.0)	110 (16.2)	
Lead surgeon grade						
Consultant	731 (65.2)	515 (63.1)	0.341	977 (77.2)	494 (72.7)	0.035
Other	390 (34.8)	301 (36.9)		289 (22.8)	184 (27.1)	
Position						
Lateral	933 (83.2)	600 (73.5)	<0.001	1096 (86.6)	500 (73.7)	<0.001
Supine	26 (2.3)	99 (12.1)		7 (0.6)	74 (10.9)	
Not recorded	162 (14.5)	117 (14.3)		163 (12.9)	104 (15.3)	

MoM – metal-on-metal, CoC – ceramic-on-ceramic, ASA – American Society of Anaesthesiologists, BMI – body mass index, VTE – venous thromboembolism, LMWH – low molecular weight heparin
* BMI data available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%)
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, Chi squared test for proportions

Table 3.2.17. Patient reported outcomes for populations studied, by surgical approach

	Cemented (Exeter V40/Contemporary flanged 28mm)			Cementless (Corail/Pinnacle MoM/CoC 36mm)		
	Posterior	Lateral	p value	Posterior	Lateral	p value
Number (%)	1121 (57.9)	816 (42.1)		1266 (65.1)	678 (34.9)	
Oxford Hip scores						
Pre-operative, mean (sd, range)	18.9 (8.0, 0 to 44)	17.4 (7.8, 2 to 43)	<0.001	19.3 (8.1, 0 to 46)	18.6 (8.2, 1 to 42)	0.078
Post-operative, median (range)	42 (4 to 48)	39 (0 to 48)	<0.001	44 (2 to 48)	43 (5 to 48)	0.004
EQ5D visual analogue score						
Pre-operative, mean (sd, range)	68.7 (19.3, 4 to 100)	65.9 (20.2, 0 to 100)	0.003	66.8 (20.3, 0 to 100)	66.6 (21.0, 0 to 100)	0.848
Post-operative, mean (sd, range)	77.4 (16.7, 0 to 100)	73.0 (19.3, 0 to 100)	<0.001	78.5 (17.9, 0 to 100)	76.4 (17.6, 15 to 100)	0.015
EQ5D index						
Pre-operative, mean (sd, range)	0.393 (0.307, -0.358 to 1)	0.341 (0.313, -0.429 to 0.883)	<0.001	0.390 (0.316, -0.594 to 1)	0.377 (0.318, -0.239 to 1)	0.401
Post-operative, median (range)	0.815 (-0.003 to 1)	0.760 (-0.016 to 1)	<0.001	0.883 (-0.074 to 1)	0.812 (-0.077 to 1)	0.010
Satisfaction						
Excellent	454 (40.5)	249 (30.5)	<0.001	595 (47.0)	273 (40.3)	<0.001
Very good	395 (35.2)	290 (35.5)		442 (34.9)	228 (29.6)	
Good	212 (18.9)	192 (23.5)		160 (12.6)	121 (17.8)	
Fair	46 (4.1)	65 (8.0)		45 (3.6)	43 (6.3)	
Poor	14 (1.2)	20 (2.5)		25 (2.0)	13 (1.9)	
Success						
Much better	1003 (89.5)	669 (82.0)	<0.001	1136 (89.7)	584 (86.1)	0.131
A little better	86 (7.7)	102 (12.5)		81 (6.4)	60 (8.8)	
About the same	19 (1.7)	20 (2.5)		29 (3.6)	16 (2.4)	
A little worse	10 (0.9)	15 (1.8)		12 (1.5)	12 (1.8)	
Much worse	3 (0.3)	10 (1.2)		8 (1.0)	6 (0.9)	
Time from operation to PROMs completion, mean days (sd, range)	208.5 (28.2, 183 to 358)	209.0 (30.0, 183 to 363)	0.729	209.9 (30.3, 183 to 362)	208.7 (27.7, 183 to 343)	0.410

MoM – metal-on-metal, CoC – ceramic-on-ceramic, PROMs – patient reported outcome measures
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, two sample Wilcoxon rank-sum (Mann-Whitney) test for non parametric data, Chi squared test for proportions

Table 3.2.18. Demographics for NJR populations studied, by surgical approach

	Cemented (Exeter V40/Contemporary flanged 28mm)			Cementless (Corail/Pinnacle MoM/CoC 36mm)		
	Posterior	Lateral	p value	Posterior	Lateral	p value
Number (%)	9345 (50.4)	9208 (49.6)		11995 (63.0)	7033 (37.0)	
Patient factors						
Age, mean years (standard deviation [sd], range)	73.8 (8.1, 26.2 to 99.5)	73.9 (7.8, 26.7 to 97.0)	0.418	64.2 (10.2, 19.4 to 106.2)	65.1 (10.0, 17.9 to 95.5)	<0.001
Females, n (%)	6277 (67.2)	5981 (65.0)	0.001	6033 (50.3)	3230 (45.9)	0.001
ASA grade						
1	1037 (11.1)	1496 (16.3)	<0.001	2615 (21.8)	1326 (18.8)	<0.001
2	6754 (72.3)	6126 (66.5)		8128 (67.7)	4878 (69.3)	
3+	1554 (16.6)	1586 (17.2)		1260 (10.5)	833 (11.8)	
BMI, mean kg/m^2 (sd, range)*	28.2 (5.0, 16 to 63)	28.5 (5.3, 16 to 63)	0.025	28.9 (5.4, 16 to 62)	29.1 (5.3, 15 to 65)	0.116
Surgical factors						
Chemical VTE prophylaxis						
LMWH only	3910 (46.6)	4386 (52.7)	<0.001	5986 (55.7)	3962 (62.6)	<0.001
Aspirin only	1169 (13.9)	970 (11.7)		1960 (18.2)	294 (4.7)	
Other	2900 (34.6)	2230 (26.8)		1284 (12.0)	1171 (18.5)	
None	409 (4.9)	736 (8.8)		1513 (14.1)	899 (14.2)	
Mechanical VTE prophylaxis						
Compression stockings (CS)	1624 (17.4)	3132 (34.0)	<0.001	2650 (24.7)	1765 (27.9)	<0.001
CS/mechanical pump combination	2628 (28.1)	2865 (31.1)		3846 (35.8)	1917 (30.3)	
Foot pump only	1973 (21.1)	383 (4.2)		1152 (10.7)	249 (3.9)	
Mechanical calf pump only	1421 (15.2)	831 (9.0)		1406 (13.1)	1260 (19.9)	
Other	534 (5.7)	762 (8.3)		119 (1.1)	18 (0.3)	
None	1165 (12.5)	1235 (13.4)		1570 (14.6)	1117 (17.7)	
Anaesthesia						
Regional	4261 (45.6)	4031 (43.8)	<0.001	5512 (45.9)	3740 (53.2)	<0.001
General	1283 (13.7)	1275 (13.9)		2461 (20.5)	1098 (15.6)	
Regional and general	2760 (29.5)	2698 (29.3)		2524 (21.0)	1225 (17.4)	
Not recorded	1041 (11.1)	1204 (13.1)		1498 (12.6)	970 (13.4)	
Lead surgeon grade						
Consultant	6972 (74.6)	6650 (72.2)	<0.001	10231 (85.2)	5563 (79.1)	<0.001
Other	2373 (25.4)	2558 (27.8)		1772 (14.8)	1474 (21.0)	
Position						
Lateral	8275 (88.6)	6916 (75.1)	<0.001	10584 (88.2)	5208 (74.0)	<0.001
Supine	119 (1.3)	1409 (15.3)		159 (1.3)	1118 (15.9)	
Not recorded	951 (10.2)	883 (9.6)		1260 (10.5)	711 (10.1)	

MoM – metal-on-metal, CoC – ceramic-on-ceramic, ASA – American Society of Anaesthesiologists, BMI – body mass index, VTE – venous thromboembolism, LMWH – low molecular weight heparin
* BMI data available for 7570 cemented implants (40.8%) and 8609 cementless implants (45.2%)
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, Chi squared test for proportions

Surgical factors

The most commonly used chemical venous thromboembolic (VTE) prophylaxis agent was low molecular weight heparin (LMWH). Patterns of chemical and mechanical venous thromboembolic prophylaxis differed across the approaches for both cemented (both p<0.001) and cementless hip replacements (p<0.001 and p=0.003 respectively). The most common anaesthesia regime was regional (46.4 to 50.3%, depending on study sub-group). Type of anaesthesia and grade of lead surgeon were equivalent. The majority of patients were in the lateral position (73.5 to 86.6%), with procedures performed through a posterior approach more likely to utilise this position (cemented and cementless p<0.001) (**Table 3.2.16**). Other than approach, surgical factors did not influence any of the multivariable models.

Oxford Hip Score improvement

For both cemented and cementless procedures, univariable analysis showed no differences in OHS improvement between the posterior and the lateral approaches. However, after adjusting for influential variables, when compared with the posterior approach (cemented: 20.8, cementless: 21.7), the lateral approach was associated with a significantly lower improvement in OHS (cemented: 18.9, p<0.001, cementless: 20.2, p=0.008) (**Table 3.2.19**).

Table 3.2.19. Change in PROMs at 7 months following hip replacement through either a posterior or a lateral approach (simple and multivariable analyses)

	Simple			Multivariable		
	Posterior	Lateral	p value	Posterior	Lateral	p value
Change in OHS (99% CI)						
Cemented	20.4 (19.6 to 21.2)	19.8 (18.9 to 20.6)	0.156	20.8 (20.0 to 21.5)	18.9 (18.0 to 19.7)	<0.001
Cementless	21.2 (20.5 to 22.0)	20.7 (19.7 to 21.8)	0.336	21.7 (20.9 to 22.4)	20.2 (19.1 to 21.4)	0.008
Change in EQ5D index						
Cemented	0.407 (0.38 to 0.43)	0.405 (0.37 to 0.44)	0.903	0.416 (0.40 to 0.43)	0.383 (0.36 to 0.40)	0.003
Cementless	0.418 (0.39 to 0.45)	0.398 (0.36 to 0.43)	0.231	0.431 (0.41 to 0.45)	0.384 (0.35 to 0.42)	0.003

PROMs – patient-reported outcome measures, OHS – Oxford Hip Score, CI – confidence intervals
Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28mm cup*
Cementless: *DePuy Corail stem with Pinnacle shell and 36mm metal-on-metal or ceramic-on-ceramic bearing*

By fixing the pre-operative OHS to its mean value we have demonstrated the effect other influential variables have on change in OHS (**Table 3.2.20**). Males, those in good health with no disability and no comorbidities, and those who have a hip replacement through a posterior approach have the greatest predicted improvement in OHS, irrespective of implant type.

Table 3.2.20. Predicted change in OHS following hip replacement performed through a posterior or lateral approach for specific patient groups

	OHS change (99% CIs)	
	Posterior approach	Lateral approach
Good health*		
Male		
Cemented	27.3 (24.7 to 29.9)	25.9 (23.2 to 28.5)
Cementless	26.9 (24.6 to 29.3)	26.0 (23.6 to 28.4)
Female		
Cemented	25.6 (23.1 to 28.2)	24.2 (21.6 to 26.8)
Cementless	26.2 (23.9 to 28.5)	25.2 (22.9 to 27.6)
Intermediate health		
Male		
Cemented	23.8 (22.4 to 25.1)	22.3 (21.0 to 23.7)
Cementless	23.7 (22.4 to 24.9)	22.7 (21.4 to 24.1)
Female		
Cemented	22.1 (21.0 to 23.2)	20.7 (19.5 to 21.9)
Cementless	22.9 (21.6 to 24.2)	22.0 (20.6 to 23.4)
Poor health		
Male		
Cemented	11.4 (7.9 to 14.9)	10.0 (6.5 to 13.5)
Cementless	10.2 (6.4 to 14.1)	9.3 (5.5 to 13.1)
Female		
Cemented	9.8 (6.3 to 13.2)	8.3 (4.9 to 11.8)
Cementless	9.5 (5.6 to 13.3)	8.5 (4.6 to 12.4)

OHS – Oxford Hip Score, CI – confidence interval
**Good health*: self-reported excellent health, no disability, no circulatory problems, *Intermediate health*: self-reported good health, no disability, no circulatory problems, *Poor health*: self-reported poor health and disability, circulatory problems. Pre-op Oxford hip score taken as the mean for the cohort.
Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28mm cup*
Cementless: *DePuy Corail stem with Pinnacle shell and 36mm metal-on-metal or ceramic-on-ceramic bearing*

EQ5D index improvement

For both cemented and cementless procedures, univariable analysis showed no differences in EQ5D index improvement between the posterior and the lateral approaches. However, after adjusting for influential variables, when compared with the posterior approach (cemented: 0.416, cementless: 0.431), the lateral approach was associated with a significantly lower improvement in EQ5D index (cemented: 0.383, p=0.003, cementless: 0.384, p=0.003) (**Table 3.2.19**).

Risk of complications

There were no significant differences after multivariable testing between surgical approaches with either a cemented or cementless hip replacement in terms of bleeding, wound complications, readmission, reoperation or one-year revision

risk (**Table 3.2.21**). However, confidence in the assessment of differences in revision rates was low as numbers of revisions were small.

Table 3.2.21. PROMs and revision rates at one-year following hip replacement through a posterior or a lateral approach (simple and multivariable analyses)

	Posterior	Lateral	Simple analysis OR (99% CI, p-value)	Multivariable OR (99% CI, p-value)
Bleeding complications				
Cemented, % (n)	4.2 (47)	5.0 (49)	1.20 (0.67 to 2.14, 0.415)	1.20 (0.67 to 2.17, 0.424)
Cementless	6.4 (81)	6.8 (46)	1.06 (0.64 to 1.76, 0.766)	1.02 (0.60 to 1.75, 0.913)
Wound complications				
Cemented	8.6 (96)	11.5 (94)	1.33 (0.88 to 2.01, 0.074)	1.02 (0.62 to 1.69, 0.916)
Cementless	9.6 (121)	13.6 (92)	1.41 (0.95 to 2.10, 0.026)	1.44 (0.97 to 2.17, 0.017)
Readmission				
Cemented	7.7 (86)	8.8 (72)	1.15 (0.73 to 1.79, 0.434)	1.16 (0.73 to 1.85, 0.405)
Cementless	5.8 (73)	7.3 (49)	1.26 (0.76 to 2.10, 0.236)	1.16 (0.68 to 1.99, 0.463)
Reoperation				
Cemented	2.6 (29)	2.5 (20)	0.98 (0.46 to 2.10, 0.948)	0.94 (0.44 to 2.02, 0.833)
Cementless	1.6 (20)	2.1 (14)	1.31 (0.53 to 3.25, 0.438)	1.26 (0.48 to 3.32, 0.546)
One-year all-cause revision rate*				
Cemented	0.3 (26)	0.2 (21)	0.82 (0.38 to 1.75, 0.497)	0.89 (0.37 to 2.12, 0.726)
Cementless	0.8 (101)	0.9 (61)	1.03 (0.68 to 1.57, 0.854)	0.82 (0.50 to 1.34, 0.295)
One-year revision rate for dislocation*				
Cemented	0.1 (12)	0.1 (6)	0.51 (0.14 to 1.84, 0.176)	0.51 (0.14 to 1.84, 0.176)
Cementless	0.2 (22)	0.2 (15)	1.16 (0.49 to 2.77, 0.644)	0.85 (0.30 to 2.41, 0.695)

OR – odds ratio, CI – confidence interval.
An odds ratio >1 indicates that the risk of a complication is greater in the lateral approach group if the confidence intervals do not cross 1.
* Analyses are based on the NJR-PROMs linked dataset (1937 cemented and 1944 cementless procedures) for the self reported complications and the unlinked NJR database (18553 cemented and 19040 cementless procedures) for one-year revision. Patients revised for other reasons were excluded from the revision for dislocation analysis.
Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28mm cup.*
Cementless: *DePuy Corail stem with Pinnacle shell and 36mm metal-on-metal or ceramic-on-ceramic bearing*.

Tests for interaction (multiplicative) between covariates were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. BMI data was available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%); therefore final OHS and EQ5D index change models analysed fewer procedures than available in the entire cohort. Despite this, testing with BMI included in the model did not qualitatively affect the change scores or significance levels.

Variables included in the change score models, and their significance levels within the final models, are shown in **Table 3.2.22**.

Table 3.2.22. Variables included in change score multivariable linear regression models

	Oxford hip score change		EQ5D index change	
	Cemented model	Cementless model	Cemented model	Cementless model
Approach	<0.001	0.008	0.003	0.003
Preoperative OHS	<0.001	<0.001	0.002	-
Preoperative EQ5D index	-	-	<0.001	<0.001
Preoperative general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	0.003	0.001	<0.001	<0.001
Circulatory problems	<0.001	<0.001	<0.001	0.002
History of depression	-	0.001	<0.001	<0.001
BMI*	<0.001	0.040	-	0.001
Sex	<0.001	-	-	
Goodness of fit of model (adjusted R^2)	36%	41%	58%	60%

BMI – body mass index, OHS – Oxford hip score

* BMI data available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%) therefore final change models analyse fewer procedures than entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels.

Cemented: *Stryker Exeter V40 stem + Flanged Contemporary internal diameter 28mm cup*.

Cementless: *DePuy Corail stem + Pinnacle shell + 36mm metal-on-metal or ceramic-on-ceramic bearing*

Summary

The posterior approach may offer a functional benefit to patients compared with the lateral, whilst appearing not to confer an additional risk of dislocation or requirement for revision during the first post-operative year. These findings were similar for both cemented and cementless implants and are clinically important as they identify a modifiable surgical parameter that may result in modestly improved patient outcome.

Influence of head size and bearing on PROMs

This analysis explores the effect of bearing surface and femoral head size on PROMs and complications following THR. There is a perception that larger head sizes may increase stability, improve function and reduce dislocation risk. It is hypothesised that larger heads and alternative bearings have no functional benefit over standard (28mm MoP) bearings.

There were 4596 NJR-PROMs linked primary procedures. MoP accounted for 47.2% (2171), CoC 44.9% (2064) and CoP 7.9% (361). A standard (28mm) head size was used in 40.6% (1864), the 36mm in 40.5% (1863) and the 32mm in 18.9% (869) of procedures. When the demographics were compared across the bearing groups, patients with a CoC bearing were generally younger and in better health, although gender distribution and mean BMI were similar. Patients who had a 36mm head size implanted were generally younger and in better health. Patients fitted with a 32mm head had a higher ASA grade and BMI, and were in poorer general health than those implanted with a 28mm head. Although there were statistically significant differences in each of the surgical factors, these differences were small and the bearing and head size groups were broadly comparable (**Tables 3.2.23, 3.2.24**).

In the unadjusted PROMs data, patients with a CoC bearing and a larger head size had higher pre- and post-operative OHS and EQ5D indices. Patient reported levels of satisfaction and success were similar across the bearing groups, and the 28mm and 36mm head size groups, although the 32mm head size had poorer scores (**Tables 3.2.25, 3.2.26**).

Table 3.2.23. Patient demographics for population studied, by bearing

	All patients	Bearing			*Differences between groups**
		Metal-on-polyethylene (Reference)	*Ceramic-on-polyethylene*	*Ceramic-on-ceramic*	
Number (%)	4596	2171 (47.2)	361 (7.9)	2064 (44.9)	
Patient factors					
Age, mean years (standard deviation [sd], range)	66.0 (9.7, 25.2 to 95.1)	70.8 (8.0, 31.0 to 95.1)	64.6 (8.3, 39.0 to 87.2)	61.1 (9.1, 25.2 to 91.5)	p<0.001
Females	2620 (57.0)	1259 (58.0)	220 (60.9)	1141 (55.3)	p=0.059
ASA					
1	804 (17.5)	246 (11.3)	64 (17.7)	494 (23.9)	p<0.001
2	3360 (73.1)	1673 (77.1)	249 (69.0)	1438 (69.7)	
3+	432 (9.4)	252 (11.6)	48 (13.3)	132 (6.4)	
BMI, mean kg/m^2 (sd, range) $^{\Psi}$	29.0 (5.4, 15 to 65)	28.7 (5.2, 15 to 56)	29.3 (5.3, 18 to 54)	29.2 (5.6, 18 to 65)	p=0.088
Co-morbidities					
Heart disease	388 (8.4)	233 (10.7)	28 (7.8)	127 (6.2)	p<0.001
Stroke	67 (1.5)	42 (1.9)	4 (1.1)	21 (1.0)	p=0.038
Diabetes	355 (7.7)	201 (9.3)	27 (7.5)	127 (6.2)	p=0.001
Hypertension	1764 (38.4)	960 (44.2)	136 (37.7)	668 (32.4)	p<0.001
Circulation	221 (4.8)	132 (6.1)	25 (6.9)	64 (3.1)	p<0.001
Lung	270 (5.9)	122 (5.6)	21 (5.8)	127 (6.2)	p=0.761
Depression	309 (6.7)	123 (5.7)	25 (6.9)	161 (7.8)	p=0.021
Preoperative general health					
Excellent	265 (5.8)	104 (4.8)	20 (5.5)	137 (6.6)	p=0.001
Very good	1413 (30.7)	649 (29.9)	93 (25.8)	669 (32.4)	
Good	2008 (43.7)	1004 (46.2)	184 (51.0)	819 (39.7)	
Fair	781 (17.0)	363 (16.7)	53 (14.7)	380 (18.4)	
Poor	129 (2.9)	51 (2.3)	11 (3.0)	59 (2.9)	
Preoperative disability	2229 (48.5)	1117 (51.5)	192 (53.2)	920 (44.6)	p<0.001
Surgical factors					
Chemical VTE prophylaxis					
LMWH only	2583 (56.2)	1322 (60.9)	211 (49.0)	2583 (56.2)	p<0.001
Aspirin only	415 (9.0)	179 (8.3)	21 (5.8)	415 (9.0)	
Other	544 (11.8)	189 (8.7)	45 (12.5)	544 (11.8)	
None	304 (6.6)	115 (5.3)	27 (7.5)	304 (6.6)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	750 (16.3)	
Mechanical VTE prophylaxis					
Compression stockings (CS)	1249 (27.2)	644 (29.7)	98 (27.2)	507 (24.6)	p<0.001
CS/mech pump combination	918 (20.0)	342 (15.8)	79 (21.9)	497 (24.1)	
Foot pump only	523 (11.4)	324 (14.9)	10 (2.8)	189 (9.2)	
Mechanical calf pump only	756 (16.5)	311 (14.3)	70 (19.4)	375 (18.2)	
Other	22 (0.5)	4 (0.2)	1 (0.3)	17 (0.8)	
None	378 (8.2)	180 (8.3)	46 (12.7)	152 (7.4)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	327 (15.4)	
Head size					
28mm	1864 (40.6)	1423 (65.6)	198 (54.9)	243 (11.8)	p<0.001
32mm	869 (18.9)	510 (23.5)	100 (27.7)	869 (18.9)	
36mm	1863 (40.5)	238 (11.0)	63 (17.5)	1562 (40.5)	
Anaesthesia					
Regional	2077 (45.2)	987 (45.5)	153 (42.4)	937 (45.4)	p=0.010
General	827 (18.0)	344 (15.9)	72 (19.9)	411 (19.9)	
Regional and general	906 (19.7)	454 (20.9)	77 (18.2)	375 (18.2)	
Not recorded	786 (17.1)	386 (17.8)	59 (16.3)	341 (16.5)	
Lead surgeon grade					
Consultant	3475 (75.6)	1600 (73.7)	294 (81.4)	1581 (76.6)	p=0.002
Other	1121 (24.4)	571 (26.3)	67 (18.6)	483 (23.4)	
Position					
Lateral	3598 (78.3)	1708 (78.7)	284 (78.7)	1606 (77.8)	p=0.100
Supine	248 (5.4)	97 (4.5)	20 (5.5)	131 (6.4)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	327 (15.8)	

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures. BMI – body mass index

* - one-way analysis of variance test (continuous data variables) or Chi squared (categorical data variables).

Ψ - BMI data available on 2726 procedures

Table 3.2.24. Patient demographics for population studied, by head size

	All patients	Head size			*Differences between groups**
		28mm (Reference)	*32mm*	*36mm*	
Number (%)	4596	1864 (40.6)	869 (18.9)	1863 (40.5)	
Patient factors					
Age, mean years (standard deviation [sd], range)	66.0 (9.7, 25.2 to 95.1)	68.0 (8.9, 31.0 to 95.1)	68.2 (10.1, 26.2 to 94.1)	62.9 (9.5, 25.2 to 90.2)	p<0.001
Females	2620 (57.0)	1303 (69.9)	535 (61.6)	782 (42.0)	p<0.001
ASA					
1	804 (17.5)	286 (15.3)	93 (10.7)	425 (22.8)	p<0.001
2	3360 (73.1)	1410 (75.6)	644 (74.1)	1306 (70.1)	
3+	432 (9.4)	168 (9.0)	132 (15.2)	132 (7.1)	
BMI, mean kg/m^2 (sd, range) $^{\Psi}$	29.0 (5.4, 15 to 65)	28.7 (5.2, 15 to 56)	29.1 (5.6, 16 to 50)	29.5 (5.4, 16 to 65)	p=0.027
Co-morbidities					
Heart disease	388 (8.4)	152 (8.2)	91 (10.5)	145 (7.8)	p=0.053
Stroke	67 (1.5)	29 (1.6)	13 (1.5)	25 (1.3)	p=0.857
Diabetes	355 (7.7)	158 (8.5)	70 (8.1)	127 (6.8)	p=0.158
Hypertension	1764 (38.4)	739 (39.7)	366 (42.1)	659 (35.4)	p=0.001
Circulation	221 (4.8)	102 (5.5)	45 (5.2)	74 (4.0)	p=0.086
Lung	270 (5.9)	112 (6.0)	42 (4.8)	116 (6.2)	p=0.336
Depression	309 (6.7)	126 (6.8)	44 (5.1)	139 (6.7)	p=0.066
Preoperative general health					
Excellent	265 (5.8)	100 (5.4)	53 (6.1)	114 (6.1)	p=0.016
Very good	1413 (30.7)	566 (30.4)	235 (27.0)	611 (32.8)	
Good	2008 (43.7)	862 (46.2)	394 (45.3)	755 (40.5)	
Fair	781 (17.0)	285 (15.3)	165 (19.0)	330 (17.7)	
Poor	129 (2.9)	51 (2.7)	22 (2.5)	53 (2.8)	
Preoperative disability	2229 (48.5)	928 (50.0)	448 (51.6)	853 (45.8)	p=0.007
Surgical factors					
Chemical VTE prophylaxis					
LMWH only	2583 (56.2)	1115 (59.8)	518 (59.6)	950 (51.0)	p<0.001
Aspirin only	415 (9.0)	146 (7.8)	50 (5.8)	219 (11.8)	
Other	544 (11.8)	163 (8.7)	98 (11.3)	283 (15.2)	
None	304 (6.6)	133 (7.1)	36 (4.1)	135 (7.3)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	
Mechanical VTE prophylaxis					
Compression stockings (CS)	1249 (27.2)	500 (26.8)	222 (25.6)	527 (28.3)	p<0.001
CS/mech pump combination	918 (20.0)	296 (15.9)	134 (15.4)	488 (26.2)	
Foot pump only	523 (11.4)	278 (14.9)	86 (9.9)	159 (8.5)	
Mechanical calf pump only	756 (16.5)	312 (16.7)	173 (19.9)	271 (14.6)	
Other	22 (0.5)	7 (0.4)	0 (0.0)	15 (1.0)	
None	378 (8.2)	164 (8.8)	87 (6.8)	127 (6.8)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	
Bearing					
Metal-on-polyethylene	2171 (47.2)	1423 (76.3)	510 (58.7)	238 (12.8)	p<0.001
Ceramic-on-polyethylene	361 (7.9)	198 (10.6)	100 (11.5)	63 (3.4)	
Ceramic-on-ceramic	2064 (44.9)	243 (13.0)	259 (29.8)	1562 (83.8)	
Anaesthesia					
Regional	2077 (45.2)	871 (46.7)	303 (34.9)	903 (48.5)	p<0.001
General	827 (18.0)	312 (16.7)	168 (19.3)	347 (18.6)	
Regional and general	906 (19.7)	357 (19.2)	224 (25.8)	325 (17.4)	
Not recorded	786 (17.1)	324 (17.4)	174 (20.0)	288 (15.5)	
Lead surgeon grade					
Consultant	3475 (75.6)	1484 (79.6)	618 (71.1)	1373 (73.7)	p<0.001
Other	1121 (24.4)	380 (20.4)	251 (28.9)	490 (26.3)	
Position					
Lateral	3598 (78.3)	1449 (77.7)	666 (76.6)	1483 (79.6)	p=0.026
Supine	248 (5.4)	108 (5.8)	36 (4.1)	104 (5.6)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures, BMI – body mass index.

* - one-way analysis of variance test (continuous data variables) or Chi squared (categorical data variables).

Ψ - BMI data available on 2726 procedures

Table 3.2.25. Patient reported outcomes for populations studied, by bearing

	Metal-on-polyethylene	Ceramic-on-polyethylene	Ceramic-on-ceramic	p value
Number (%)	2171 (47.2)	361 (7.9)	2064 (44.9)	
Oxford Hip scores				
Pre-operative, mean (sd, range)	18.4 (8.0, 1 to 43)	18.5 (8.4, 0 to 43)	19.2 (8.1, 1 to 46)	0.003
Post-operative, median (range)	42 (0 to 48)	41 (7 to 48)	43 (2 to 48)	<0.001
EQ5D index				
Pre-operative, mean (sd, range)	0.368 (0.314, -0.34 to 1)	0.375 (0.331, -0.48 to 0.88)	0.394 (0.311, -0.59 to 1)	0.011
Post-operative, median (range)	0.815 (-0.319 to 1)	0.796 (-0.319 to 1)	0.848 (-0.594 to 1)	0.008
Satisfaction				
Excellent	882 (40.6)	144 (39.9)	887 (43.0)	
Very good	804 (37.0)	123 (34.1)	728 (35.3)	
Good	364 (16.8)	66 (18.3)	321 (15.6)	0.269
Fair	90 (4.2)	23 (6.4)	89 (4.3)	
Poor	31 (1.4)	5 (1.4)	39 (1.9)	
Success				
Much better	1936 (89.2)	303 (83.9)	1828 (88.6)	
A little better	157 (7.2)	46 (12.7)	158 (7.7)	
About the same	33 (1.5)	3 (0.8)	35 (1.7)	0.045
A little worse	26 (1.2)	6 (1.7)	29 (1.4)	
Much worse	19 (0.9)	3 (0.8)	14 (0.7)	
Time from operation to PROMs completion, mean days (sd, range)	207.8 (28.1, 183 to 363)	207.2 (22.9, 183 to 333)	209.7 (28.6, 183 to 361)	0.002

PROMs – patient reported outcome measures
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Outcome score improvement

When compared with a MoP bearing (OHS improvement: 21.2, EQ5D index improvement: 0.419), there were no significant benefits of either CoP (OHS: 20.5, p=0.211, EQ5D index: 0.404, p=0.388) or CoC (OHS: 21.2, p=0.959, EQ5D index: 0.411, p=0.387) (**Table 3.2.27**).

When compared with 28mm head (OHS improvement: 21.5, EQ5D index improvement: 0.426), there were no significant benefits of a 36mm head (OHS: 21.3, p=0.488, EQ5D index: 0.417, p=0.339). Although the difference was small, the 32mm head was associated with a poorer outcome (OHS: 20.1, p=0.002, EQ5D index: 0.388, p=0.004) (**Table 3.2.28**).

Table 3.2.26. Patient reported outcomes for populations studied, by head size

	28mm	32mm	36mm	p value
Number (%)	1864 (40.6)	869 (18.9)	1863 (40.5)	
Oxford Hip scores				
Pre-operative, mean (sd, range)	18.2 (8.0, 1 to 44)	18.3 (7.9, 2 to 43)	19.6 (8.2, 0 to 46)	<0.001
Post-operative, median (range)	43 (0 to 48)	41 (4 to 48)	48 (2 to 48)	<0.001
EQ5D index				
Pre-operative, mean (sd, range)	0.366 (0.315, -0.484 to 1)	0.365 (0.316, -0.319 to 1)	0.401 (0.311, -0.594 to 1)	0.001
Post-operative, median (range)	0.848 (-0.319 to 1)	0.796 (-0.126 to 1)	0.850 (-0.594 to 1)	<0.001
Satisfaction				
Excellent	791 (42.4)	319 (36.7)	803 (43.1)	<0.001
Very good	683 (36.6)	299 (34.4)	673 (36.1)	
Good	288 (15.5)	190 (21.9)	273 (14.7)	
Fair	77 (4.1)	46 (5.3)	79 (4.2)	
Poor	25 (1.3)	15 (1.7)	35 (1.9)	
Success				
Much better	1673 (89.8)	736 (84.7)	1658 (89.0)	0.001
A little better	124 (6.7)	103 (11.9)	134 (7.2)	
About the same	27 (1.5)	14 (1.6)	30 (1.6)	
A little worse	22 (1.2)	10 (1.2)	29 (1.6)	
Much worse	18 (1.0)	6 (0.7)	12 (0.6)	
Time from operation to PROMs completion, mean days (sd, range)	207.2 (26.1, 183 to 361)	208.8 (28.4, 184 to 357)	209.9 (29.4, 183 to 363)	0.002

PROMs – patient reported outcome measures
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Table 3.2.27. Patient reported outcome scores following primary hip replacement, by bearing (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS						
Metal-on-polyethylene	21.3	20.8 to 21.9	Reference	21.2	20.6 to 21.8	Reference
Ceramic-on-polyethylene	19.7	18.4 to 21.0	0.003	20.5	19.1 to 21.8	0.211
Ceramic-on-ceramic	20.9	20.3 to 21.4	0.139	21.2	20.6 to 21.8	0.959
Change EQ5D index						
Metal-on-polyethylene	0.428	0.409 to 0.448	Reference	0.419	0.402 to 0.436	Reference
Ceramic-on-polyethylene	0.385	0.337 to 0.433	0.032	0.404	0.365 to 0.444	0.388
Ceramic-on-ceramic	0.406	0.386 to 0.426	0.040	0.411	0.393 to 0.428	0.387

CI – confidence intervals, OHS – Oxford Hip Score

Table 3.2.28. Patient reported outcome scores following primary hip replacement, by head size (simple and multivariable analyses)

	Simple			Multivariable		
	Value	99% CI	P value	Value	99% CI	P value
Change in OHS						
28mm	21.6	20.0 to 22.2	Reference	21.5	20.9 to 22.1	Reference
32mm	20.3	19.4 to 21.2	0.001	20.1	19.2 to 21.1	0.002
36mm	20.8	20.3 to 21.3	0.004	21.3	20.7 to 21.8	0.488
Change EQ5D index						
28mm	0.429	0.408 to 0.450	Reference	0.426	0.408 to 0.444	Reference
32mm	0.408	0.377 to 0.440	0.162	0.388	0.361 to 0.416	0.004
36mm	0.407	0.389 to 0.425	0.045	0.417	0.401 to 0.433	0.339

CI – confidence intervals, OHS – Oxford Hip Score

Risk of complications

When bearings were compared, there were no significant differences in risk of bleeding, wound complications, readmission or reoperation after case-mix adjustment (**Table 3.2.29**). Bleeding risk was significantly higher in the 32mm head size group (OR 1.83, p<0.001) but not the 36mm head size (OR 1.32, p=0.063) when compared with 28mm. However, there were no other significant differences in risk of wound complications, readmission and reoperation when the different head sizes were compared (**Table 3.2.30**).

Table 3.2.29. Patient reported complications following primary hip replacement, by bearing (simple and multivariable analyses)

	%	n	Simple			Multivariable		
			OR	99% CI	P value	OR	99% CI	P value
Bleeding complications								
Metal-on-polyethylene	5.8	(125)	1			1		
Ceramic-on-polyethylene	4.2	(15)	0.71	0.34 to 1.49	0.212	0.70	0.34 to 1.44	0.200
Ceramic-on-ceramic	5.9	(122)	1.02	0.73 to 1.43	0.864	1.00	0.71 to 1.41	0.974
Wound complications								
Metal-on-polyethylene	7.3	(158)	1			1		
Ceramic-on-polyethylene	8.6	(31)	1.20	0.71 to 2.04	0.373	1.33	0.67 to 2.62	0.284
Ceramic-on-ceramic	9.9	(204)	1.40	1.05 to 1.86	0.002	1.25	0.75 to 2.08	0.262
Readmission								
Metal-on-polyethylene	7.2	(157)	1			1		
Ceramic-on-polyethylene	7.2	(26)	0.99	0.57 to 1.76	0.995	1.10	0.61 to 2.00	0.667
Ceramic-on-ceramic	5.6	(115)	0.76	0.55 to 1.05	0.030	0.85	0.58 to 1.25	0.283
Reoperation								
Metal-on-polyethylene	1.8	(40)	1			1		
Ceramic-on-polyethylene	1.4	(5)	0.75	0.22 to 2.57	0.548	0.75	0.22 to 2.59	0.549
Ceramic-on-ceramic	2.0	(41)	1.08	0.61 to 1.93	0.723	1.12	0.62 to 2.01	0.625

OR – Odds ratio, CI – confidence intervals

Table 3.2.30. Patient reported complications following primary hip replacement, by head size (simple and multivariable analyses)

	%	n	Simple			Multivariable		
			OR	99% CI	P value	OR	99% CI	P value
Bleeding complications								
28mm	4.5	(84)	1			1		
32mm	7.9	(69)	1.83	1.19 to 2.82	<0.001	1.83	1.19 to 2.82	<0.001
36mm	5.6	(109)	1.31	0.92 to 1.89	0.051	1.32	0.90 to 1.95	0.063
Wound complications								
28mm	7.7	(144)	1			1		
32mm	7.6	(66)	0.98	0.66 to 1.46	0.887	1.12	0.65 to 1.93	0.594
36mm	9.8	(183)	1.27	0.96 to 1.68	0.030	1.68	1.10 to 2.59	0.002
Readmission								
28mm	6.3	(117)	1			1		
32mm	7.6	(66)	1.22	0.81 to 1.84	0.211	1.26	0.83 to 1.93	0.157
36mm	6.2	(115)	1.00	0.73 to 1.37	0.974	1.10	0.76 to 1.60	0.500
Reoperation								
28mm	2.3	(42)	1			1		
32mm	1.3	(11)	0.55	0.23 to 1.31	0.075	0.55	0.23 to 1.32	0.079
36mm	1.8	(33)	0.71	0.41 to 1.26	0.124	0.85	0.46 to 1.57	0.499

OR – Odds ratio, CI – confidence intervals

Statistical considerations

Tests for interaction (multiplicative) between covariates were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. BMI data was available for 2726 procedures (59%). BMI had a significant influence on the OHS change models and the wound complications models; thus, these models analysed fewer procedures than were available from the entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels, and so the final models retained the BMI variable. Variables included in the statistical models, and their significance levels within the final models, are shown in **Tables 3.2.31, 3.2.32**.

Table 3.2.31. Variables included in the change score analysis of covariance models

	OHS change		EQ5D index change	
	Head size model	Bearing model	Head size model	Bearing model
Head size	0.930	-	0.976	-
Bearing	-	0.895	-	0.320
Approach	<0.001	0.008	0.003	0.003
Preoperative OHS	<0.001	<0.001	0.002	-
Preoperative EQ5D index	-	-	<0.001	<0.001
Preop general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	0.003	0.001	<0.001	<0.001
Circulatory problems	<0.001	<0.001	<0.001	0.002
History of depression	-	0.001	<0.001	<0.001
BMI*	<0.001	0.040	-	0.001
Sex	<0.001	-	-	
Goodness of fit of model (adjusted R^2)	36%	41%	58%	60%

BMI – body mass index, OHS – Oxford hip score

* BMI data available for 2726 implants (59%) therefore final change models analyse fewer procedures than entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels.

Table 3.2.32. Variables included in the complications multivariable logistic regression

	Bleeding		Wound		Readmitted		Reoperation	
	Head size model	Bearing model	Head size model	Bearing model	Head size model	Bearing model	Head size model	Bearing model
Head size	0.334	-	0.001	0.014	0.191	-	0.885	-
Bearing	-	0.967	-	0.671	-	0.936	-	0.472
Approach	-	-	0.028	0.033	-	-	-	-
Preoperative OHS	-	-	-	-	-	-	0.025	0.024
Preoperative general health	-	-	0.009	0.009	0.028	0.027	-	-
History of depression	-	-		-	0.024	0.028	-	-
BMI*	-	-	0.001	0.001	-	-	-	-
Sex	-	0.067	0.002	0.003	-	-	-	-
Age	-	-	-	-	0.006	0.026	-	-
Type of mechanical VTE prophylaxis	0.013	0.017	-	-	-	-	0.076	0.083

BMI – body mass index, OHS – Oxford hip score, VTE – venous thromboembolic

* BMI data available for 2726 implants (59%) therefore final change models analyse fewer procedures than entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels.

Summary

No clinically important functional benefits of larger head sizes or alternative bearings were found. Risks of complications, including self-reported readmissions and reoperations were similar across head sizes and bearings.

Part 3. Comparison of survival models

Cox versus the competing risk model

The Cox model is currently the recommended tool for multivariable survival analysis of registry data. However, adjusting for competing risks (such as death) in implant survival analyses may be important when there are differences in baseline patient demographics between groups. A number of studies have recently used complex competing risks models for survival analysis of registry data. In this section the Cox model and the competing risks model are evaluated when comparing survival following two commonly used hip brands.

There were 19033 cemented and 7528 cementless implants, of which 104 cemented and 73 cementless had been revised at time of censoring. Patients implanted with a cementless prosthesis were younger, in better health and were more likely to be male (**Table 3.3.1**). Regardless of the model used, univariable testing found the following variables had a significant effect on implant survival (selection threshold $p<0.10$): age, BMI (continuous or categorical), hip type, mechanical prophylaxis and chemical prophylaxis, with very similar estimates and statistical precision (**Table 3.3.2**).

When BMI data were included within the models the number of procedures available for analysis dropped to 11708 (44%). Gender, ASA group, chemical prophylaxis and mechanical prophylaxis were included in both the Cox model and CRM. Hazard ratios and significance levels were qualitatively similar. There was little difference between the two models for adjusted influence of implant type on survival (Cox model: cementless implant HR=1.51, 99% CI 0.78 to 2.94, p=0.106; CRM: HR=1.52, 99% CI 0.83 to 2.83, p=0.081) (**Table 3.3.2**).

A similar statistical result was found when the two methodologies were compared (Cox model: cementless HR=1.60, 99% CI 1.03 to 2.50, p=0.006; CRM HR=1.61, 99% CI, 99% CI 1.06 to 2.45, p=0.004) (**Table 3.3.3**), when BMI was excluded from the model

Summary

Findings suggest that differences between survival modeling techniques are negligible when using mid-term implant survival data. Despite the theoretical value of a competing risk model, choice between Cox and CRM had no impact upon findings in these analyses. The challenges remain careful variable selection and interpretation.

Table 3.3.1. Demographics of hip replacements included in study (England and Wales, 2003-2010)

	Cemented (n=19033)		Cementless (n=7528)		P value
	Exeter V40 stem, 28mm head, Contemporary flanged cup		Corail stem (size 11+), 28mm head, Pinnacle shell with PE liner		
Age, mean years (SD, range)	73.9 (7.9, 26-100)		70.6 (8.1, 27-98)		<0.001
<60 years	853	(4.5)	683	(9.1)	<0.001
60<75 years	9497	(49.9)	4605	(61.2)	
75+ years	8683	(45.6)	2240	(29.8)	
Gender					
Female	12585	(66.1)	4322	(57.4)	<0.001
Male	6448	(33.9)	3206	(42.6)	
ASA grade					
1	2599	(13.7)	1154	(15.3)	<0.001
2	13224	(69.5)	5416	(71.9)	
≥3	3210	(16.9)	958	(12.7)	
Body mass index, mean kg/m^2 (SD, range) *	28.4 (5.1, 15-63)		28.4 (5.1, 15-64)		0.829
<30kg/m^2	4971	(63.1)	2459	(64.3)	0.193
30+kg/m^2	2913	(37.0)	1366	(35.7)	
Surgical approach					
Anterolateral	9345	(49.1)	4289	(57.0)	<0.001
Posterior	9208	(48.4)	2994	(45.9)	
Other/unknown	480	(2.5)	245	(3.3)	
Primary surgeon					
Consultant	13984	(73.5)	6114	(81.2)	<0.001
Other	5049	(26.5)	1414	(18.8)	
Consultant vol, median (range)	140 (1 to 737)		144 (1 to 1114)		<0.001
Low (<50)	4136	(21.7)	1772	(23.5)	
Medium (50-249)	8360	(43.9)	3345	(44.4)	<0.001
High (≥250)	6537	(34.4)	2411	(32.0)	
Anaesthesia type					
Regional only	8447	(44.4)	4213	(56.0)	<0.001
General only	2653	(13.9)	1149	(15.3)	
General and regional	5621	(29.5)	1199	(15.9)	
Unknown	2312	(12.2)	967	(12.9)	
Chemical VTE prophylaxis					
Yes	15888	(92.8)	6315	(94.1)	<0.001
No/unknown	1238	(7.2)	397	(5.9)	
Mechanical VTE prophylaxis					
Calf compression	14185	(74.5)	4786	(71.3)	<0.001
Foot compression/other	2378	(12.5)	838	(12.5)	
No/unknown	2470	(13.0)	1088	(16.2)	

Two sample Wilcoxon rank-sum test (Mann-Whitney) for non-parametric data, t-test for parametric data, Chi^2 for proportions

SD – standard deviation, ASA – American Society of Anaesthesiologists, * - based on 11708 procedures, VTE – venous thromboembolism

Table 3.3.2. Independent predictors of revision following cemented and cementless THR with body mass index data included: simple and multivariable analyses (England and Wales, 2003-2010)

Covariate	Simple analyses			Cox Proportional Hazards multivariable model			Competing Risks multivariable model		
	HR	99% CI	P value	HR	99% CI	P value	HR	99% CI	P value
Gender									
Female	1			1			1		
Male	1.27	0.86 to 1.89	0.111	1.52	0.81 to 2.83	0.086	1.51	0.81 to 2.82	0.088
Age	0.98	0.96 to 1.00	0.027						
Category			0.074						
<60 years	1								
60<75 years	1.03	0.47 to 2.25	0.927						
75+ years	0.71	0.31 to 1.61	0.283						
ASA grade									
Category			0.492			0.026			0.038
1	1			1			1		
2	0.79	0.48 to 1.31	0.235	0.50	0.23 to 1.06	0.017	0.49	0.23 to 1.05	0.016
≥3	0.83	0.42 to 1.63	0.470	0.43	0.14 to 1.31	0.052	0.43	0.14 to 1.29	0.048
Body mass index *	1.05	1.00 to 1.10	0.019	1.06	1.01 to 1.12	0.003	1.06	1.02 to 1.12	0.001
<30kg/m^2	1								
30+kg/m^2	1.72	0.96 to 3.10	0.017						
Hip type									
Cemented	1			1			1		
Cementless	1.91	1.29 to 2.83	<0.001	1.51	0.78 to 2.94	0.106	1.52	0.83 to 2.83	0.081
Surgical approach									
Category			0.956						
Posterior	1								
Lateral	0.96	0.65 to 1.41	0.766						
Other/unknown	0.96	0.26 to 3.60	0.942						
Primary surgeon									
Consultant	1								
Other	1.11	0.69-1.78	0.564						
Consultant volume	1.00	1.00 to 1.00	0.859						
Category			0.614						
Low (<50)	1								
Medium (50-249)	0.84	0.52 to 1.38	0.371						
High (≥250)	0.84	0.50 to 1.41	0.386						
Anaesthesia type									
Category			0.481						
Regional only	1								
General only	1.28	0.74 to 2.23	0.248						
General and regional	0.96	0.59 to 1.56	0.835						
Unknown	1.26	0.69 to 2.29	0.330						
Chemical VTE prophylaxis									
Yes	1			1			1		
No/unknown	1.65	0.82 to 3.32	0.066	2.37	0.95 to 5.95	0.016	2.37	0.93 to 6.02	0.017
Mechanical VTE prophylaxis			0.002			<0.001			<0.001
Category	1			1			1		
Calf compression	1.72	1.01 to 2.93	0.009	2.92	1.31 to 6.51	0.001	2.91	1.31 to 6.45	0.001
Foot comp/other	1.79	1.07 to 2.99	0.004	3.48	1.50 to 8.07	<0.001	3.48	1.61 to 7.53	<0.001

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, VTE – venous thromboembolism
Hip type was forced into the model to assess differences

Table 3.3.3. Independent predictors of revision following cemented and cementless THR with Body Mass Index data excluded: simple and multivariable analyses (England and Wales, 2003-2010)

Covariate	Simple analysis			Multivariable analysis (Cox Proportional Hazards)			Multivariable analysis (Competing risks model)		
	HR	99% CI	P value	HR	99% CI	P value	HR	99% CI	P value
Gender									
Female	1			1			1		
Male	1.27	0.86 to 1.89	0.111	1.26	0.83 to 1.90	0.157	1.25	0.82 to 1.89	0.169
Age	0.98	0.96 to 1.00	0.027						
Category			0.074						
<60 years	1								
60<75 years	1.03	0.47 to 2.25	0.927						
75+ years	0.71	0.31 to 1.61	0.283						
ASA grade									
Category			0.492			0.367			0.338
1	1			1			1		
2	0.79	0.48 to 1.31	0.235	0.75	0.44 to 1.27	0.163	0.75	0.44 to 1.27	0.160
≥3	0.83	0.42 to 1.63	0.470	0.81	0.40 to 1.66	0.458	0.79	0.38 to 1.61	0.385
Hip type									
Cemented	1			1			1		
Cementless	1.91	1.29 to 2.83	<0.001	1.60	1.03 to 2.50	0.006	1.61	1.06 to 2.45	0.004
Surgical approach									
Category			0.956						
Posterior	1								
Lateral	0.96	0.65 to 1.41	0.766						
Other/unknown	0.96	0.26 to 3.60	0.942						
Primary surgeon									
Consultant	1								
Other	1.11	0.69-1.78	0.564						
Consultant volume	1.00	1.00 to 1.00	0.859						
Category			0.614						
Low (<50)	1								
Medium (50-249)	0.84	0.52 to 1.38	0.371						
High (≥250)	0.84	0.50 to 1.41	0.386						
Anaesthesia type									
Category			0.481						
Regional only	1								
General only	1.28	0.74 to 2.23	0.248						
General and regional	0.96	0.59 to 1.56	0.835						
Unknown	1.26	0.69 to 2.29	0.330						
Chemical VTE prophylaxis									
Yes	1			1			1		
No/unknown	1.65	0.82 to 3.32	0.066	1.97	0.97 to 4.01	0.014	1.96	0.96 to 4.02	0.016
Mechanical VTE prophylaxis			0.002			<0.001			<0.001
Category	1			1			1		
Calf compression	1.72	1.01 to 2.93	0.009	1.83	1.07 to 3.13	0.004	1.83	1.07 to 3.13	0.004
Foot comp/other	1.79	1.07 to 2.99	0.004	2.18	1.17 to 4.06	0.001	2.19	1.20 to 3.97	0.001

HR – hazards ratio, CI – confidence intervals, ASA – American Society of Anaesthesiologists, VTE – venous thromboembolism

Part 4. Multi-outcome analyses of subgroups

Younger patient population (under 60 years at time of surgery)

Hip replacement in younger people is a complex issue. These patients are more active, with greater life expectancy and may have higher functional expectations than older patients. Many still work and want to pursue active lifestyles. Implants in these patients must perform to a higher level whilst lasting as long as possible. Different types of replacement were compared to identify optimal combinations for young patients, employing the best performing and most commonly used standard cemented hip replacement as the reference case. Implant survival and functional outcomes are compared, with a cost analysis featuring in the final section.

The cohort of hip replacements comprises the most commonly used individual brands of cemented, cementless, hybrid and resurfacing implants across all ages within the NJR dataset. Of these, 24 709 procedures were performed during the study period in patients aged less than 60 years. Results from earlier sections informed the categorisation of implant types into component sets with the 'best' outcome (based on implant survival) and those that had statistically lower survival ('other'). A summary of this data for young patients (<60 years) is provided in **Table 3.4.1**.

Table 3.4.1. Breakdown of implant types included in the young patient population

			Best			**Other**		
Type	N	(%)	Details	N	(%)	Details	N	(%)
Cemented	1552	(6.3)	>28mm head and flanged cup	885	(9.2)	All hooded cups or all with head sizes <28mm	667	(4.4)
Hybrid	3238	(13.1)	MoXLPE or CoXLPE or CoC and solids shell cups	1140	(11.8)	All multi-hole shells or standard polyethylene bearings	2098	(13.9)
Cementless	9517	(38.5)	Stem sizes >10 and MoP or CoP bearings	920	(9.6)	All small stems (<10) or CoC or COM or MoM	8597	(57.0)
Resurfacing	10402	(42.1)	≥48mm head size	6679	(69.3)	<48mm head size	3723	(24.7)
Total	*24 709*			*9624*			*15 085*	

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal, MoXLPE – metal-on-highly cross-linked polyethylene, CoXLPE – ceramic-on-highly cross-linked polyethylene

Resurfacing procedures were more likely to have been performed in younger, fitter patients (**Table 3.4.2**). The majority of smaller resurfacing procedures ('other') were performed in females. Across the total hip replacement groups, patient variables were clinically very similar, although the 'best' hybrid procedures were more likely to be performed in younger, fitter patients. The entire NJR population demographics profile was qualitatively similar to that of the smaller NJR-PROMs linked population (**Table 3.4.3**).

Table 3.4.2. Patient demographics for population studied, by implant group (National Joint Registry data)

	Cemented		Hybrid		Cementless		Resurfacing		Differences between groups
	Best	Other	Best	Other	Best	Other	Best	Other	
Number (%)	885 (3.6)	667 (2.7)	1140 (4.6)	2098 (8.5)	920 (3.7)	8597 (34.8)	6679 (27.0)	3723 (15.1)	
Age, median years (range)	56.8 (23 to 60)	57.4 (26 to 60)	54.9 (18 to 60)	55.3 (20 to 60)	57.1 (27 to 60)	54.8 (16 to 60)	52.7 (19 to 60)	52.7 (19 to 60)	p<0.001
Females	548 (61.9)	412 (61.8)	642 (56.3)	1340 (63.9)	454 (49.4)	4880 (56.8)	432 (6.5)	2914 (78.3)	p<0.001
ASA grade									
1	263 (29.7)	193 (28.9)	430 (37.7)	677 (32.3)	252 (27.4)	2815 (32.7)	3750 (56.2)	1969 (52.9)	
2	543 (61.4)	421 (63.1)	664 (58.3)	1246 (59.4)	603 (65.5)	5233 (60.9)	2748 (41.1)	1677 (45.0)	p<0.001
3+	79 (8.9)	53 (8.0)	46 (4.0)	175 (8.3)	65 (7.1)	549 (6.4)	181 (2.7)	77 (2.1)	
BMI, mean kg/m^2 (sd, range)*	29.9 (6.2, 18 to 59)	29.6 (5.6, 16 to 50)	29.6 (5.4, 18 to 56)	29.7 (6.1, 16 to 54)	29.6 (5.7, 17 to 52)	29.7 (5.9, 16 to 65)	28.9 (4.5, 16 to 51)	27.6 (5.3, 16 to 63)	p<0.001

ASA – American Society of Anesthesiologists, BMI – body mass index (*data based on 9544 procedures [39%]). Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Table 3.4.3. Patient demographics for population studied, by implant group (National Joint Registry-PROMs linked data)

	Cemented		Hybrid		Cementless		Resurfacing		Differences between groups
	Best	Other	Best	Other	Best	Other	Best	Other	
Number (%)	111 (5.5)	52 (2.6)	118 (5.9)	213 (10.6)	159 (7.9)	1117 (55.5)	187 (9.3)	57 (2.8)	
Age, median years (range)	56.0 (37 to 60)	56.7 (48 to 60)	53.7 (30 to 60)	55.5 (28 to 60)	57.1 (39 to 60)	54.3 (25 to 60)	52.0 (32 to 60)	53.7 (35 to 60)	p<0.001
Females	70 (63.1)	37 (71.5)	73 (61.9)	147 (69)	82 (51.6)	671 (60.1)	8 (4.3)	41 (71.9)	p<0.001
ASA grade									
1	34 (30.6)	11 (21.2)	44 (37.3)	75 (35.2)	40 (25.2)	377 (33.8)	84 (44.9)	24 (42.1)	
2	63 (56.8)	33 (63.5)	67 (56.8)	123(57.8)	109(68.6)	687 (61.5)	101 (54.0)	31 (54.4)	p<0.001
3+	14 (12.6)	8 (15.4)	7 (5.9)	15 (7.0)	10 (6.3)	53 (4.7)	2 (1.1)	2 (3.5)	
BMI, mean kg/m^2 (sd, range)*	29.4 (6.3, 19 to 59)	30.0 (6.0, 19 to 49)	29.8 (5.4, 20 to 47)	30.1 (6.1, 18 to 50)	31.0 (5.1, 17 to 46)	29.9 (6.1, 18 to 65)	29.1 (4.0, 18 to 45)	28.9 (6.0, 19 to 43)	p=0.712

PROMs – patient reported outcome measures, ASA – American Society of Anesthesiologists, BMI – body mass index (*data based on 1293 procedures [64%]). Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Patient reported outcomes were available for 2014 procedures (8.2%), comprising cemented (163, 10.5% of NJR data), hybrid (331, 10.2%), cementless (1276, 13.4%) and resurfacing (244, 2.3%) replacements. Pre-operative OHS and EQ5D indices were similar across implant groups, except the large head resurfacing group ('best') where patients had an average 3.3 to 6.0 point higher pre-operative OHS. Post-operative OHS was generally lower in the cemented group, but post-operative EQ5D indices were similar across all groups. There were no significant differences across groups in those reporting satisfaction with the procedure (85 to 94%) and those reporting the operation to have been successful (90 to 98%, **Table 3.4.4**).

Table 3.4.4. Patient reported outcomes for populations studied, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		p value
	Best	Other	Best	Other	Best	Other	Best	Other	
Number (%)	111 (5.5)	52 (2.6)	118 (5.9)	213 (10.6)	159 (7.9)	1117 (55.5)	187 (9.3)	57 (2.8)	
OHS									
Pre-operative Mean (sd, range)	18.9 (8.5, 3 to 40)	16.2 (7.2, 3 to 33)	18.9 (7.8, 4 to 37)	17.7 (7.6, 1 to 36)	16.7 (7.2, 2 to 39)	18.0 (7.8, 2 to 46)	22.2 (8.2, 4 to 43)	19.4 (8.1, 4 to 37)	0.018
Post-operative Median (range)	41 (0 to 48)	40 (4 to 48)	43 (8 to 48)	43 (7 to 48)	42 (4 to 48)	43 (2 to 48)	46 (2 to 48)	43 (5 to 48)	<0.001
EQ5D index									
Pre-operative Mean (sd, range)	0.404 (0.30, -0.2 to 0.9)	0.279 (0.32, -0.2 to 0.8)	0.405 (0.32, -0.2 to 0.8)	0.352 (0.33, -0.6 to 0.8)	0.324 (0.31, -0.4 to 0.7)	0.352 (0.32, -0.3 to 1)	0.474 (0.31, -0.2 to 1)	0.379 (0.34, -0.2 to 0.8)	0.332
Post-operative Median (range)	0.814 (-0.5 to 1)	0.727 (0 to 1)	0.812 (-0.2 to 1)	0.815 (-0.4 to 1)	0.796 (-0.1 to 1)	0.815 (-0.2 to 1)	1 (-0.4 to 1)	0.812 (-0.2 to 1)	<0.001
Satisfaction									
Good to excellent	99 (89.2)	44 (84.6)	110 (93.2)	198 (93.0)	150 (94.3)	1033 (92.5)	170 (90.9)	50 (87.7)	0.264
Poor/fair	12 (10.8)	8 (15.4)	8 (6.8)	15 (7.0)	9 (5.7)	84 (7.5)	17 (9.1)	7 (12.3)	
Success									
Better	105 (94.6)	47 (90.4)	113 (95.8)	207 (97.5)	155 (97.5)	1072 (96.0)	181 (96.8)	53 (93.0)	0.319
About same or worse	6 (5.4)	5 (9.6)	5 (4.2)	6 (2.8)	4 (2.5)	45 (4.0)	6 (3.2)	4 (7.0)	
Time from op to PROMs complete, mean days (sd, range)	212.6 (32.3, 188 to 343)	218.9 (36.7, 186 to 329)	210.5 (25.5, 186 to 315)	210.2 (28.3, 183 to 332)	210.3 (30.0, 187 to 350)	210.2 (28.1, 183 to 361)	271.6 (44.8, 186 to 360)	268.9 (49.0, 186 to 353)	<0.001

PROMs – patient reported outcome measures
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

In females, revision was significantly higher in 'other' cementless implants (HR=3.35, p=0.040) and resurfacings ('best': HR=4.95, p=0.011; 'other': HR=6.36, p=0.002) when compared to the reference (cemented) group. The 'best' hybrid group (solid shell with a CoC or metal/ceramic on highly cross-linked PE) had similar implant survival (HR=1.39, p=0.654) (**Table 3.4.5**). Significantly greater improvements in OHS were seen in the hybrid groups ('best': 22.3, p=0.006; 'other', multi-hole shells or standard PE liner: 21.9, p=0.005) and the cementless groups ('best', PE liners: 21.3, p=0.031; 'other': 22.2, p<0.001) when compared with the 'best' cemented (18.2). The 'best' resurfacing procedures displayed good results, but this was based on only eight procedures (**Table 3.4.6**). There were no differences in EQ5D indices across groups.

In males, revision (**Table 3.4.5**) and PROMs improvements were equivalent across all groups when compared to the reference (**Table 3.4.7**).

Table 3.4.5. Risk of revision following hip replacement in patients aged under 60 years (simple and multivariable analyses)

	Simple			Multivariable		
	HR	95% CI	P value	HR	95% CI	P value
Females (n=11622)						
Best cemented (n=548)	1			1		
Other cemented (n=412)	3.06	0.81 to 11.5	0.099	3.12	0.83 to 11.8	0.093
Best hybrid (n=642)	1.42	0.34 to 5.94	0.628	1.39	0.33 to 5.78	0.654
Other hybrid (n=1340)	2.87	0.85 to 9.65	0.088	2.78	0.83 to 9.35	0.098
Best cementless (n=454)	1.47	0.30 to 7.24	0.638	1.50	0.30 to 7.38	0.621
Other cementless (n=4880)	3.45	1.10 to 10.9	0.034	3.35	1.06 to 10.6	0.040
Best resurfacing (n=432)	5.12	1.50 to 17.5	0.009	4.95	1.45 to 16.9	0.011
Other resurfacing (n=2914)	6.57	2.09 to 20.6	0.001	6.36	2.02 to 30.0	0.002
Males (n=13087)						
Best cemented (n=337)	1			1		
Other cemented (n=255)	0.78	0.17 to 3.46	0.741	0.77	0.17 to 3.45	0.738
Best hybrid (n=498)	0.48	0.11 to 2.16	0.342	0.48	0.11 to 2.16	0.342
Other hybrid (n=758)	1.40	0.45 to 4.35	0.558	1.34	0.43 to 4.17	0.608
Best cementless (n=466)	0.62	0.14 to 2.79	0.537	0.62	0.14 to 2.78	0.534
Other cementless (n=3717)	1.51	0.55 to 4.18	0.425	1.46	0.53 to 4.05	0.464
Best resurfacing (n=6247)	1.01	0.37 to 2.76	0.977	1.02	0.37 to 2.78	0.973
Other resurfacing (n=809)	2.08	0.72 to 6.00	0.175	2.06	0.71 to 5.97	0.272

HR – hazard ratio, CI – confidence intervals

Table 3.4.6. Patient reported outcome change scores following hip replacement in female patients aged under 60 years (simple and multivariable analyses)

	Simple			Multivariable		
	Value	95% CI	P value	Value	95% CI	P value
Change in OHS (n=1129)						
Best cemented (n=70)	18.0	15.6 to 20.4	Reference	18.2	16.1 to 20.3	Reference
Other cemented (n=37)	22.2	18.8 to 25.5	0.051	21.7	18.8 to 24.6	0.052
Best hybrid (n=73)	21.2	18.8 to 23.6	0.065	22.3	20.2 to 24.3	0.006
Other hybrid (n=147)	22.2	20.5 to 23.9	0.006	21.9	20.4 to 23.3	0.005
Best cementless (n=82)	23.1	20.8 to 25.3	0.003	21.3	19.4 to 23.3	0.031
Other cementless (n=671)	22.1	21.3 to 22.9	0.002	22.2	21.6 to 22.9	<0.001
Best resurfacing (n=8)	29.4	22.2 to 36.5	0.003	26.6	20.2 to 33.0	0.014
Other resurfacing (n=41)	22.0	18.8 to 25.2	0.053	21.0	18.1 to 24.0	0.126
Change in EQ5D index (n=1129)						
Best cemented (n=70)	0.367	0.280 to 0.453	Reference	0.407	0.347 to 0.466	Reference
Other cemented (n=37)	0.458	0.334 to 0.581	0.237	0.432	0.348 to 0.517	0.625
Best hybrid (n=73)	0.462	0.375 to 0.548	0.127	0.486	0.428 to 0.545	0.062
Other hybrid (n=147)	0.462	0.401 to 0.523	0.076	0.453	0.411 to 0.495	0.209
Best cementless (n=82)	0.453	0.372 to 0.535	0.154	0.430	0.372 to 0.487	0.581
Other cementless (n=671)	0.440	0.412 to 0.468	0.114	0.438	0.418 to 0.457	0.327
Best resurfacing (n=8)	0.623	0.377 to 0.870	0.054	0.517	0.338 to 0.696	0.249
Other resurfacing (n=41)	0.454	0.341 to 0.567	0.229	0.421	0.338 to 0.503	0.782

OHS – Oxford Hip Score, CI – confidence intervals

Table 3.4.7. Patient reported outcome scores following hip replacement in male patients aged under 60 years (simple and multivariable analyses)

	Simple			Multivariable		
	Value	95% CI	P value	Value	95% CI	P value
Change in OHS (n=885)						
Best cemented (n=41)	18.4	15.4 to 21.4	Reference	20.1	17.6 to 22.7	Reference
Other cemented (n=15)	17.9	12.9 to 22.9	0.848	17.9	13.7 to 22.1	0.368
Best hybrid (n=45)	21.0	18.1 to 23.8	0.238	21.0	18.5 to 23.4	0.643
Other hybrid (n=66)	21.6	19.2 to 24.0	0.112	20.8	18.8 to 22.8	0.682
Best cementless (n=77)	20.4	18.2 to 22.6	0.294	19.8	17.9 to 21.6	0.829
Other cementless (n=446)	20.9	19.9 to 21.7	0.139	20.3	19.6 to 21.1	0.882
Best resurfacing (n=179)	19.7	18.3 to 21.2	0.450	20.8	19.5 to 22.1	0.649
Other resurfacing (n=16)	18.4	13.6 to 23.3	1.000	20.0	15.8 to 24.2	0.954
Change in EQ5D index (n=885)						
Best cemented (n=41)	0.368	0.262 to 0.475	Reference	0.392	0.318 to 0.467	Reference
Other cemented (n=15)	0.397	0.219 to 0.574	0.786	0.336	0.212 to 0.459	0.437
Best hybrid (n=45)	0.255	0.157 to 0.354	0.127	0.325	0.255 to 0.394	0.192
Other hybrid (n=66)	0.419	0.340 to 0.498	0.454	0.413	0.357 to 0.469	0.675
Best cementless (n=77)	0.395	0.320 to 0.470	0.686	0.388	0.335 to 0.442	0.919
Other cementless (n=446)	0.410	0.379 to 0.441	0.463	0.396	0.374 to 0.417	0.946
Best resurfacing (n=179)	0.370	0.321 to 0.419	0.976	0.398	0.361 to 0.435	0.902
Other resurfacing (n=16)	0.307	0.142 to 0.472	0.541	0.357	0.238 to 0.476	0.615

OHS – Oxford Hip Score

Table 3.4.8. Variables included in the competing risks survival model

	Females		Males	
	Simple	Multivariable	Simple	Multivariable
Age	<0.001	0.074	0.249	0.235
ASA grade	0.918	0.082	0.107	0.045
BMI	0.445	-	0.024	(0.082)*
Hip type	<0.001	<0.001	0.197	0.167
Approach	0.176	-	0.051	-
Surgeon grade	0.586	-	0.933	-
Surgeon volume	0.651	-	0.453	
Anaesthesia type	0.314	-	0.282	-
Mechanical VTE prophylaxis	0.721	-	0.016	-
Chemical VTE prophylaxis	0.654	-	0.745	-

BMI – body mass index

* - BMI data available for only 4781 procedures (37%) therefore excluded from the model. Results in appendix table 3 show similar results for models with and without BMI.

Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction led to the same final models. BMI was selected as a variable within the competing risks survival model for males. However this approach excluded 63% of data. BMI was therefore excluded and the model was constructed with age and ASA group. The output from these models (simple and multivariable with either BMI or age and ASA group included) is shown in **Table 3.4.8**. Variables included in the statistical models, and their significance levels within the final models, are shown in **Tables 3.4.9, 3.4.10**.

Table 3.4.9. Competing risks survival modeling of hip type using different variable sets, in male patients

	Simple (HR, 95% CI)	Multivariable (BMI included, HR, 95% CI)	Multivariable (BMI excluded, ASA/age included, HR 95% CI)
Best cemented	1	1	1
Other cemented	0.78 (0.17 to 3.46, p=0.741)	-	0.77 (0.17 to 3.45, p=0.738)
Best hybrid	0.48 (0.11 to 2.16, p=0.342)	-	0.48 (0.11 to 2.16, p=0.342)
Other hybrid	1.40 (0.45 to 4.35, p=0.558)	1.16 (0.23 to 5.74, p=0.853)	1.34 (0.43 to 4.17, p=0.608)
Best cementless	0.62 (0.14 to 2.79, p=0.537)	0.31 (0.03 to 3.45, p=0.340)	0.62 (0.14 to 2.78, p=0.534)
Other cementless	1.51 (0.55 to 4.18, p=0.425)	1.00 (0.23 to 4.25, p=0.995)	1.46 (0.53 to 4.05, p=0.464)
Best resurfacing	1.01 (0.37 to 2.76, p=0.977)	0.67 (0.16 to 2.77, p=0.569)	1.02 (0.37 to 2.78, p=0.973)
Other resurfacing	2.08 (0.72 to 6.00, p=0.175)	1.91 (0.41 to 8.86, p=0.408)	2.06 (0.71 to 5.97, p=0.272)

HR – hazard ratio, CI – confidence intervals, BMI – body mass index
* BMI data available for 4781 implants (37%)

Table 3.4.10. Variables included in the change score analysis of covariance models

	Oxford hip score change		EQ5D index change	
	Females	Males	Females	Males
Hip type	0.005	0.774	0.724	0.337
Age	-	-	-	-
Approach	0.024	-	-	-
Preoperative Oxford hip score	<0.001	<0.001	-	0.001
ASA group	-	0.002	-	0.005
Preoperative EQ5D index	-	-	<0.001	<0.001
Preoperative general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	0.001	0.001	0.001	0.001
Circulatory problems	-	0.001	-	<0.001
History of depression	<0.001	-	<0.001	0.015
BMI	-	-	-	-
History of heart disease	<0.001	0.014	0.005	-
Time from op to PROMs completion	-	-	-	-
Goodness of fit of model (adjusted R^2)	33%	32%	60%	52%

BMI – body mass index.

Summary

No advantage was identified in using resurfacing, fully cementless or hybrid implants instead of standard cemented hip replacement in male patients under 60 years. For females, functional outcome may be modestly better with hybrid and cementless implants. However, the number of patients contributing to the analyses is relatively small and may be underpowered to detect differences. Although revision risk was similar to cemented for the best cementless and hybrid implants, risk was 3.5 times higher with the more commonly used hard-bearing cementless implants.

Traditional hip replacement population (60 years+ at time of surgery)

The majority of *hip replacements are performed in patients over 60 years (80%) in England and Wales. Patients require a stable, well functioning, pain-free hip. Lower functional demand enhances longevity of the implant. In most patients in this age group the implant will outlast the patient. Different types of replacement were compared to identify optimal combinations for the older hip replacement population, employing the most commonly used cemented hip replacement with the best performing component configuration as the reference case. Implant survival, functional outcome, complications, early mortality and costs are compared.*

As before, the best performing component sets (in terms of implant survival) from each of the commonent brands of cemented, cementless, hybrid and resurfacing implants were analysed, together with the remaining 'other' configurations from each group, providing eight groups for comparison (**Table 3.4.11**).

Table 3.4.11. Breakdown of implant types included in the young patient population

Type	Total	Best		Other	
	N (%)	Details	N (%)	Details	N (%)
Cemented	33 488 (41.9)	>28mm head and flanged cup	19 815 (24.8)	All hooded cups or all with head sizes <28mm	13 673 (17.1)
Hybrid	12 156 (15.2)	MoXLPE or CoXLPE or CoC and solids shell cups	2388 (3.0)	All multi-hole shells or standard polyethylene bearings	9768 (12.2)
Cementless	29 593 (37.1)	Stem sizes >10 and MoP or CoP bearings	9867 (12.4)	All small stems (<10) or CoC or COM or MoM	19 726 (24.7)
Resurfacing	4538 (5.8)	≥48mm head size	3317 (4.2)	<48mm head size	1221 (1.5)
Total	*79 775*		*35 387*		*44 388*

MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC – ceramic-on-ceramic, CoM – ceramic-on-metal, MoM – metal-on-metal, MoXLPE – metal-on-highly cross-linked polyethylene, CoXLPE – ceramic-on-highly cross-linked polyethylene

There were 79 775 procedures available for analysis within the NJR dataset. Significant baseline differences were seen in age, ASA grade, proportions of females and BMI across the groups (**Table 3.4.12**). Linkage of PROMs and NJR datasets was possible in 9159 procedures. The demographics across hip types for the linked procedures were qualitatively similar to the NJR population (**Table 3.4.13**). Unadjusted pre-operative OHS and EQ5D index scores were clinically similar across the total hip replacement groups, but higher in the resurfacing groups (**Table 3.4.14**). Post-operative scores were lowest in the 'other' cemented group and highest after any resurfacing. Unadjusted levels of satisfaction (88 to 100%) and success (92 to 100%) after the procedure were very high; similar rates were found across types in both males and females, although there were statistically significant differences in satisfaction across types in females.

Table 3.4.12. Patient demographics for National Joint Registry population studied, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		Differences
	Best	*Others*	*Best*	*Others*	*Best*	*Others*	*Best*	*Others*	
Number (%)	19815 (24.8)	13673 (17.1)	2388 (3.0)	9768 (12.2)	9867 (12.4)	19726 (24.7)	3317 (4.2)	1221 (1.5)	
Age, median years (range)	74.8 (60 to 100)	74.8 (60 to 97)	67.6 (60 to 97)	71.7 (60 to 103)	72.2 (60 to 98)	68.7 (60 to 106)	63.8 (60 to 89)	63.3 (60 to 88)	p<0.001
Females	12788 (64.5)	9163 (67.0)	1238 (51.8)	6142 (62.9)	5303 (53.7)	11559 (58.6)	166 (5.0)	872 (71.4)	p<0.001
ASA									
1	2461 (12.4)	1822 (13.3)	508 (21.3)	1336 (13.7)	1219 (12.4)	2921 (14.8)	1343 (40.5)	542 (44.4)	p<0.001
2	13835 (69.8)	9496 (69.5)	1637 (68.6)	6888 (70.5)	7186 (72.8)	14280 (72.4)	1833 (55.3)	644 (52.7)	
3+	3519 (17.8)	2355 (17.2)	243 (10.2)	1544 (15.8)	1462 (14.8)	2525 (12.8)	141 (4.3)	35 (2.9)	
BMI, mean kg/m^2 (sd, range)	28.3 (5.0, 15 to 63)	27.9 (5.0, 15 to 65)	28.4 (5.1 16 to 56)	28.1 (5.1, 15 to 61)	28.4 (5.1, 15 to 64)	28.5 (5.2, 15 to 64)	27.8 (4.3, 18 to 64)	27.3 (4.2, 18 to 40)	p=0.015

ASA – American Society of Anesthesiologists, BMI – body mass index (data based on 34756 procedures [44%])
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Table 3.4.13. Patient demographics for National Joint Registry-PROMs linked population, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		Differences
	Best	*Others*	*Best*	*Others*	*Best*	*Others*	*Best*	*Others*	
Number (%)	2369 (25.9)	1133 (12.4)	300 (3.3)	1168 (12.8)	1582 (17.3)	2485 (27.2)	97 (1.1)	15 (0.2)	
Age, median years (range)	74.0 (60 to 93)	75.2 (60 to 94)	68.1 (60 to 91)	71.6 (60 to 93)	72.0 (60 to 95)	67.8 (60 to 96)	64.2 (60 to 75)	62.8 (60 to 67)	p<0.001
Females	1463 (61.8)	747 (65.9)	164 (54.7)	744 (63.7)	776 (49.1)	1425 (57.3)	1 (1.0)	13 (86.7)	p<0.001
ASA									
1	213 (9.0)	96 (8.5)	53 (17.7)	122 (10.5)	162 (10.2)	345 (13.9)	35 (36.1)	5 (33.3)	p<0.001
2	1709 (72.1)	829 (73.2)	217 (72.3)	888 (76.0)	1201 (75.9)	1897 (76.3)	59 (60.8)	10 (66.6)	
3+	447 (18.9)	208 (18.4)	30 (10.0)	158 (13.5)	219 (13.8)	243 (9.8)	3 (3.1)	0 (0)	
BMI, mean kg/m^2 (sd, range)	28.6 (5.0, 16 to 55)	28.1 (4.7, 15 to 46)	28.4 (4.6 17 to 44)	28.2 (4.8, 17 to 43)	28.5 (4.9, 16 to 56)	28.6 (5.2, 15 to 50)	28.0 (4.0, 20 to 38)	27.8 (2.9, 23 to 32)	p=0.679

PROMs – patient reported outcome measures, ASA – American Society of Anesthesiologists, BMI – body mass index (data based on 5843 procedures [64%])
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

Table 3.4.14. Patient reported outcomes for populations studied, by implant group and gender

	Cemented		Hybrid		Cementless		Resurfacing		p value
	Best	*Others*	*Best*	*Others*	*Best*	*Others*	*Best*	*Others*	
Females (n, %)	1463 (27.4)	747 (14.0)	164 (3.1)	744 (14.0)	776 (14.6)	1425 (26.7)	1 (0.0)	13 (0.2)	
Oxford Hip scores									
Pre-operative									
Mean (sd, range)	17.4 (8.0, 0 to 44)	16.8 (8.0, 0 to 42)	19.7 (7.8, 4 to 37)	18.3 (8.0, 1 to 38)	17.3 (7.7, 1 to 43)	18.5 (8.1, 0 to 44)	13	25.9 (4.5, 18 to 33)	<0.001
Post-operative									
Median (range)	40 (4 to 48)	38 (2 to 48)	43 (13 to 48)	42 (5 to 48)	42 (6 to 48)	42 (2 to 48)	48	46 (21 to 48)	<0.001
EQ5D index									
Pre-operative									
Mean (sd, range)	0.342 (0.31, -0.4 to 1)	0.319 (0.33, -0.5 to 1)	0.432 (0.30, -0.2 to 0.9)	0.356 (0.32, -0.6 to 1)	0.346 (0.32, -0.4 to 1)	0.366 (0.32, -0.6 to 1)	0.516	0.586 (0.19, 0.1 to 0.8)	0.008
Post-operative									
Median (range)	0.796 (-0.2 to 1)	0.760 (-0.2 to 1)	0.850 (-0.2 to 1)	0.814 (-0.2 to 1)	0.812 (-0.1 to 1)	0.796 (-0.3 to 1)	1	1 (0.5 to 1)	<0.001
Satisfaction									
Good to excellent	1332 (91.1)	658 (88.1)	151 (92.1)	703 (94.5)	730 (94.1)	1337 (93.8)	1 (100.0)	12 (92.3)	<0.001
Poor/fair	131 (9.0)	89 (11.9)	13 (7.9)	41 (5.5)	46 (5.9)	88 (6.2)	0	1 (7.7)	
Success									
Better	1394 (95.3)	700 (93.7)	158 (96.3)	716 (96.2)	745 (96.0)	1359 (95.4)	1 (100.0)	12 (92.3)	0.397
About the same or worse	69 (4.7)	47 (6.3)	6 (3.7)	28 (3.8)	31 (4.0)	66 (4.6)	0	1 (7.7)	
Time to post-op PROMs, mean days (sd, range)	209 (29, 183 to 358)	210 (29, 183 to 358)	210 (31, 184 to 360)	209 (29, 183 to 364)	207 (26, 185 to 357)	208 (28, 183 to 360)	193	259 (47, 192 to 316)	0.323
Males (n, %)	906 (23.7)	386 (10.1)	136 (3.6)	424 (11.1)	806 (21.1)	1060 (27.8)	96 (2.5)	2 (0.1)	
Oxford Hip scores									
Pre-operative									
Mean (sd,range)	19.8 (7.9, 0 to 44)	19.1 (8.1, 2 to 48)	22.1 (7.9, 4 to 41)	20.4 (8.5, 2 to 42)	19.9 (8.0, 2 to 42)	20.4 (8.3, 3 to 44)	25.7 (8.2, 4 to 43)	21.5 (0.7, 21 to 22)	0.001
Post-operative									
Median (range)	43 (7 to 48)	41 (12 to 48)	44 (14 to 48)	43 (11 to 48)	43 (2 to 48)	44 (1 to 48)	45 (13 to 48)	48	<0.001
EQ5D index									
Pre-operative									
Mean (sd, range)	0.425 (0.30, -0.3 to 1)	0.439 (0.29, -0.5 to 0.9)	0.439 (0.29, -0.1 to 0.8)	0.422 (0.30, -0.4 to 1)	0.418 (0.30, -0.4 to 1)	0.425 (0.31, -0.4 to 1)	0.551 (0.25, -0.2 to 81)	0.516	0.016
Post-operative									
Median (range)	0.814 (-0.2 to 1)	0.814 (-0.2 to 1)	0.883 (0.9 to 1)	1 (-0.2 to 1)	0.850 (-0.2 to 1)	0.883 (-0.6 to 1)	1 (0.0 to 1)	1	<0.001
Satisfaction									
Good to excellent	853 (94.2)	362 (93.8)	128 (94.1)	396 (93.4)	766 (95.0)	1002 (94.5)	91 (94.8)	2 (100.0)	0.962
Poor/fair	53 (5.9)	24 (6.2)	8 (5.9)	28 (6.6)	40 (5.0)	58 (5.5)	5 (5.2)	0	
Success									
Better	876 (96.7)	370 (95.9)	129 (94.9)	408 (96.2)	785 (97.4)	1020 (96.2)	93 (96.9)	2 (100.0)	0.777
About the same or worse	30 (3.3)	16 (4.2)	7 (5.2)	16 (3.8)	21 (2.6)	40 (3.8)	3 (3.1)	0 (0)	
Time to post-op PROMs, mean days (sd, range)	208 (29, 183 to 363)	208 (27, 183 to 355)	209 (27, 183 to 336)	205 (22, 184 to 355)	208 (29, 183 to 363)	207 (28, 183 to 362)	272 (44, 184 to 336)	196 (4, 193 to 198)	0.192

SD – standard deviation, PROMs – patient reported outcome measures
Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

In females (47 231), when compared to the reference hip, the following had significantly higher revision risks: 'other' cemented (HR=1.85, p<0.001), 'other' hybrid (HR=1.68, p=0.012), best cementless (HR=2.22, p<0.001), 'other' cementless (HR=3.60, p<0.001), and 'other' resurfacing (HR=8.74, 95% CI 5.81 to 13.2, p<0.001). Best hybrid and best resurfacing had equivalent survival, but confidence intervals were wide for the resurfacings (**Table 3.4.15, Figure 3.4.3**).

Table 3.4.15. Risk of revision following hip replacement in patients aged 60 years and over (simple and multivariable analyses)

	Simple			Multivariable		
	HR	95% CI	P value	HR	95% CI	P value
Females (n=47231)						
Best cemented (n=12788)	1			1		
Others cemented (n=9163)	1.77	1.28 to 2.44	0.001	1.85	1.31 to 2.61	<0.001
Best hybrid (n=1238)	1.30	0.60 to 2.85	0.507	1.26	0.56 to 2.81	0.578
Others hybrid (n=6142)	1.73	1.19 to 2.52	0.004	1.68	1.12 to 2.52	0.012
Best cementless (n=5303)	2.15	1.47 to 3.14	<0.001	2.22	1.48 to 3.34	<0.001
Others cementless (n=11559)	3.62	2.70 to 4.85	<0.001	3.60	2.63 to 4.94	<0.001
Best resurfacing (n=166)	1.98	0.49 to 8.07	0.339	2.31	0.57 to 9.41	0.244
Others resurfacing (n=872)	7.66	5.21 to 11.3	<0.001	8.74	5.81 to 13.2	<0.001
Males (n=32544)						
Best cemented (n=7027)	1			1		
Others cemented (n=4510)	2.03	1.36 to 3.04	0.001	2.09	1.37 to 3.18	0.001
Best hybrid (n=1150)	0.94	0.40 to 2.21	0.882	0.68	0.26 to 1.76	0.425
Others hybrid (n=3626)	1.47	0.92 to 2.37	0.108	1.28	0.78 to 2.11	0.327
Best cementless (n=4564)	2.08	1.36 to 3.16	0.001	1.95	1.25 to 3.05	0.003
Others cementless (n=8167)	2.79	1.95 to 3.98	<0.001	2.53	1.74 to 3.68	<0.001
Best resurfacing (n=3151)	3.30	2.23 to 4.88	<0.001	3.46	2.28 to 5.26	<0.001
Others resurfacing (n=349)	6.13	3.37 to 11.2	<0.001	6.21	3.36 to 11.5	<0.001

HR – hazard ratio, CI – confidence interval

In males (32544), all implants except the hybrids had significantly higher revision risk: 'other' cemented (HR=2.09, p=0.001), best cementless (HR=1.95, p=0.003), 'other' cementless (HR=2.53, p<0.001), best resurfacing (HR=3.46, p<0.001) and others resurfacing (HR=6.21, p<0.001) (**Table 3.4.15, Figure 3.4.4**).

Figure 3.4.3. Estimated cumulative incidence of revision by hip type for female patients over 60 years (modelled with American Society of Anaesthesiologists grade 1 and low molecular weight heparin prophylaxis)

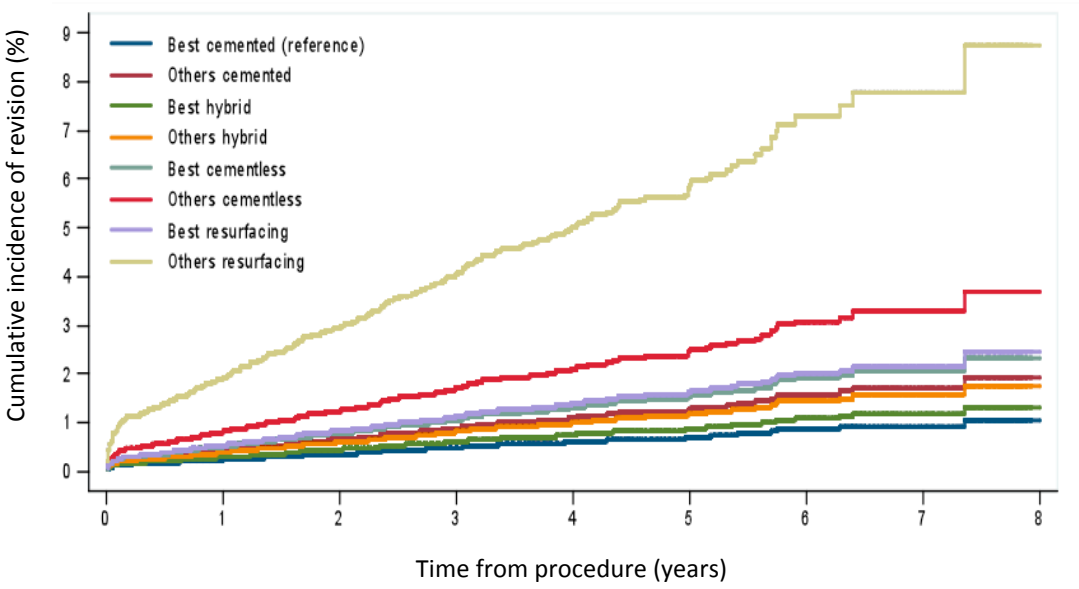
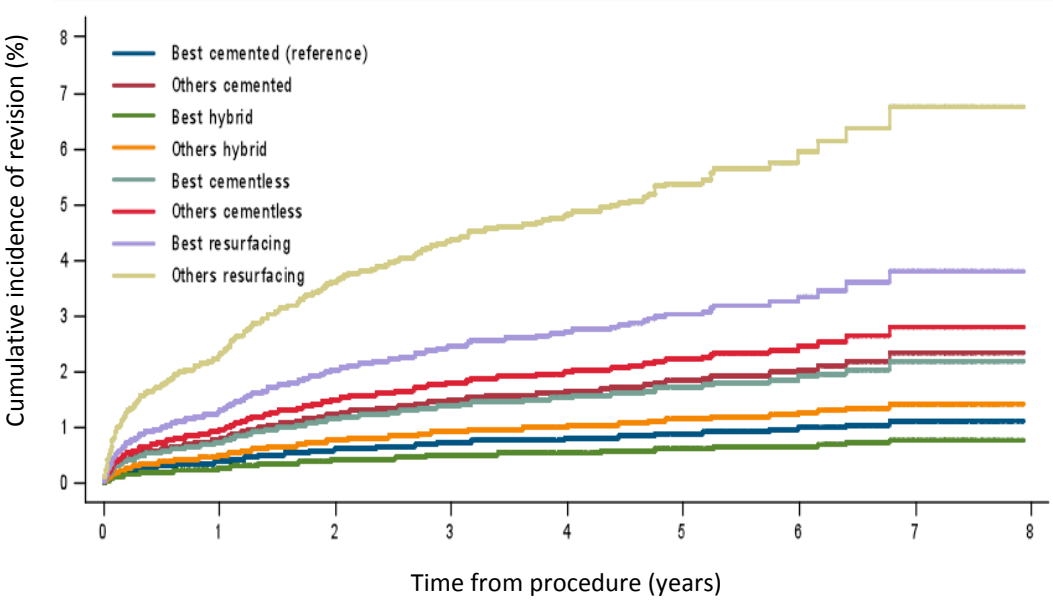


Figure 3.4.4. Estimated cumulative incidence of revision by hip type for male patients over 60 years (modelled with regional anaesthesia and low molecular weight heparin prophylaxis)



In females OHS change was significantly higher (20.5 versus 22.1, p<0.001) in the best cementless group when compared with the reference implant. No other implant combination had a significantly better OHS improvement. There were no significant OHS improvement benefits across the implant types in males. No implant combination displayed an EQ5D index improvement significantly greater than the reference in either sex (**Table 3.4.16**).

Table 3.4.16. Patient reported outcome scores following hip replacement in patients aged 60 years and over (simple and multivariable analyses)

	Simple			Multivariable		
	Value	95% CI	P value	Value	95% CI	P value
Females (n=5333)						
Change in OHS						
Best cemented (n=1463)	20.2	19.7 to 20.7	Reference	20.5	20.1 to 21.0	Reference
Others cemented (n=747)	19.2	18.4 to 19.9	0.029	19.7	19.0 to 20.5	0.075
Best hybrid (n=164)	20.4	18.9 to 21.9	0.773	21.7	20.0 to 23.4	0.207
Others hybrid (n=744)	20.7	20.0 to 21.4	0.227	20.9	20.1 to 21.6	0.463
Best cementless (n=776)	21.9	21.2 to 22.6	<0.001	22.1	21.3 to 22.8	<0.001
Others cementless (n=1425)	20.7	20.2 to 21.2	0.169	21.0	20.4 to 21.5	0.270
Change in EQ5D index						
Best cemented (n=1463)	0.421	0.402 to 0.439	Reference	0.426	0.414 to 0.439	Reference
Others cemented (n=747)	0.429	0.403 to 0.454	0.619	0.418	0.398 to 0.439	0.502
Best hybrid (n=164)	0.373	0.320 to 0.427	0.103	0.452	0.404 to 0.499	0.312
Others hybrid (n=744)	0.433	0.408 to 0.459	0.421	0.436	0.416 to 0.457	0.430
Best cementless (n=776)	0.446	0.421 to 0.471	0.100	0.447	0.427 to 0.467	0.086
Others cementless (n=1425)	0.417	0.398 to 0.435	0.765	0.420	0.404 to 0.435	0.182
Males (n=3826)						
Change in OHS						
Best cemented (n=906)	20.1	19.5 to 20.7	Reference	20.3	19.7 to 20.9	Reference
Others cemented (n=386)	20.4	19.5 to 21.4	0.553	19.9	18.9 to 20.9	0.521
Best hybrid (n=136)	20.0	18.3 to 21.6	0.882	18.9	17.2 to 20.6	0.140
Others hybrid (n=424)	20.5	19.6 to 21.4	0.488	20.6	19.7 to 21.5	0.603
Best cementless (n=806)	20.7	20.0 to 21.3	0.222	20.6	19.9 to 21.3	0.521
Others cementless (n=1060)	20.2	19.6 to 20.8	0.820	19.8	19.1 to 20.5	0.295
Best resurfacing (n=96)	17.1	15.2 to 19.0	0.004	19.1	17.2 to 21.1	0.282
Change in EQ5D index						
Best cemented (n=906)	0.379	0.357 to 0.401	Reference	0.390	0.374 to 0.407	Reference
Others cemented (n=386)	0.417	0.384 to 0.450	0.060	0.391	0.364 to 0.418	0.988
Best hybrid (n=136)	0.377	0.322 to 0.432	0.941	0.364	0.316 to 0.411	0.302
Others hybrid (n=424)	0.419	0.387 to 0.450	0.044	0.415	0.389 to 0.441	0.121
Best cementless (n=806)	0.395	0.371 to 0.418	0.345	0.401	0.381 to 0.421	0.428
Others cementless (n=1060)	0.390	0.370 to 0.410	0.482	0.358	0.340 to 0.377	0.011
Best resurfacing (n=96)	0.340	0.273 to 0.406	0.270	0.398	0.343 to 0.453	0.790

OHS – Oxford Hip Score, CI – confidence interval

Note: No predicted values are available for resurfacings in females (14 PROMs available only) and others resurfacing in males (2 PROMs only)

Table 3.4.17. Risk of perioperative mortality following hip replacement in patients aged 60 years and over (simple and multivariable analyses)

		Simple			Multivariable		
	Number (%)	OR	95% CI	P value	OR	95% CI	P value
Females (n=47231)							
30-day							
Best cemented (n=12788)	25 (0.20)	1			1		
Others cemented (n=9163)	17 (0.19)	0.94	0.51 to 1.76	0.868	0.96	0.52 to 1.78	0.902
Best hybrid (n=1238)	2 (0.16)	0.83	0.20 to 3.50	0.795	1.42	0.33 to 6.04	0.635
Others hybrid (n=6142)	10 (0.16)	0.83	0.40 to 1.73	0.625	1.06	0.51 to 2.21	0.877
Best cementless (n=5303)	6 (0.11)	0.58	0.24 to 1.41	0.229	0.73	0.30 to 1.79	0.492
Others cementless (n=11559)	12 (0.10)	0.53	0.27 to 1.06	0.071	0.90	0.45 to 1.82	0.778
Best resurfacing (n=166)	0	-					
Others resurfacing (n=872)	1 (0.11)	0.59	0.08 to 4.33	0.601	2.62	0.33 to 20.5	0.359
90-day							
Best cemented (n=12788)	60 (0.47)	1			1		
Others cemented (n=9163)	45 (0.49)	1.05	0.71 to 1.54	0.816	1.07	0.72 to 1.57	0.746
Best hybrid (n=1238)	3 (0.24)	0.52	0.16 to 1.65	0.263	0.88	0.27 to 2.81	0.824
Others hybrid (n=6142)	20 (0.33)	0.69	0.42 to 1.15	0.156	0.87	0.52 to 1.44	0.583
Best cementless (n=5303)	12 (0.23)	0.48	0.26 to 0.89	0.021	0.60	0.32 to 1.13	0.112
Others cementless (n=11559)	25 (0.22)	0.46	0.29 to 0.73	0.001	0.79	0.49 to 1.27	0.325
Best resurfacing (n=166)	0	-					
Others resurfacing (n=872)	1 (0.11)	0.24	0.03 to 1.76	0.162	1.08	0.14 to 8.03	0.943
Males (n=32544)							
30-day							
Best cemented (n=7027)	37 (0.53)	1			1		
Others cemented (n=4510)	35 (0.78)	1.48	0.93 to 2.35	0.099	1.46	0.89 to 2.39	0.130
Best hybrid (n=1150)	5 (0.43)	0.82	0.32 to 2.10	0.687	1.28	0.44 to 3.73	0.650
Others hybrid (n=3626)	13 (0.36)	0.68	0.36 to 1.28	0.232	0.75	0.38 to 1.50	0.424
Best cementless (n=4564)	14 (0.31)	0.58	0.31 to 1.08	0.084	0.89	0.47 to 1.68	0.718
Others cementless (n=8167)	24 (0.29)	0.56	0.33 to 0.93	0.026	0.88	0.50 to 1.56	0.664
Best resurfacing (n=3151)	1 (0.03)	0.06	0.01 to 0.44	0.006	0.21	0.03 to 1.56	0.126
Others resurfacing (n=349)	1 (0.29)	0.54	0.07 to 3.97	0.547	2.05	0.27 to 15.5	0.489
90-day							
Best cemented (n=7027)	57 (0.81)	1			1		
Others cemented (n=4510)	51 (1.13)	1.39	0.96 to 2.04	0.083	1.39	0.84 to 2.32	0.090
Best hybrid (n=1150)	6 (0.52)	0.64	0.28 to 1.49	0.302	1.17	0.44 to 4.17	0.711
Others hybrid (n=3626)	22 (0.61)	0.75	0.46 to 1.22	0.246	0.89	0.44 to 1.73	0.632
Best cementless (n=4564)	18 (0.39)	0.48	0.28 to 0.82	0.007	0.59	0.32 to 1.31	0.050
Others cementless (n=8167)	44 (0.54)	0.66	0.45 to 0.98	0.041	1.07	0.67 to 1.99	0.735
Best resurfacing (n=3151)	2 (0.06)	0.08	0.02 to 0.32	<0.001	0.26	0.05 to 2.01	0.064
Others resurfacing (n=349)	1 (0.29)	0.35	0.05 to 2.54	0.301	1.23	0.10 to 19.44	0.840

OR – odds ratio, CI – confidence interval

There were no significant differences across the groups in either sex for mortality at 30 or 90 days, with 30-day mortality ranging from 0% to 0.78% and 90-day mortality ranging from 0% to 1.13% (**Table 3.4.17**). However, risk of mortality at 90 days in males approached the significance threshold in the best cementless and resurfacing groups, suggesting that with greater numbers or at a later time point significant differences may be seen. There were no significant differences in wound complications, readmission or further surgery (**Table 3.4.18**).

Table 3.4.18. Risk of complication following hip replacement in patients aged 60 years and over (simple and multivariable analyses)

		Simple			Multivariable		
	Number (%)	OR	95% CI	P value	OR	95% CI	P value
Females (n=5333)							
Wound complications							
Best cemented (n=1463)	154 (10.5)	1			1		
Others cemented (n=747)	82 (11.0)	1.05	0.79 to 1.39	0.745	1.08	0.76 to 2.53	0.666
Best hybrid (n=164)	17 (10.4)	0.98	0.58 to 1.67	0.949	1.17	0.57 to 2.41	0.674
Others hybrid (n=744)	70 (9.4)	0.88	0.66 to 1.19	0.411	1.05	0.72 to 1.53	0.804
Best cementless (n=776)	66 (8.5)	0.79	0.58 to 1.07	0.127	0.66	0.44 to 1.01	0.054
Others cementless (n=1425)	136 (9.5)	0.90	0.70 to 1.14	0.380	0.99	0.73 to 1.34	0.949
Readmission							
Best cemented (n=1463)	92 (6.3)	1			1		
Others cemented (n=747)	67 (8.9)	1.47	1.06 to 2.04	0.022	1.67	1.11 to 2.51	0.013
Best hybrid (n=164)	8 (4.9)	0.76	0.36 to 1.60	0.477	1.76	0.23 to 2.50	0.651
Others hybrid (n=744)	47 (6.3)	1.00	0.70 to 1.44	0.979	1.24	0.77 to 2.00	0.379
Best cementless (n=776)	56 (7.2)	1.16	0.82 to 1.64	0.401	1.25	0.79 to 1.98	0.340
Others cementless (n=1425)	82 (5.8)	0.91	0.67 to 1.24	0.547	1.18	0.78 to 1.78	0.423
Reoperation							
Best cemented (n=1463)	29 (2.0)	1			1		
Others cemented (n=747)	20 (2.7)	1.36	0.76 to 2.42	0.296	1.22	0.67 to 2.22	0.522
Best hybrid (n=164)	3 (1.8)	0.92	0.28 to 3.06	0.894	0.99	0.29 to 3.31	0.982
Others hybrid (n=744)	15 (2.0)	1.02	0.54 to 1.91	0.957	0.95	0.50 to 1.82	0.879
Best cementless (n=776)	6 (0.8)	0.39	0.16 to 0.93	0.034	0.46	0.16 to 1.35	0.156
Others cementless (n=1425)	27 (1.9)	0.96	0.56 to 1.62	0.865	0.83	0.47 to 1.46	0.519
Males (n=3826)							
Wound complications							
Best cemented (n=906)	57 (6.3)	1			1		
Others cemented (n=386)	26 (6.7)	1.08	0.67 to 1.74	0.766	1.61	0.87 to 2.99	0.130
Best hybrid (n=136)	13 (9.6)	1.57	0.84 to 2.96	0.159	2.96	1.38 to 6.36	0.005
Others hybrid (n=424)	24 (5.7)	0.89	0.55 to 1.46	0.654	1.23	0.66 to 2.31	0.516
Best cementless (n=806)	50 (6.2)	0.99	0.67 to 1.46	0.940	1.19	0.70 to 2.05	0.517
Others cementless (n=1060)	84 (7.9)	1.28	0.90 to 1.82	0.163	1.31	0.79 to 2.16	0.297
Best resurfacing (n=96)	7 (7.3)	1.17	0.52 to 2.65	0.703	1.13	0.33 to 3.84	0.843
Readmission							
Best cemented (n=906)	88 (9.7)	1			1		
Others cemented (n=386)	32 (8.3)	0.84	0.55 to 1.28	0.420	0.97	0.57 to 1.63	0.894
Best hybrid (n=136)	14 (4.5)	1.07	0.59 to 1.93	0.832	0.74	0.29 to 1.93	0.542
Best cementless (n=806)	69 (8.6)	0.87	0.63 to 1.21	0.410	0.82	0.53 to 1.27	0.381
Others cementless (n=1060)	68 (6.4)	0.64	0.46 to 0.87	0.007	0.77	0.50 to 1.19	0.238
Best resurfacing (n=96)	4 (4.2)	0.40	0.15 to 1.13	0.083	0.60	0.18 to 2.03	0.411
Reoperation							
Best cemented (n=906)	21 (2.3)	1			1		
Others cemented (n=386)	6 (1.6)	0.67	0.27 to 1.66	0.383	0.85	0.31 to 2.34	0.749
Best hybrid (n=136)	5 (3.7)	1.61	0.59 to 4.34	0.348	1.34	0.37 to 4.83	0.658
Others hybrid (n=424)	6 (1.4)	0.60	0.24 to 1.51	0.281	0.55	0.18 to 1.68	0.297
Best cementless (n=806)	17 (2.1)	0.91	0.48 to 1.73	0.770	0.47	0.18 to 1.21	0.116
Others cementless (n=1060)	18 (1.7)	0.73	0.39 to 1.37	0.328	0.72	0.33 to 1.56	0.409
Best resurfacing (n=96)	1 (1.0)	0.44	0.06 to 3.33	0.430	1		-

OR – odds ratio, CI – confidence interval

Note: No predicted values are available for resurfacings in females (14 PROMs available only) and others resurfacing in males (2 PROMs only)

Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. BMI was selected as a variable within the competing risks survival model for males. However this approach excluded 63% of data. BMI was therefore excluded and the model was constructed with age and ASA group (**Table 3.4.19**). The output from these models (simple and multivariable with either BMI or age and ASA group included) is shown in **Table 3.4.20**.

Table 3.4.19. Variables included in the competing risks survival model

	Females		Males	
	Simple	Multivariable	Simple	Multivariable
Age	<0.001	-	0.001	-
ASA grade	0.371	0.046	0.868	-
BMI	0.003	(0.003)*	0.003	(0.036)*
Hip type	<0.001	<0.001	<0.001	<0.001
Approach	0.634	-	0.961	-
Surgeon grade	0.496	-	0.068	-
Surgeon volume	0.513	-	0.675	
Anaesthesia type	0.790	-	0.088	0.095
Mechanical VTE prophylaxis	0.376	-	0.019	-
Chemical VTE prophylaxis	0.044	0.024	0.012	0.007

ASA – America Society of Anaesthesiologists, BMI – body mass index. * - BMI data available for only 20708 (44%) females and 14048 (43%) males therefore excluded. VTE – venous thromboembolism. **Table 3.4.20** show similar results for models with/without BMI.

Table 3.4.20. Competing risks survival modelling of hip type using different variable sets

	Simple (HR, 95% CI)	BMI included (HR, 95% CI)	BMI excluded (HR, 95% CI)
Females			
Best cemented	1	1	1
Other cemented	1.77 (1.28 to 2.44, p=0.001)	2.48 (1.40 to 4.39, p=0.002)	1.85 (1.31 to 2.61, p<0.001)
Best hybrid	1.30 (0.60 to 2.85, p=0.507)	0.85 (0.19 to 3.74, p=0.831)	1.26 (0.56 to 2.81, p=0.578)
Other hybrid	1.73 (1.19 to 2.52, p=0.004)	1.58 (0.81 to 3.06, p=0.180)	1.68 (1.12 to 2.52, p=0.012)
Best cementless	2.15 (1.47 to 3.14, p<0.001)	1.68 (0.85 to 3.30, p=0.134)	2.22 (1.48 to 3.34, p<0.001)
Other cementless	3.62 (2.70 to 4.85, p<0.001)	3.56 (2.16 to 5.86, p<0.001)	3.60 (2.63 to 4.94, p<0.001)
Best resurfacing	1.98 (0.49 to 8.07, p=0.339)	3.77 (0.55 to 25.9, p=0.177)	2.31 (0.57 to 9.41, p=0.244)
Other resurfacing	7.66 (5.21 to 11.3, p<0.001)	9.21 (4.57 to 18.6, p<0.001)	8.74 (5.81 to 13.2, p<0.001)
Males			
Best cemented	1	1	1
Other cemented	2.03 (1.36 to 3.04, p=0.001)	1.24 (0.53 to 2.89, p=0.615)	2.09 (1.37 to 3.18, p=0.001)
Best hybrid	0.94 (0.40 to 2.21, p=0.882)	0.78 (0.22 to 2.80, p=0.704)	0.68 (0.26 to 1.76, p=0.425)
Other hybrid	1.47 (0.92 to 2.37, p=0.108)	1.02 (0.43 to 2.42, p=0.971)	1.28 (0.78 to 2.11, p=0.327)
Best cementless	2.08 (1.36 to 3.16, p=0.001)	1.77 (0.90 to 3.50, p=0.100)	1.95 (1.25 to 3.05, p=0.003)
Other cementless	2.79 (1.95 to 3.98, p<0.001)	2.29 (1.19 to 4.42, p=0.013)	2.53 (1.74 to 3.68, p<0.001)
Best resurfacing	3.30 (2.23 to 4.88, p<0.001)	2.81 (1.29 to 6.18, p=0.010)	3.46 (2.28 to 5.26, p<0.001)
Other resurfacing	6.13 (3.37 to 11.2, p<0.001)	7.36 (2.54 to 21.3, p<0.001)	6.21 (3.36 to 11.5, p<0.001)

HR – hazard ratio, CI – confidence intervals, BMI – body mass index. * BMI data available for 20708 of 47231 procedures in females (44%) and 14048 of 32544 procedures in males (43%)

Variables included in the statistical models, and their significance levels within the final models, are shown in **Tables 3.4.21** to **3.4.24**. The PROMs change score models had reasonable goodness of fit, with 40% to 42% of variation within the models explained by known variables in the OHS model and 61% to 63% in the EQ5D index model (**Table 3.4.21**).

Table 3.4.21. Variables included in the change score analysis of covariance models

	Oxford hip score change		EQ5D index change	
	BMI included	BMI excluded	BMI included	BMI excluded
Females				
Hip type	0.003	0.001	0.519	0.119
Age	<0.001	<0.001	0.039	0.036
BMI	<0.001	-	<0.001	-
Preoperative OHS	<0.001	<0.001	-	-
Preoperative EQ5D index	<0.001	<0.001	<0.001	<0.001
Preoperative general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	<0.001	<0.001	<0.001	0.001
Circulatory problems	<0.001	<0.001	<0.001	<0.001
History of depression	0.007	<0.001	<0.001	<0.001
History of heart disease	0.066	-	-	-
History of stroke	0.001	0.008	0.011	-
History of cancer	-	-	0.047	-
Approach	<0.001	<0.001	<0.001	<0.001
Surgeon grade	0.017	-	0.002	0.018
Time from op to PROMs completion	0.074	0.003	0.004	0.006
Goodness of fit of model, adjusted R^2 (number in model)	40% (3091)	37% (4804)	63% (2937)	60% (4585)
Males				
Hip type	0.901	0.270	0.372	0.651
Age	0.030	-	-	-
BMI	<0.001	-	0.061	-
Preoperative OHS	<0.001	<0.001	0.001	<0.001
Preoperative EQ5D index	-	-	<0.001	<0.001
Preoperative health scale	0.054	0.034	0.007	<0.001
Preoperative general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	<0.001	<0.001	<0.001	<0.001
Circulatory problems	<0.001	<0.001	<0.001	<0.001
History of depression	0.002	0.003	<0.001	<0.001
History of lung disease	0.050	-	-	-
History of stroke	0.016	0.035	0.047	0.041
Approach	0.002	0.002	0.002	0.036
Anaesthesia	0.037	0.045	0.034	0.078
ASA group	-	-	0.008	<0.001
Goodness of fit of model, adjusted R^2 (number in model)	42% (2130)	42% (3410)	61% (1999)	60% (3179)

BMI – body mass index, OHS – Oxford Hip Score, ASA – America Society of Anaesthesiologists

Table 3.4.22. Variables included in the complications multivariable logistic regression models

	Wound complications		Readmission		Reoperation	
	Females	Males	Females	Males	Females	Males
Hip type	0.499	0.619	0.638	0.230	0.122	0.089
Age	-	-	0.012	0.036	-	0.058
BMI	<0.001	0.001	0.045	0.001	-	0.044
ASA group	-	-	-	-	0.017	-
Preoperative Oxford hip score	-	-	0.001	-	-	-
Preoperative EQ5D index	-	-	-	0.065	0.001	-
Preoperative VAS	-	0.080	-	-	-	-
Preoperative general health	0.012	-	-	-	-	-
Preoperative disability	0.073	-	-	-	-	-
History of kidney disease	-	-	-	-	-	0.029
Diabetes	-	-	-	-	0.026	-
Circulatory problems	-	0.025	-	-	-	-
History of heart disease	-	-	-	-	0.052	0.069
History of depression	-	-	0.013	-	-	-
History of liver disease	-	-	-	0.069	-	-
History of stroke	-	-	0.034	-	-	-
Approach	<0.001	-	-	0.015	-	-
Surgeon grade	-	-	0.022	0.039	-	-
Chemical VTE prophylaxis	-	0.033	-	-	-	=
Time from operation to PROMs completion	-	-	0.009	-	-	-
Number in model	3441	2183	3421	2314	5035	2393

BMI – body mass index, ASA – America Society of Anaesthesiologists, VTE – venous thromboembolism

Table 3.4.23. Variables included in the perioperative mortality multivariable logistic regression models

	30-day mortality		90-day mortality	
	Females	Males	Females	Males
Hip type	0.784	0.081	0.094	0.088
Age	<0.001	<0.001	<0.001	<0.001
ASA group	-	<0.001	<0.001	<0.001
Chemical VTE prophylaxis	-	0.058	-	-

ASA – American Society of Anaesthesiologists grade, VTE – venous thromboembolic

Summary

For patients over 60 years, hip replacements performed using a cemented taper slip stem design, a cemented polyethylene cup and a standard sized head offered good outcomes, with the lowest risks. Poorer implant survival is demonstrated in resurfacing and cementless implants. No important functional benefit differences were found for any implant in men or women. Complication rates and perioperative mortality were similar across all groups.

Implant cost data

The cost of hip prostheses varies markedly. Modularity and newer technologies are costly. Implant list prices are difficult to ascertain, and manufacturers often offer discounts based on a unit's hip replacement volume. Cementless prostheses are the most commonly used type of hip implant used in England and Wales, Australia and North America, despite uncertain evidence of benefit. These are also perceived to be more costly, due to expensive surface coatings to encourage bony in-growth, and modularity to provide a range of sizing and bearings options. A cost-effective implant is one that offers equivalent or better survival and functional outcomes, at the lowest cost. Whilst the cost of providing a hip replacement includes hospital (theatre and ward) overheads and staffing costs in addition to the material costs, these are unlikely to vary according to type of implant. This section utilises actual implant costs incurred during 2012 in England and Wales.

Costing data showed the standard cemented replacement in this analysis (Exeter V40 femoral stem, stainless steel 28mm head, standard polyethylene Contemporary flanged cup) to be the cheapest (median and modal price £928, with a range from £899 to £1250). Resurfacing implants ranged from £1662 to £2472. A cementless 36mm ceramic-on-ceramic implant cost the NHS between £2063 and £3551. Cost data was obtained from units across England and Wales, including teaching and district general hospitals (**Figure 3.4.5**). A full breakdown of the costs of implants used in this analysis is provided in **Table 3.4.24**.

Figure 3.4.5. Chart showing geographical location of 37 NHS Trusts across England and Wales providing implant cost data

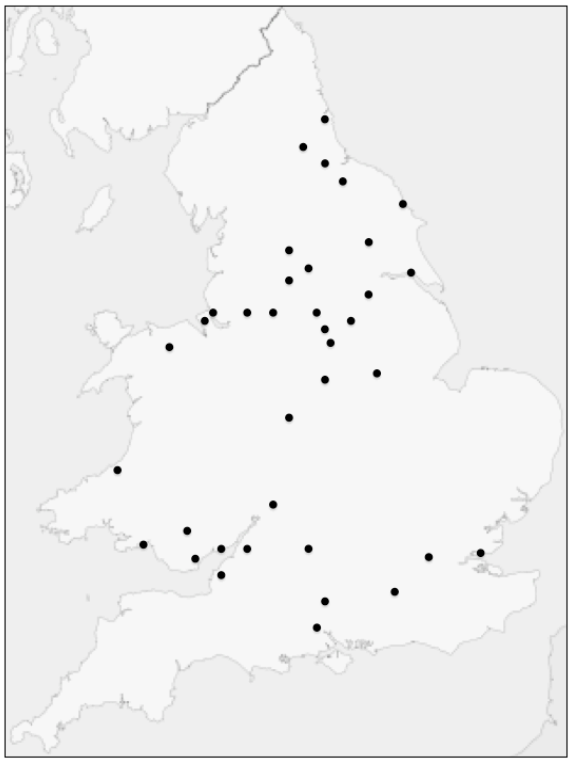


Table 3.4.24. Cost of specific hip implant combinations
(National Health Service costs 2011/12)

Implant description	Stem		Femoral head		Cup		Ancillary items*		Cost, mode and range (£)*
	Description (code)	Cost (£)	Description (code)	Cost (£)	Description (code)	Cost (£)	Description	Cost (£)	
CEMENTED Stryker Exeter V40 Contemporary									
Most commonly used 'best' component set Flanged cup / 28mm metal head	44/size 1 (05801441)	397.90 to 547.40	Stainless steel (Orthinox) V40 standard offset 28mm (6364212B)	145.00 to 257.60	Flanged cup (630448XX)	138.40 to 227.50	Heraeus Palacos R+Gentamycin antibiotic cement (4 mixes required)	26.75 /mix	**928.41** (898.88 to 1250.08)
Alternative 'best' Flanged cup / 32mm ceramic head	44/size 1	397.90 to 547.40	Ceramic (Alumina) V40 standard offset 32mm (6364013 2)	415.00 to 588.00	Flanged cup	138.40 to 227.50	DePuy Hardinge restrictor	22.00	**1343.41** (951.30 to 1580.48)
Most commonly used from 'others' Hooded cup/26mm head	44/ size 1	397.90 to 547.40	Stainless steel (Orthinox) standard offset 26mm (6364212B)	138.40 to 227.50	Hooded cup (630456XX)	138.40 to 227.50	Biomet Optivac vacuum mixing and delivery system (2 required)	44.29 /kit	**928.41** (898.88 to 1250.08)
HYBRID Stryker Exeter V40 Trident									
Most commonly used 'best' component set Solid shell/ 36mm CoC	44/ size 1	397.90 to 547.40	Ceramic (Alumina) V40 standard offset 36mm (6364013 6)	415.00 to 588.00	Ceramic 36mm liner (6430036X) plus PSL solid back shell (5401 1XXX)	415.00 to 717.50 & 432.40 to 646.10	Heraeus Palacos R+Gentamycin antibiotic cement (2 mixes required)	26.75 /mix	**1780.09** (1780.09 to 2618.79)
Alternative 'best' Solid shell/32mm MoXLP	44/ size 1	397.90 to 547.40	Cobalt-chrome (Vitallium) V40 standard offset 32mm (6260513 2)	145.00 to 271.60	X3 XLPE 32mm 10 deg liner (6231032X) plus PSL solid back shell (5401 1XXX)	345.14 to 506.80 & 432.40 to 646.10	DePuy Hardinge restrictor	22.00	**1465.00** (1440.23 to 2091.69)
							Biomet Optivac vacuum mixing and delivery system (1 required)	44.29	
Most commonly used from 'others' Multi-hole shell/28mm MoP	44/ size 1	397.90 to 547.40	Cobalt-chrome (Vitallium) V40 standard offset 28mm (6364012 8)	145.00 to 271.60	Conventional Polyethylene 28mm liner (6200028X) plus PSL 5-hole (5421 1XXX)	230.09 to 375.20 & 432.40 to 646.10	*As above, plus* 2 Stryker acetabular screws	40.00 to 51.10	**1405.18** (1405.18 to 2040.09)
RESURFACING Smith & Nephew Birmingham Hip Resurfacing									
Best Head size ≥48mm	-	-	BHR head (7412 1XX)	540.00 to 865.52	BHR cup (7412 01XX)	1050.00 to 1534.81	Stryker Antibiotic Simplex cement (1 mix required)	27.72	**1943.71** (1662.01 to 2472.34)
Others Head size <48mm	-	-	BHR head	540.00 to 865.52	BHR cup	1050.00 to 1534.81			**1943.71** (1662.01 to 2472.34)
CEMENTLESS DePuy Corail Pinnacle									
Most commonly used 'best' component set 28mm MoP	Size 11 KS (3192511)	642.85 to 1118	Metal standard offset 28mm (3651 1000)	130.53 to 227.00	Marathon 28mm PE neutral lipped liner (1219282XX) *plus* Sector cluster-hole Duofix (1217120XX)	252.43 to 439.00 & 510.03 to 887.00			**1586.94** (1586.94 to 2722.10)
Commonly used from 'others' 36mm MoM	Size 11 KS (3192511)	642.85 to 1118	Ultamet standard offset 36mm (3655 1000)	249.55 to 434.00	Metal liner (1218873XX) *plus* Sector cluster-hole Duofix	249.55 to 434.00 & 510.03 to 887.00	1 DePuy acetabular screw included	51.10	**1790.78** (1703.08 to 2924.10)
Commonly used from 'others' 36mm CoC	Size 11 KS (3192511)	642.85 to 1118	Ceramic 36mm standard offset (3653631 0)	431.25 to 750.00	Ceramic liner (1218817XX) *plus* Sector cluster-hole Duofix	428.38 to 745.00 & 510.03 to 887.00			**2209.95** (2063.61 to 3551.10)

Figures based on actual implant costs paid to manufacturers by NHS Wales (seven Trusts) and NHS Supply chain (30 Trusts in England), excluding Value Added Tax (20%) and NJR levy costs (£20). Note – Exeter stems 44/5, 44/6 and all 50 offsets increase cost by £614.27 (<5% Exeter stems – see part 1 results). CoC – ceramic-on-ceramic, MoXLP – metal-on-highly cross-linked polyethylene, MoP – metal-on polyethylene, MoM – metal-on-metal, PE – polyethylene

Summary

Material costs, approximating to NHS costs, were lowest with a standard cemented hip replacement and highest with hard bearing cementless implants.

Interpretation and Summary of evidence

Hip replacement is an essential and highly successful surgical procedure, improving general health and joint specific measures, with low revision and complication rates and high satisfaction. Analyses reported in this chapter provide comparative evidence to optimise these outcomes across a population, in the most cost-effective manner, and establish recommendations to inform healthcare provision.

Despite extensive use in England and Wales, cementless and resurfacing implants did not outperform the reference implant in any of the patient group analyses (**Tables 3.4.25 to 3.4.28**). In young females, the best hybrid and the best cementless implants had a significantly better OHS improvement than the reference implant, but this may be balanced by possibly greater revision risks (although this did not reach significance) and higher costs (**Table 3.4.25**). It must be noted that OHS change for the reference implant was low (18.2) compared to the improvements seen in the other group analyses (20.1, 20.3 and 20.5), suggesting this is erroneously low and may not be a robust finding. Additionally, there may be selection bias in this data resulting in young females in poorer health with greater disability receiving a cemented implant (due to the perception of poorer outcome compared with cementless implants), which may not be fully adjusted with known variables.

Table 3.4.25. Summary of young females hip replacement type comparison

	Cemented *Exeter Contemporary*		**Hybrid** *Exeter Trident*		**Cementless** *Corail Pinnacle*		**Resurfacing** *BHR*	
Outcomes	Best (reference)	Other	Best	Other	Best	Other	Best	Other
Revision (HR) (n=11622)	1	3.1	1.4	2.8	1.5	3.4	5.0	6.4
OHS change (n=1129)	18.2	+3.5	+4.1	+3.7	+3.1	+4.0	+8.6*	+2.8
EQ5D index change (n=1129)	0.407	+0.025	+0.079	+0.046	+0.023	+0.031	+0.110	+0.014
Relative costs	1	1	1.82	1.40	1.69	2.41	2.12	2.12

Significantly better compared with reference group

Significantly worse compared with reference group / higher cost

BHR – Birmingham Hip Resurfacing, HR – hazard ratio, OHS – Oxford Hip Score, significance p<0.05, * - less than 10 patients available for analysis

Overall, the reference implant (cemented Exeter with a Contemporary Flanged polyethylene cup and a 28 or 32mm metal or ceramic head) appeared to have a good outcome profile across age groups and gender, and equivalent or better than all comparators in females over 60 years and males of all ages. Based on OHS improvement, it would be reasonable to consider a hybrid with a solid shell and a highly cross-linked polyethylene liner in young females, although failure to

achieve adequate press-fit would increase revision risk (as a multi-hole shell would be required, with poorer survival). Equally, a fully cementless implant with a MoP bearing may also offer a functional benefit, if a small Corail stem and high patient BMI could be avoided (both of which carry greater risks of revision).

Table 3.4.26. Summary of young males hip replacement type comparison

	Cemented *Exeter Contemporary*		Hybrid *Exeter Trident*		Cementless *Corail Pinnacle*		Resurfacing *BHR*	
Outcomes	Best (reference)	Other	Best	Other	Best	Other	Best	Other
Revision (HR) (n=13087)	1	0.8	0.5	1.3	0.6	1.5	1.0	2.1
OHS change (n=885)	20.1	-2.2	+0.9	+0.7	-0.3	+0.2	+0.7	-0.1
EQ5D index change (n=885)	0.392	-0.056	-0.067	+0.021	-0.004	+0.004	+0.006	-0.035
Relative costs	1	1	1.82	1.40	1.69	2.41	2.12	2.12

Significantly better compared with reference group

Significantly worse compared with reference group / higher cost

BHR – Birmingham Hip Resurfacing, HR – hazard ratio, OHS – Oxford Hip Score, significance p<0.05

Table 3.4.27. Summary hip replacement type comparison in females over 60 years

	Cemented *Exeter Contemporary*		Hybrid *Exeter Trident*		Cementless *Corail Pinnacle*		Resurfacing *BHR*	
Outcomes	Best (reference)	Other	Best	Other	Best	Other	Best	Other
Revision (HR) (n=47231)	1	1.9	1.3	1.7	2.2	3.6	2.3	8.7
OHS change (n=5333)	20.5	-0.8	+1.2	+0.4	+1.6	+0.5	N/A[a]	N/A[a]
EQ5D index change (n=5333)	0.426	-0.008	+0.026	+0.010	+0.021	-0.006	N/A[a]	N/A[a]
30d mortality (OR) (n=47231)	1	1.0	1.4	1.1	0.7	0.9	N/A[b]	2.6
90d mortality (OR) (n=47231)	1	1.0	0.7	1.0	0.7	0.9	N/A[b]	1.1
Relative costs	1	1	1.82	1.40	1.69	2.41	2.12	2.12

Significantly better compared with reference group

Significantly worse compared with reference group / higher costs

BHR – Birmingham Hip Resurfacing, HR – hazard ratio, OHS – Oxford Hip Score OR – odds ratio, significance p<0.05, a – less than 10 patients available for analysis, b – no deaths

Table 3.4.28. Summary hip replacement type comparison in males over 60 years

Outcomes	Cemented *Exeter Contemporary*		Hybrid *Exeter Trident*		Cementless *Corail Pinnacle*		Resurfacing *BHR*	
	Best (reference)	Other	Best	Other	Best	Other	Best	Other
Revision (HR) (n=32544)	1	2.0	0.7	1.3	2.0	2.5	3.5	6.2
OHS change (n=3826)	20.3	-0.4	-1.4	+0.3	+0.3	-0.5	-1.2	N/A[a]
EQ5D index change (n=3826)	0.390	+0.001	-0.026	+0.025	+0.011	-0.032	+0.008	N/A[a]
30d mortality (OR) (n=32544)	1	1.5	1.3	0.8	0.9	0.9	0.2	2.1
90d mortality (OR) (n=32544)	1	1.4	1.2	0.9	0.6	1.1	0.3	1.2
Relative costs	1	1	1.82	1.40	1.69	2.41	2.12	2.12

Significantly better compared with reference group

Significantly worse compared with reference group / higher costs

BHR – Birmingham Hip Resurfacing, HR – hazard ratio, OHS – Oxford Hip Score OR – odds ratio, significance $p<0.05$, a – less than 10 patients available for analysis

Perioperative mortality was low, although male risk may be higher (0 to 0.2% for females, 0 to 0.8% for males at 30 days), reflecting known differences between genders. There were no differences in mortality at 30 or 90 days across implant groups, suggesting that cement-related embolic disease remains a theoretical but unproven risk, despite analyses of large databases.

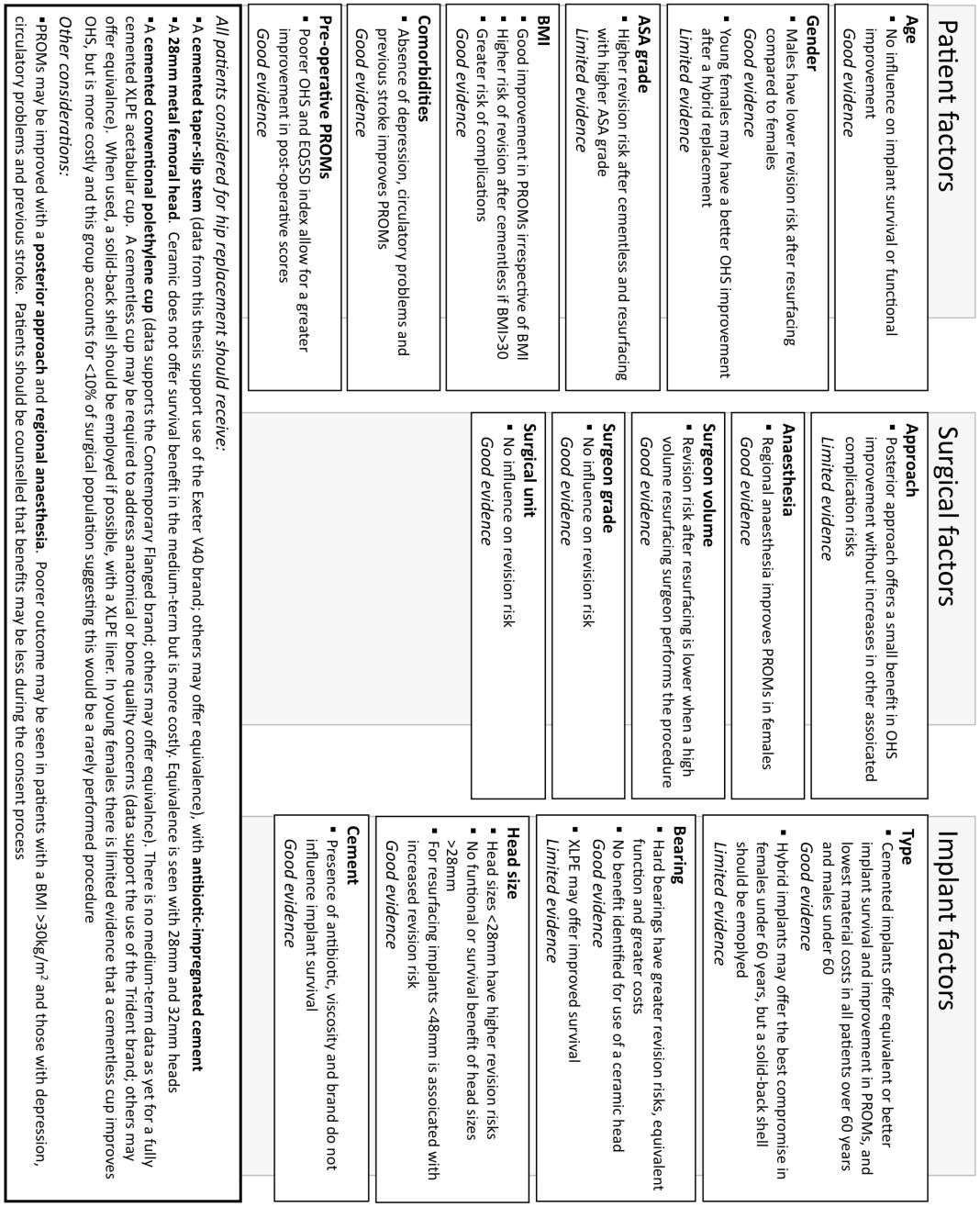
The posterior approach appears to have benefit over the direct lateral approach without other associated increased risks. Patients with a high BMI show good improvement in outcome scores (albeit slightly lower than normal weight patients) but do have greater complication risks; it would be incorrect on the basis of capacity to benefit to deny patients hip replacement because of a high BMI if the procedure is technically possible, but patients should be counseled that their risks of complications are higher. Specific aspects of hip replacement modularity such as head size and bearing type had no influence on outcome scores. A summary and flowchart to inform decision-making for the management of patients with OA requiring hip replacement is proposed in **Figure 3.4.6**.

Although a number of factors influence PROMs, much of the variation cannot be explained by the known variables in NJR-PROMs linked databases. A greater understanding of a patient's response to hip replacement is required in order explore methods of improving outcome.

Analyses of statistical tests show no benefit of using CRM for survival analyses over Cox Proportional Hazards models at this point using the vast NJR dataset,

although as patient numbers and follow-up time increases this may need further exploration as (theoretically) differences in the models become clearer over time.

Figure 3.4.6. A summary of evidence and flowchart to inform decision-making for the management of patients with osteoarthritis requiring hip replacement



4. Discussion

Overview

In this chapter the results of each analysis are discussed, with reference to the published literature and the implications these findings have on clinical practice. The limitations of the data and the analysis techniques are discussed in detail, and areas for further research are proposed. Finally, some potential future directions of registry data are identified.

There is evidence that hip replacement is an effective treatment for osteoarthritis of the hip with good improvement in general health and joint specific measures, low complication rates and high levels of satisfaction. The implant configuration is robustly associated with the risk of failure, but currently appears to have little effect on functional improvement. This picture may change in time as the PROMs dataset grows and matures. The range and variation in implants impedes robust understanding of patient and surgical variables and how these might affect implant decision-making. These issues have been carefully explored and are summarized from a policy perspective.

Part 1. Individual survival analyses

Summary

These analyses provide the largest, in-depth scrutiny of single brand leader combinations of implants to date. In the cemented analysis, significantly greater revision rates were independently associated with a hooded cup design and small femoral head sizes (<28mm). In the hybrid analysis, significantly greater revision rates were associated with conventional polyethylene bearings and multi-hole shells. Significantly greater revision rates were associated with hard bearings (MoM, CoC) and small femoral stem sizes (sizes 8-10) in the cementless implants. Higher BMI was also a significant predictor of revision in those procedures with valid data. Other potentially modifiable factors, including surgical approach, femoral head material and type of cement used, did not significantly influence revision.

The resurfacing analysis was more complex. Significantly greater revision rates were associated with certain brands (ASR, Durom, Conserve, Cormet, Recap), female sex, smaller femoral component sizes, ASA grade and lower consultant resurfacing volume. Increasing age was not associated with a greater revision risk. There was no significant difference between posterior and lateral approaches.

These findings are clinically important as they identify several modifiable parameters in the control of the operating surgeon in order to improve outcome when using these implants. Moreover, they demonstrate why simple registry analyses can mislead; examination by implant type or even by brand fail to identify the subtle differences in revision risk associated with specific component configurations within each brand.

Limitations

Revision and its use as a determinant of failure

The revision rates described are limited to mid-term data only. The relative rates at which particular implants require revision may change with further follow-up and more informative data. Revision within registry data is taken as a surrogate marker of implant failure, as other endpoints are often unavailable [91]. This does not take into account patients living with a painful hip, those awaiting revision at the time of censoring or, for patients with a large MoM bearing, high metal ion levels and the presence of soft tissue lesions. Therefore, these analyses assume a common spectrum of, and progression to, failure regardless of prosthesis. Nor does it take into account any functional benefit (if any) of different implant components. NJR-PROMs linked analyses are required to establish functional differences.

The definition of failure is also uncertain, in terms of registry data collection. Important data which is yet to be collected by registry MDS forms include closed reduction of a dislocated hip, reoperation without implant change (e.g. joint

debridement for infection), fixation of periprosthetic fracture and liner/head exchange in a cementless cup, all of which constitute a failure of the original procedure and may cause significant patient morbidity. A solution to this would be the development of a third MDS form for reoperation around a hip replacement (excluding femoral / acetabular revision) to capture this important data and improve the accuracy of failure rates.

Unmeasured data and study design

These analyses are observational and thus vulnerable to omitted variables, which may confound our findings. For example, registries may not capture all the issues driving component selection; higher revision may be a result of unmeasured patient or surgical factors rather than specific component factors. Information regarding duration and severity of symptoms, activity levels prior to and following the procedure, and patient race and socioeconomic status were not available in the NJR data. Although no radiographic predictors affect patient reported pain, function or satisfaction at 1-3 years after standard hip replacement [137], it is apparent that poor component position may contribute to early failure following hip resurfacings [26, 27]; unfortunately registry analyses lack radiographic data from which implant position can be ascertained. However, the relative performance of prostheses is likely to be robust within analyses of such large numbers, unless there are systematic differences in the ease of aligning different components or prostheses.

Solutions to these issues include the ability to attach radiographic data to an NJR patient episode, linkage to HES data in order to capture more patient demographics, and the development of methods to combine randomised trials with NJR-PROMs outcome data to reduce costs associated with long-term follow-up.

Incomplete, missing or unlinkable data

Revision procedures may be missed by the NJR due to compliance and linkage issues, but these should affect all groups equally when comparing implants. One major problem in the NJR data is the poor recording of BMI data. This can lead to confounded findings; when BMI is included in models, differences between components may not reach significance thresholds, due to a reduction in population size. When BMI is excluded, significant influences may be found with greater precision, but may not necessarily be correct; these could act as a surrogate for BMI, such as ASA grade, which was positively correlated with BMI in the cementless analysis. However, in this case sensitivity analyses including and excluding BMI provided similar findings. But there may be disparity if implant decisions are made based on BMI, for example. Imputation of incomplete variable data is possible, but due the amount of missing data, a decision was made to avoid this technique. In the hybrid analysis, another example of incomplete data was found; in this case, the highly cross-linked PE in the Trident system has only been available, and subsequently used in considerable numbers,

since around 2007. This limits comparisons with other bearings, which have been available for a longer period.

Missing data may not be an issue when the number of procedures available for analysis is large. The assumption that data is missing at random has been described earlier. However, bias may be introduced into analyses when this missing data is not random. For example, units failing to collect or submit data may also have poorer patient outcomes. BMI data was poorly collected during the earlier years of the registry but data collection may have been more thorough in patients with BMI values outside the normal range, rather than by random. This may have implications for conclusions drawn from analyses that rely on this data.

As discussed with BMI and ASA grade, several covariates are correlated. In the resurfacing analysis, females tended to have smaller prosthesis head sizes. However, multiplicative interactions between covariates were analysed and, in the final resurfacing model, all significant covariate categories were independent of each other i.e. both smaller head size and female sex were independent predictors of implant failure.

Despite these limitations, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

Literature

Cemented

The hooded Contemporary cup option was found to be associated with a significantly higher risk of revision for all causes, and for revision when dislocation was the cause. Two main design differences distinguish the hooded cups from the flanged: the hooded cup incorporates a large posterior elevation (or hood) with the intention of reducing the risk of dislocation; and the flanged cup incorporates a wide circumferential rim of polyethylene (the flange) that can be trimmed by the surgeon to enclose the acetabulum, thereby preventing cement escape during pressurisation. This outer rim, together with the absence of the posterior hood, may allow easier cup positioning. The hood may also (paradoxically) increase the risk of dislocation by allowing the implant neck to impinge on the hood and pivot the head anteriorly out from the cup. Within the thresholds set for covariates, there is no evidence from this analysis to suggest the influence of cup design was related to surgeon experience, head offset or surgical approach. Although the NJR reports revision for Contemporary cups as one group [30], ODEP has recommended that revision be divided by hooded and flanged types [95]. The findings of this work support the ODEP recommendation.

Data from the Swedish arthroplasty register have previously demonstrated that an Exeter stem with head size of 22mm has a significantly higher revision rate than 28mm (p=0.004) in over 21000 THRs [138]. Although the majority of smaller

heads in this current work were sized 26mm, the findings were similar. The benefit of 32mm has yet to be established.

A 'plus' offset head was also a significant influence for risk of revision for dislocation. This may reflect a failure to adequately restore offset with the stem options available, or a perception of instability from the operating surgeon at the time of trial reduction with a standard head following stem implantation. Although this covariate did not have a significant influence on the all-cause revision model, this should be considered when selecting the most appropriate femoral stem and head offset.

In the NJR Annual Report brand specific analyses are reported up to five years only. For 37 995 Exeter V40/Contemporary THRs five year revision was 1.26% (95% CI 1.10 to 1.44) [16]. As expected, the overall revision presented in this current analysis at five years was similar (1.26%, 99% CI 1.03 to 1.48). However, 5-year revision when a 28mm head was used in combination with a flanged cup was only 0.85% (99% CI 0.60 to 1.10). Although in 2010 the majority of components used were 28mm heads (78.4%) with flanged cups (69.7%), only 54.0% of procedures employed this combination over the entire study. Overall revision, as described in the analyses of brands in the NJR Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of smaller head sizes and hooded cups). Components that are now most commonly used in current practice have lower revision rates than those reported by the NJR.

Risk of revision was independent of age and gender in this work, despite previous reports in the literature of poorer outcomes in young, male patients after cemented THR [43, 131]. Contrasting with cementless THR, BMI ≥30kg/m^2 and higher ASA were not significant influences of failure [131]. It is possible that failure to fit BMI within models was due to the small population with BMI data available (only 39.7% of records), emphasising the importance of efforts to improve BMI recording to allow for appropriate adjustment in future explanatory analysis. Increasing femoral head size is thought to contribute to lower dislocation and revision [76, 84]. However, in this study, revision of the larger head size (32mm) was similar to 28mm, although longer-term analyses are needed as 32mm heads have a shorter follow-up. Of note, surgical approach did not influence all cause revision nor revision for dislocation, after adjustment for other factors. Cement brand, viscosity and presence of antibiotic also failed to influence risk of revision.

The commonest primary reason for revision was dislocation (35.1%); infection accounted for only 25.8% of revisions. This study reports mid-term data: as expected, only a small number of implants (21.9%) were revised for aseptic loosening/lysis.

Hybrid

Highly cross-linked polyethylene has improved resistance to wear compared to standard PE, resulting in generation of fewer wear particles [139]. A meta-analysis of ongoing clinical trials found XLPE liners exhibited reduced radiological wear

and osteolysis at a mean follow-up of 5.1 years (1.8 to 9.0) compared to conventional PE. Although there was no difference in revision rates between the types of PE, concerns regarding early failures attributable to brittleness of the XLPE were unfounded [66]. A mid- to long-term implant survival analysis of almost 9000 primary procedures from the Mayo clinic using thirteen different cementless cup systems suggested improved survival (although not statistically significant) with XLPE liners compared to conventional PE liners [133]. The analysis presented in this thesis is the first to identify an implant survival benefit of XLPE liners within a single acetabular system, albeit using short- to mid-term data.

Ceramic-on-ceramic bearings have good mid- to long-term survival data [140]. It is anticipated that a low wearing CoC bearing should provide adequate longevity for the young, active patient. However, there are concerns regarding higher risks of dislocation, fracture and squeaking [67, 140]. This current work has identified that MoXLPE is currently (marginally) outperforming CoC in the Trident system. However, CoC and MoXLPE bearings may have equivalent survival in patients aged ≤60 years. CoC bearings may ultimately provide greater longevity in younger patients, but longer-term data is required.

The use of the multi-hole shell option allows supplementary screw fixation of the cup, rather than reliance on press-fit alone. The decision to use a multi-hole shell may be explained by: inadequate press-fit of the trial/solid shell; anatomical factors (e.g. wall defects) precluding the use of cemented cups or press-fit components without screw augmentation; or the operating surgeon's normal practice. From the data presented in this thesis, multi-hole shells may be associated with higher revision in younger patients. Although we have no data on screw usage, it is assumed that a multi-hole shell would be used in conjunction with screws in the majority of cases, to supplement inadequate press-fit. This potentially poorer method of fixation, the reduced surface area for bony in-growth, or wear debris migrating through the holes, may contribute to the higher revision seen in these multi-hole shells in younger patients. Conversely, in older patients with poorer bone quality, reliance on press-fit alone may not be adequate in any patients, and supplementary fixation with screws may provide greater fixation. Of note, no difference in revision was found between PSL and Hemispherical Trident shells.

The association with increasing age and lower revision rates after cemented THR is well-documented [43, 131]. We found an interaction with shell type, which may explain the lower revision rates in older patients in this analysis. However, it is important to remember that older patients have lower functional demands, and some patients requiring revision surgery may not be fit enough for surgery in the oldest age group, limiting the conclusions that can be drawn. Furthermore, 10-year patient survival following THR performed in older patients (aged ≥80 years) is less than 25% according to Norwegian Registry data [141]. The literature reports no superiority of cementless over cemented cups at ten years and, given costs are higher than cemented, we question the cost-effectiveness of the use of cementless cups in older patients [142].

As expected, the overall revision presented here at five years 1.56% (95% CI 1.23 to 1.89) was similar to reports from the NJR Annual Report for 18 358 Exeter V40/Trident THRs (1.69%, 95% CI 1.39 to 2.07) [61]. However, revision at five years when the commonest bearing (CoC) was used in combination with a solid-back shell in patients ≤75 years was only 1.13% (95% CI 0.43 to 1.83). Although the follow-up time is shorter, this data suggests that MoXLPE, in combination with a solid shell has even lower revision. Overall revision, as described in the analyses of brands alone in the NJR Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of conventional PE). Components that are now most commonly used in current practice (MoXLPE, CoC bearings) have lower revision rates than those reported by the NJR.

Of note, there were no differences in revision rates across head sizes and surgical approach did not influence revision after adjustment for other factors. Although BMI appeared to have an influence on the model, with the degree of missing data it was felt that excluding this parameter was the most appropriate solution.

The commonest primary reason for revision was infection (27.0%); dislocation accounted for 25.5% of revisions. This analysis reports mid-term data: as expected, only a small number of implants (23.4%) were revised for aseptic loosening/lysis. Excluding dislocation, cup related failures (aseptic loosening/lysis, malalignment, dissociation of liner, and liner wear) were cited in 39.7% (56) of revisions, compared with 9.9% (14) for stems. Previous concerns regarding high rates of mal-seating of the Trident ceramic liners (8 to 16.4% of all procedures) do not appear to translate into liner dissociation and subsequent revision procedures (3.5% of revisions were attributable to ceramic liner dissociations in this series) [143, 144].

Cementless

All MoM hip replacement bearings are currently of concern and, despite the large numbers implanted and the cost involved, the Medicines and Healthcare products Regulatory Agency (MHRA) have recently recommended yearly follow-up in all of these patients [22]. After performing a systematic review of the literature on hip implant bearings, Sedrakyan at al found that MoM bearings provided no superiority in outcome scores in comparison studies with MoP bearings, but were associated with significantly higher risk of revision (after risk adjusting) in over 720 000 hip replacements drawn from registry data world-wide [40]. An in-depth analysis of NJR data by Smith et al supports these poorer findings with MoM of all head sizes [84]. Given the reports from independent centres and the risks associated with MoM bearings (metal ion levels, excessive bearing and taper wear, soft tissue destruction, possible systemic complications) [19], combined with the poorer survival reported here from the commonest cementless hip system combination used in England and Wales, the role of these bearings in modern hip arthroplasty should be questioned.

Ceramic-on-ceramic bearings have previously been shown to have higher revision rates due to dislocation when compared with MoP in over 100 000 THRs from the Australian registry [67]. Despite significantly poorer survival when compared with MoP in the mid-term analysis presented here, CoC bearings may ultimately provide greater longevity, without the concerns associated with MoM. Therefore, CoC may have a role in younger patients, but longer-term data is required.

CoM bearings have only been available for a short time and numbers are small; it is important to note that although the hazard ratio for the CoM group was consistent with the other hard bearings, there were no significant differences when compared with CoP due to statistical imprecision. As CoM is thought to offer some benefits over MoM, we felt the inclusion of this bearing was important (despite the limited data available).

CoP bearings did not significantly influence revision risk compared to MoP. Whilst the 5-year revision rate for the entire group of Corail/Pinnacle THRs was 2.41% in this study, MoP bearings reduced the revision rate to only 1.36%. Of note, the 5-year all-cause revision rate following the commonest cemented THR (Exeter V40 stem/Contemporary cup, 37 995 procedures) is 0.92%, according to the NJR Annual Report [61]. Bearings, rather than fixation method, may explain much of the differences in revision rates across registry data.

The influence of femoral stem size may result from inadequate press-fit or poor bone quality but, without more data, this work cannot explain this fully. While it may be difficult to assess preoperatively, patients requiring smaller Corail stems may be less suitable for cementless implants. A trend towards higher revision in very large implants was also seen, but disappeared when BMI was included in the model, suggesting it may be high BMI rather than large stem size which is associated with failure. The finding of higher revision in patients with a BMI over 30kg/m^2 is logical and important, given an apparent year-on-year increase in average BMI values within the arthroplasty population [61]. It should also be considered as an important covariate in future similar analyses and, as mentioned previously, further effort should be made to increase BMI data compliance when collecting joint registry data.

Risk of revision was independent of age and gender, despite the previous reports of poorer outcomes in young, male patients after THR [131]. Although head size has been found to influence implant revision across a range of implants [84], we failed to find an association in this analysis. Type of polyethylene (conventional or highly cross-linked) did not influence revision risk in standard bearings, but longer-term analyses are needed. Although we did not find surgical volume to influence the risk of revision, there are limitations associated with this analysis; a surgeon's volume prior to the study period is unknown and their use of other types of hip replacement performed over the same period was not analysed (a high volume hip surgeon performing only a small number of Corail/Pinnacle THRs may potentially be more successful than an occasional hip surgeon performing solely Corail/Pinnacles).

The commonest primary reason for revision was dislocation (24.1%); infection accounted for only 15.4% of revisions. As expected with mid-term data, the number of implants revised for aseptic loosening/lysis (20.0%) was low. The quality of recording of reasons for revision should be improved to consistently list primary and secondary causes; currently multiple causes of failure may be described, without any clear primary cause being identified. In-depth scrutiny of high-risk subsets is needed (for example, immunocompromised patients – those with diabetes, Rheumatoid arthritis - and their risk of infection), and prospective studies of cause of revision combined with explant analysis will be of benefit [145].

Resurfacing

Despite evidence of good long-term implant survival in young male patients [14], the use of hip resurfacing is now falling in England and Wales [30]. It is accepted that there are now fewer indications for hip resurfacing. It has previously been reported that males under 60 years of age undergoing resurfacing for OA have an estimated 5-year implant revision rate of 6.05% (95% CI 5.55-6.60), significantly poorer when compared with hybrid (2.79% [2.30-3.37]) and cemented THR (3.25% [2.83-3.73]), according to the NJR [61]. However, our current work found a 5-year estimated revision rate of 1.59% in men under 60 in the BHR brand when compared with 4.76% for the entire study population. Thus, previous NJR analysis may have failed to reflect this heterogeneity, and revision rates for the BHR in young males may be considered more acceptable.

Femoral neck fracture and reactions to metal wear debris are the most commonly reported reasons for revision following hip resurfacing [20, 146, 147]. The major cause of revision in our work was component loosening or lysis. Metal wear debris and soft tissue reactions were uncommon, although descriptions of failure associated with metal debris have only been commonplace in the recent years, and the categories of revision within the NJR have evolved through revisions to the data collection forms. Many failures described in the component loosening, pain and infection categories may actually be a result of metal debris reactions. Given these limitations, it is difficult to refute the evidence from in-depth reporting of revision in smaller studies.

Although several studies have found that higher failure rates in females is component size related, and independent of sex [24, 148], this current work identified female patients to have an independent increased risk compared to males. A combination of factors may contribute to this, such as lower bone density (resulting in decreased cement penetration [149] or an increase in risk of fracture), anatomical differences (leading to implant malalignment and impingement [150]) and immunological responses [151]. It is not clear why higher ASA grade would result in greater implant failure, but there may be an association with poorer bone quality or immunological reserve.

Five brands are associated with a significantly higher risk of revision when compared with the UK market leader (BHR). There appears to be a brand influence after risk adjustment, suggesting there are specific design features of

some brands that may predispose to failure. This may relate to cup characteristics, such as shell thickness (and the ability to prevent deflection) or lower head coverage, which has been implicated in the ASR and other sub-hemispheric designs [152, 153]. Lower clearance, as seen with the ASR design, may also increase wear and subsequent failure. The BHR currently holds an ODEP 10A rating in the UK – good evidence that this implant has a greater than 90% survival at 10 years [95]. However, this latest data shows smaller implants have significantly higher revision rates across all resurfacing brands, including the BHR. Smaller resurfacing components may function in boundary lubrication rather than mixed or fluid-film as intended, resulting in increased wear and reactions to metal debris, and this may explain the poorer results with these sizes. Even in BHR patients, implant survival will drop below 90% at 10 years, based on current data. For resurfacing femoral components sized 47mm or less a 10A ODEP rating may not be appropriate. Restricted to medium and large head sizes only (femoral head size of 48mm and above) all resurfacing brands have an eight-year survival greater than 90%.

Consultant volume conflates the number of years a surgeon has been working with their rate of surgery. Thus low volume long serving surgeons are grouped with higher volume but less experienced surgeons. However, many authors have described a learning curve in hip resurfacing surgery related simply to the number of procedures performed, similar to the thesis findings: these support the expert opinions from surgeons at the Ghent hip resurfacing meeting [154].

Implications

The Exeter V40/Contemporary hip replacement is the most commonly used cemented implant with an overall brand survival rate comparable to the best performing brands within group [30]. In this latest work, revision risk was further reduced when used with a flanged design cup and a metal head of size 28mm. For the head, increasing size to 32mm and using ceramic was of no benefit. Surgical and patient factors did not influence implant survival, suggesting this implant provides good results across a spectrum of surgical skills and patient demographics.

The Exeter Trident hip replacement is the most commonly used hybrid with an overall brand survival rate comparable to the best performing brands within group [30]. MoXLPE with a solid-shell reduced revision risk, and appeared to be the best choice in patients ≤75 years. If supplementary screw fixation is required, and a multi-hole cup is used, revision risk is increased. A ceramic head or a greater head size does not confer additional survival benefit. CoC bearings may have a role in the youngest patients, but long-term data is lacking. For older patients, a multi-hole shell may be required to achieve adequate fixation. Success of this implant is dependent on adequate acetabular fixation, which may be influenced by patient (bone quality, dysplasia) and surgical (skill level, technique) factors.

Although the Corail Pinnacle is the most commonly used cementless implant, overall brand survival is now poorer than other, lesser-used brands. Revision rate at seven years for the entire series is now 4.1% [30]. This higher rate is due to the predominance of hard-bearings used with this implant (specifically MoM), which have a higher revision risk in these current analyses. A MoP bearing provides the lowest risk of revision in a patient with BMI less than 30kg/m^2 and a femoral canal that can accommodate a Corail stem size ≥11. For the head, increasing size to 36mm and use of ceramic provide no survival benefit. Patient factors, such as skeletal morphology, bone quality and BMI contribute to the success of this implant. Surgical factors that may account for under-sizing of the femoral component may also play a role.

The BHR is the most commonly used resurfacing (with a market share of around 60%) and appears to have superior results to other brands. Large BHR components (≥48mm) have the lowest revision risk. Male patients who are healthy (ASA grade 1 or 2) appear to benefit most, in terms of revision risk. Surgical factors contribute to success, with those surgeons performing larger numbers of resurfacings having lower failure rates. A consultant is recorded as the primary surgeon more commonly than for other types of replacement. This may reflect the greater difficulty in performing resurfacing procedures, and the additional skills required compared with traditional hip replacement. There are also training implications for surgeons wishing to perform resurfacing. Few training opportunities are routinely offered to learn these additional skills during surgical training, resulting in difficulty in achieving competency. Surgeons are generally trained in standard hip replacement, with skill development targeted to achieve competency in cemented and cementless procedures.

These analyses of observational data demonstrate the difficulty encountered if the goal is to perform comparisons of implants. It would be diminishingly informative to perform similar analyses on less commonly used brands, as numbers diminish while variation increases causing greater uncertainty in findings. Joint registry analyses are potentially flawed if specific implant and surgical factors are omitted from multivariable implant comparison models. Interestingly, across several of our analyses, the most commonly used implant component sets employed within each brand today have better results than those previously used, so overall mid-term revision rates as described in registry reports may actually over-estimate an implant's revision risk in the modern era. These survival analyses have provided stratification of revision risk within brands, allowing a more robust comparison across implant types.

Part 2. PROMs analyses

Summary

Causes of variation in OHS and EQ-5D index can be modeled to a certain degree by the variables available for analysis. The most important source for both OHS and EQ-5D index was the pre-operative score – an unremarkable finding given the ceiling effect in post-operative scores. Patients with the poorest pre-operative scores generally had the greatest improvement. However, in males and females across both OHS change and EQ-5D index change, a number of patient and surgical variables also contributed to the models. Patient factors associated with improved change scores were: better pre-operative general health, lower BMI, absence of a self-perceived disability, and no history of depression, circulatory problems or stroke. In terms of surgical factors, only the type of surgical approach influenced change score in all models, favouring the posterior approach. Interestingly, use of regional anaesthesia improved both OHS and EQ-5D change scores in females, but not males; the underlying reason for this is likely to relate to adequacy of pain control, although the gender split is inadequately understood.

Patients experience a good improvement in outcome following THR irrespective of BMI. However, improvements were slightly smaller and complication rates higher in obese patients, after adjusting for other influences. In terms of improvement in health and function, a high BMI in isolation should not be a justifiable reason for denying surgery within a public funded health service. This sub-group of patients should be counselled that improvement following hip replacement is likely to be less than that for an equivalent normal weight individual, and complication risk higher.

The posterior approach may offer a functional benefit to patients compared with the lateral, whilst appearing not to confer an additional risk of dislocation or requirement for revision during the first post-operative year. These findings were similar for both cemented and cementless implants and are clinically important as they identify a modifiable surgical parameter that may result in improved patient outcome.

No functional benefits of larger head sizes or alternative bearings were found. Risks of complications, including self-reported readmissions and reoperations were similar across head sizes and bearings. Given the higher costs associated with larger head sizes and hard bearings, these findings have cost-saving implications.

Limitations

There are limitations for the findings when analysing NJR/PROMs linked data. By its nature, an analysis of observational data is vulnerable to omitted variables and selection bias, potentially confounding the results.

Missing and unlinkable data

There were large numbers of procedures that could not be analysed, either because of dataset linkage issues, missing NJR or PROMs data fields or absent BMI data (35% of the linked NJR-PROMs data). A failure to obtain patient consent for NJR data collection and poor surgical unit compliance can restrict data availability. Additionally, PROMs response rate is uncertain as the provider supplied only the returned patient questionnaire data fields.

Unmeasured data

Radiological data are currently unavailable within the NJR dataset. Cup positioning and femoral anteversion may be technically more demanding in patients with higher BMI, and variations in practice may influence risk of dislocation and subsequent revision. However, in terms of analysing surgical approach, both afford good exposure to the acetabulum so poorly positioned implants are unlikely to influence the results of one approach more than the other. In addition, previous studies have found no radiographic predictors of patient reported pain, function or satisfaction at 1-3 years following THR [137].

Dislocation rates were unavailable. However, 12-month revision rates (all cause and revision for dislocation) were used as a surrogate endpoint. The majority of dislocations following primary hip replacement occur within the first five weeks following surgery [155] and it is therefore likely that revision for recurrent dislocations would be performed within one-year of the primary surgery. Moreover, patient reported complications associated with a dislocation, such as readmission and reoperation, were reported in this study. Any differences in dislocation risk should be apparent from these outcome measures.

Methods for assessing unexplained variation in Cox regression are available within the STATA software [156], but these scripts could not be added to the closed package provided for use on the server at Northgate Information Services. Therefore, these methods could not be explored. Univariable analyses show the problems with this; inadequate adjustment may misattribute variables that are not in reality associated.

Quality of data

The quality and accuracy of the findings from these analyses is open to criticism if systematic bias in the reporting of certain variables is apparent. For example, BMI data have been poorly recorded within the registry. However, it is unclear whether BMI data have been missed randomly, or whether reporting is influenced by a patient's BMI i.e. a higher BMI is more likely to be recorded, hence analyses of procedures with BMI data available may be skewed towards less healthy individuals.

Selection of procedures to analyse

It could be argued that all THR brands should be examined to increase numbers for analysis and broaden the scope of findings of the study. By restricting the

implants to only the most commonly used we were able to remove the variation in brand performance. The cemented and cementless implants employed in the PROMs subset represent 29% (100 803 of 344 185) of all used in England and Wales since 2003. The remaining 71% are made up of 140 different femoral stem brands and 117 different acetabular components [30]. It would be impossible to robustly adjust for the heterogeneity across this vast array of implants. Despite the exclusion of other brands, adequate numbers of procedures were available for analysis according to recommendations for sample size arising from the PROMs feasibility study [134] and by the Oxford score design group [100]. Additionally, our sensitivity analyses, based on commonly used component sets in each type of hip, provided similar results, suggesting the findings from the BMI analysis may generalize across different bearings, head sizes and fixation methods.

For the head size and bearing analysis, the Corail Pinnacle was used. This represents 14% of all hip implants used in England and Wales since 2003. Cementless components now predominate, and around 40% implanted in 2011 were Corail/Pinnacle [30]. This implant combination also offers a wide range of bearing options and head sizes, making it a logical choice for analysis. As this population was larger, false negative results are unlikely, especially as OHS and EQ5D indices for each of the groups were qualitatively similar, irrespective of confidence intervals. In addition, the literature reports little difference in change of OHS between one and five years following replacement, suggesting that the results in our current short-term study are a reliable indication of longer-term outcome [157, 158].

Limitations of functional scoring systems

In the BMI analysis it may be argued that pre-operative health scores should not be included in multivariable analyses, since patients with higher BMI are more likely to have poorer function. However, demographic data supports inclusions; whilst different BMI groups were not exactly matched in terms of pre-operative scores, the differences were clinically small. Moreover, by providing predicted OHS improvements for different clinical situations, this analysis has confirmed that BMI is only one of several important variables influencing outcome, and its (independent) influence on change score is small. This also highlights the influence baseline score has on the ability to improve following surgery, and is an essential variable for inclusion when constructing multivariable models. However, this does identify a limitation of both the OHS and the EQ-5D index; patients with better pre-operative scores are unable to improve to the same extent as patients with poorer scores, as the score 'ceilings' constrain top end variation. This ceiling effect may reduce the perceived benefit of certain procedures if, for example, patients undergoing one type of procedure are pre-selected based on higher pre-operative scores. This further emphasises the importance of appropriate adjustment when making PROMs comparisons.

Another issue that became apparent during the PROMs analysis was the distribution of EQ-5D index change score. Although this was analysed as a parametric variable, in reality it may not be. Rather, it may be distributed with

many peaks, as would be expected with an index created from values with discrete responses. Although other authors have identified this, no solution has been proposed as yet. Analysis of its constituent parts is also likely to have limitations. Distribution of OHS change also lacks a perfectly normal distribution but, due to the large numbers of patients in these analyses, the central limit theorem would suggest that parametric tests as utilised here are robust.

Despite these problems, similarities between the unadjusted and adjusted models, similarities in sensitivity analyses, and robustness under different model fitting assumptions support the stability of estimates.

Literature

Body mass index and PROMs

Previous analyses have demonstrated that risk of revision is significantly (1.5 times) higher in patients with a BMI >30kg/m^2 following cementless hip replacement with a Corail/Pinnacle, although BMI was not found to influence implant survival in analyses of the cemented Exeter Contemporary (**Part 1 - Preliminary survival analyses**). This could be a result of greater subsidence risk with cementless implants in patients with a higher BMI, or may be an artefact finding, as previously published work has proposed that weight rather than BMI directly influences implant survival [159].

Other studies suggest that arthroplasty patients with a high BMI may have more complications [111], including a greater risk of infection [160] and dislocation [161], slower recovery [162], and poorer function [114] after THR. However, several studies have found consistently good improvement irrespective of BMI with comparable satisfaction and implant survival [163, 164]. A study of 3290 THR patients found that morbidly obese (BMI>40kg/m^2) patients had a similar change in outcome scores postoperatively to those with a lower BMI. Although final outcome scores were found to be lower (as in this current analysis) and complications higher, the authors concluded that morbidly obese patients may have as much to gain from THR as patients with a lower BMI [165]. This view was supported by an analysis of 1421 THRs by Andrew et al, in which no difference in OHS was found at 5 years between BMI groups [158]. In addition, they found little difference in change of OHS between 3 months and 5 years following replacement, suggesting that the results at 6 to 12 months post-operatively in our current study are a reliable indication of longer-term outcome. Interestingly, a similar study on TKR patients (without separate brand analysis) found no difference in change scores across different BMIs in 13 673 procedures [166].

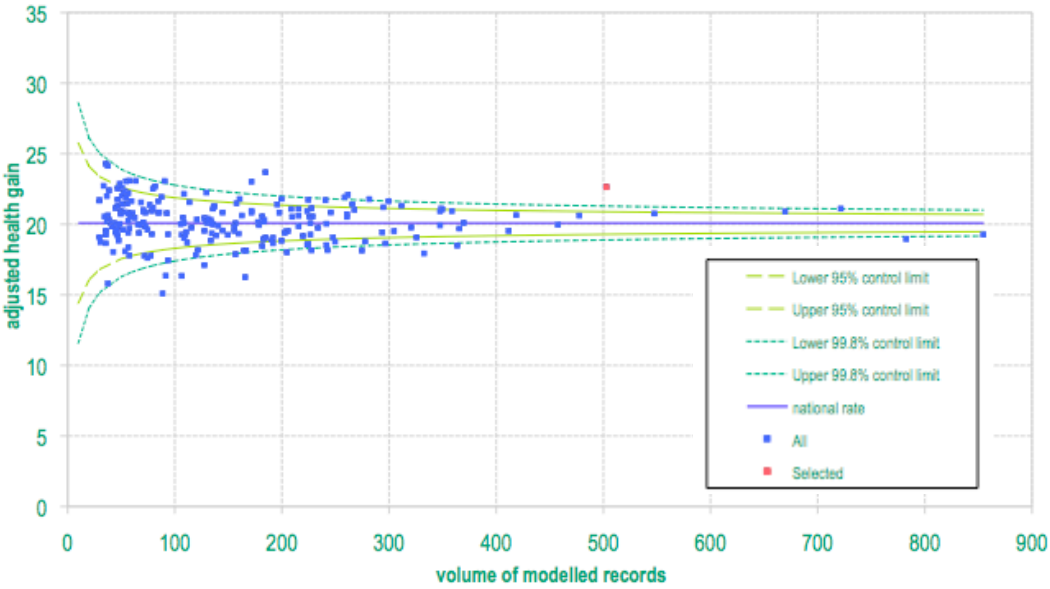
Surgical approach and PROMs

In this analysis implants were limited to the commonest component specification of the most popular brands in England and Wales. This ensured control over certain variables, such as bearings and head size, which may influence risk of dislocation, revision and functional outcome.

Other published studies demonstrate mixed findings when surgical approaches to the hip are compared. A single unit analysis of PROMs data in 911 patients demonstrated a functional benefit of the posterior approach at 1-3 years following THR [105], whilst a multi-centre study of 1035 patients found there were no differences in change in OHS and in dislocation or revision rates between surgical approaches at 5 years [106]. Both of these analyses are limited by the heterogeneity of implants used.

Although a statistical significant benefit of the posterior approach was found in this analysis, the difference was small and may not be clinically important. The Oxford score design group has previously described the minimum clinically important difference to be between 2 and 5 points [100, 106]. The difference found in this study was only 1.9 in the cemented analysis. Nevertheless, it would seem prudent to explore all avenues of benefit to optimize patient outcome, especially in the immediate post-operative phase. Although this is early outcome data, previous analyses have shown the functional benefits of the posterior approach may persist for up to three years [105]. Comparison of OHS improvement following primary THR is now possible between surgical units in England (DoH HES online website, **Figure 4.1**) [97], and the data presented here may prompt practicing surgeons to reconsider their choice of surgical approach in order to improve their patient scores. Whilst this should not be discouraged, it is important to appreciate that the benefits are small, and complications may be higher in the learning curve period associated with perfecting an alternative surgical approach.

Figure 4.1. Funnel plot describing mean OHS improvement after hip replacement, by surgical unit (England and Wales data, 2013)
(Source: Department of Health in the UK, HES online)



Head size, bearings and PROMs

This analysis using NJR-PROMs-linked data from a single hip system showed no functional benefit when femoral head sizes greater than 28mm and bearings other than MoP were used for primary THR.

Greater femoral head size may lower dislocation risk. In a randomised trial of patients undergoing MoXLPE hip replacements, Howie et al found head size of 36mm reduced the one-year dislocation risk compared with 28mm in 533 primary procedures from 4.4% to 0.8% [167]. In addition, a large cohort study of over 240 000 THRs performed in England and Wales found a reduction in one-year dislocation risk from 1.4% to 1.1% over a period of five years, during which the use of large femoral head sizes increased. However, there was no change in the 12-month revision rate [76]. Without radiographic data, dislocation risk is difficult to analyse. The one-year risk in the study by Howie et al is high compared to others; Stohl et al report dislocation in head sizes less than 36mm of only 1.8% (10 in 559) at five years [168], similar to the English figures (taking into account most dislocations occur in the first year after surgery) [76]. Before larger head sizes are recommended, the incidence of late dislocation, wear, periprosthetic osteolysis, and liner fracture should also be established [167]. Importantly, revision risk did not decrease in the English data, suggesting most early dislocations are relatively benign and do not require a revision procedure. Although dislocation data was unavailable in this current study, other outcomes were used as surrogate endpoints. The majority of dislocations following primary THR occur within the first five weeks following surgery [155]; therefore, patient reported complications associated with a dislocation, such as readmission and reoperation, should demonstrate a difference if, for example, one head size had a lower risk than another. Increasing femoral head size may also increase range of movement, but several studies demonstrate that it is the patients' bony anatomy that causes impingement, and therefore limits this range irrespective of head size [169, 170]. Interestingly, PROMs were poorer and bleeding risk higher in patients implanted with a 32mm head. This may be explained by the patient demographics, which show a slightly greater mean BMI, and relatively more patients with higher ASA grade and poorer health. In these patients a surgeon may choose to increase head size from 28mm in an attempt to increase stability, thereby potentially reducing a need for further revision surgery.

Mid- to long-term risk of revision is lowest in MoP bearings across worldwide registries and published trials, and no functional benefit of alternative bearings has thus far been found [40]. When implant survival of Corail Pinnacle THRs were examined in **Part 1 - Preliminary survival analyses**, MoM bearings had twice the revision risk and CoC 1.5 times the revision risk of MoP bearings. In a randomised trial of 49 pts receiving either large head MoM articulations or standard (28-32mm) MoP THR, no significant benefits were found in function, dislocation or implant failure [85], although numbers are small and this could be a consequence of a failure to adequately power the study.

MoM bearings were not included in this analysis. Although a large number of Corail/Pinnacle THRs have been implanted in England and Wales with these bearings, their use is now low due to high revision rates and concerns regarding the systemic effects of excessive metal wear debris.

Implications

Overall, PROMs scores demonstrate excellent improvement in validated joint specific and general health outcome scores at six months following primary hip replacement in the majority of patients. A number of patient and surgical factors may affect the amount these outcome scores improve, although PROMs data needs to grow and improve in completeness. Type of hip replacement may have a small influence on level of joint specific (OHS) improvement in females, but there appears to be no influence on OHS improvement in males, and no influence on EQ-5D improvement in either gender. Expensive replacement configurations, such as large head sizes and hard bearings, offer no functional benefits.

Patients experience a good improvement in outcome following THR irrespective of BMI. However, improvements were slightly smaller and complication rates higher in obese patients, after adjusting for other influences. This sub-group of patients should be counselled that improvement is likely to be less than that for an equivalent normal weight individual. A greater focus on pre-operative weight loss programmes, including bariatric intervention [171], should be considered.

Although differences between surgical approaches are small and may not be clinically important, the posterior approach offered significantly better early functional outcome scores to patients without an increased risk of revision or other complications. This potentially modifiable aspect of a surgeon's practice may improve patient outcomes.

Part 3. Methodological issues

Summary

Comparison of the Cox Proportional Hazards and Competing Risks models in a subset of NJR data has demonstrated that differences between modeling techniques is small and inconsequential. Previous analysis of the entire registry dataset has shown a similarly small effect of using CRM [16]. CRM has theoretical benefits, especially beyond 10 years following the intervention, but for this mid-term implant survival data results were similar. Accounting for competing risks is a more thorough approach to survival modeling.

Implications

Little difference was found in the analysis of revision risk when the competing risk of death was modeled. Cox proportional hazards models are adequate for large population analyses in the medium term if populations are adjusted appropriately. Competing risks models appear to fine tune results, but in longer-term or very elderly cohorts this may ultimately be the most appropriate survival modelling strategy to use.

Part 4. Comparative analysis

Summary

There appears to be no advantage in using resurfacing or cementless implants in place of standard cemented hip replacement in male patients under 60 years. For females, functional outcome may be better with hybrid and cementless implants (although clinically, reported differences are small). Even though revision risk was similar to cemented for the best cementless and hybrid implants, risk was 3.5 times higher with the most commonly used, hard-bearing cementless variant. Material costs, approximating to NHS costs, were lowest with a standard cemented hip replacement and highest with hard bearing cementless implants. Hard bearing cementless implants and resurfacing devices account for the majority of implants used in this age group.

For patients 60 years and over, hip replacements performed using a cemented stem, a cemented PE cup and a standard sized head offered good outcomes, with the lowest risks and at the lowest costs. Poorer implant survival was demonstrated in resurfacing and cementless implants, which were also the most costly implants. No differences in functional benefit were found in males for any implant. A small difference of uncertain clinical value may occur in OHS in females when using the best cementless implants. Complication rates and perioperative mortality were similar across all groups.

These findings are clinically important for clinicians and health care providers attempting to determine the most suitable and cost-effective implant for patients requiring a hip replacement.

Limitations

Many of the limitations associated with NJR and PROMs analyses have been discussed in **Parts 1 and 2.** Registry databases across the world have now been adopted for analytic research, although they were not necessarily intended for this role. A decision on a particular patient's surgical treatment is based on patient, surgical and unit factors, and is not randomly determined. Thus, even when known variables are considered in statistical testing, the methodology is not as robust as randomised trial comparisons - some potentially important sources of variation may remain unknown and unrecorded. Patient experiences, levels of perioperative pain and expectations are known to influence satisfaction but are unmeasured in these datasets [172].

Although the analyses were limited to specific brands only (to reduce the confounding effect of implant heterogeneity), the numbers within groups were adequate in order to identify meaningful differences in PROMs in the older patient group [134]. However, numbers within some groups in the younger patient analysis were inadequate; potentially, the analyses are underpowered to detect differences between implants and this might, in isolation, explain the lack of significant findings in men. However, values generated were clearly significant in females, with similar patient numbers. Qualitatively this is unlikely to have

occurred by chance given the consistent interaction with gender, although these findings could usefully be replicated confirming these findings in other database analyses.

Younger patients requiring hip replacement are a difficult group to treat as they are generally more active, have a greater life expectancy and may have higher functional expectations compared to older patients. It has been suggested that patients of different ages, gender and comorbidities should be analysed separately [173]. We therefore analysed patients by age and gender, and adjusted for general health as reported data allowed.

The NJR informs implant survival at mid-term follow-up only, with first records dating from 2003. Polyethylene-wear associated revision may occur in greater numbers beyond ten years and hard bearings may ultimately have greater longevity, but there is currently no evidence to support this. A systematic review of worldwide registry and cohort study data failed to show a benefit of other bearings when compared with MoP [40]. Australian joint registry data suggests that MoXLPE now has the lowest 10-year revision risk [38] and dislocation rates are higher with CoC [67]. In England and Wales the use of MoM has declined dramatically due to concerns surrounding metal wear debris reactions [30]. Despite proponents of hard bearings citing longevity as a reason for use, the current evidence suggests otherwise, and the possibility of survival curves 'crossing over' between the 1st and 2nd decades in favour of hard bearings is perhaps optimistic.

The PROMs data are recorded at six months only. This may be too early to determine success of a joint replacement. However, the Oxford group have published data showing that PROMs improve to 12 months with the greatest improvement in the first three months. No improvements are seen between 12 months and five years, suggesting that the results in our current short-term anlayses are a reliable indication of longer-term outcome [157, 158]. There is some evidence that poor early PROMs scores are associated with a higher risk of revision.

There may be selection bias within the PROMs data. The questionnaires are randomly distributed, but response rates may be different in patients of different ages, different socioeconomic groups and different races. The point at which a patient undergoes a hip procedure may also be different (reflecting the need to adjust for pre-operative scores), depending on age, expectations and occupation. Patients undergoing resurfacing tended to have higher pre-operative scores. This may in turn limit their ability to improve following joint replacement, due to the ceiling effect of the OHS and EQ5D index.

The discrepancy between the ratio of NJR-PROMS linked episodes to total NJR episodes across implants (1:10 for cemented versus 1:50 for resurfacing) in the younger age group analysis is difficult to explain, but may be due to a generally younger resurfacing population, or because a higher percentage of resurfacings are performed in the private sector (for which PROMs are not available). This may limit conclusions that can be drawn from the resurfacing data.

Literature

Younger patients

Pennington et al recently published a cost effectiveness paper using NJR, PROMs and implant cost data that compared types of hip replacement [174]. Hybrid implants were found to have the most cost effective profile. As in this thesis, the authors found that cementless implants offered no net advantage whilst being more costly. However, there were a number of limitations, which may influence the reliability of their results: resurfacings were not included; all brands within each group were analysed together with no adjustment for the heterogeneity of implants; and analyses were limited to MoP bearings only.

Although hybrid implants appeared to offer a balance between implant survival and functional benefit for young females in this current study, it must be stressed this requires adequate fixation with a solid-back acetabular shell. Analysis of the hybrid data demonstrated multi-hole shell (with screw fixation) to have a 37% higher risk of revision (**Part 1 - Preliminary survival analyses**). The risk of revision in females with this combination was 2.8 times greater than the best cemented implant in this current data, which approached significance. Whilst a cemented procedure will have reproducible results, without compromise due to bone quality or anatomical constraints, cementless cup success is reliant on adequacy of the press-fit. In addition, there is no obvious explanation for the difference in the effect of implant type on males and females in this study. It is reasonable to suggest, therefore, that a surgeon using cemented implants in the majority of patients could also use the same implants in young females with acceptable and reproducible results.

Despite the poor results of cemented implants in the literature during the 1980s, more contemporary analyses have shown equivalent or better survival when compared with cementless implants [36, 39, 41, 42], supporting the encouraging results of registry data. The findings from the earlier studies may have been influenced by previous generations of implants and rudimentary cementation techniques. Data from **Part 1 - Preliminary survival analyses** suggests the Exeter Contemporary system utilising the flanged cup design and a head size of 28mm or greater had good and reproducible results in all patients, by all surgeons across England and Wales. Moreover, no additional survival benefit was seen when 32mm and/or ceramic heads were used in place of 28mm metal heads. Additionally, head size and bearing type appear to have no influence on PROMs and complications across a range of implant options (**Part 2 - PROMs analyses**)

Although this analysis demonstrates no benefit of a resurfacing procedure in young males compared with a standard cemented replacement (despite inclusion of only the best performing brand and use of larger femoral head sizes), there may be long-term implant survival benefit. However, it is known that high volume surgeons have lower revision rates (**Part 1 - Preliminary survival analyses**), and there remain concerns regarding the local and systemic complications associated with MoM bearings [19]; the regulatory body in the UK

currently stipulates that all MoM implants are reviewed on an annual basis, with blood metal ion testing, radiographs and magnetic resonance imaging where required [22]. In addition, Costa et al found no evidence of benefit at 12 months when patients were randomised to resurfacing versus total hip arthroplasty (THA) [29]. A cost analysis performed on the same cohort found resurfacing to offer only very short-term efficiency benefits over THA within a selected patient group [175]. A dramatic fall in the use of resurfacings, with clustered use predominantly in the young male group during 2011 suggests surgeons across England and Wales are responding to the evidence [30].

Cementless implants with mid/large stems and MoP or CoP performed well in young females with equivalent survival and better OHS improvement compared with cemented implants. However, this group represented only 8.5% (454 of 5334) of cementless implants used in females. Moreover, 39% of females required a small stem size (7932 of 20166) (**Part 1 - Preliminary survival analyses**) and implant failure increased with higher BMI, suggesting the group of females that could benefit is small.

Older patients

There is little doubt that a fully cemented hip replacement works well in older patients; contemporary analyses consistently show better survival when compared with cementless implants supporting the results from both mid- and long-term joint registry data. Fordham et al stated that the most cost-effective implants are those with the best survival rates (and hence the fewest revisions), with the best patient outcomes and the least cost [121]. In this analysis of specific brands across England and Wales, the most cost-effective implant was therefore a standard cemented Exeter flanged Contemporary hip replacement with a 28mm metal head.

The Contemporary cup used in this analysis is manufactured using conventional PE. Australian registry shows MoXLPE to have the lowest 10-year revision risk [38]. The use of a XLPE cemented cup (Stryker X3 'Rimfit') with the Exeter stem may enhance the survival benefit even further. Survival data is currently of limited value as this cup was introduced to the UK market in July 2010. However, the same XLPE has shown superior survival when compared to conventional PE with a cementless acetabular shell (**Part 1 - Preliminary survival analyses**).

Cementless implants in this analysis have a 1.9 to 3.6 times higher revision risk than a standard cemented implant. Any functional benefit is minimal (1.6 points on the OHS) and unlikely to be of clinical importance; the OHS designers suggest a threshold of 3 points [100]. Proponents of fully cementless procedures argue that the costs are lower than those of cemented implants, which require extra equipment to perform cementation and a greater operative time for each case [173]. But this is dependent on implant brand, bearing choice and operative duration. Although we chose to analyse the commonest cementless implant, others may have lower costs. Manufacturer's price (excluding VAT) for the JRI Furlong (JRI Orthopaedics Ltd, Sheffield, United Kingdom) cementless stem is

quoted as only £740 for example, whilst the Exeter stem in the same study was over £1200, including equipment for cementation [176]. However, according to our data the NHS paid around half this quoted figure for the Exeter stem during 2012 (£544.44 to £693.94, including three mixes of cement [as in the referenced study], vacuum mixing pack and restrictor). The Corail stem ranged from £542.85 to £1118.00. The price of cementless cup modularity may have a bigger impact on the costs of cementless implants (Pinnacle cluster hole shell with Marathon liner £762.46 to £1326.00 [plus £54.05 per acetabular screw], flanged Contemporary cup £236.19 to £325.29 [including two mixes of cement and mixing pack]). Moreover, there remains no good evidence of improved theatre efficiency in the literature; savings of 15 to 20 minute per case have been suggested [173, 176, 177], but equating this to a £150-200 saving is only tangible where extra replacements are actually performed on an operating list. Therefore, it seems unlikely that cementless implants actually improve theatre efficiency and cost less, irrespective of brand used. More importantly, the cost-efficiency argument is only relevant when implants offer equivalent clinical benefit, which cementless implants fail to do in this analysis. The high costs of subsequent revision surgery (which occurs more commonly with cementless and resurfacing procedures) must also be considered in any cost-effectiveness analysis. One study found that annual hip replacement costs in the US (where cementless implants are used almost exclusively) could be reduced by $2billion if there was a joint registry comparable to the Sweden registry (enabling reductions in revision rates) [178]. The use of cement on the femoral side has many advantages that outweigh the disadvantage of a slightly longer operative time [62], and the available literature suggests that cemented fixation of acetabular components is more reliable than cementless beyond the first postoperative decade [42].

This thesis demonstrates no benefit of a resurfacing procedure in patients over 60 years across any of the domains studied in this analysis. Given the high failure rates, the risks of local and systemic complications, and the long-term concerns surrounding these implants, including a medical device warning and mandatory annual follow-up, there appears to be no place for a resurfacing procedure in patients over 60 years [19, 22].

Advocates of cementless and resurfacing procedures also cite a higher risk of cementation-related death as a reason to avoid cement usage. Long-term mortality was found to be highest following cemented hip replacement and lowest with the BHR in an analysis performed by McMinn et al using NJR data [179, 180]. When compared to the general population, mortality risk is initially higher after hip replacement, but returns to baseline risk after the early post-operative phase (30 to 60 days) [181]. If cementation were the cause of any differences in mortality across implant types, an excess of perioperative deaths due to embolisation during intra-operative cementation would occur. Multivariable modelling of associations with death is therefore appropriate only during this perioperative period. The analysis performed by McMinn et al adjusted for age, gender and ASA grade (widely acknowledged as a crude measure of general health). Without data on comorbidities, social deprivation and health scores [182],

and a background non-surgical population for comparison, survival analyses may be flawed. In our current study, there was very low perioperative mortality risk at 30 and 90 days across implants, with no significant differences despite use of the same (limited) variables as McMinn et al. Moreover, McMinn chose to censor revised patients rather than following up to death. Revision hip replacements carry a further mortality insult, which is greater than that associated with the primary procedure, so implants with a higher revision risk (resurfacing and cementless) may actually have equivalent (or higher) risk of death, once the revision mortality burden and the baseline patient factors are taken into account.

Although we have no data on early dislocation risk in this study, patient reported readmission and reoperation in the period between surgery and post-operative PROMs questionnaire completion could be used as a surrogate of dislocation. After adjusting for baseline differences, there were no implants with significantly lower or higher readmission or reoperation rates compared with the standard cemented implant. However, as with mortality, numbers of events were small, limiting the strength of conclusions drawn.

Implications

When compared with a standard cemented hip replacement, this analysis has found no advantage in the use of fully cementless or resurfacing implants in young patients. For the young female population, hybrid implants with adequate press-fit acetabular fixation and highly cross-linked PE or ceramic bearings may provide the best balance of early outcome improvement and revision risk.

There were no benefits for the routine use of cementless or resurfacing implants in patients over 60 years. Across this multi-outcome analysis, a cemented taper slip stem with a cemented PE cup and a standard sized head offered the best outcomes, with the lowest risks and at the lowest costs. This category of implant should be the gold standard for hip replacement. In the current era of increasing hip replacement demand, rising material costs, and dwindling health budgets, surgeons and healthcare providers will be encouraged (and possibly required) to use cost-effective implants. This practice may stifle innovation. However, the impact new materials and implant designs may have on patients needs careful consideration. For example, the DePuy Articular Surface Replacement (ASR, DePuy Orthopaedics, Leeds, United Kingdom) resurfacing device was introduced with limited in vivo data, marketed extensively and ultimately failed in high numbers, leaving a legacy of patient morbidity, expensive revision procedures and costly legal fees [183]. Robust, randomised clinical trials where newly marketed implants are compared to the existing 'gold standard' implants should be considered, with industry collaboration where necessary to improve transparency, in order to reduce unnecessary revision procedures, patient morbidity and healthcare resource wastage.

Current worldwide surgical practice is increasingly moving towards cementless implants, contrary to the global registry and cohort study evidence, and the

findings presented in this thesis. It is difficult to understand the reasons for this; surgeons may feel that the current evidence is not sufficient to discount the possible long-term benefits of cementless implants, hard bearings and larger head sizes. Operation speed is often cited as a reason for using cementless (which may be rational only when other outcome domains offer equivalence). Surgeons and their patients may also believe that these options are better and prestigious (as is often thought when considering newer technology). And for younger patients there is a perception that cementless and resurfacing devices offer the chance to function at a greater level than with cemented implants, when in reality few patients will actually return to high demand activities in order to test these claims. For older patients, it is highly likely their prosthesis will outlive them. The evidence is clear in this group of patients, and the lack of long-term evidence of implant survival should not be a reason to use prostheses with higher mid-term survival. Some of the blame for this practice must lie with the industry for aggressive marketing to surgeons and patients. However, surgeons, professional associations and healthcare providers should embrace evidence-based practice; a lack of long-term evidence should encourage the use of tried and tested implants with the best mid-term data.

Future work to explore and understand the decision-making process when surgeons make implant choices, and appreciate patients' expectations and wishes surrounding hip replacement would be informative.

Future direction

Good quality registries will play an increasingly major role in health outcome improvement. Methods to enhance their effectiveness include technology to provide real time analyses, the development of cross-registry collaboration, and greater involvement in research, including clinical trials. With anticipated improvements in quality, it is envisaged that this data could be used to inform health and regulatory policy and decision-making.

The development of soft tissue registries in the UK has created the potential for cross-registry linkage with the NJR, allowing a greater understanding of the patient pathway from pre-cursor disease stages (for example, meniscal injury within the knee), through early stages of the degenerative process (such as minor chondral defects) to established osteoarthritis. Evidence for the benefits of specific treatments (such as meniscal repair, partial meniscal excision and regenerative chondral procedures) could be explored, with eventual failure of treatment defined as progression to joint replacement. Linkage to the General Practice and the HES databases would improve risk adjustment modeling, though data on medications, co-morbidities and smoking status.

International joint replacement registry collaboration can offer the potential for improving safety surveillance of devices and for conducting patient-centered comparative outcomes studies. The International Collaboration of Orthopaedic Registries (ICOR, http://www.icor-initiative.org) initiative has already established several multinational collaborations in order to explore pertinent issues. Benefits include the ability to pool large numbers of patients and their outcomes, to centralise analytic expertise and to provide recommendations that are generalisable to the global joint replacement population (rather than regionally specific). However, this process is challenging in terms of adequate logistical support and infrastructure provision, especially for well-established registries where changes may be needed in order to collaborate effectively. Differences in data collection methods, the compatibility of datasets and the diversity of international data regulations are potential problems.

Ensuring data quality by improving reporting practices, reducing data errors and ensuring robust audit practices are critical steps in the development of the NJR in England and Wales. In order to effectively determine the impact of joint replacement on a patient population a change to the current definition of failure ('revision') is required. 'Reoperation' data should instead be collected, to include revisions as well as operations where components are not changed, such as washout for infection, reduction of a hip dislocation and fixation of periprosthetic fracture. It is essential that a patient's requirements for joint replacement care are satisfied, with development of more robust outcome measures to avoid the current pitfalls of OHS and EQ-5D index. Patient recorded experience measures (PREMs), which provide an indication of quality of care (through specific questions focusing on dignity, information, trust in staff, cleanliness, and timeliness), will become increasingly important. A greater understanding of the natural history of joint replacement (in terms of patient function and presence of

symptoms) from the index procedure to reoperation is also needed. Passive motion tracking devices to measure distance walked and activity levels, such as those integrated within smart phones, may provide a solution to improving the accuracy of activity levels prior to and following surgery, and could show deterioration in activity level as an implant begins to fail.

Effective integration of the Beyond Compliance (BC) service is crucial to the development of the NJR, and could form the basis for a more systematic approach to implant development. This service assesses the relative risk of failure of a new prosthesis and determines the rate at which it should be introduced to the market. It is now available to manufacturers of hip and knee joint implants on a voluntary basis but it is envisaged that this process would become mandatory. Data are provided to surgeons using the implant, to the manufacturer, and to independent assessors in real-time in order to monitor performance.

The use of joint registry data for research purposes has increased exponentially over the last ten years. Key deficiencies include the current inability to accurately risk adjust, the lack of data collection audit, levels of incorrect or missing data (which may not be randomly distributed) and the limited outcome measures. Whilst large cohort observational studies based on this data add to the evidence base, criticism of the potential for bias is justified. The use of registries to provide long-term follow-up data for clinical trials may be a solution to the difficulties of designing RCTs for these patients, in terms of reducing research costs and providing adequate population sizes.

The purpose of this thesis was to assimilate evidence to determine the best hip replacement. Whilst it is clear that a polished tapered cemented stem and a cemented cup with standard materials and component sizes provides good outcomes in the vast majority of patients undergoing primary THR for OA, other types of implants also produce good results. However, extra costs and complexities do not appear to be justified for the majority of patients. Outcomes that are important to the patient may be influenced by a number of variables. Implant type and specification appears to have little impact on this. Surgical factors may have a role. But there is much variation that cannot be explained using the variable set available within these analyses. The importance of expectation, education and levels of post-operative discomfort (as well as other symptoms) may be more important. Qualitative studies of joint replacement patients examining the relative importance of different outcomes are needed. Randomised trials to determine differences in patient outcomes following the instigation of an education programme, changes to pain management pathways and enhanced hospital and aftercare experience may be more worthy of research support from funding bodies than comparisons of types of implants.

Healthcare providers are obliged to cut costs whilst driving up standards. Analyses of linked national databases, as demonstrated in this thesis, together with longer-term strategies for ensuring data quality should ultimately provide the evidence-base by which cost-effective surgical practice can be implemented. The statistical methods explored in this thesis, together with the findings, are generalisable to hip replacement populations globally.

Thesis summary

Outcome following hip replacement is multifaceted and thus difficult to summarise. Patients wish to have implants that: relieve pain, allow greater function, restoration of normal activities, and that minimise complications such as infection, dislocation, fracture or aspetic loosening and further surgery (in the short and long term). Surgical goals include minimising mortality and morbidity. Healthcare providers demand a cost-effective operation informed by material costs, length of stay, re-admission for complications and further revision surgery.

Although there are limitations of observational study analyses, for hip replacement this type of study design has many advantages over experimental studies, which are costly and impractical on this scale. Whilst randomised controlled trials will remain the gold standard for comparing treatments, the ability of this approach to inform the multifaceted aspects of care in the enduring absence of trial data is crucial.

In younger males, resurfacing and cementless devices provide no additional benefits, but have greater material costs. Females may have marginally better functional outcomes at 6 months following a cementless or hybrid replacement, but clinically this may not be important, and costs are higher. Standardisation of hip replacement type across all patients is likely to improve outcome, reduce error and enhance training. Cemented hip replacement with a taper slip stem, a MoP bearing and a 28mm head is recommended for all patients. Cost data from the NHS suggest these implants are the cheapest to purchase. The posterior approach has been identified as having a marginally better functional outcome. Patients with a high BMI have greater risks of complications with only marginally poorer improvement in function.

Cox proportional hazards and competing risks models provide similar assessments of implant survival in medium term follow-up data. However, analyses may ultimately be more robust if competing risks are taken into account in older populations or for longer durations of follow-up (>10 years). Currently available and widely used joint specific and general health outcome measures are limited by data quality and numbers but should improve with time.

Glossary

A	
Acetabular component / cup / prosthesis	The portion of a total hip replacement prosthesis that is inserted into the acetabulum – the socket part of a ball and socket joint.
Arthrodesis	A procedure where a natural joint is fused together (stiffened).
Arthroplasty	A procedure where a natural joint is reconstructed with an artificial prosthesis.
ASA	American Society of Anaesthesiology scoring system for grading the overall physical condition of the patient, as follows: P1 – fit and healthy; P2 – mild disease, not incapacitating; P3 incapacitating systemic disease; P4 – life threatening disease; P5 – expected to die within 24 hrs with or without an operation.
B	
Bearing type	The two surfaces that articulate together in a joint replacement. Options include metal-on-polyethylene, metal-on-metal, ceramic-on-polyethylene and ceramic-on-ceramic.
Bilateral operation	Operation performed on both sides, e.g. left and right hip procedures, carried out during a single operation.
BMI	Body mass index. A statistical tool used to estimate a healthy body weight based on an individual's height. The BMI is calculated by dividing a person's weight (kg) by the square of their height (m^2).
Brand (of prosthesis)	The brand of a prosthesis (or implant) is the manufacturer's product name, e.g. the Exeter V40 brand
C	
Case mix	Term used to describe variation in surgical practice, relating to factors such as indications for surgery, patient age and sex.
Cement	The material used to fix cemented joint replacements to bone – polymethyl methacrylate (PMMA). Antibiotic is added to bone cement to try and reduce the risk of infection.
Cemented	Prostheses designed to be fixed into the bone using cement.
Cementless	Prostheses designed to be fixed into the bone by bony ingrowth or ongrowth, without using cement.
Compliance	The percentage of all total joint procedures that have been entered into the NJR within any given period compared with the expected number of procedures performed. The expected number of procedures can be the number of levies returned, or for the NHS Sector only, the number of procedures submitted to HES.

Competing risks survival analysis	An alternative to standard survival analysis methods (such as Kaplan-Meier estimation or the Cox proportional hazards model) when there are competing risks. A competing risk can prevent the event of interest from occurring (in this case, death is a competing risk to the risk of revision as patients who die will never experience revision). A competing-risks survival analysis adjusts the results accordingly.
Confidence Interval (CI)	A confidence interval gives an estimated range of values that are likely to include the unknown population parameter (e.g. a revision rate) being estimated from the given sample. If independent samples are taken repeatedly from the same population, and a confidence interval calculated for each sample, then a certain percentage (confidence level: e.g. 95%) of the intervals will include the unknown population parameter.
Confounding	Systematic variation due to the presence of factors which are not causal, which affect the outcome, and which are unequally distributed amongst interventions being compared, leading to inaccurate inferences about the results.
Cox proportional hazards model	A semi-parametric survival analysis model commonly used to model time-to-event data. As it is a multi variable model, it can be used to explore the effects of covariates on the outcome of interest and reduce the impact of confounding.
Cumulative Hazard	The cumulative hazard function indicates the probability of failure at a particular time given survival until that time.
Complications	Post-operative adverse events. In the case of the PROMs data collection, these include wound infection, bleeding complications, readmission, reoperation.
D	
Direct Lateral approach	Surgical approach to the hip where the abductor muscles are divided mid-tendon and reflected from the anterior aspect of the femoral neck.
Dislocation of hip	Dissociation of the ball from the socket, resulting in disarticulation of the joint. Requires intervention to restore normal anatomy, although this is rarely open surgical reduction.
E	
EQ-5D index	The EQ-5D-3L index is derived by combining patients' responses to questions on five different dimensions of health (mobility/self-care/usual activities/pain & discomfort/anxiety & depression) and 3 levels, using weightings based on population norms. This produces a single EQ-5D index value (referenced to 0 to 1, where 1 represents perfect health and 0 represents death, but negative values are possible for states perceived as being worse than death).
EQ-VAS	The EQ-VAS (0 to 100) provides an additional visual analogue assessment of patient well-being. Condition specific measures

	relate to the procedure under investigation and hence can only be compared within that procedure.
F	
Femoral component	Part of a total hip joint that is inserted into the femur (thigh bone) of the patient. It normally consists of a stem and head (ball).
Femoral head	Spherical portion of the femoral component of the artificial hip replacement.
Femoral prosthesis	Portion of a total joint replacement used to replace damaged parts of the femur (thigh bone).
Femoral stem	The part of a modular femoral component inserted into the femur (thigh bone). Has a femoral head mounted onto it to form the complete femoral component.
Funnel plot	A graphical representation of analyses that plots observed values against expected values. Control limits based on standard deviation are superimposed on the plot.
H	
Hard bearings	Articulating surface in the absence of polyethylene (metal-on-metal, ceramic-on-ceramic, or a combination).
Head size	Femoral head ball, standard sizes of 28mm and 32mm. Smaller (22 and 26mm) and larger heads (36+mm are available)
Healthcare provider	NHS or independent sector organisation that provides healthcare.
HES	Hospital Episode Statistics. Data on case mix, procedures, length of stay and other hospital statistics collected routinely by NHS hospitals in England.
Hip replacement	Femoral and acetabular surfaces replaced, either with a standard hip components of a resurfacing
Hybrid procedure	Joint replacement procedure in which cement is used to fix one prosthetic component while the other is cementless. For hip procedures, the term hybrid covers both reverse hybrid (cementless stem, cemented socket) and hybrid (cemented stem, cementless socket).
J	
Joint registries	National or regional bodies established to collect and monitor provision of prosthetic joint replacements.
K	
Kaplan-Meier	A statistical method of carrying out a survivorship analysis that can take into account 'censored' data, i.e. patient losses from the sample before the final outcome is observed (for instance, if a patient dies). It is a form of univariable analysis and so does not

	adjust for any confounding factors.
L	
Levy	Additional payment placed on the sales of hip implants to cover the costs associated with the ongoing operation and development of the NJR.
Linkable percentage	Linkable percentage is the percentage of all relevant procedures that have been entered into the NJR, which may be linked via NHS number to other procedures performed on the same patient.
Linkable procedures	Procedures entered into the NJR database, which are linkable to a patient's previous or subsequent procedures by the patient's NHS number.
LHMoM	Large head metal-on-metal. Large metal femoral head placed on the end of a femoral stem. Normally used with a metal resurfacing cup
M	
MDS	Minimum dataset, the set of data fields collected by the NJR. Some of the data fields are mandatory (i.e. they must be filled in). Fields that relate to patients' personal details must only be completed where informed patient consent has been obtained.
MHRA	Medicines and Healthcare products Regulatory Agency – the UK regulatory body for medical devices.
Modular	Component composed of more than one piece, e.g. a modular acetabular cup shell component with a modular cup liner, or femoral stem coupled with a femoral head.
Monobloc	Component composed of, or supplied as, one piece.
N	
NHS	National Health Service.
NICE	National Institute for Health and Clinical Excellence.
NJR	National Joint Registry for England and Wales. The NJR has collected and analysed data on hip replacements since 1 April 2003. It covers both the NHS and independent healthcare sectors to ensure complete recording of national activity in England and Wales.
O	
ODEP	Orthopaedic Data Evaluation Panel of the NHS Supply Chain. www.supplychain.nhs.uk/portal/page/portal/Communities/Orthopaedics/ODEP%20%database

ODEP ratings	ODEP ratings are the criteria for product categorisation of prostheses for primary total hip replacement against NICE benchmarks. The categorisation is based on NICE benchmarks: pre-entry benchmark (products commercially available that are involved in post-market clinical follow up studies); entry benchmark (after three, five and seven years; level A – acceptable evidence, level B – weak evidence); full benchmark (10 years; level A – strong evidence, level B reasonable evidence, level C – weak evidence). For each year, there is a level for unacceptable evidence, where products should only be used as part of a clinical trial.
OHS	PROMs for hip replacements within the NHS are measured using the Oxford Hip Score (OHS, 0 lowest to 48 highest)
Osteoarthritis	Inflammation of the joint resulting from wear of the articular cartilage, characterised by pain, stiffness and activity restriction in the hip joint
P	
Patient consent	Patient personal details may only be submitted to the NJR where explicit informed patient consent has been given or where patient consent has not been recorded. If a patient refuses to consent, only the anonymous operation and implant data may be submitted.
Polyethylene	Plastic, used to manufacture the acetabular component in hard-on-soft bearings (metal-on-polyethylene, ceramic-on-polyethylene). Conventional or highly cross-linked (stronger) versions
Posterior approach	Surgical approach to the hip where the joint capsule is approached through the external rotator muscles on the posterior aspect of the femoral neck
Primary hip replacement	The first time a total joint replacement operation is performed on any individual joint in a patient.
Prosthesis	Orthopaedic implant used in joint replacement procedures, e.g. a total hip, a unicondylar knee or a total ankle.
PROMs	Patient Reported Outcome Measures.
R	
Resurfacing	Resurfacing of the femoral head with a surface replacement femoral prosthesis and insertion of a monobloc acetabular cup, with or without cement.
Revision hip replacement	Operation performed to remove (and usually replace) one or more components of a total joint prosthesis.
S	
Surgical approach	Method used by a surgeon to gain access to, and expose, the joint.

Survivorship analysis	A statistical method that is used to determine what fraction of a population, such as those who have had a particular hip implant, has survived unrevised past a certain time. See Kaplan-Meier.

References

1. Arthritis-Research-UK. 2011 [cited 2011 13/12/2011]; Available from: http://www.arthritisresearchuk.org/.

2. (CDC) CfDCaP. Prevalence of disabilities and associated health conditions among adults--United States, 1999. MMWR Morb Mortal Wkly Rep. 2001 Feb 23;50(7):120-5.

3. No-authors-listed. Office for National Statistics. 2013.

4. Charnley J, Cupic Z. The nine and ten year results of the low-friction arthroplasty of the hip. Clin Orthop Relat Res. 1973 Sep(95):9-25.

5. Wylde V, Blom A, Dieppe P, Hewlett S, Learmonth I. Return to sport after joint replacement. J Bone Joint Surg Br. 2008 Jul;90(7):920-3.

6. Naal FD, Maffiuletti NA, Munzinger U, Hersche O. Sports after hip resurfacing arthroplasty. Am J Sports Med. 2007 May;35(5):705-11.

7. Scheerlinck T, Casteleyn PP. The design features of cemented femoral hip implants. J Bone Joint Surg Br. 2006 Nov;88(11):1409-18.

8. Spencer RF. Evolution in hip resurfacing design and contemporary experience with an uncemented device. J Bone Joint Surg Am. 2011 May;93 Suppl 2:84-8.

9. Freeman MA, Bradley GW. ICLH surface replacement of the hip. An analysis of the first 10 years. J Bone Joint Surg Br. 1983 Aug;65(4):405-11.

10. Howie DW, Cain CM, Cornish BL. Pseudo-abscess of the psoas bursa in failed double-cup arthroplasty of the hip. J Bone Joint Surg Br. 1991 Jan;73(1):29-32.

11. August AC, Aldam CH, Pynsent PB. The McKee-Farrar hip arthroplasty. A long-term study. J Bone Joint Surg Br. 1986 Aug;68(4):520-7.

12. Daniel J, Pynsent PB, McMinn DJ. Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis. J Bone Joint Surg Br. 2004 Mar;86(2):177-84.

13. Daniel J, Ziaee H, Kamali A, Pradhan C, Band T, McMinn DJ. Ten-year results of a double-heat-treated metal-on-metal hip resurfacing. J Bone Joint Surg Br. 2010 Jan;92(1):20-7.

14. Grammatopoulos GP, H. McLardy-Smith P, Gundle, R, Gill, HS. Murray, DW. The ten-year survival of the Birmingham Hip Resurfacing in men - an independent series. Journal of Bone and Joint Surgery - British Volume. 2011;Supplement - in press.

15. Treacy RB, McBryde CW, Shears E, Pynsent PB. Birmingham hip resurfacing: a minimum follow-up of ten years. J Bone Joint Surg Br. 2011 Jan;93(1):27-33.

16. National-Joint-Registry. National Joint Registry for England and Wales 8th Annual Report. 2011.

17. Kwon YM, Glyn-Jones S, Simpson DJ, Kamali A, McLardy-Smith P, Gill HS, et al. Analysis of wear of retrieved metal-on-metal hip resurfacing implants revised due to pseudotumours. J Bone Joint Surg Br. 2010 Mar;92(3):356-61.

18. Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natu S, Nargol AV. Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A consequence of excess wear. J Bone Joint Surg Br. 2010 Jan;92(1):38-46.

19. Haddad FS, Thakrar RR, Hart AJ, Skinner JA, Nargol AV, Nolan JF, et al. Metal-on-metal bearings: the evidence so far. J Bone Joint Surg Br. 2011 May;93(5):572-9.

20. Langton DJ, Joyce TJ, Jameson SS, Lord J, Van Orsouw M, Holland JP, et al. Adverse reaction to metal debris following hip resurfacing: the influence of component type, orientation and volumetric wear. J Bone Joint Surg Br. 2011 Feb;93(2):164-71.

21. Smith AJ, Dieppe P, Porter M, Blom AW. Risk of cancer in first seven years after metal-on-metal hip replacement compared with other bearings and general population: linkage study between the National Joint Registry of England and Wales and hospital episode statistics. BMJ. 2012;344:e2383.

22. Medicines-and-Healthcare-products-Regulatory-Agency. Medical Device Alert: All metal-on-metal (MoM) hip replacements (MDA/2012/008). 2011 [21/03/2012]; Available from: http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON143782.

23. Jameson SS, Langton DJ, Nargol AV. Articular surface replacement of the hip: a prospective single-surgeon series. J Bone Joint Surg Br. 2010 Jan;92(1):28-37.

24. Australian-National-Joint-Registry. Annual Report. 2011.

25. Naal FD, Pilz R, Munzinger U, Hersche O, Leunig M. High revision rate at 5 years after hip resurfacing with the Durom implant. Clin Orthop Relat Res. 2011 Sep;469(9):2598-604.

26. Langton DJ, Jameson SS, Joyce TJ, Webb J, Nargol AV. The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip. J Bone Joint Surg Br. 2008 Sep;90(9):1143-51.

27. Grammatopoulos G, Pandit H, Glyn-Jones S, McLardy-Smith P, Gundle R, Whitwell D, et al. Optimal acetabular orientation for hip resurfacing. J Bone Joint Surg Br. 2010 Aug;92(8):1072-8.

28. Smith AJ, Dieppe P, Howard PW, Blom AW. Failure rates of metal-on-metal hip resurfacings: analysis of data from the National Joint Registry for England and Wales. Lancet. 2012 Nov 17;380(9855):1759-66.

29. Costa ML, Achten J, Parsons NR, Edlin RP, Foguet P, Prakash U, et al. Total hip arthroplasty versus resurfacing arthroplasty in the treatment of patients with arthritis of the hip joint: single centre, parallel group, assessor blinded, randomised controlled trial. BMJ. 2012;344:e2147.

30. No-authors-listed. National Joint Registry for England and Wales 9th Annual Report. 2012; Available from: http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf.

31. Berry DJ, Harmsen WS, Cabanela ME, Morrey BF. Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components. J Bone Joint Surg Am. 2002 Feb;84-A(2):171-7.

32. Finnish-National-Arthoplasty-Registry. Annual Report 2006. Finnish National Arthroplasty Register. 2006; Available from: http://www.nam.fi/english/publications.

33. Wroblewski BM, Siney PD, Fleming PA. Charnley low-friction arthroplasty: survival patterns to 38 years. J Bone Joint Surg Br. 2007 Aug;89(8):1015-8.

34. New-Zealand-National-Joint-Registry. Annual Report 2008, 8 year report. New Zealand National Joint Registry. 2008 [23/03/2012]; Available from: http://www.cdhb.govt.nz/njr/reports/A2D65CA3.pdf.

35. Callaghan JJ, Bracha P, Liu SS, Piyaworakhun S, Goetz DD, Johnston RC. Survivorship of a Charnley total hip arthroplasty. A concise follow-up, at a minimum of thirty-five years, of previous reports. J Bone Joint Surg Am. 2009 Nov;91(11):2617-21.

36. Busch V, Klarenbeek R, Slooff T, Schreurs BW, Gardeniers J. Cemented hip designs are a reasonable option in young patients. Clin Orthop Relat Res. 2010 Dec;468(12):3214-20.

37. No-authors-listed. Annual report 2010. Swedish Hip Registry. 2010; Available from: http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sflb.ashx.

38. Australian-National-Joint-Registry. Australian National Joint Replacement Registry Annual Report 2012. 2012; Available from: https://aoanjrr.dmac.adelaide.edu.au/documents/10180/60142/Annual%20Report%202012?version=1.3&t=1361226543157.

39. Pakvis D, van Hellemondt G, de Visser E, Jacobs W, Spruit M. Is there evidence for a superior method of socket fixation in hip arthroplasty? A systematic review. Int Orthop. 2011 Aug;35(8):1109-18.

40. Sedrakyan A, Normand SL, Dabic S, Jacobs S, Graves S, Marinac-Dabic D. Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. BMJ. 2011;343:d7434.

41. Schmitz MW, Busch VJ, Gardeniers JW, Hendriks JC, Veth RP, Schreurs BW. Long-term results of cemented total hip arthroplasty in patients younger than 30 years and the outcome of subsequent revisions. BMC Musculoskelet Disord. 2013;14:37.

42. Toossi N, Adeli B, Timperley AJ, Haddad FS, Maltenfort M, Parvizi J. Acetabular components in total hip arthroplasty: is there evidence that cementless fixation is better? J Bone Joint Surg Am. 2013 Jan 16;95(2):168-74.

43. Chandler HP, Reineck FT, Wixson RL, McCarthy JC. Total hip replacement in patients younger than thirty years old. A five-year follow-up study. J Bone Joint Surg Am. 1981 Dec;63(9):1426-34.

44. Dorr LD, Takei GK, Conaty JP. Total hip arthroplasties in patients less than forty-five years old. J Bone Joint Surg Am. 1983 Apr;65(4):474-9.

45. Collis DK. Cemented total hip replacement in patients who are less than fifty years old. J Bone Joint Surg Am. 1984 Mar;66(3):353-9.

46. Ranawat CS, Atkinson RE, Salvati EA, Wilson PD, Jr. Conventional total hip arthroplasty for degenerative joint disease in patients between the ages of forty and sixty years. J Bone Joint Surg Am. 1984 Jun;66(5):745-52.

47. Sharp DJ, Porter KM. The Charnley total hip arthroplasty in patients under age 40. Clin Orthop Relat Res. 1985 Dec(201):51-6.

48. Lord GA, Hardy JR, Kummer FJ. An uncemented total hip replacement: experimental study and review of 300 madreporique arthroplasties. Clin Orthop Relat Res. 1979 Jun(141):2-16.

49. Tanzer M, Maloney WJ, Jasty M, Harris WH. The progression of femoral cortical osteolysis in association with total hip arthroplasty without cement. J Bone Joint Surg Am. 1992 Mar;74(3):404-10.

50. Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS. The porous-coated anatomic total hip prosthesis, inserted without cement. Results after five to seven years in a prospective study. J Bone Joint Surg Am. 1993 Jan;75(1):77-91.

51. Xenos JS, Callaghan JJ, Heekin RD, Hopkinson WJ, Savory CG, Moore MS. The porous-coated anatomic total hip prosthesis, inserted without cement. A prospective study with a minimum of ten years of follow-up. J Bone Joint Surg Am. 1999 Jan;81(1):74-82.

52. Kim YH, Oh SH, Kim JS. Primary total hip arthroplasty with a second-generation cementless total hip prosthesis in patients younger than fifty years of age. J Bone Joint Surg Am. 2003 Jan;85-A(1):109-14.

53. Butler JB, Lansky D, Duwelius PJ. Prospective evaluation of total hip arthroplasty with a cementless, anatomically designed, porous-coated femoral implant: mean 11-year follow-up. J Arthroplasty. 2005 Sep;20(6):709-16.

54. Little BS, Wixson RL, Stulberg SD. Total hip arthroplasty with the porous-coated anatomic hip prosthesis: results at 11 to 18 years. J Arthroplasty. 2006 Apr;21(3):338-43.

55. Sandiford N, Doctor C, Rajaratnam SS, Ahmed S, East DJ, Miles K, et al. Primary total hip replacement with a Furlong fully hydroxyapatite-coated titanium alloy femoral component: Results at a minimum follow-up of 20 years. Bone Joint J. 2013 Apr;95-B(4):467-71.

56. Vidalain JP. Twenty-year results of the cementless Corail stem. Int Orthop. 2011 Feb;35(2):189-94.

57. Hallan G, Lie SA, Furnes O, Engesaeter LB, Vollset SE, Havelin LI. Medium- and long-term performance of 11,516 uncemented primary femoral stems from the Norwegian arthroplasty register. J Bone Joint Surg Br. 2007 Dec;89(12):1574-80.

58. Gebuhr P, Stentzer K, Thomsen F, Levi N. Failure of total hip arthroplasty with Boneloc bone cement. Acta Orthop Belg. 2000 Dec;66(5):472-6.

59. Shah NN, Edge AJ, Clark DW. Hydroxyapatite-ceramic-coated femoral components in young patients followed-up for 16 to 19 years: an update of a previous report. J Bone Joint Surg Br. 2009 Jul;91(7):865-9.

60. Davey JR, Harris WH. A preliminary report of the use of a cementless acetabular component with a cemented femoral component. Clin Orthop Relat Res. 1989 Aug(245):150-5.

61. No-authors-listed. National Joint Registry for England and Wales 8th Annual Report. 2011 [25/03/2012]; Available from: http://www.njrcentre.org.uk/NjrCentre/LinkClick.aspx?fileticket=1TQ%2bEiNejm0%3d&tabid=86&mid=523.

62. Murray DW. Cemented femoral fixation: the North Atlantic divide. Orthopedics. 2011 Sep;34(9):e462-3.

63. Sedel L, Kerboull L, Christel P, Meunier A, Witvoet J. Alumina-on-alumina hip replacement. Results and survivorship in young patients. J Bone Joint Surg Br. 1990 Jul;72(4):658-63.

64. Cuckler JM, Moore KD, Lombardi AV, Jr., McPherson E, Emerson R. Large versus small femoral heads in metal-on-metal total hip arthroplasty. J Arthroplasty. 2004 Dec;19(8 Suppl 3):41-4.

65. Delaunay CP, Bonnomet F, Clavert P, Laffargue P, Migaud H. THA using metal-on-metal articulation in active patients younger than 50 years. Clin Orthop Relat Res. 2008 Feb;466(2):340-6.

66. Kuzyk PR, Saccone M, Sprague S, Simunovic N, Bhandari M, Schemitsch EH. Cross-linked versus conventional polyethylene for total hip replacement: a meta-analysis of randomised controlled trials. J Bone Joint Surg Br. 2011 May;93(5):593-600.

67. Sexton SA, Walter WL, Jackson MP, De Steiger R, Stanford T. Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg Br. 2009 Nov;91(11):1448-53.

68. Williams S, Schepers A, Isaac G, Hardaker C, Ingham E, van der Jagt D, et al. The 2007 Otto Aufranc Award. Ceramic-on-metal hip arthroplasties: a comparative in vitro and in vivo study. Clin Orthop Relat Res. 2007 Dec;465:23-32.

69. Amstutz HC, Lodwig RM, Schurman DJ, Hodgson AG. Range of motion studies for total hip replacements. A comparative study with a new experimental apparatus. Clin Orthop Relat Res. 1975 Sep(111):124-30.

70. Chandler DR, Glousman R, Hull D, McGuire PJ, Kim IS, Clarke IC, et al. Prosthetic hip range of motion and impingement. The effects of head and neck geometry. Clin Orthop Relat Res. 1982 Jun(166):284-91.

71. Bartz RL, Nobel PC, Kadakia NR, Tullos HS. The effect of femoral component head size on posterior dislocation of the artificial hip joint. J Bone Joint Surg Am. 2000 Sep;82(9):1300-7.

72. Bystrom S, Espehaug B, Furnes O, Havelin LI. Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. Acta Orthop Scand. 2003 Oct;74(5):514-24.

73. Berry DJ, von Knoch M, Schleck CD, Harmsen WS. Effect of femoral head diameter and operative approach on risk of dislocation after primary total hip arthroplasty. J Bone Joint Surg Am. 2005 Nov;87(11):2456-63.

74. Hummel MT, Malkani AL, Yakkanti MR, Baker DL. Decreased dislocation after revision total hip arthroplasty using larger femoral head size and posterior capsular repair. J Arthroplasty. 2009 Sep;24(6 Suppl):73-6.

75. Matsushita A, Nakashima Y, Jingushi S, Yamamoto T, Kuraoka A, Iwamoto Y. Effects of the femoral offset and the head size on the safe range of motion in total hip arthroplasty. J Arthroplasty. 2009 Jun;24(4):646-51.

76. Jameson SS, Lees D, James P, Serrano-Pedraza I, Partington PF, Muller SD, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. J Bone Joint Surg Br. 2011 Jul;93(7):876-80.

77. Charnley J, Kamangar A, Longfield MD. The optimum size of prosthetic heads in relation to the wear of plastic sockets in total replacement of the hip. Med Biol Eng. 1969 Jan;7(1):31-9.

78. Dowling JM, Atkinson JR, Dowson D, Charnley J. The characteristics of acetabular cups worn in the human body. J Bone Joint Surg Br. 1978 Aug;60-B(3):375-82.

79. Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg Am. 1990 Apr;72(4):518-28.

80. Bragdon CR, Doerner M, Martell J, Jarrett B, Palm H, Malchau H. The 2012 John Charnley Award: Clinical multicenter studies of the wear performance of highly crosslinked remelted polyethylene in THA. Clin Orthop Relat Res. 2013 Feb;471(2):393-402.

81. Jack CM, Walter WL, Shimmin AJ, Cashman K, de Steiger RN. Large diameter metal on metal articulations. Comparison of total hip arthroplasty and hip resurfacing arthroplasty. J Arthroplasty. 2013 Apr;28(4):650-3.

82. Langton DJ, Sidaginamale R, Lord JK, Nargol AV, Joyce TJ. Taper junction failure in large-diameter metal-on-metal bearings. Bone Joint Res. 2012 Apr;1(4):56-63.

83. Meyer H, Mueller T, Goldau G, Chamaon K, Ruetschi M, Lohmann CH. Corrosion at the cone/taper interface leads to failure of large-diameter metal-on-metal total hip arthroplasties. Clin Orthop Relat Res. 2012 Nov;470(11):3101-8.

84. Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. Lancet. 2012 Mar 12.

85. Hanna SA, Sewell MD, Sri-Ram K, Miles J, Aston WJ, Pollock RC, et al. The effect of femoral head size on functional outcome in primary total hip arthroplasty: a single-blinded randomised controlled trial. Hip Int. 2012 Nov-Dec;22(6):592-7.

86. Zagra L, Anasetti F, Bianchi L, Licari V, Giacometti Ceroni R. No Difference in Gait Recovery After THA With Different Head Diameters: A Prospective Randomized Study. Clin Orthop Relat Res. 2013 May 3.

87. Graves SE, Davidson D, Ingerson L, Ryan P, Griffith EC, McDermott BF, et al. The Australian Orthopaedic Association National Joint Replacement Registry. Med J Aust. 2004 Mar 1;180(5 Suppl):S31-4.

88. Havelin LI, Espehaug B, Vollset SE, Engesaeter LB. Early failures among 14,009 cemented and 1,326 uncemented prostheses for primary coxarthrosis. The Norwegian Arthroplasty Register, 1987-1992. Acta Orthop Scand. 1994 Feb;65(1):1-6.

89. Knutson K, Lindstrand A, Lidgren L. Survival of knee arthroplasties. A nation-wide multicentre investigation of 8000 cases. J Bone Joint Surg Br. 1986 Nov;68(5):795-803.

90. Lansky D, Milstein A. Quality measurement in orthopaedics: the purchasers' view. Clin Orthop Relat Res. 2009 Oct;467(10):2548-55.

91. Wylde V, Blom AW. The failure of survivorship. J Bone Joint Surg Br. 2011 May;93(5):569-70.

92. The-Health-and-Social-Care-Information-Centre. Patient Reported Outcome Measures (PROMs). 2011.

93. NICE. National Institute for Health and Clinical Effectiveness. 2011; Available from: http://www.nice.org.uk/.

94. NICE. Technology Appraisal Guidelines. 2011 [21/09/2014]; Available from: https://www.nice.org.uk/guidance/TA304.

95. No-authors-listed. Orthopaedic Data Evaluation Panel. 2014 [23/09/2014]; Available from: http://www.odep.org.uk/.

96. Devlin NJ, Parkin D, Browne J. Patient-reported outcome measures in the NHS: new methods for analysing and reporting EQ-5D data. Health Econ. 2010 Aug;19(8):886-905.

97. The-Health-and-Social-Care-Information-Centre. Hospital Episode Statistics online. 2011.

98. group E. EuroQol (EQ5D Score). 2009 [29/08/2012]; Available from: http://www.euroqol.org/.

99. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg Br. 1996 Mar;78(2):185-90.

100. Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br. 2007 Aug;89(8):1010-4.

101. Smith SC, Cano S, Lamping DL, Staniszewska S, Browne J, Lewsey J, et al. Patient-Reported Outcome Measures (PROMs) for routine use in Treatment Centres: recommendations based on a review of the scientific evidence. Final report to the Department of Health, December 20052005.

102. Gibson A. Posterior exposure of the hip joint. J Bone Joint Surg Br. 1950 May;32-B(2):183-6.

103. Hardinge K. The direct lateral approach to the hip. J Bone Joint Surg Br. 1982;64(1):17-9.

104. Masonis JL, Bourne RB. Surgical approach, abductor function, and total hip arthroplasty dislocation. Clin Orthop Relat Res. 2002 Dec(405):46-53.

105. Smith AJ, Wylde V, Berstock JR, Maclean AD, Blom AW. Surgical approach and patient-reported outcomes after total hip replacement. Hip Int. 2012 Jul-Aug;22(4):355-61.

106. Palan J, Beard DJ, Murray DW, Andrew JG, Nolan J. Which approach for total hip arthroplasty: anterolateral or posterior? Clin Orthop Relat Res. 2009 Feb;467(2):473-7.

107. Finucane MM, Stevens GA, Cowan MJ, Danaei G, Lin JK, Paciorek CJ, et al. National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9.1 million participants. Lancet. 2011 Feb 12;377(9765):557-67.

108. Jia H, Lubetkin EI. The impact of obesity on health-related quality-of-life in the general adult US population. J Public Health (Oxf). 2005 Jun;27(2):156-64.

109. Lohmander LS, Gerhardsson de Verdier M, Rollof J, Nilsson PM, Engstrom G. Incidence of severe knee and hip osteoarthritis in relation to different measures of body mass: a population-based prospective cohort study. Ann Rheum Dis. 2009 Apr;68(4):490-6.

110. Vasarhelyi EM, MacDonald SJ. The influence of obesity on total joint arthroplasty. J Bone Joint Surg Br. 2012 Nov;94(11 Suppl A):100-2.

111. Jain NB, Guller U, Pietrobon R, Bond TK, Higgins LD. Comorbidities increase complication rates in patients having arthroplasty. Clin Orthop Relat Res. 2005 Jun(435):232-8.

112. Namba RS, Paxton L, Fithian DC, Stone ML. Obesity and perioperative morbidity in total hip and total knee arthroplasty patients. J Arthroplasty. 2005 Oct;20(7 Suppl 3):46-50.

113. Busato A, Roder C, Herren S, Eggli S. Influence of high BMI on functional outcome after total hip arthroplasty. Obes Surg. 2008 May;18(5):595-600.

114. Davis AM, Wood AM, Keenan AC, Brenkel IJ, Ballantyne JA. Does body mass index affect clinical outcome post-operatively and at five years after primary unilateral total hip replacement performed for osteoarthritis? A multivariate analysis of prospective data. J Bone Joint Surg Br. 2011 Sep;93(9):1178-82.

115. Lacobucci g. CCGs ration care for obese and smokers with new wave of restrictions 2012 [24/02/2014]; Available from: http://www.pulsetoday.co.uk/ccgs-ration-care-for-obese-and-smokers-with-new-wave-of-restrictions/13569559.article#.UP3dUKWSJpI.

116. Ewan M. 2012 [24/02/2014]; Available from: http://67.18.16.98/~hertford/images/stories/ResourceCentre/BHPrioritiesForum/Guidance32HipReferralandSurgeryThresholdsUpdatedNov09.pdf.

117. Brander V, Gondek S, Martin E, Stulberg SD. Pain and depression influence outcome 5 years after knee replacement surgery. Clin Orthop Relat Res. 2007 Nov;464:21-6.

118. National-Joint-Registry. 7th Annual Report. 2010.

119. Health-Protection-Agency. Sixth report of the mandatory surveillance of surgical site infection in orthopaedic surgery. 2011.

120. NHFD. National Hip Fracture Database Programme. 2011.

121. Fordham R, Skinner J, Wang X, Nolan J. The economic benefit of hip replacement: a 5-year follow-up of costs and outcomes in the Exeter Primary Outcomes Study. BMJ Open. 2012;2(3).

122. Jenkins PJ, Clement ND, Hamilton DF, Gaston P, Patton JT, Howie CR. Predicting the cost-effectiveness of total hip and knee replacement: a health economic analysis. Bone Joint J. 2013 Jan;95-B(1):115-21.

123. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. 2007 Apr;89(4):780-5.

124. Briggs TW. Getting it Right First Time. 2013 [22/09/2014]; Available from: http://www.gettingitrightfirsttime.com/report/.

125. Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovitch C, Song F, et al. Evaluating non-randomised intervention studies. Health Technol Assess. 2003;7(27):iii-x, 1-173.

126. Rosenbaum PR RD. The central role of the propensity score in observational studies for causal effects Biometrika. 1983;70(1):41-55.

127. Pearl J. Understanding propensity scores. In Causality: Models, Reasoning, and Inference. Second ed: Cambridge University Press; 2009.

128. Ranstam J, Karrholm J, Pulkkinen P, Makela K, Espehaug B, Pedersen AB, et al. Statistical analysis of arthroplasty data. II. Guidelines. Acta Orthop. 2011 Jun;82(3):258-67.

129. Ranstam J, Karrholm J, Pulkkinen P, Makela K, Espehaug B, Pedersen AB, et al. Statistical analysis of arthroplasty data. I. Introduction and background. Acta Orthop. 2011 Jun;82(3):253-7.

130. Johnsen SP, Sorensen HT, Lucht U, Soballe K, Overgaard S, Pedersen AB. Patient-related predictors of implant failure after primary total hip replacement in the initial, short- and long-terms. A nationwide Danish follow-up study including 36,984 patients. J Bone Joint Surg Br. 2006 Oct;88(10):1303-8.

131. Roder C, Bach B, Berry DJ, Eggli S, Langenhahn R, Busato A. Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case-control study of 4420 patients. J Bone Joint Surg Am. 2010 Aug 18;92(10):1954-63.

132. Stilling M, Rahbek O, Soballe K. Inferior survival of hydroxyapatite versus titanium-coated cups at 15 years. Clin Orthop Relat Res. 2009 Nov;467(11):2872-9.

133. Howard JL, Kremers HM, Loechler YA, Schleck CD, Harmsen WS, Berry DJ, et al. Comparative survival of uncemented acetabular components following primary total hip arthroplasty. J Bone Joint Surg Am. 2011 Sep 7;93(17):1597-604.

134. Browne J, Jamieson L, Lewsey J. Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health, 2007. 2007 [29/08/2012]; Available from: http:// www.lshtm.ac.uk/php/hsrp/research/proms_report_12_dec_07.pdf.

135. Hill AB. The Environment and Disease: Association or Causation? Proc R Soc Med. 1965 May;58:295-300.

136. Fine J, Gray, R. A proportional hazards model for the subdistribution of a competing risk. Journal of the American Statistical Association. 1999;94:496-509.

137. Wylde V, Maclean A, Blom AW. Post-operative radiographic factors and patient-reported outcome after total hip replacement. Hip Int. 2012 Mar-Apr;22(2):153-9.

138. Thien TM, Karrholm J. Design-related risk factors for revision of primary cemented stems. Acta Orthop. 2010 Aug;81(4):407-12.

139. Jacobs CA, Christensen CP, Greenwald AS, McKellop H. Clinical performance of highly cross-linked polyethylenes in total hip arthroplasty. J Bone Joint Surg Am. 2007 Dec;89(12):2779-86.

140. Hannouche D, Zaoui A, Zadegan F, Sedel L, Nizard R. Thirty years of experience with alumina-on-alumina bearings in total hip arthroplasty. Int Orthop. 2011 Feb;35(2):207-13.

141. Lie SA, Engesaeter LB, Havelin LI, Gjessing HK, Vollset SE. Mortality after total hip replacement: 0-10-year follow-up of 39,543 patients in the Norwegian Arthroplasty Register. Acta Orthop Scand. 2000 Feb;71(1):19-27.

142. Hailer NP, Garellick G, Karrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register. Acta Orthop. 2010 Feb;81(1):34-41.

143. Howcroft DW, Qureshi A, Graham NM. Seating of ceramic liners in the uncemented trident acetabular shell: is there really a problem? Clin Orthop Relat Res. 2009 Oct;467(10):2651-5.

144. Langdown AJ, Pickard RJ, Hobbs CM, Clarke HJ, Dalton DJ, Grover ML. Incomplete seating of the liner with the Trident acetabular system: a cause for concern? J Bone Joint Surg Br. 2007 Mar;89(3):291-5.

145. Langton DJ, Sidaginamale RP, Holland JP, Deehan D, Joyce TJ, Nargol AV, et al. Practical considerations for volumetric wear analysis of explanted hip arthroplasties. Bone Joint Res. 2014;3(3):60-8.

146. Amstutz HC, Le Duff MJ, Campbell PA, Wisk LE, Takamura KM. Complications after metal-on-metal hip resurfacing arthroplasty. Orthop Clin North Am. 2011 Apr;42(2):207-30, viii.

147. Glyn-Jones S, Pandit H, Kwon YM, Doll H, Gill HS, Murray DW. Risk factors for inflammatory pseudotumour formation following hip resurfacing. J Bone Joint Surg Br. 2009 Dec;91(12):1566-74.

148. McBryde CW, Theivendran K, Thomas AM, Treacy RB, Pynsent PB. The influence of head size and sex on the outcome of Birmingham hip resurfacing. J Bone Joint Surg Am. 2010 Jan;92(1):105-12.

149. Graham J, Ries M, Pruitt L. Effect of bone porosity on the mechanical integrity of the bone-cement interface. J Bone Joint Surg Am. 2003 Oct;85-A(10):1901-8.

150. Nevelos J, Ingham E, Doyle C, Streicher R, Nevelos A, Walter W, et al. Microseparation of the centers of alumina-alumina artificial hip joints during simulator testing produces clinically relevant wear rates and patterns. J Arthroplasty. 2000 Sep;15(6):793-5.

151. Hallab NJ, Anderson S, Caicedo M, Skipor A, Campbell P, Jacobs JJ. Immune responses correlate with serum-metal in metal-on-metal hip arthroplasty. J Arthroplasty. 2004 Dec;19(8 Suppl 3):88-93.

152. Campbell P, Beaule PE, Ebramzadeh E, Le Duff MJ, De Smet K, Lu Z, et al. The John Charnley Award: a study of implant failure in metal-on-metal surface arthroplasties. Clin Orthop Relat Res. 2006 Dec;453:35-46.

153. Fisher J. Bioengineering reasons for the failure of metal-on-metal hip prostheses: an engineer's perspective. J Bone Joint Surg Br. 2011 Aug;93(8):1001-4.

154. De Smet K, Campbell PA, Gill HS. Metal-on-metal hip resurfacing: a consensus from the Advanced Hip Resurfacing Course, Ghent, June 2009. J Bone Joint Surg Br. 2010 Mar;92(3):335-6.

155. Bourne RB, Mehin R. The dislocating hip: what to do, what to do. J Arthroplasty. 2004 Jun;19(4 Suppl 1):111-4.

156. Royston P. Explained variation for survival models. The STATA Journal. 2006;6(1):83-96.

157. Judge A, Arden NK, Batra RN, Thomas G, Beard D, Javaid MK, et al. The association of patient characteristics and surgical variables on symptoms of pain and function over 5 years following primary hip-replacement surgery: a prospective cohort study. BMJ Open. 2013;3(3).

158. Andrew JG, Palan J, Kurup HV, Gibson P, Murray DW, Beard DJ. Obesity in total hip replacement. J Bone Joint Surg Br. 2008 Apr;90(4):424-9.

159. Traina F, Bordini B, De Fine M, Toni A. Patient weight more than body mass index influences total hip arthroplasty long term survival. Hip Int. 2011 Nov-Dec;21(6):694-9.

160. Namba RS, Inacio MC, Paxton EW. Risk factors associated with surgical site infection in 30,491 primary total hip replacements. J Bone Joint Surg Br. 2012 Oct;94(10):1330-8.

161. Chee YH, Teoh KH, Sabnis BM, Ballantyne JA, Brenkel IJ. Total hip replacement in morbidly obese patients with osteoarthritis: results of a prospectively matched study. J Bone Joint Surg Br. 2010 Aug;92(8):1066-71.

162. Jones CA, Cox V, Jhangri GS, Suarez-Almazor ME. Delineating the impact of obesity and its relationship on recovery after total joint arthroplasties. Osteoarthritis Cartilage. 2012 Jun;20(6):511-8.

163. McLaughlin JR, Lee KR. The outcome of total hip replacement in obese and non-obese patients at 10- to 18-years. J Bone Joint Surg Br. 2006 Oct;88(10):1286-92.

164. Collins RA, Walmsley PJ, Amin AK, Brenkel IJ, Clayton RA. Does obesity influence clinical outcome at nine years following total knee replacement? J Bone Joint Surg Br. 2012 Oct;94(10):1351-5.

165. McCalden RW, Charron KD, MacDonald SJ, Bourne RB, Naudie DD. Does morbid obesity affect the outcome of total hip replacement?: an analysis of 3290 THRs. J Bone Joint Surg Br. 2011 Mar;93(3):321-5.

166. Baker P, Petheram T, Jameson S, Reed M, Gregg P, Deehan D. The association between body mass index and the outcomes of total knee arthroplasty. J Bone Joint Surg Am. 2012 Aug 15;94(16):1501-8.

167. Howie DW, Holubowycz OT, Middleton R. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. J Bone Joint Surg Am. 2012 Jun 20;94(12):1095-102.

168. Stroh DA, Issa K, Johnson AJ, Delanois RE, Mont MA. Reduced Dislocation Rates and Excellent Functional Outcomes With Large-Diameter Femoral Heads. J Arthroplasty. 2013 Apr 17.

169. Bunn A, Colwell CW, Jr., D'Lima DD. Bony impingement limits design-related increases in hip range of motion. Clin Orthop Relat Res. 2012 Feb;470(2):418-27.

170. Klingenstein GG, Yeager AM, Lipman JD, Westrich GH. Increased range of motion to impingement with large head total hip arthroplasty: point of diminishing returns. Hip Int. 2012 May-Jun;22(3):261-5.

171. Kulkarni A, Jameson SS, James P, Woodcock S, Muller S, Reed MR. Does bariatric surgery prior to lower limb joint replacement reduce complications? Surgeon. 2011 Feb;9(1):18-21.

172. Hamilton DF, Lane JV, Gaston P, Patton JT, Macdonald D, Simpson AH, et al. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. BMJ Open. 2013;3(4).

173. Kallala R, Anderson P, Morris S, Haddad FS. The cost analysis of cemented versus cementless total hip replacement operations on the NHS. Bone Joint J. 2013 Jul;95-B(7):874-6.

174. Pennington M, Grieve R, Sekhon JS, Gregg P, Black N, van der Meulen JH. Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis. BMJ. 2013;346:f1026.

175. Edlin R, Tubeuf S, Achten J, Parsons N, Costa M. Cost-effectiveness of total hip arthroplasty versus resurfacing arthroplasty: economic evaluation alongside a clinical trial. BMJ Open. 2012;2(5).

176. Yates P, Serjeant S, Rushforth G, Middleton R. The relative cost of cemented and uncemented total hip arthroplasties. J Arthroplasty. 2006 Jan;21(1):102-5.

177. Barrack RL, Castro F, Guinn S. Cost of implanting a cemented versus cementless femoral stem. J Arthroplasty. 1996 Jun;11(4):373-6.

178. Larsson S, Lawyer P, Garellick G, Lindahl B, Lundstrom M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Aff (Millwood). 2012 Jan;31(1):220-7.

179. McMinn DJ, Snell KI, Daniel J, Treacy RB, Pynsent PB, Riley RD. Mortality and implant revision rates of hip arthroplasty in patients with osteoarthritis: registry based cohort study. BMJ. 2012;344:e3319.

180. MacGregor AJ. Clarification from the National Joint Registry. BMJ. 2012;345:e7199.

181. Lie SA, Pratt N, Ryan P, Engesaeter LB, Havelin LI, Furnes O, et al. Duration of the increase in early postoperative mortality after elective hip and knee replacement. J Bone Joint Surg Am. 2010 Jan;92(1):58-63.

182. Clement ND, Muzammil A, Macdonald D, Howie CR, Biant LC. Socioeconomic status affects the early outcome of total hip replacement. J Bone Joint Surg Br. 2011 Apr;93(4):464-9.

183. Cohen D. Revision rates for metal on metal hip joints are double that of other materials. BMJ. 2011;343:d5977.

Appendix

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■ HIP

The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements

A RETROSPECTIVE COHORT STUDY OF MEDIUM-TERM DATA FROM A NATIONAL JOINT REGISTRY

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Despite excellent results, the use of cemented total hip replacement (THR) is declining. This retrospective cohort study records survival time to revision following primary cemented THR using the most common combination of components that accounted for almost a quarter of all cemented THRs, exploring risk factors independently associated with failure. All patients with osteoarthritis who had an Exeter V40/Contemporary THR (Stryker) implanted before 31 December 2010 and recorded in the National Joint Registry for England and Wales were included in the analysis. Cox's proportional hazard models were used to analyse the extent to which risk of revision was related to patient, surgeon and implant covariates, with a significance threshold of $p < 0.01$. A total of 34 721 THRs were included in the study. The overall seven-year rate of revision for any reason was 1.70% (99% confidence interval (CI) 1.28 to 2.12). In the final adjusted model the risk of revision was significantly higher in THRs with the Contemporary hooded component (hazard ratio (HR) 1.88, $p < 0.001$) than with the flanged version, and in smaller head sizes (< 28 mm) compared with 28 mm diameter heads (HR 1.50, $p = 0.005$). The seven-year revision rate was 1.16% (99% CI 0.69 to 1.63) with a 28 mm diameter head and flanged component. The overall risk of revision was independent of age, gender, American Society of Anesthesiologists grade, body mass index, surgeon volume, surgical approach, brand of cement/presence of antibiotic, femoral head material (stainless steel/alumina) and stem taper size/offset. However, the risk of revision for dislocation was significantly higher with a 'plus' offset head (HR 2.05, $p = 0.003$) and a hooded acetabular component (HR 2.34, $p < 0.001$).

In summary, we found that there were significant differences in failure between different designs of acetabular component and sizes of femoral head after adjustment for a range of covariates.

Primary cemented total hip replacement (THR) is a successful operation with good medium- to long-term survival in several registries and meta-analyses.[1-6] However, the use of cemented THR is declining, with cementless implants being used in most THRs recorded in the England and Wales and Australian registries.[6,7] In 2005, 54% of 56 350 THRs in England and Wales were cemented, in 2010 this had fallen to 36% of 68 907 procedures.[6]

Data from national registries allow the independent analysis of large volumes of procedures over an entire population, but with some limitations. Despite the many different types of implants and materials used, the analysis in many registries uses simple discriminators, such as the type of fixation or bearing surface, when in reality no two brands of implants are alike, and assumptions of similarity may be misplaced.

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single type of cemented THR, using data from the National Joint Registry for England and Wales (NJR).[8] Each brand of implant has a range of parameters that may influence the risk of failure over time, not all of which are comparable across brands, for example the design of the acetabular component. In order to explore the determinants of failure we have limited the analysis to the most common cemented combination recorded in the NJR.

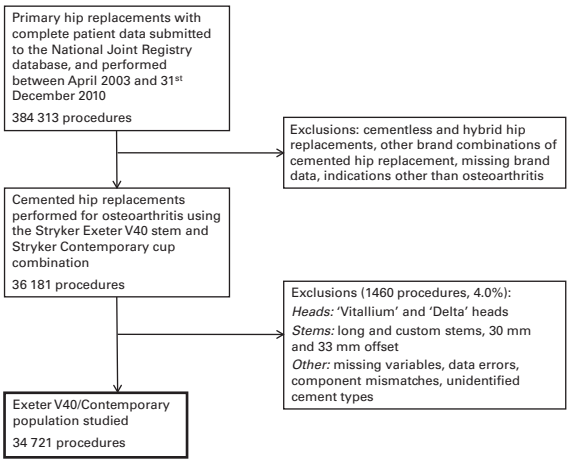


Fig. 1

Flowchart describing the procedures included.

Table I. Covariates used in the analysis

Category	Variable type	Covariate
Age	Ordinal	≤ 60 years, 61 to 75 years, ≥ 76 years
Gender	Binary	Female, male
ASA* grade	Ordinal	Grade ≤ 2, Grade ≥ 3
Body mass index	Ordinal	< 30 kg/m^2, ≥ 30 kg/m^2
Stem offset	Ordinal	35 mm, 37.5 mm, 44 mm, 50 mm
Stem taper	Ordinal	0, 1, 2, 3, ≥ 4
Head size	Ordinal	< 28 mm, 28 mm, 32 mm
Head offset	Ordinal	Standard, 'Plus' head, 'Minus' head
Cup design	Nominal	Flanged, hooded
Bearing	Nominal	Metal-on-polyethylene, ceramic-on-polyethylene
Cement type†	Nominal	High viscosity antibiotic-impregnated (Palacos HV, CMW HV)
		Low viscosity antibiotic-impregnated (Simplex LV, Other (Palacos LV, CMW LV))
		High viscosity, no antibiotic (Palacos HV, CMW HV)
		Low viscosity, no antibiotic (Simplex LV, Other (CMW LV, Palacos LV))
Surgical approach	Nominal	Anterolateral, posterior, other
Primary surgeon	Binary	Consultant, other
Consultant volume	Ordinal	Low (≤ 50 cases throughout study period), Medium (51 to 300), high (≥ 301)

* ASA, American Society of Anesthesiologists
† HV, high viscosity; LV, low viscosity

Materials and Methods

Design. We conducted a retrospective cohort study using NJR data to assess survival to revision for the commonest used brand of primary cemented THR, exploring risk factors independently associated with failure.

Data. The NJR has assimilated data on patients, surgeons and implants performed in both the private and public sectors in England and Wales since 2003. According to the 8th Annual Report, the most common combination of cemented THR used in England and Wales since 2003 features the Exeter V40 femoral and Contemporary acetabular components (Stryker Orthopaedics, Newbury, United Kingdom), which account for 23.2% of all cemented THRs (37 995 of 163 981).[6] This is a polished, double-tapered collarless stainless steel stem with a 'V40' morse taper and a hollow distal centraliser to allow subsidence for compressive loading throughout the cement mantle. It is available in a range of sizes. The monobloc Contemporary component is manufactured from standard (non-cross-linked) ultra-high molecular-weight polyethylene (UHMWPE (Duration; Stryker Orthopaedics)) and incorporates four polymethylmethacrylate (PMMA) spacer beads on the outer surface to prevent medialisation within the cement mantle. It is available in flanged and hooded varieties, with a range of external (40 mm to 60 mm) and internal diameters (22 mm to 32 mm). Femoral heads are available in stainless steel (Orthinox; Stryker: 22 mm to 32 mm diameter), cobalt–chrome (Vitallium; Stryker: 28 and 32 mm diameter) and ceramic (Alumina and Delta zirconium–alumina; Stryker: 28 and 32 mm diameter). Three brands of cement have been used with these components: Palacos (three manufacturers: Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corp., Kenilworth, New Jersey; Biomet, Bridgend, United Kingdom); CMW (DePuy Orthopaedics, Leeds, Stryker, Newbury, United Kingdom); and Simplex (Stryker). Palacos and CMW are available as high- and low-viscosity versions, and all brands have plain or antibiotic-impregnated formulations. Data were extracted for all Exeter/Contemporary THRs performed and submitted to the NJR until 31 December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely, these were excluded from the analyses. A summary of inclusion criteria is shown in Figure 1.

Covariate categories thought to have an influence on the risk of revision were the age of the patient at the time of surgery, gender, body mass index (BMI), stem and femoral head size.[9] We also examined the influence of American Society of Anesthesiologists (ASA) grade,[10] head offset, and the primary surgeon characteristics of grade and surgical volume. Covariates used are summarised in Table I.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) in the NJR, a complete record of the revision procedure (including side of operation) is submitted from the treating hospital and linked to the original index procedure by matching the unique patient identifier. A number of causes of revision can be recorded for each operation, which was interpreted hierarchically for cause, pre-selecting infection and then peri-prosthetic fracture. Pain was taken as the primary indication only when none other was provided.

Statistical analysis. Continuous and discrete continuous covariates (age, head offset, consultant volume) were analysed as categorical data (informed by spread of the data)

Table II. Demographics of patients receiving Exeter 40/Contemporary cemented hip replacements (Stryker) and the implants used (England and Wales, 2003 to 2010)

Demographics*	n = 34 721
Mean age (yrs) (SD; range)	73.9 (7.0; 23 to 100)
Age group (n, %)	
≤ 60 years	1603 (*4.6*)
61 to 75 years	16 965 (*48.9*)
≥ 76 years	16 153 (*46.5*)
Gender (n, %)	
Female	22 790 (*65.6*)
Male	11 931 (*34.4*)
ASA grade (n, %)	
1 to 2	28 747 (*82.8*)
≥ 3	5974 (*17.2*)
Mean (SD) BMI (kg/m^2)	28.2 (5.1)†
BMI group (n, %)	
< 30 kg/m^2	8929 (*25.7*)
≥ 30 kg/m^2	4868 (*14.0*)
Data missing	20 924 (*60.3*)
Stem offset (n, %)	
35 mm	1690 (*4.9*)
37.5 mm	13 449 (*38.7*)
44 mm	18 161 (*52.3*)
50 mm	1421 (*4.1*)
Stem taper (n, %)	
0	10 656 (*30.7*)
1	10 925 (*31.5*)
2	8770 (*25.3*)
3	3227 (*9.3*)
≥ 4	1143 (*3.3*)
Head size (n, %)	
< 28 mm	5036 (*14.5*)
22 mm	104
26 mm	4932
28 mm	27 218 (*78.4*)
32 mm	2467 (*7.1*)
Head offset (n, %)	
Standard (0)	22 446 (*64.6*)
Plus (+ 2 mm to + 12 mm)	5686 (*16.4*)
Minus (-2 mm to -4 mm)	6589 (*19.0*)
Cup design (n, %)	
Flanged	24 212 (*69.7*)
Hooded	10 509 (*30.3*)
Bearing (n, %)	
Metal-on-polyethylene	32 724 (*94.2*)
Ceramic-on-polyethylene	1997 (*5.8*)
Cement (n, %)	
High-viscosity (HV) antibiotic-impregnated	21 674 (*62.4*)
Palacos HV	20 664
CMW HV	1011
Low-viscosity (LV) antibiotic-impregnated	8561 (*24.7*)
Simplex LV	8280
Other (Palacos LV, CMW LV)	281
High-viscosity (HV), no antibiotics	1426 (*4.1*)
Palacos HV	831
CMW HV	595
Low-viscosity (LV), no antibiotics	1570 (*4.5*)
Simplex LV	1567
Other (Palacos LV, CMW LV)	3
Data missing	1490 (*4.3*)
Surgical approach (n, %)	
Anterolateral	17 065 (*49.1*)
Posterior	15 386 (*44.3*)
Other	1067 (*3.1*)
Missing data	1203 (*3.5*)
Primary surgeon (n, %)	
Consultant	25 962 (*74.8*)
Other	8759 (*25.2*)
Number of consultants (n)	973
Consultant volume (n, %)	
Low (≤ 50 cases)	9033 (*26.0*)
Medium (51 to 250 cases)	15 978 (*46.0*)
High (≥ 251 cases)	9710 (*28.0*)
Number of surgical units (n)	271

* ASA, American Society of Anesthesiologists; BMI, body mass index
† based on 13 797 procedures

because of the greater clinical relevance when making group comparisons. Preliminary analysis of age as a continuous variable was also reported. In order to explore the influence of covariates the most common category was generally used as the baseline case: for example, 28 mm heads were used as the baseline against which all other head sizes were compared. Exceptions to this were age (where the youngest group was used as the baseline) and consultant volume (where the highest-volume group was used).

A revision procedure was considered to be a 'failure event', where the time between the primary THR and the revision was the measure of survival. Survival times for patients who had not undergone revision were censored at the study census date (31 December 2010). Kaplan–Meier survival charts with 95% confidence intervals (CI) were generated to display differences in unadjusted covariates. The log-rank (Mantel–Cox) test was used to perform paired comparisons between each of the covariates using the pairwise over strata method. Covariate categories with unadjusted significant influences are presented, with life tables to describe numbers within each covariate category entering each year of the study.

In order to adjust for differences in known patient, surgeon and implant covariates, Cox's proportional hazard models were used. The Cox model assumes an underlying baseline risk of revision (hazard) that stays constant through time and is influenced proportionately by covariates, which may mitigate or enhance the risk of revision. Two separate models were constructed: the first for all revisions, and the second for revisions where dislocation was recorded as an indication for revision (other indications were treated as an alternative outcome, thereby effectively excluding these from the analysis). Results are presented as hazard ratios (HRs) with 99% CIs: ratios > 1 indicate that risk is higher than the reference covariate category. Owing to the statistical methods used and the large population size, only covariates fitting models with $p < 0.01$ were considered significant influences, to reduce the risk of type 1 error.

Life tables were produced to report unadjusted one-, three-, five- and seven-year revision rates (with 99% CIs estimated using the normal approximation) for each design of acetabular component and size of femoral head, and for all 34 721 procedures included in the study. Survival was not reported if the number entering a year was < 5% of the original number entering that particular group. A p-value of < 0.01 was applied to denote statistical significance.

Results

Of 34 721 primary procedures, most were performed in women (22 790, 65.6%) with ASA grade ≤ 2 (28 747, 82.8%) and aged ≤ 75 years (18 598, 53.5%); the mean age at operation was 74 years (23 to 100). There were 13 797 (39.7%) procedures with complete BMI data; of these, most patients had a BMI of < 30 kg/m^2 (8929, 64.7%). Most stems used a 44 mm offset (18 161, 52.3%) and the most commonly used stem taper was size 1 (10 925, 31.5%). The commonest design of acetabular component was flanged (24 212, 69.7%) and the commonest head was stainless steel (32 724, 94.2%), 28 mm diameter (27 218, 78.4%) with standard offset (22 446, 64.6%). Most

Table III. Proportion of acetabular component designs and head sizes used by year (England and Wales, 2003 to 2010)

	Acetabular component design		Head size		
Year	Flanged	Hooded	< 28 mm	28 mm	32 mm
2003	470 (*56.2*)	367 (*43.8*)	472 (*56.4*)	365 (*43.6*)	0 (*0.0*)
2004	1038 (*63.4*)	599 (*36.6*)	745 (*45.5*)	884 (*54.0*)	8 (*0.5*)
2005	2273 (*64.6*)	1243 (*35.4*)	839 (*23.9*)	2642 (*75.1*)	35 (*1.0*)
2006	3045 (*69.9*)	1327 (*30.4*)	779 (*17.8*)	3507 (*80.2*)	86 (*2.0*)
2007	4168 (*71.0*)	1702 (*29.0*)	788 (*13.4*)	4916 (*83.7*)	166 (*2.8*)
2008	4402 (*69.8*)	1904 (*30.2*)	599 (*9.5*)	5270 (*83.6*)	437 (*6.9*)
2009	4477 (*72.9*)	1666 (*27.1*)	505 (*8.2*)	4822 (*78.5*)	816 (*13.3*)
2010	4339 (*71.8*)	1701 (*28.2*)	309 (*5.1*)	4812 (*79.7*)	919 (*15.2*)
Total	24 212 (*69.7*)	10 509 (*30.3*)	5036 (*14.5*)	27 218 (*78.4*)	2467 (*7.1*)

Table IV. Reasons recorded for revision following Exeter V40/Contemporary (Stryker) cemented hip replacement (England and Wales, 2003 to 2010)

Indication (n, %)	n = 279
Dislocation	98 (*35.1*)
Infection	72 (*25.8*)
Aseptic loosening/lysis	61 (*21.9*)
Stem only	19
Acetabular component only	41
Both	1
Malalignment	33 (*11.8*)
Stem only	5
Acetabular component only	23
Both	5
Peri-prosthetic fracture	22 (*7.9*)
Stem only	20
Acetabular component only	2
Unexplained pain	9 (*3.2*)
Polyethylene wear	8 (*2.9*)
Implant fracture	4 (*1.4*)
Stem only	2
Acetabular component only	2
Other	28 (*6.3*)

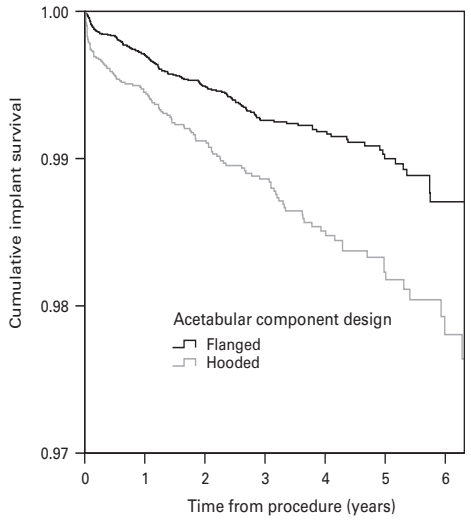
procedures were performed with high-viscosity antibiotic-impregnated cement (21 674, 62.4%), and the commonest brand was Palacos HV with antibiotic (20 664, 59.5%). In most cases the consultant performed the procedure (25 962, 74.8%) through an anterolateral approach (17 065, 49.1%), and was a medium- or high-volume surgeon (≥ 51 cases over the study period: 25 688, 74.0%).

Patients were under the care of 973 different consultants in 271 different units. Demographic details are shown in Table II. The proportion of flanged acetabular components used increased from 56.2% (n = 470) in 2003 to 71.8% (n = 4339) in 2010 (Table III). Over the period of the study the use of heads with a diameter < 28 mm declined from 56.4% (n = 472) in 2003 to 5.1% (n = 309) in 2010, whereas the use of heads with a diameter of 28 mm increased from 43.6% (n = 365) to 79.7% (n = 4812). From 2004, 32 mm diameter modular heads were used in small numbers but by 2010 they accounted for 15.2% (n = 919) of the heads used (Table III). A total of 54.0% (18 746) of procedures were performed with a combination of a 28 mm head and a flanged acetabular component.

Reasons for revision. In all, 279 patients had undergone a revision procedure by the census date. The most common reason was dislocation (98 revisions, 35.1% of all revisions). Infection was recorded as the main indication for revision in 72 THRs (25.8%), followed by aseptic component loosening/lysis infection (61, 21.9%), malalignment (33, 11.8%) and peri-prosthetic fracture (22, 7.9%). Revision data are summarised in Table IV.

All-cause revision model. In simple (univariable) regression analysis of 'all revisions', only acetabular component design influenced implant revision risk ($p < 0.001$) (Fig. 2), although there was a trend towards significance in femoral head sizes < 28 mm ($p = 0.022$) (Fig. 3). The brand of cement was not found to be a significant influence for survival: these covariates were therefore merged into common cement type categories. After risk adjustment, hooded acetabular component design (HR 1.88 (99% CI 1.38 to 2.57); $p < 0.001$) and heads with a diameter of < 28 mm (HR 1.50 (99% CI 1.03 to 2.17); $p = 0.005$) were independent influences associated with revision. The risk of revision for heads with a diameter of 32 mm (HR 0.84 (99% CI 0.36 to 1.94); $p = 0.595$) and ceramic heads (HR 1.10 (99% CI 0.57 to 2.13); $p = 0.720$) was not significantly different from those with a head of 28 mm diameter and stainless steel heads, respectively. Cement viscosity and impregnation with antibiotic did not influence risk of revision. The risk of revision was independent of gender, age, ASA grade, BMI, stem characteristics, head offset, surgical approach and consultant experience.

Revision for dislocation model. Revisions performed for dislocation were then analysed. Using simple (univariable) regression analysis, acetabular component design ($p < 0.001$) and 'plus' head offsets ($p = 0.003$) influenced the risk of revision. After risk adjustment, the design of the acetabular component (HR 2.34 (99% CI 1.38 to 3.96); $p < 0.001$) and plus head offset (HR 2.05 (99% CI 1.10 to 3.80); $p = 0.003$) remained significant influences on the risk of revision.



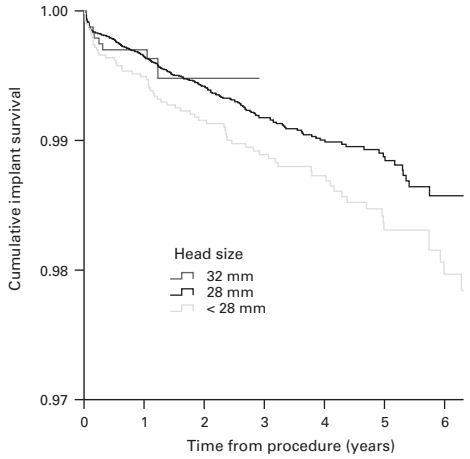
Log rank (Mantel-Cox)	Flanged	Hooded
Flanged (p-value)	-	< 0.001
Hooded	< 0.001	-

Life table showing numbers at risk in each year

Acetabular component design	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Flanged	24 212	19 491	14 795	10 276	6176	3282	1281	375
Hooded	10 609	8582	6793	4846	3176	1913	790	283

Fig. 2

Kaplan-Meier survival curves showing unadjusted cumulative implant survival of Exeter V40/Contemporary (Stryker) by design of acetabular component (England and Wales, 2003 to 2010).



Log rank (Mantel-Cox)	< 28 mm	28 mm	32 mm
< 28 mm (p-value)	-	0.022	0.101
28 mm	0.022	-	0.615
32 mm	0.101	0.615	-

Life table showing numbers at risk in each year

Femoral size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
< 28 mm	5036	4619	4032	3365	2547	1783	1034	378
28 mm	27 218	21 946	16 873	11 482	6691	3374	1031	280
32 mm	2467	1508	683	275	114	38	6	0

Fig. 3

Kaplan–Meier survival curves showing unadjusted cumulative implant survival of Exeter V40/Contemporary (Stryker) by head size (England and Wales, 2003 to 2010).

Revision rates. The overall seven-year revision rate was 1.70% (99% CI 1.28 to 2.12) for the entire population and was lowest with flanged acetabular components and heads of 28 mm diameter (1.16% (99% CI 0.69 to 1.63)). A hooded acetabular component used with a head of < 28mm diameter resulted in a seven-year revision rate of 3.49% (99% CI 1.50 to 5.48). Although 32 mm diameter heads have only been used in the last four years, early (three-year) revision for THRs with flanged components (0.53% (99% CI 0.00 to 1.17)) was similar to that for 28 mm diameter heads and flanged components (0.67% (99% CI 0.49 to 0.86)).

Discussion

This retrospective cohort study provides the largest in-depth analysis of a single brand combination of cemented THRs to date. After risk adjustment significantly greater revision rates following THR were independently associated with a hooded acetabular component design and small femoral heads (< 28 mm diameter). These findings are clinically important, as they identify modifiable parameters within the control of the surgeon. Other factors, including the surgical approach, the material of the femoral head and the type of cement used, did not significantly influence the rate of revision.

This study has limitations. The rates of revision are mid-term, as the earliest operation recorded was in April 2003. The relative rates at which particular implants require revision may change with further follow-up. Revision was taken as a surrogate marker of failure, as other endpoints were unavailable. Therefore, those patients living with a painful hip, or those awaiting revision at the time of censoring, have not been identified.[11] Information regarding the duration and severity of symptoms, radiological appearance and activity levels pre- and post-operatively were not available. Additionally, the design of the study is observational and thus vulnerable to omitted variables, which may have confounded our findings. The Registry does not capture all the issues determining the selection of components: a higher rate of revision may be a result of unmeasured patient or surgical factors, rather than factors relating to a specific component. Nevertheless, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the reliability of the estimates.

The hooded Contemporary acetabular component was associated with a significantly higher risk of revision for all indications and revision when dislocation was the indication. Two main differences in design distinguish the hooded from the flanged components: the hooded component incorporates a large posterior elevation (or hood) with the

intention of reducing the risk of dislocation, and the flanged component incorporates a wide circumferential rim of polyethylene (the flange) that can be trimmed by the surgeon to enclose the acetabulum, thereby preventing the escape of cement during pressurisation. This outer rim, together with the absence of the posterior hood, may allow easier positioning. The hood might increase the risk of dislocation by being the source of impingement. Within the thresholds set for covariates there is no evidence from this study to suggest that the influence of the design of the acetabular component was related to surgeon experience, head offset or surgical approach. Although the NJR reports revision for Contemporary acetabular components as one group,[6] the Orthopaedic Device Evaluation Panel (ODEP) has recommended that revision be divided by hooded and flanged types.[12] The findings of our study support this recommendation.

Data from the Swedish arthroplasty register have previously demonstrated that an Exeter stem with head size of 22 mm diameter has a significantly higher revision rate than stem with a 28 mm diameter head ($p = 0.004$) in over 21 000 THRs.[13] Although most smaller heads in this study were 26 mm diameter, the findings were similar. The benefit of a 32 mm diameter modular head has yet to be established.

A 'plus' offset head was also a significant influence for the risk of revision for dislocation. This might reflect a failure to adequately restore offset with the stem options available, or a perception of instability at operation when the trial heads were used following introduction of the stem.

In the most recent NJR Annual Report (8th), brand-specific analyses are reported up to five years only. For 37 995 Exeter V40/Contemporary THRs the five-year revision rate was 1.26% (95% CI 1.10 to 1.44).[6] Drawn from the same basic dataset, our five-year result for overall revision was similar (1.26% (99% CI 1.03 to 1.48)). However, revision at five years when a 28 mm diameter head was used in combination with a flanged acetabular component was only 0.85% (99% CI 0.60 to 1.10). Although in 2010 most components had 28 mm diameter heads (78.4%) with flanged acetabular components (69.7%), only 54.0% of procedures used this combination over the entire study. Therefore, the analysis of brands in the NJR 8th Annual Report is skewed by longer follow-up data from poorer-performing components.

The risk of revision was independent of age and gender, despite previous reports of poorer outcomes in young male patients after cemented THR.[9,14] In contrast to cementless THR, BMI ≥ 30 kg/m^2 and higher ASA grade were not significant influences on failure.[9,15] It is possible that failure to fit BMI within the models may be as a result of only 39.7% of records including BMI data. Increasing femoral head size is thought to contribute to lower rates of dislocation[16] and revision,[17] but in our study revision of THRs with 32 mm diameter heads was similar to that for 28 mm diameter heads, although longer-term analyses are needed as 32 mm diameter heads have a shorter follow-up.

In summary, there were significant differences in failure between types of design of acetabular components and sizes of femoral heads after adjustment for a range of covariates in a large cohort of single-brand cemented THRs. In this study, hooded Contemporary acetabular components and femoral head sizes of < 28 mm diameter had significantly higher rates of revision. In terms of revision for dislocation, a 'plus' offset femoral head was significantly associated with increased risk. This study demonstrated that many factors can influence the risk of revision; registry data analyses may mislead if they fail to adjust for all relevant covariates when comparing across brands and types.

Supplementary material

An appendix further detailing the reliability assessment of the statistical models, two tables detailing the simple and multiple variable Cos regressions of independent predictors of revision for i) all revisions and ii) revision for dislocation, and a table detailing the one-, three-, five- and seven-year rates of revision by head size and acetabular component design, are available with the electronic version of this article on our website www.bjj.boneandjoint.org.uk

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References

1. **Morshed S, Bozic KJ, Ries MD, Malchau H, Colford JM Jr.** Comparison of cemented and uncemented fixation in total hip replacement: a meta-analysis. *Acta Orthop* 2007;78:315–326.
2. **Rothwell A, Taylor J, Wright M, et al.** New Zealand Orthopaedic Association. The New Zealand Joint Registry: eleven year report, 2010. http://www.cdhb.govt.nz/njr/reports/A2D65CA3.pdf (date last accessed 13 August 2012).
3. **No authors listed.** Annual Report 2008. Norwegian Arthroplasty Register 2008 http://nrlweb.ihelse.net/eng/default.htm (date last accessed 13 August 2012).
4. **No authors listed.** Swedish Hip Registry. Annual report, 2010. http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sflb.ashx (date last accessed 13 August 2012).
5. **Corbett KL, Losina E, Nti AA, Prokopetz JJ, Katz JN.** Population-based rates of revision of primary total hip arthroplasty: a systematic review. *PLoS One* 2010;5:13520.
6. **No authors listed.** National Joint Registry for England and Wales: 8th Annual report, 2011. http://www.njrcentre.org.uk (date last accessed 13 August 2012).
7. **No authors listed.** Australian Orthopaedic Association, National Joint Replacement Registery, annual report 2010. http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp (date last accessed 13 August 2012).
8. **No authors listed.** National Joint Registry (NJR) website. http://www.njrcentre.org.uk/njrcentre/default.aspx (date last accessed 15 August 2012).
9. **Röder C, Bach B, Berry DJ, et al.** Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case-control study of 4420 patients. *J Bone Joint Surg [Am]* 2010;92-A:1954–1963.

10. Dripps RD. New classification of physical status. *Anesthesiol* 1963;24:111.

11. Wylde V, Blom AW. The failure of survivorship. *J Bone Joint Surg [Br]* 2011;93-B:569–570.

12. No authors listed. NHS Supply Chain. Orthopaedic Device Evaluation Panel (ODEP), 2012. http://www.supplychain.nhs.uk/odep/ (date last accessed 13 August 2012).

13. Thien TM, Kärrholm J. Design-related risk factors for revision of primary cemented stems. *Acta Orthop* 2010;81:407–412.

14. Chandler HP, Reineck FT, Wixson RL, McCarthy JC. Total hip replacement in patients younger than thirty years old: a five-year follow-up study. *J Bone Joint Surg [Am]* 1981;63:1426–1434.

15. Jameson SS, Rymaszewska M, Mason J, et al. Higher revision with hard bearings following 35 386 single-brand cementless hip replacements: a retrospective cohort study using National Joint Registry Data. Presented at the British Hip Society Meeting Manchester, 2012.

16. Jameson SS, Lees D, James P, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. *J Bone Joint Surg [Br]* 2011;93-B:876–880.

17. Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. *Lancet* 2012;379:1199–1204.

■ HIP

Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements

A RETROSPECTIVE COHORT STUDY USING NATIONAL JOINT REGISTRY DATA

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The popularity of cementless total hip replacement (THR) has surpassed cemented THR in England and Wales. This retrospective cohort study records survival time to revision following primary cementless THR with the most common combination (accounting for almost a third of all cementless THRs), and explores risk factors independently associated with failure, using data from the National Joint Registry for England and Wales. Patients with osteoarthritis who had a DePuy Corail/Pinnacle THR implanted between the establishment of the registry in 2003 and 31 December 2010 were included within analyses. There were 35 386 procedures. Cox proportional hazard models were used to analyse the extent to which the risk of revision was related to patient, surgeon and implant covariates. The overall rate of revision at five years was 2.4% (99% confidence interval 2.02 to 2.79). In the final adjusted model, we found that the risk of revision was significantly higher in patients receiving metal-on-metal (MoM: hazard ratio (HR) 1.93, p < 0.001) and ceramic-on-ceramic bearings (CoC: HR 1.55, p = 0.003) compared with the best performing bearing (metal-on-polyethylene). The risk of revision was also greater for smaller femoral stems (sizes 8 to 10: HR 1.82, p < 0.001) compared with mid-range sizes. In a secondary analysis of only patients where body mass index (BMI) data were available (n = 17 166), BMI ≥ 30 kg/m^2 significantly increased the risk of revision (HR 1.55, p = 0.002). The influence of the bearing on the risk of revision remained significant (MoM: HR 2.19, p < 0.001; CoC: HR 2.09, p = 0.001). The risk of revision was independent of age, gender, head size and offset, shell, liner and stem type, and surgeon characteristics.

We found significant differences in failure between bearing surfaces and femoral stem size after adjustment for a range of covariates in a large cohort of single-brand cementless THRs. In this study of procedures performed since 2003, hard bearings had significantly higher rates of revision, but we found no evidence that head size had an effect. Patient characteristics, such as BMI and American Society of Anesthesiologists grade, also influence the survival of cementless components.

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Cementless total hip replacement (THR) was introduced in the 1970s in an attempt to improve implant survival in younger patients.[1] Technological advances have led to an increase in the available implant options with various types of cementless fixation, size of the modular head, bearing material and design philosophy. Different sizes of femoral head have been introduced in an attempt to decrease risk of dislocation[2-4] and increase range of movement.[5] Additionally a range of 'hard' bearings (metal-on-metal (MoM), ceramic-on-ceramic (CoC) and ceramic-on-metal (CoM)), have become available in an endeavour to reduce wear and possibly prolong survival.[6]

Cementless implants are used in most THRs undertaken in Australia.[7] In 2005, only 22% of THRs in England and Wales were cementless.[8] However, by 2009 their popularity surpassed cemented THR, and the trend persists (43% uncemented in 2010 *versus* 36% cemented).[8] Despite this, there remains little evidence for their superiority. According to the National Joint Registry for England and Wales (NJR), the unadjusted five-year rate of revision for cementless THR is twice that of cemented THR.[8]

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single type of cementless THR, using data from the NJR.[9]

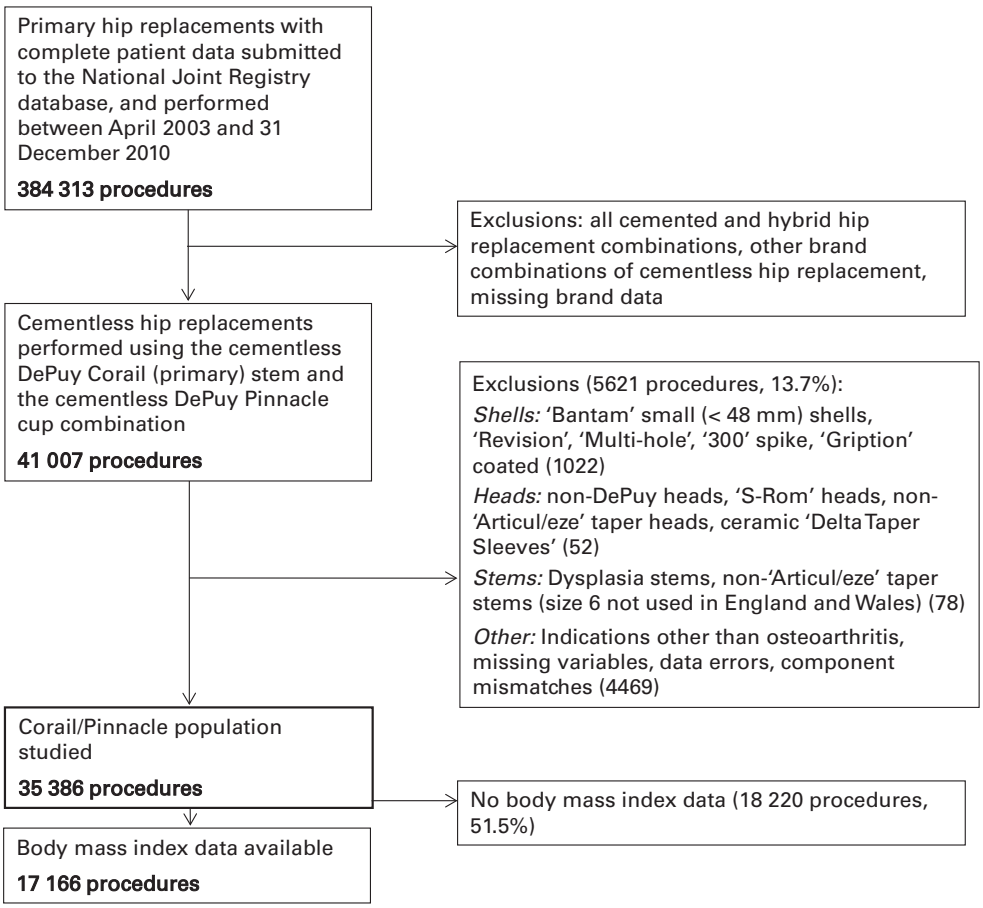


Fig. 1

Flow chart showing the inclusion criteria for the study.

Each brand of implant has a range of parameters that may influence the risk of failure. These parameters are not all comparable across brands such as the liner types used. In order to explore the determinants of failure it was appropriate to limit the analysis to the most common brand of cementless THR and in simplistic analysis one of the best performing, in terms of overall revision risk at five years in England and Wales.[8]

Patients and Methods

The NJR collects data on patients, surgeons and implants performed in the private and public sector (National Health Service, NHS) in England and Wales. According to its Eighth Annual Report, the most common combination of components used in cementless THR is the Corail stem and the Pinnacle acetabular component (DePuy Ltd, Leeds, United Kingdom), accounting for 31.2% of cementless THRs (40 879 of 130 920) since the establishment of the registry in 2003.[8] The Corail stem is a fully hydroxyapatite (HA) coated non-porous forged titanium alloy stem with a trapezoid cross section proximally and a quadrangular cross section distally. It has a polished, low profile neck and a 12/14 taper ('Articul/eze', DePuy). It is available in a range of sizes (6 mm to 20 mm) and neck offsets (standard, 'Lateralised Coxa Vara', and 'High Offset') and can be used with or without a collar. The Pinnacle acetabular system comprises a hemispherical titanium shell with coating options including 'Porocoat' (DePuy, titanium sintered beads), 'Duofix' (DePuy, Porocoat with a HA coating) and 'Gription' (DePuy, high friction porous titanium surface). The shell accepts polyethylene ('Enduron', DePuy, standard polyethylene or 'Marathon', DePuy, highly cross-linked polyethylene), ceramic (Biolox Delta; CeramTec, Plochingen, Germany) and metal liners ('Ultamet', DePuy). It is available in diameters from 38 mm to 66 mm and the shell comes in four varieties: solid backed '100', spiked solid back '300', the three-hole 'Sector', and a 'Multi-hole'. Data were extracted for all Corail/Pinnacle THRs performed and submitted to the NJR until 31 December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were only used on < 200 occasions during the study period, these were excluded from analyses. A summary of the inclusion criteria is shown in Figure 1.

Covariate categories previously thought to influence the risk of revision (patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), the size of the

Table I. Covariates used in the event analysis

Category*	Variable type	Covariate
Age	Ordinal	≤ 60 years
		61 to 75 years
		> 75 years
Gender	Binary	Female
		Male
ASA grade	Ordinal	Grade 1 or 2
		Grade ≥ 3
Body mass index	Ordinal	< 30 kg/m^2
		≥ 30 kg/m^2
Stem size	Ordinal	8 to 10
		11 to 13
		≥ 14
Stem design	Nominal	Collarless
		Collared
Cup shell type	Nominal	Solid hydroxyapatite (HA) coated
		Solid, non-HA
		Cluster-hole HA
		Cluster-hole, non-HA
Bearing	Nominal	Metal-on-polyethylene (PE)
		Metal-on-PE, posterior lip
		Metal-on-highly cross-linked PE (XLPE)
		Metal-on-XLPE, posterior lip
		Ceramic-on-PE
		Ceramic-on-PE, posterior lip
		Ceramic-on-XLPE
		Ceramic-on-XLPE, posterior lip
		Ceramic-on-ceramic
		Ceramic-on-metal
		Metal-on-metal
Head size	Ordinal	28 mm or 32 mm
		≥ 36 mm
Combined offset	Ordinal	Low (0 mm to 4 mm)
		Medium (5 mm to 10 mm)
		High (≥ 11 mm)
		Minus
Primary surgeon	Binary	Consultant
		Other
Consultant volume	Ordinal	Low (≤ 50 cases throughout study period)
		Medium (51 to 300 cases)
		High (≥ 301 cases)

* ASA, American Society of Anesthesiologists

stem, the type and coating of the acetabular shell, the bearing materials and head size)[10-14] were included in these analyses, with American Society of Anesthesiologists (ASA)[15] grade taken to be a surrogate for the comorbidity score. We also examined the influence of stem design, combined offset (stem+head+liner) and primary surgeon characteristics. The covariates that were used are summarised in Table I.

In order for a THR to have been recorded as revised, where one implant is exchanged for another, or removed as part of a staged procedure, on the NJR dataset, a complete record of the revision procedure (including side of operation) is linked to the original procedure by matching unique patient identifiers. Several causes of revision can be recorded. Where many reasons were cited, all except pain have been recorded here. Should infection or peri-prosthetic fracture have been recorded, these individually were assumed to be the only indication for revision. Pain was only taken as a cause when no other reason was provided. Due to multiple reporting for individual procedures, the sum of causes is greater than 100%.

Statistical analysis. Age, stem size and the volume of the consultant's practice were analysed as categorical data (informed by spread of the data) because of the greater clinical relevance when making group comparisons. As available head diameter differs across bearing surfaces, these were partitioned into two groups (< 36 mm and ≥ 36 mm) in order to ensure all sizes and bearings were represented within the model. Categories of bearing surface were initially partitioned based on head and liner combination, including the presence of a posterior lip and the type (standard or highly cross-linked) for the

Table II. Demographics of patients undergoing Corail/Pinnacle cementless total hip replacement (England and Wales, 2003-2010)

Characteristic	n = 35 386
Mean (SD) age (yrs)	66.3 (10.0)
Age group (n, %)	
≤ 60 years	8835 (*25.0*)
61 to 75 years	19 662 (*55.6*)
> 75 years	6889 (*19.5*)
Gender (n, %)	
Female	20 166 (*57.0*)
Male	15 220 (*43.0*)
American Society of Anesthesiologists grade (n, %)	
1 or 2	31 286 (*88.4*)
≥ 3	4100 (*11.6*)
Mean (SD) body mass index (kg/m^2)	28.8 (5.3)
Body mass index group (n, %)	
< 30 kg/m^2	10 553 (*29.8*)
≥ 30 kg/m^2	6613 (*18.7*)
Data unavailable	18 220 (*51.5*)
Stem size (n, %)	
8 to 10	10 168 (*28.7*)
11 to 13	20 774 (*58.7*)
≥ 14	4444 (*12.6*)
Stem design (n, %)	
Collarless	24 404 (*69.0*)
Collared	10 982 (*31.0*)
Cup shell type (n, %)	
Solid hydroxyapatite (HA) coated	7496 (*21.2*)
Solid, non-HA	2805 (*7.9*)
Cluster-hole HA	16 071 (*45.4*)
Cluster-hole, non-HA	9014 (*25.5*)
Bearing (n, %)	
Metal-on-polyethylene (PE) (all)	9242 (*26.1*)
Standard PE	3892
Standard lipped PE	453
Highly cross-linked (XL) PE	4198
Lipped XLPE	699
Ceramic-on-PE (all)	4681 (*13.2*)
Standard PE	1742
Standard lipped PE	406
Highly cross-linked (XL) PE	1678
Lipped XLPE	855
Ceramic-on-ceramic	10 540 (*29.8*)
Ceramic-on-metal	1187 (*3.4*)
Metal-on-metal	9736 (*27.5*)
Head size (n, %)	
28 mm or 32 mm	16 042 (*45.3*)
≥ 36 mm	19 344 (*54.7*)
Combined offset category (n, %)	
Low (0 mm to 4 mm)	11 770 (*33.2*)
Medium (5 mm to 10 mm)	15 907 (*45.0*)
High (≥ 11 mm)	5977 (*16.9*)
Minus	1732 (*4.9*)
Primary surgeon (n, %)	
Consultant	29 954 (*84.6*)
Other	5432 (*15.4*)
Consultants (n)	854
Mean consultant volume (cases) (SD; range)	242 (275; 1 to 1208)
Low (≤ 50 cases)	7485 (*21.2*)
Medium (51 to 300 cases)	17 902 (*50.6*)
High (≥ 301 cases)	9999 (*28.3*)
Surgical units (n)	301

polyethylene group. As the femoral offset can be adjusted according to the type of stem, head and polyethylene liner, a combination of these values (based on the manufacturer's figures[16,17]) were used to calculate the combined offset for each hip.

In order to explore the influence of covariates, the most common category was generally used as the reference: for example, a mid-range size of stem group was used as the baseline against which all other stem size groups were compared. Similarly, for bearings, the most commonly used

Table III. Indication recorded for revision following Corail/Pinnacle cementless total hip replacement (England and Wales, 2003-2010). Several causes of revision can be recorded (see methods section for further details)

Indication (n, %)	Revision (n = 448)
Dislocation	108 (*24.1*)
All aseptic component loosening/lysis	94 (*21.0*)
Stem only	64
Acetabular component only	20
Both components	10
Infection	69 (*15.4*)
All malalignments	51 (*11.4*)
Stem only	20
Acetabular component only	28
Both components	3
Peri-prosthetic stem fracture	47 (*10.5*)
Soft-tissue reaction/'metallosis'	31 (*6.9*)
Unexplained pain	22 (*4.9*)
All implant fractures	20 (*4.5*)
Stem only	7
Acetabular component only	13
Dissociation of liner	10 (*2.2*)
Liner wear	5 (*1.1*)
'Stem subsidence'	3 (*0.7*)
Other	28 (*6.3*)

standard (polyethylene acetabular liner) bearing was metal-on-polyethylene (MoP). Exceptions to this were age (where the youngest group was used as the baseline), head diameter (where the smallest head sizes were used), combined offset (where the standard/smaller 'plus' offsets were used) and consultant volume (where the highest volume group was used).

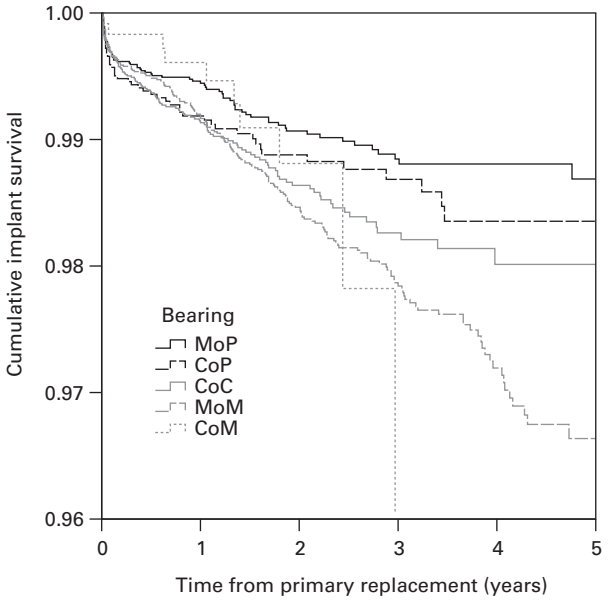
A revision procedure was considered to be the 'failure event', where the time between the index procedure and revision measured joint survival. Survival times for patients who had not undergone revision were censored at the study census date (31 December 2010). Kaplan-Meier survival charts were generated to display differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates using the pair-wise over strata method. An adjusted significance threshold is provided (Bonferroni-correction method) to account for multiple testing. Covariate categories with significant influences are presented, with life tables to describe numbers within each category entering each year of the study.

Cox proportional hazard models were used to assess the extent to which the timing of revision could be explained in terms of the recorded patient, surgeon and implant covariates. The results are presented as hazard ratios (HRs) with 99% CIs: ratios > 1 indicate that risk is higher when compared with the reference covariate category. Due to the statistical methods employed, and the large population size, only covariates fitting models with a p-value < 0.01 were considered significant influences, in order to reduce the risk of a Type I error.

Life tables were produced to report unadjusted one-, three- and five-year revision rates (with 99% confidence intervals (CI) estimated using the normal approximation) for each bearing, and for all 35 386 procedures included in the study. Survival was not reported if the number entering a year was < 5% of the original total in that particular bearing group.

Results

Of a total of 35 386 primary procedures, 20 166 (57.0%) were performed in females. Most procedures took place in patients with an ASA grade ≤ 2 (n = 31 286, 88.4%) and those aged ≤ 75 years (n = 28 497, 80.5%). The mean age at operation was 66.3 years (15 to 106). There were 17 166 procedures (48.5%) with complete BMI data; of these 17 166, most had a BMI of < 30 kg/m^2 (n = 10 553, 61.5%). Most stems were mid-range sizes (11 to 13: n = 20 774, 58.7%) and collarless (n = 24 404, 69.0%). The most common acetabular shell was a HA-coated cluster-hole (n = 16 071, 45.4%). The most common single type of bearing was CoC (n = 10 540, 29.8%); MoM accounted for 27.5% of implants (n = 9736), and MoP accounted for 26.1% (n = 9242). Most polyethylene bearings were highly cross-linked without a posterior lip (n = 5876, 16.6%) and most were 28 mm diameter (n = 10 162, 28.7%). Just over half the modular heads were 36 mm diameter or larger (n = 19 344, 54.7%) and the combined offset was between zero and 10 mm in most (n = 27 677, 78.2%). In total, 21 463 hard bearings were used, of which 18 005 (83.9%) were 36 mm diameter. In 27 901 procedures (79%) the consultant performing the procedure completed ≥ 51 Corail Pinnacle THRs during the study period.



Life table showing numbers at risk in each year

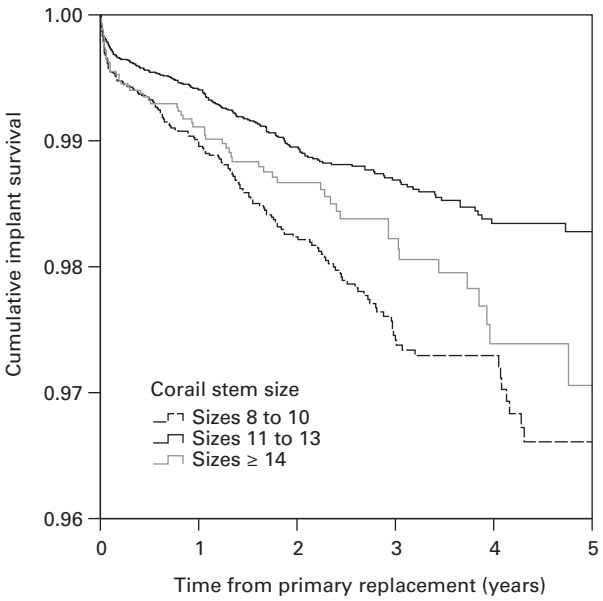
Brand	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoP	9242	6211	4066	2513	1489	640
CoP	4681	3077	1938	1148	520	167
CoC	10 540	6587	3816	1877	772	289
MoM	9736	8689	6370	3781	1733	592
CoM	1187	711	238	28	8	2

Log rank (Mantel-Cox)	CoP	MoP	CoC	CoM	MoM
MoP(p-value)	-	0.160	0.006	0.321	< 0.001
CoP	0.160	-	0.398	0.800	0.024
CoC	0.006	0.398	-	0.819	0.101
CoM	0.321	0.800	0.819	-	0.685
MoM	< 0.001	0.024	0.101	0.685	-

Bonferroni-corrected significance threshold p = 0.001

Fig. 2

Kaplan–Meier unadjusted cumulative implant survival of Corail/Pinnacle cementless total hip replacements by bearing (CoP, ceramic-on-polyethylene; MoP, metal-on-polyethylene; CoC, ceramic-on-ceramic; MoM, metal-on-metal; CoM, ceramic-on-metal).



Life table showing numbers at risk each year

Femoral size	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
8 - 10	10229	7221	4616	2532	1133	431
11 - 13	20 897	14 976	9771	5613	2769	1043
≥ 14	4260	3078	2041	1202	620	216

Log rank (Mantel-Cox)	Sizes 8 to 10	Sizes 11 to 13	Sizes ≥ 14
Sizes 8-10 (p-value)	-	< 0.001	0.132
Sizes 11 - 13	< 0.001	-	0.011
Sizes ≥ 14	0.132	0.011	-

Bonferroni-corrected significance threshold p = 0.003

Fig. 3

Kaplan–Meier unadjusted cumulative implant survival of Corail/Pinnacle cementless total hip replacements by stem size.

Patients were under the care of 854 different consultants in 301 different surgical units with consultants performing most of the operations (n = 29 954, 84.6%). The demographics are shown in Table II. There were 1690 (4.8%) procedures with more than five years of follow-up.

In all, 448 patients (1.27% of the cohort) had undergone a revision procedure by the census date. The most common reason was dislocation (108 revisions, 24.1% of all revisions). Aseptic loosening or lysis accounted for 94 revisions (21.0%), followed by infection (n = 69, 15.4%), malalignment (n = 51, 11.4%) and peri-prosthetic fracture (n = 47, 10.5%). Revision data are summarised in Table III.

In simple (univariable) analysis, the following categories influenced the risk of revision: BMI (p = 0.001), bearing (p < 0.001) (Fig. 2), femoral stem size (p < 0.001) (Fig. 3) and head size (p = 0.001) (Table IV). There was a trend towards ASA grade influencing the risk of revision (p = 0.014). The type of polyethylene (standard shape: MoP/MoXLPE, p = 0.580; CoP/CoXLPE, p = 0.061; posterior lip: MoP/MoXLPE, p = 0.457; CoP/CoXLPE, p = 0.415) and the presence of a posterior lip (standard PE: ceramic head + standard/posterior lip, p = 0.800; metal head + standard/posterior lip, p = 0.114; XLPE: ceramic head + standard/posterior lip, p = 0.948; metal head + standard/posterior lip, p = 0.195) were not found to be significant influences on survival: these covariates were therefore merged into one common polyethylene liner category to improve the efficiency of the model. BMI was a significant influence but was unavailable in 51.5% of procedures and, as imputation might be unreliable with large amounts of missing data, we chose to present the final adjusted model in two ways: firstly, by removing BMI from the model and presenting adjusted results for the entire population, and secondly, using only those procedures (n = 17 166) where a valid BMI was available.

After risk adjustment for the entire study population, following removal of BMI from the model, MoM (HR 1.93 (99% CI 1.36 to 2.73); p < 0.001) and CoC (HR 1.55 (99% CI 1.07 to 2.26); p = 0.003) bearings, and small femoral stem sizes (8 to 10 mm: HR 1.82 (99% CI 1.40 to 2.37);

Table IV. Independent predictors of revision following entire series of 35 386 Corail/Pinnacle cementless total hip replacements: simple and multi-variable Cox regressions (body mass index excluded, England and Wales, 2003-2010) (HR, hazard ratio; CI, confidence interval)

	Simple analysis		Multi-variable analysis	
Variable*	**HR (99% CI)**	**p-value**	**HR (99% CI)**	**p-value**
Gender				
Female	Reference	-		
Male	1.03 (0.81 to 1.32)	0.725		
Age category		0.796		
Age group				
≤ 60 years	Reference	-		
61 to 75 years	0.94 (0.70 to 1.25)	0.553		
> 75 years	0.92 (0.63 to 1.33)	0.559		
ASA grade				
1 or 2	Reference	-	-	-
≥ 3	1.38 (0.98 to 1.94)	0.014	1.39 (0.99 to 1.96)	0.013
Stem size category		< 0.001		< 0.001
Stem size group				
8 to 10	1.79 (1.38 to 2.33)	< 0.001	1.82 (1.40 to 2.37)	< 0.001
11 to 13	Reference	-	Reference	-
≥ 14	1.44 (0.99 to 2.09)	0.012	1.43 (0.98 to 2.07)	0.014
Stem design				
Collarless	Reference	-		
Collared	1.05 (0.80 to 1.37)	0.670		
Acetabular shell category		0.354		
Acetabular shell group				
Solid, HA-coated	0.82 (0.59 to 1.15)	0.128		
Solid, non-HA	1.10 (0.69 to 1.75)	0.591		
Cluster, HA-coated	Reference	-		
Cluster, non-HA	0.92 (0.68 to 1.24)	0.447		
Bearing category		< 0.001		< 0.001
Bearing group				
Metal-on-PE	Reference	-	Reference	-
Ceramic-on-PE	1.32 (0.82 to 2.11)	0.135	1.33 (0.83 to 2.12)	0.123
Ceramic-on-ceramic	1.54 (1.06 to 2.25)	0.003	1.55 (1.07 to 2.26)	0.003
Ceramic-on-metal	1.47 (0.64 to 3.37)	0.237	1.45 (0.63 to 3.33)	0.253
Metal-on-metal	1.92 (1.36 to 2.72)	< 0.001	1.93 (1.36 to 2.73)	< 0.001
Head size				
28 mm or 32 mm	Reference	-		
≥ 36 mm	1.38 (1.07 to 1.77)	0.001		
Combined offset category		0.352		
Combined offset group				
Low	Reference	-		
Medium	1.05 (0.79 to 1.40)	0.639		
High	1.23 (0.86 to 1.76)	0.136		
Minus	1.30 (0.76 to 2.21)	0.213		
Surgeon				
Consultant	Reference	-		
Other	0.84 (0.59 to 1.20)	0.206		
Consultant volume category		0.230		
Consultant volume group				
Low (≤ 50 cases)	1.02 (0.73 to 1.43)	0.869		
Medium (51 to 300 cases)	0.86 (0.65 to 1.13)	0.152		
High (≥ 301 cases)	Reference	-		

* ASA, American Society of Anesthesiologists; HA, hydroxyapatite; PE, polyethylene

p < 0.001) were independent influences associated with revision. There was a trend towards a higher rate of revision with a large stem (≥ 14: HR 1.43 (99% CI 0.98 to 2.07); p = 0.014) and ASA grade ≥ 3 (HR 1.39 (99% CI 0.99 to 1.96); p = 0.013). The risk of revision for ceramic-on-polyethylene (CoP) bearings was not significantly different to that for MoP bearings (HR 1.33 (99% CI 0.83 to 2.12); p = 0.123) (Table IV).

Table V. Independent predictors of revision following entire series of 35 386 Corail/Pinnacle cementless total hip replacements based on 17 166 patients with valid body mass data using simple and multi-variable Cox regressions (England and Wales, 2003-2010) (HR, hazard ratio; CI, confidence interval)

	Simple analysis		Multi-variable analysis	
Variable*	**HR (99% CI)**	**p-value**	**HR (99% CI)**	**p-value**
Gender				
Female	Reference	-		
Male	1.03 (0.81 to 1.32)	0.725		
Age category		0.796		
Age group				
≤ 60 years	Reference	-		
61 to 75 years	0.94 (0.70 to 1.25)	0.553		
> 75 years	0.92 (0.63 to 1.33)	0.559		
ASA grade				
1 or 2	Reference	-		
≥ 3	1.38 (0.98 to 1.94)	0.014		
Body mass index				
< 30 kg/m^2	Reference		Reference	-
≥ 30 kg/m^2	1.58 (1.11 to 2.26)	0.001	1.55 (1.08 to 2.22)	0.002
Stem size category		< 0.001		0.002
Stem size group				
8 to 10	1.79 (1.38 to 2.33)	< 0.001	1.70 (1.16 to 2.51)	< 0.001
11 to 13	Reference	-	Reference	-
≥ 14	1.44 (0.99 to 2.09)	0.012	1.44 (0.83 to 2.49)	0.092
Stem design				
Collarless	Reference	-		
Collared	1.05 (0.80 to 1.37)	0.670		
Acetabular shell category		0.354		
Acetabular shell group				
Solid, HA-coated	0.82 (0.59 to 1.15)	0.128		
Solid, non-HA	1.10 (0.69 to 1.75)	0.591		
Cluster, HA-coated	Reference	-		
Cluster, non-HA	0.92 (0.68 to 1.24)	0.447		
Bearing category		< 0.001		0.001
Bearing group				
Metal-on-PE	Reference	-	Reference	-
Ceramic-on-PE	1.32 (0.82 to 2.11)	0.135	1.36 (0.69 to 2.68)	0.242
Ceramic-on-ceramic	1.54 (1.06 to 2.25)	0.003	2.09 (1.21 to 3.63)	0.001
Ceramic-on-metal	1.47 (0.64 to 3.37)	0.237	1.31 (0.45 to 3.83)	0.514
Metal-on-metal	1.92 (1.36 to 2.72)	< 0.001	2.19 (1.29 to 3.72)	< 0.001
Head size				
28 mm or 32 mm	Reference	-		
≥ 36 mm	1.38 (1.07 to 1.77)	0.001		
Combined offset category		0.352		
Combined offset group				
Low	Reference	-		
Medium	1.05 (0.79 to 1.40)	0.639		
High	1.23 (0.86 to 1.76)	0.136		
Minus	1.30 (0.76 to 2.21)	0.213		
Surgeon				
Consultant	Reference	-		
Other	0.84 (0.59 to 1.20)	0.206		
Consultant volume category		0.230		
Consultant volume group				
Low (≤ 50 cases)	1.02 (0.73 to 1.43)	0.869		
Medium (51 to 300 cases)	0.86 (0.65 to 1.13)	0.152		
High (≥ 301 cases)	Reference	-		

* ASA, American Society of Anesthesiologists; HA, hydroxyapatite; PE, polyethylene

After risk adjustment with BMI included (17 166 patients), bearing (p = 0.001) and stem size (p = 0.002) categories remained significant influences on the risk of revision. ASA grade was no longer selected in the final model. Despite the smaller numbers, the influence of bearing type on the risk of revision was similar to that in the model for the entire population (MoM: HR 2.19 (99% CI 1.29 to 3.72); p < 0.001; CoC: HR 2.09 (99% CI 1.21 to 3.63); p = 0.001), validating model estimates on the larger population, without adjustment for BMI. Small femoral

Table VI. Revision rates for the entire series of Corail/Pinnacle cementless total hip replacements by bearing, and overall (England and Wales, 2003-2010) (CI, confidence interval; MoP, metal-on-polyethylene; CoP, ceramic-on-polyethylene; CoC, ceramic-on-ceramic; CoM, ceramic-on-metal; MoM, metal-on-metal)

	Bearing revision rate (%, 99% CI)					
	MoP	**CoP**	**CoC**	**CoM**	**MoM**	**Overall (%, 99% CI)**
1-year	0.61 (0.38 to 0.83)	0.90 (0.51 to 1.29)	0.93 (0.66 to 1.20)	0.42 (0.00 to 0.96)	0.82 (0.58 to 1.06)	0.79 (0.66 to 0.93)
3-year	1.22 (0.84 to 1.60)	1.41 (0.85 to 1.97)	1.82 (1.35 to 2.29)	3.46 (0.01 to 6.91)	2.17 (1.72 to 2.61)	1.77 (1.53 to 2.01)
5-year	1.36 (0.90 to 1.83)	1.76 (0.99 to 2.53)	2.05 (1.47 to 2.62)	-	3.47 (2.63 to 4.31)	2.41 (2.02 to 2.79)
Total number	9242	4681	10 540	1187	9736	35 386

Table VII. Revision rates following Corail/Pinnacle cementless total hip replacement by bearing in patients with body mass index (BMI) data (17 166 patients), and overall (England and Wales, 2003-2010) (CI, confidence interval; MoP, metal-on-polyethylene; CoP, ceramic-on-polyethylene; CoC, ceramic-on-ceramic; CoM, ceramic-on-metal; MoM, metal-on-metal)

	Bearing revision rate (%, 99% CI)					
	MoP	**CoP**	**CoC**	**CoM**	**MoM**	**Overall (%, 99% CI)**
1-year						
Total	0.63 (0.30 to 0.97)	0.86 (0.34 to 1.38)	1.33 (0.84 to 1.82)	0.29 (0.00 to 0.83)	0.95 (0.55 to 1.35)	0.92 (0.71 to 1.13)
BMI < 30 kg/m^2	0.50 (0.13 to 0.88)	0.84 (0.19 to 1.49)	1.00 (0.45 to 1.54)	0.23 (0.00 to 0.83)	0.76 (0.30 to 1.22)	0.73 (0.50 to 0.97)
BMI ≥ 30 kg/m^2	0.86 (0.22 to 1.49)	0.90 (0.03 to 1.77)	1.84 (0.94 to 2.75)	0.40 (0.00 to 1.42)	1.25 (0.52 to 1.99)	1.22 (0.83 to 1.60)
3-year						
Total	1.13 (0.60 to 1.66)	1.59 (0.68 to 2.50)	2.27 (1.35 to 3.19)	3.29 (0.00 to 7.39)	2.61 (1.77 to 3.46)	2.03 (1.61 to 2.44)
BMI < 30 kg/m^2	0.85 (0.25 to 1.45)	1.58 (0.39 to 2.78)	1.75 (0.65 to 2.85)	2.82 (0.00 to 7.47)	2.19 (1.24 to 3.13)	1.66 (1.18 to 2.14)
BMI ≥ 30 kg/m^2	1.61 (0.60 to 2.62)	1.58 (0.25 to 2.92)	3.06 (1.47 to 4.65)	4.11 (0.00 to 11.91)	3.34 (1.73 to 4.95)	2.63 (1.85 to 3.40)
5-year						
Total	1.13 (0.60 to 1.66)	1.59 (0.68 to 2.50)	-	-	4.17 (2.32 to 6.02)	2.68 (1.91 to 3.45)
BMI < 30 kg/m^2	0.85 (0.25 to 1.45)	1.58 (0.39 to 2.78)	-	-	3.70 (1.60 to 5.80)	2.25 (1.37 to 3.13)
BMI ≥ 30 kg/m^2	1.61 (0.60 to 2.62)	1.58 (0.25 to 2.92)	-	-	5.01 (1.38 to 8.64)	3.41 (1.92 to 4.89)
Total number	4763	2612	4827	836	4128	17 166

stem sizes remained a significant influence (HR 1.82 (95% CI 1.40 to 2.37); $p < 0.001$) but the large size category was not present in the final model (Table V). Spearman's rank correlation coefficient between ASA grade and BMI for 17 166 patients (with recorded BMI) was 0.177 (two-tailed significance, $p < 0.001$), indicating a weakly positive correlation and possible explanation for the role of these covariates in the entire and BMI-subset models.

The risk of revision was independent of age, gender, stem design, acetabular shell type, head size, combined offset, operating surgeon grade and consultant volume.

The overall five-year revision rate was 2.41% (99% CI 2.02 to 2.79) for the entire study population and the revision rates by bearing surface are shown in Table VI.

For patients with BMI data, overall one, three and five year results were similar to those for the entire population. Although the risk of revision at five years with MoP and MoM bearings was higher in patients with BMI ≥ 30 kg/m^2 (BMI < 30 kg/m^2: MoP 0.85%, MoM 3.70%, BMI ≥ 30 kg/m^2: MoP 1.61%, MoM 5.01%), CIs were wide because of the small numbers analysed (Table VII).

Discussion

This retrospective cohort study provides the largest, in-depth analysis of a single brand combination of cementless THRs to date. Significantly greater revision rates following THR were independently associated with hard bearings (MoM, CoC) and small sizes of femoral stem (sizes 8 to 10), after risk adjustment. These findings are clinically important as they identify modifiable parameters in the control of the operating surgeon. BMI was also a significant predictor of revision in those procedures with valid data. Other implant factors, including head size, did not significantly influence revision in this analysis.

While this study reports a large analysis of a single brand of THR, we accept that there are limitations in its interpretation. The revision rates described in this study are short-term, with a maximum follow-up of 7.5 years. The relative rates at which particular implants require revision may change with further follow-up. Revision is taken as a surrogate marker of implant failure, as other endpoints are unavailable in this dataset, in particular patients living with a painful hip or those awaiting revision at the time of censoring.[18] Incomplete BMI data might lead to confounding when BMI is excluded from the models but sensitivity analyses including and excluding BMI provide similar findings. There was a weak positive correlation between ASA grade and BMI, which may explain the presence of ASA grade in the final, entire population model, when BMI was excluded. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. However, similarities between the unadjusted

and adjusted models, robustness under different model fitting assumptions and time independence support the stability of estimates.

All MoM bearings are currently of concern and, despite the large numbers implanted and the cost involved, the Medicines and Healthcare products Regulatory Agency (MHRA) have recently recommended yearly follow-up for all of these patients.[19] In a systematic review on hip implant bearings, Sedrakyan at al[20] found that MoM bearings provided no superiority in outcome in comparison studies with MoP bearings but were associated with a significantly higher risk of revision (after risk adjusting) in over 720 000 THRs in world-wide registry data. An in-depth analysis of NJR data by Smith et al[21] supports these poorer findings with MoM of all head sizes. Given the reports from independent centres and the risks associated with MoM bearings (metal ion levels, excessive bearing and taper wear, soft-tissue destruction, possible systemic complications),[22] combined with the poorer survival reported here from the most common combination of cementless THR used in England and Wales, we question the role of these bearings in modern THR.

CoC bearings have been shown to have higher rates of revision due to dislocation when compared with MoP bearings in over 100 000 THRs from the Australian registry.[23] Despite significantly poorer survival when compared with MoP in the mid-term analysis presented here, CoC bearings might ultimately provide greater longevity but longer-term data are required.

CoM bearings were only available for a short time and few were implanted; it is important to note that although the hazard ratio for the CoM group was consistent with the other hard bearings, there were no significant differences when compared with MoP due to the wide confidence intervals. As CoM is thought to offer some benefits over MoM, we felt the inclusion of this bearing was important despite the limited data available.

CoP bearings did not significantly influence the risk of revision compared with MoP. While the five year revision rate for the entire group of Corail/Pinnacle THRs was 2.41% in this study, MoP bearings reduced the revision rate to only 1.36%. Of note, the five year all-cause revision rate following the most common cemented THR (Exeter V40 stem/Contemporary acetabular component, 37 995 procedures; Stryker Howmedica International, London, United Kingdom) is 1.26% in all patients in England and Wales, according to the NJR 8th Annual Report.[8] It is possible that the bearing material rather than the method of fixation may explain much of the difference in rates of revision across registry data.

The influence of femoral stem size may result from inadequate press-fit or poor bone quality but without more data, our study cannot explain this fully. While it may be difficult to assess pre-operatively, patients requiring smaller stems may be less suitable for cementless THR. A trend towards higher revision in very large implants was also seen but disappeared when BMI was included in the model, suggesting it may be high BMI rather than large stem size which is associated with failure. The finding of a higher rate of revision in patients with a BMI > 30 kg/m^2 is logical and important, given an apparent year-on-year increase in average BMI values within the arthroplasty population.[8] It should also be considered as an important covariate in future similar analyses and greater effort should be made to include BMI when submitting data to the registry.

The risk of revision was independent of age and gender, despite previous reports of poorer outcomes in young, male patients after THR.[10] Although head size has been found to influence the rate of revision across a range of implants,[21] we failed to find an association in this analysis. The type of polyethylene (standard or highly cross-linked) did not influence the risk of revision in standard bearings but longer-term analyses are needed. Although we did not find surgical volume to influence the risk of revision, there are limitations associated with this analysis; a surgeon's volume before the study period is unknown and their use of other types of THR performed during the same period was not analysed. A high-volume surgeon performing a small number of Corail/Pinnacle THRs may potentially be more successful than an occasional hip surgeon performing solely Corail/Pinnacle THRs.

The most common primary reason for revision was dislocation (24.1%); infection accounted for only 15.4% of revisions. As expected with mid-term data, the proportion of implants revised for aseptic loosening/lysis (20.0%) was low. The quality of recording of reasons for revision should be improved to list primary and secondary causes consistently; currently many causes of failure may be described, without any clear primary cause being identified. In-depth scrutiny of high-risk subsets is needed and prospective studies of the indications for revision combined with explant analysis will be of benefit.

In summary, bearing surfaces, femoral stem sizes and BMI were found to influence survival in a large cohort of single-brand cementless THRs. Hard bearings had significantly higher rates of revision. This study demonstrates that many factors influence the risk of revision. Analyses of registry data may mislead if they fail to adjust for all relevant covariates when comparing across brands and types. For surgeons using cementless THR, these data may help guide their practice and the findings may provide a reference for comparison with future analyses comparing types of implant.

Supplementary material

An appendix providing supplementary statistical reasoning is available with the electronic version of this article on our website www.bjj.boneandjoint.org.uk

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References

1. **Charnley J, Cupic Z.** The nine and ten year results of the low-friction arthroplasty of the hip. *Clin Orthop Relat Res* 1973;95:9–25.
2. **Jameson SS, Lees D, James P, et al.** Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. *J Bone Joint Surg [Br]* 2011;93-B:876–880.
3. **Berry DJ, von Knoch M, Schleck CD, Harmsen WS.** Effect of femoral head diameter and operative approach on risk of dislocation after primary total hip arthroplasty. *J Bone Joint Surg [Am]* 2005;87-A:2456–2463.
4. **Byström S, Espehaug B, Furnes O, Havelin LI.** Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. *Acta Orthop Scand* 2003;74:514–524.
5. **Chandler DR, Glousman R, Hull D, et al.** Prosthetic hip range of motion and impingement: the effects of head and neck geometry. *Clin Orthop Relat Res* 1982;166:284–291.
6. **Santavirta S, Böhler M, Harris WH, et al.** Alternative materials to improve total hip replacement tribology. *Acta Orthop Scand* 2003;74:380–388.
7. **No authors listed.** Australian Orthopaedic Association National Joint Replacement Registry. Annual Report 2011. https://aoanjrr.dmac.adelaide.edu.au/annual-reports-2011 (date last accessed 7 February 2013).
8. **No authors listed.** National Joint Registry for England and Wales: 8th Annual report, 2011. http://www.njrcentre.org.uk (date last accessed 7 February 2013).
9. **No authors listed.** National Joint Registry for England and Wales. http://www.njrcentre.org.uk (date last accessed 7 February 2013).
10. **Röder C, Bach B, Berry DJ, et al.** Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case-control study of 4420 patients. *J Bone Joint Surg [Am]* 2010;92-A:1954–1963.
11. **Hallan G, Lie SA, Havelin LI.** High wear rates and extensive osteolysis in 3 types of uncemented total hip arthroplasty: a review of the PCA, the Harris Galante and the Profile/Tri-Lock Plus arthroplasties with a minimum of 12 years median follow-up in 96 hips. *Acta Orthop* 2006;77:575–584.
12. **Howard JL, Kremers HM, Loechler YA, et al.** Comparative survival of uncemented acetabular components following primary total hip arthroplasty. *J Bone Joint Surg [Am]* 2011;93-A:1597–1604.
13. **Stilling M, Rahbek O, Søballe K.** Inferior survival of hydroxyapatite versus titanium-coated cups at 15 years. *Clin Orthop Relat Res* 2009;467:2872–2879.
14. **Johnsen SP, Sørensen HT, Lucht U, et al.** Patient-related predictors of implant failure after primary total hip replacement in the initial, short- and long-terms: a nationwide Danish follow-up study including 36,984 patients. *J Bone Joint Surg [Br]* 2006;88-B:1303–1308.
15. **Dripps RD.** New classification of physical status. *Anesthesiol* 1963;24:111.
16. **No authors listed.** Depuy Orthopaedics Ltd. Corail Hip System: Surgical Technique, 2011. http://www.depuy.com/sites/default/files/products/files/0612-82-501r5%20 SCRN%20 (2)_0.pdf (date last accessed 7 February 2013).
17. **No authors listed.** Depuy Orthopaedics Ltd. Pinnacle Acetabular Cup System Surgical Technique, 2011. http://www.depuy.com/sites/default/files/products/files/DO_Pinnacle_Cup_Acetab_Surgtech_0611-42-050r4.pdf (date last accessed 7 February 2013).
18. **Wylde V, Blom AW.** The failure of survivorship. *J Bone Joint Surg [Br]* 2011;93-B:569–570.
19. **No authors listed.** Medicines and Healthcare Products Regulatory Agency. Medical Device Alert: All metal-on-metal (MoM) hip replacements (MDA/2012/008). http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON143782 (date last accessed 7 February 2013).
20. **Sedrakyan A, Normand SL, Dabic S, et al.** Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. *BMJ* 2011;343:7434.
21. **Smith AJ, Dieppe P, Vernon K, Porter M, Blom AW.** Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. *Lancet* 2012;379:1199–1204.
22. **Haddad FS, Thakrar RR, Hart AJ, et al.** Metal-on-metal bearings: the evidence so far. *J Bone Joint Surg [Br]* 2011;93-B:572–579.
23. **Sexton SA, Walter WL, Jackson MP, De Steiger R, Stanford T.** Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. *J Bone Joint Surg [Br]* 2009;91-B:1448–1453.

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Factors Influencing Revision Risk Following 15 740 Single-Brand Hybrid Hip Arthroplasties
A Cohort Study From a National Joint Registry

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acetabular shell

ABSTRACT

This retrospective cohort study of a National Joint Registry data examines survival time to revision following the commonest brand of primary hybrid THA, exploring risk factors independently associated with failure. Overall 5-year revision was 1.56%. In the final adjusted model, revision risk was significantly higher with standard polyethylene (PE) liners (metal-on-PE: hazard ratio [HR] = 2.52, $P = 0.005$, ceramic-on-PE: HR = 2.99, $P = 0.025$) when compared to metal-on-highly-cross-linked (XL) PE. Risk of revision with ceramic-on-ceramic bearings was borderline significant (HR = 1.86, $P = 0.061$). A significant interaction between age and acetabular shell type (solid or multi-hole) was found ($P = 0.022$), suggesting that solid shells performed significantly better in younger patients. In summary, we found that there were significant differences in implant failure between different bearing surfaces and shell types after adjusting for a range of covariates.

Primary cemented total hip arthroplasty (THA) has good medium- to long-term implant survival across national joint registries and meta-analyses globally [1–8]. However, for younger patients with higher demands, a cemented polyethylene cup may fail at a greater rate, and may not provide sufficient longevity. Hybrid THAs, where a cemented stem is coupled with a cementless cup, maybe an attractive option in these patients. Cementless modular acetabular components allow the use of a range of bearing surfaces in combination with larger head sizes. When these implants were examined in patients under 70 years in England and Wales, the National Joint Registry (NJR) found that hybrid THAs had equivalent 5-year revision rates when compared to cemented implants, and superior revision rates when compared to cementless implants in females [7]. In addition, Australian registry data for patients aged 50 to 64 years have demonstrated superior results with hybrid implants compared to both cemented and cementless implants [8]. In 2010, 16% of 68 907 THAs in England and Wales were hybrid procedures [7].

National registry data allow independent analyses of large volumes of procedures over an entire population. However, there are limitations to these analyses. Despite the numerous implant options and materials used, many registries analyze implants using simple discriminators, such as fixation type, when in reality no two brands of implants are alike, and assumptions of similarity may be misplaced.

The aim of this study was to explore factors that may affect the risk of revision in a national cohort of patients undergoing a single combination of hybrid THA, using data from the NJR [9]. Each brand of implant has a range of parameters that may influence the risk of failure over time. These parameters are not all comparable across brands, e.g., acetabular shell type. Thus, to explore the determinants of

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failure it was appropriate to limit the analysis to the most common hybrid brand combination recorded on the NJR [7].

Materials and Methods

Design

A retrospective cohort study was conducted to assess patient-level NJR data for survival time to revision for the commonest brand of primary hybrid THA.

Data

The NJR has assimilated data on patients, surgeons and implants performed in both the private and public sector (National Health Service, NHS) in England and Wales since 2003. According to the NJR 8th Annual Report, the commonest brand combination of hybrid THA used in England and Wales since 2003 features the Stryker Exeter V40 hip and Trident socket (Stryker Orthopaedics, Mahwah, NJ, USA), accounting for 33.0% of all hybrid THAs (18 358 of 55 551) [7]. The Exeter V40 femoral stem is a polished, double-tapered, collarless stainless steel design with a "V40" taper and a hollow distal centralizer to allow subsidence for compressive loading throughout the cement mantle. It is available in a range of stem widths (0–5), offsets (30–56 mm) and lengths (short: 104–134 mm, standard: 158 mm, and "long stem" options: 200–260 mm). The Trident Acetabular System is an uncemented modular cup manufactured from hydroxyapatite (HA)-coated porous titanium (non-HA-coated Trident cups are not available in the United Kingdom). Liner options include standard polyethylene (PE), highly cross-linked (XL) PE (first generation: "Crossfire," and second generation: "X3"), alumina ceramic, and constrained. The shells are available as a press-fit no-hole ("Solid-back") type, or in multi-hole ("5-hole," "Cluster-hole (3-hole)," and "Multi-hole") form, allowing supplementary fixation with acetabular screws. Two types of shell geometry are manufactured: "Hemispherical and Peripheral self-locking" (PSL, or rim-fitting). Femoral heads are available in stainless steel ("Orthinox": 22, 26, 28, 30, 32, and 36 mm), cobalt-chrome ("Vitallium": 28, 32, 36, 40, and 44 mm) and ceramic ("Alumina": 28, 32, and 36 mm). Three brands of cement have been used with these components: "Palacos" (three manufacturers: Heraeus Holding GmbH, Hanau, Germany; Schering-Plough Corporation, Kenilworth, NJ, USA; Biomet Inc., Warsaw, IN, USA), "CMW" (DePuy Orthopaedics Inc., Warsaw, IN, USA) and "Simplex" (Stryker Corporation, Kalamazoo, MI, USA). Palacos and CMW are available as high and low viscosity, and all brands have plain or antibiotic impregnated versions. Data were extracted for all Exeter/Trident THAs performed and submitted to the NJR until 31st December 2010 with the primary diagnosis of osteoarthritis (OA). As several options were used rarely, these were excluded from analyses. A summary of inclusion criteria is shown in Fig. 1.

Covariate categories thought to have an influence on revision risk were patient age at time of procedure, gender, co-morbidity score, body mass index (BMI), stem size, bearing surface material and head size [10–12]. American Society of Anaesthesiology (ASA) grade was used as a surrogate for co-morbidity. We also examined the influence of head offset, acetabular shell type and primary surgeon characteristics. Covariates used are summarized in Table 1.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure), a complete record of the revision procedure (including side of operation) must be linked to the original index procedure by matching the unique patient identifier. A number of causes of revision can be recorded for each operation; these were interpreted hierarchically for infection and peri-prosthetic fracture, pre-selecting in that order. Pain was only taken as the primary cause when no other reason was provided.

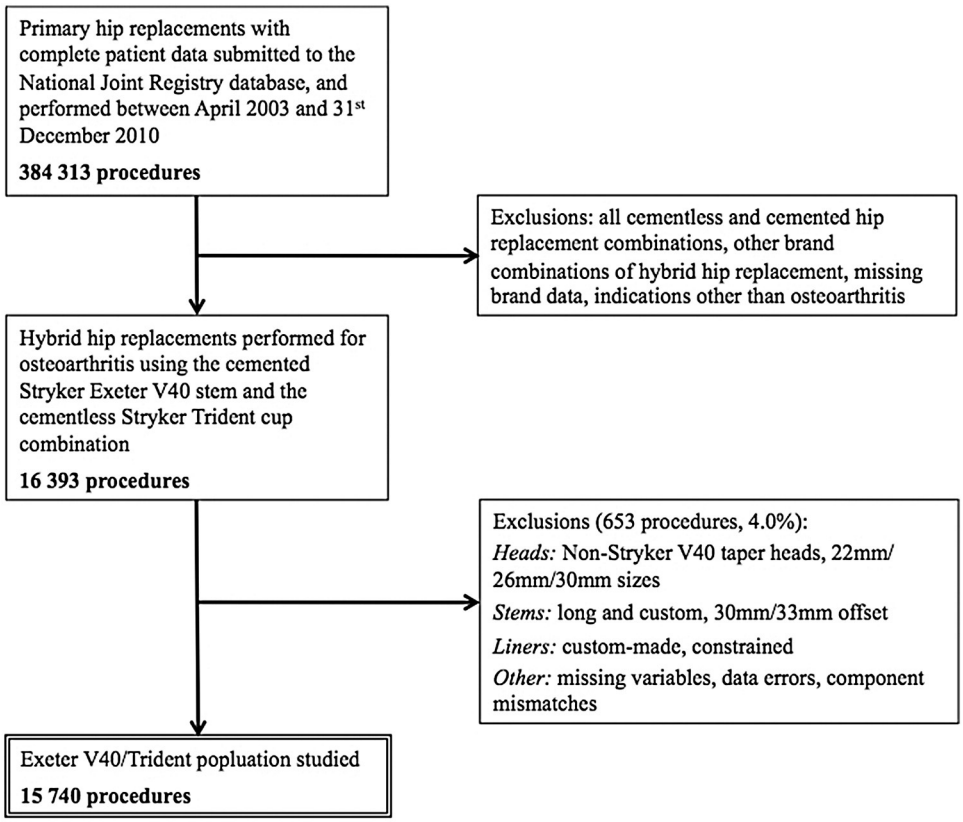


Fig. 1. Flowchart describing the procedures included.

Table 1
Final Covariates Used in the Event Analyses.

Category	Variable Type	Covariate
Age (y)	Ordinal	≤ 60, 61–75, ≥ 76
Gender	Binary	Female, male
ASA grade	Ordinal	Grade ≤ 2, grade ≥ 3
Body mass index (kg/m^2)	Ordinal	< 30, ≥ 30
Stem offset (mm)	Ordinal	35, 37.5, 44, 50
Stem taper	Ordinal	≤ 2, ≥ 3
Head size (mm)	Ordinal	28, 32, ≥ 36
Neck offset	Ordinal	Standard, "Plus" head, "Minus" head
Shell design	Nominal	Solid-back, multi-/cluster-hole
Bearing	Nominal	Metal-on-standard polyethylene (PE) Metal-on-highly-cross-linked (XL) PE Ceramic-on-standard PE Ceramic-on-XLPE Ceramic-on-ceramic
Cement type	Nominal	Palacos high-viscosity antibiotic impregnated, Simplex P antibiotic impregnated, other
Surgical approach	Nominal	Posterior, anterolateral, other
Year of procedure	Continuous	2003–2010
Primary surgeon	Binary	Consultant, other
Consultant Exeter/ Trident volume	Ordinal	Low (≤ 50 cases throughout the study period), medium (51–200), high (≥ 201)

ASA, American Society of Anaesthesiologists.

Statistical Analysis

Continuous and discrete continuous covariates (age, head offset, consultant volume) were analyzed as categorical data (informed by spread of the data) because of the greater clinical relevance when making group comparisons. Preliminary analysis of age as a continuous variable is also reported. To explore the influence of covariates the most common category was generally used as the baseline case: for example, 32-mm heads were used as the baseline against which all other head sizes were compared. Exceptions to this were age (where the youngest group was used as the baseline), consultant volume (where the highest volume group was used) and bearing (where the type most commonly used in 2010 was used).

A revision procedure was considered to be a "failure event," where the time between the index procedure and revision was the measure of joint survival. Survival times for patients who had not undergone revision were censored at the study census date (31st December 2010). Kaplan–Meier survival charts were generated to display visual differences in unadjusted covariates. The log-rank (Mantel–Cox) test was used to perform paired comparisons between each of the covariates using the pairwise over-strata method. Covariate categories with significant influences are presented, with life tables to describe numbers within each covariate category entering each year of the study.

Cox proportional hazard models were used to assess the extent to which the timing of revision could be explained in terms of the measured patient, surgeon and implant covariates. Results are presented as hazard ratios (HRs) with 95% confidence intervals (CI): ratios greater than 1 indicate that risk is higher when compared with the reference covariate category. Covariates fitting models with $P < 0.05$ were considered significant influences.

Life tables were produced to report unadjusted 1-, 3-, and 5-year revision rates (with 95% CIs estimated using the normal approximation) for each shell type and bearing in patients ≤ 75 years. Survival was not reported if the number entering the first year was less than 500, or the number entering any subsequent year was less than 5% of the original number entering in that group.

Results

Of 15 740 primary procedures, the majority were performed in females (9573, 60.8%), with ASA ≤ 2 (13 693, 87.0%) and 75 years of age or less (11 764, 74.7%); the mean age at implantation was 68 years. There were 6641 (42.2%) procedures with complete BMI data; of the procedures with data, the majority were less than 30 kg/m^2 (4638, 69.8%). The most commonly used stem was 44 mm offset (8627, 54.8%) and taper sizes ≤ 2 (14 255, 90.6%) accounted for the majority. A standard neck offset (63.4%, 9986) and a 32-mm diameter (45.4%, 7153) were the most commonly used heads. The commonest cup design was a PSL multi-hole (10 497, 66.7%) and only 33.3% (5243) relied on press-fit fixation with a solid-back shell. Over the entire study, the commonest bearing was ceramic-on-ceramic (CoC, 6144, 39.0%). However, in 2010 this was metal-on-XLPE (MoXLPE). Palacos high-viscosity antibiotic impregnated (52.5%, 8264) was most commonly used to cement the stem. The procedure was performed through a posterior approach in 67.5% of cases (10 620). In most cases the consultant performed the procedure (12 886, 81.9%). Medium- or high-volume Exeter/Trident hybrid arthroplasty surgeons (≥ 51 cases over the study period) accounted for 70.8% (11 147) of procedures. Patients were under the care of 575 different consultants in 239 different surgical units. Demographics are shown in Table 2 and bearing use by year in Table 3.

Reasons for Revision

One hundred forty-one patients had undergone a revision procedure by the census date. The most common reason was infection (38 revisions, 27.0% of all revisions). Reason for revision was determined to be dislocation in 36 cases (25.5%), followed by aseptic component loosening/lysis (33, 23.4%), malalignment (18, 12.8%) and peri-prosthetic fracture (17, 12.1%). Revision for dissociation of liner occurred in seven patients (5.0%), five of which were ceramic liners (3.5%). Revision data are summarized in Table 4.

Associations With Implant Revision

In simple (univariable) regression analysis, age ($P = 0.033$), bearing ($P = 0.050$, Fig. 2), shell type ($P = 0.024$, Fig. 3), and surgical approach ($P = 0.036$) influenced implant revision risk (Table 5). Although bearing category was on the threshold of significance, several individual bearings had $P < 0.05$. Brand of cement, shell geometry and type of femoral head metal (stainless steel or cobalt-chrome) were not found to be significant influences for survival: these covariates were therefore merged into common categories. First- ("Crossfire") and second-generation ("X3") XLPE liners were combined into one group, as the "Crossfire" liner was used rarely.

After risk adjustment, procedures performed using standard PE liners (metal-on-PE bearings: HR = 2.64, 95% CI 1.39–4.99, $P = 0.003$, ceramic-on-PE: HR = 3.07, 95% CI 1.18–8.00, $P = 0.022$) and CoC bearings (HR = 1.93, 95% CI 1.00–3.69, $P = 0.049$) were associated with significantly higher revision rates when compared with procedures using a MoXLPE bearing. Procedures employing multi-hole acetabular shells (HR = 1.70, 95% CI 1.16–2.48, $P = 0.006$) had a greater risk of revision compared with solid-back shells. Older patients (≥ 76 years) were associated with a lower revision risk (HR = 0.46, 95% CI 0.25–0.83, $P = 0.010$) compared to patients aged ≤ 60 years (Table 5). After risk adjusting, surgical approach was not selected for the final model.

When covariates were tested for multiplicative relations a significant interaction between age group and shell type was found ($P = 0.022$). Bearing category remained significant ($P = 0.048$) but age group and shell type as individual covariates no longer met the inclusion criteria for the model. This suggests that lower risk of revision in patients aged ≥ 76 years was associated with multi-hole shells and lower risk of revision in patients aged ≤ 60 years was associated with solid-back shells (Table 6). In this model, CoC bearings were not associated with significantly higher revision, although this was marginal (HR = 1.86, 95% CI 0.97–3.56, $P = 0.061$).

Table 2
Demographics of Exeter V40/Trident Hybrid Hip Arthroplasties (England and Wales, 2003–2010).

	$n = 15\,740$
Age (y), mean (SD, range)	67.5 (10.7, 15–102)
≤ 60, *n* (%)	3535 (22.5)
61–75	8229 (52.3)
≥ 76	3976 (25.3)
Gender	
Female	9573 (60.8)
Male	6167 (39.2)
ASA grade	
1/2	13 693 (87.0)
≥ 3	2047 (13.0)
Body mass index (kg/m^2), mean kg/m^2 (SD)	28.4 (5.3)[a]
< 30, *n* (%)	4638 (29.5)
≥ 30	2003 (12.7)
No data	9099 (57.8)
Stem offset (mm)	
35.5	1186 (7.5)
37.5	5135 (32.6)
44	8627 (54.8)
50	792 (5.0)
Stem taper	
≤ 2	14 255 (90.6)
≥ 3	1485 (9.4)
Head size (mm)	
28	4764 (30.3)
32	7153 (45.4)
≥ 36	3823 (24.3)
Neck offset	
Standard (0)	9986 (63.4)
Plus (+4 to +8 mm)	2534 (16.1)
Minus (−2.7 to −5 mm)	3220 (20.5)
Shell design	
Solid back	5243 (33.3)
PSL	3882 (24.7)
Hemispherical	1361 (8.6)
Multi-hole	10 497 (66.7)
PSL	6934 (44.1)
Hemispherical	3563 (22.6)
Bearing	
Metal-on-standard polyethylene (PE)	4265 (27.1)
Metal-on-highly cross-linked (XL) PE	3829 (24.3)
Stainless steel-on-XLPE	1661 (10.6)
Cobalt-chrome-on-XLPE	2168 (13.8)
Ceramic-on-standard PE	354 (2.2)
Ceramic-on-XLPE	1148 (7.3)
Ceramic-on-ceramic	6144 (39.0)
Cement	
Palacos high-viscosity antibiotic impregnated	8264 (52.5)
Simplex P antibiotic impregnated	5530 (35.1)
Other	1484 (9.4)
Missing	462 (2.9)
Surgical approach	
Posterior	10 620 (67.5)
Anterolateral	4662 (29.6)
Other	319 (2.0)
Missing data	139 (0.9)
Year of procedure	
2003	74 (0.5)
2004	376 (2.4)
2005	1125 (7.1)
2006	1755 (11.1)
2007	2590 (16.5)
2008	2867 (18.2)
2009	3610 (22.9)
2010	3343 (21.2)
Primary surgeon	
Consultant	12 886 (81.9)
Other	2854 (18.1)
Number of consultants (*n*)	575
Consultant Exeter/Trident volume	
Low (≤ 50 cases over the study period)	4593 (29.2)
Medium (51–200)	6969 (44.3)
High (≥ 201)	4178 (26.5)
Number of surgical units (*n*)	239

SD, standard deviation.
[a] Based on 6641 procedures.

Table 3
Bearings Used for Exeter v40/Trident Hybrid Hip Arthroplasties, By Year (England and Wales, 2003–2010).

	Bearing				
Year	MoXLP	MoSP	CoSP	CoXLP	CoC
2003, *n* (%)	0 (0)	26 (35.1)	5 (6.8)	0 (0)	43 (58.1)
2004	1 (0.3)	140 (37.2)	28 (7.4)	0 (0)	207 (55.1)
2005	6 (0.5)	453 (40.3)	62 (5.5)	1 (0.1)	603 (53.6)
2006	25 (1.4)	785 (44.7)	88 (5.0)	10 (0.6)	847 (48.3)
2007	383 (14.8)	956 (36.9)	56 (2.2)	65 (2.5)	1130 (43.6)
2008	782 (27.3)	671 (23.4)	40 (1.4)	242 (8.4)	1132 (39.5)
2009	1292 (25.8)	666 (18.4)	45 (1.2)	425 (11.8)	1182 (32.7)
2010	1340 (40.1)	568 (17.0)	30 (0.9)	405 (12.1)	1000 (29.9)
Total	3829 (24.3)	4265 (27.1)	354 (2.2)	1148 (7.3)	6144 (39.0)

MoXLP, metal-on-cross-linked polyethylene; MoSP, metal-on-standard polyethylene; CoSP, ceramic-on-standard polyethylene; CoXLP, ceramic-on-cross-linked polyethylene; CoC, ceramic-on-ceramic.

Revision risk was independent of gender, ASA grade, stem characteristics, head size, neck offset, cement type, operator grade and consultant experience.

Revision Rates

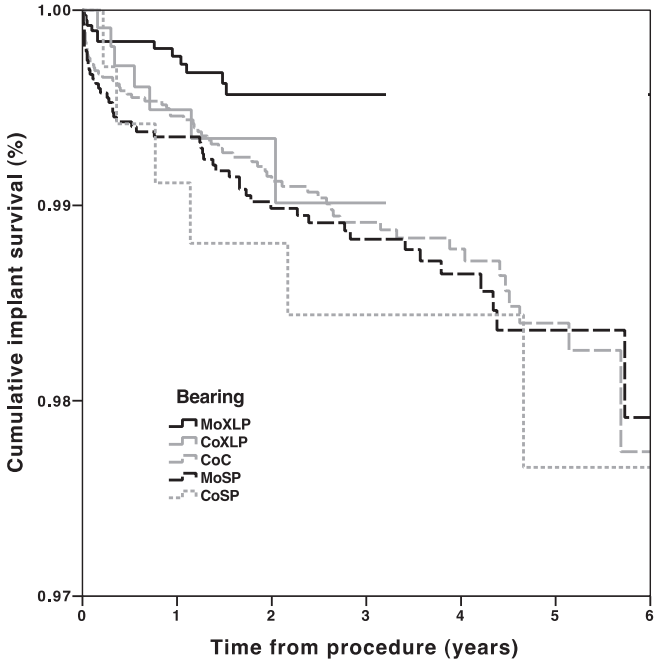
The overall 5-year revision rate was 1.56% (95% CI 1.23–1.89) for the entire study population. In patients aged ≤ 75 years, 5-year revision rates for solid-back shells were 1.21% (95% CI 0.67–1.76) compared with 2.07% (95% CI 1.52–2.62) for multi-holes (Table 7). Three-year revision rates for bearing and shell type indicate that the use of a MoXLPE bearing with a solid-back shell may ultimately have the lowest revision rate, although there were no statistically significant differences across these small groups.

Discussion

This retrospective cohort study provides the largest, in-depth analysis of a single-brand combination of hybrid THAs. Significantly greater revision rates were associated with bearing surface material and shell type after risk adjustment. These findings identify modifiable parameters in the control of the operating surgeon. Other potentially modifiable factors, including surgical approach and femoral head size, were not found to significantly influence revision.

Table 4
Reasons Recorded for Revision Following Exeter V40/Trident Hybrid Hip Arthroplasty (England and Wales, 2003–2010).

	Revision ($n = 141$)
Infection, *n* (%)	38 (27.0)
Dislocation	36 (25.5)
All aseptic component loosening/lysis	33 (23.4)
Stem only	4 (2.8)
Cup only	23 (16.3)
Both	6 (4.3)
All malalignments	18 (12.8)
Stem only	3 (2.1)
Cup only	14 (9.9)
Both	1 (0.7)
Periprosthetic fracture	17 (12.1)
Stem only	13 (9.2)
Cup only	4 (2.8)
Dissociation of liner	7 (5.0)
All implant fractures	6 (4.3)
Stem only	4 (2.8)
Cup only	2 (1.4)
Unexplained pain	8 (5.7)
Liner wear	5 (3.5)
Other	5 (3.5)

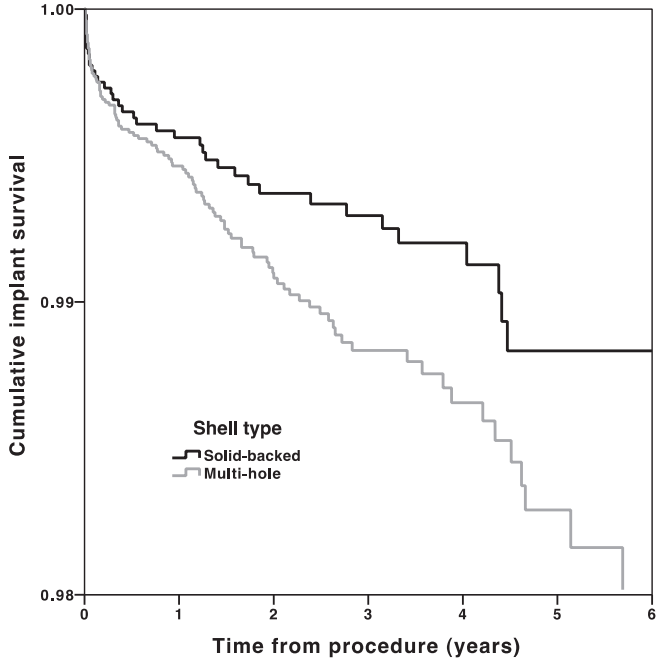


Log rank (Mantel-Cox)	MoXLP	MoSP	CoSP	CoXLP	CoC
MoXLP (p-value)	-	0.003	0.015	0.149	0.010
MoSP	0.003	-	0.368	0.521	0.706
CoSP	0.015	0.368	-	0.399	0.296
CoXLP	0.149	0.521	0.399	-	0.798
CoC	0.010	0.706	0.296	0.798	-

Life table showing numbers at risk in each year

Cup design	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
MoXLP	3829	2452	1146	395	30	7
MoSP	4265	3618	2911	2196	1276	554
CoSP	354	320	274	232	175	91
CoXLP	1148	728	305	72	8	1
CoC	6144	5100	3885	2753	1637	814

Fig. 2. Kaplan–Meier: unadjusted cumulative implant survival of Exeter V40/Trident by bearing (England and Wales, 2003–2010).



Log rank (Mantel-Cox)	Solid	Multi-hole
Solid-back shell (p-value)	-	0.023
Multi-hole shell	0.023	-

Life table showing numbers at risk each year

Shell type	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Solid-back shell	5243	4187	3098	2413	1343	597
Multi-hole shell	10497	8031	5423	3235	1783	870

Fig. 3. Kaplan–Meier: unadjusted cumulative implant survival of Exeter V40/Trident by shell type (England and Wales, 2003–2010).

While these data are the largest to date reporting a single-brand combination analysis of hybrid THAs, we accept that there are limitations in its interpretation. The revision rates described in this study are limited to mid-term data only (the earliest implanted was 2003). The relative rates at which particular implants require revision may change with further follow-up and more informative data. In addition, the highly cross-linked PE in this system has only been used in considerable numbers since 2007, limiting comparisons across bearings. Revision is a hard end point and may be considered a surrogate marker of implant failure, as other end points are unavailable. This does not take into account patients living with a painful hip, or those awaiting revision at the time of censoring [13]. Furthermore, revision procedures may be missed by the NJR due to compliance and linkage issues, but these should affect all groups equally. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Information regarding duration and severity of symptoms, radiographic appearance and activity levels prior to and following the procedure was not available. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and time independence support the stability of estimates.

Highly cross-linked polyethylene has improved resistance to wear compared to standard PE, resulting in generation of fewer wear particles [14]. A meta-analysis of ongoing clinical trials found XLPE liners exhibited reduced radiological wear and osteolysis at a mean follow-up of 5.1 years (1.8–9.0) compared to standard PE. Although there was no difference in revision rates between the types of PE, concerns regarding early failures attributable to brittleness of the XLPE were unfounded [15]. A mid- to long-term implant survival analysis of almost 9000 primary procedures from the Mayo clinic using 13 different cementless cup systems found improved survival (although not statistically significant) with XLPE liners compared to standard PE liners [16]. This current study is the first to identify an implant survival benefit of XLPE liners within a single acetabular system, albeit using short- to mid-term data.

Ceramic-on-ceramic bearings have good mid- to long-term survival data [17]. It is anticipated that a low-wearing CoC bearing should provide adequate longevity for the young, active patient. However, there are concerns regarding higher risks of dislocation [18], fracture and squeaking [17]. This current study has identified that MoXLP is currently (marginally) outperforming CoC in the Trident system. However, CoC and MoXLPE bearings may have equivalent survival in patients aged $\leq$ 60 years. CoC bearings may ultimately provide greater longevity in younger patients, but longer-term data are required.

The use of the multi-hole shell option allows supplementary screw fixation of the cup, rather than reliance on press fit alone. The decision to use a multi-hole shell may be explained by inadequate press fit of the trial solid shell; anatomical factors (e.g. wall defects) precluding the use of cemented cups or press-fit components without screw augmentation; or the operating surgeon's normal practice. From the data presented here, multi-hole shells are associated with higher revision in younger patients, but possibly lower revision in older patients. Although we have no data on screw usage, it is assumed that a (more expensive) multi-hole shell would be used in conjunction with screws in the majority of cases, to supplement inadequate press

Table 5
Independent Predictors of Revision Following 15 740 Exeter/Trident Hybrid Hip Arthroplasties: Simple and Multivariable Cox Regressions (England and Wales, 2003–2010).

	Simple Analysis			Multivariable Analysis		
Covariate	HR	95% CI	*P* value	HR	95% CI	*P* value
Gender						
Female	1	0.74–1.45	0.829			
Male	1.04					
Age (y)						
Category			0.033			0.037
≤ 60	1			1		
61–75	0.79	0.54–1.14	0.201	0.75	0.50–1.11	0.148
≥ 76	0.50	0.30–0.84	0.009	0.46	0.25–0.83	0.010
ASA grade						
1/2	1					
≥ 3	1.08	0.66–1.77	0.766			
Stem offset (mm)						
Category			0.613			
35.5	0.73	0.34–1.59	0.429			
37.5	1.01	0.70–1.46	0.943			
44	1					
50	1.38	0.74–2.60	0.316			
Stem taper						
≤ 2	1					
≥ 3	0.63	0.32–1.24	0.180			
Head size (mm)						
Category			0.152			
28	1.28	0.89–1.84	0.176			
32	1					
≥ 36	0.82	0.51–1.33	0.421			
Neck offset						
Category			0.139			
Standard	1					
Plus	1.38	0.89–2.15	0.152			
Minus	1.41	0.95–2.10	0.085			
Bearing						
Category			0.050			0.035
Metal-on-XLPE	1			1		
Metal-on-standard PE	2.46	1.30–4.65	0.006	2.64	1.39–4.99	0.003
Ceramic-on-standard PE	3.51	1.37–9.00	0.009	3.07	1.18–8.00	0.022
Ceramic-on-XLPE	1.98	0.78–5.04	0.150	1.86	0.72–4.77	0.198
Ceramic-on-ceramic	2.29	1.23–4.26	0.009	1.93	1.00–3.69	0.049
Shell						
Solid back	1			1		
Multi-hole	1.54	1.06–2.24	0.024	1.70	1.16–2.48	0.006
Cement						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67–1.41	0.876			
Other	1.55	0.95–2.52	0.082			
Surgical approach						
Category			0.036			
Posterior	1					
Anterolateral	1.53	1.09–2.15	0.015			
Other	0.51	0.07–3.63	0.497			
Year of procedure	1.06	0.94–1.19	0.341			
Operator						
Consultant	1					
Other	1.28	0.85–1.91	0.237			
Consultant Exeter/Trident volume						
Category			0.273			
Low (≤ 50)	1.14	0.71–1.83	0.597			
Medium (51–200)	1.40	0.91–2.13	0.130			
High (≥ 201)	1					

HR, hazards ratio; CI, confidence intervals; ASA, American Society of Anaesthesiologists; XLPE, highly cross-linked polyethylene; PE, polyethylene.

Table 6
Revision Following 15 740 Exeter/Trident Hybrid Hip Arthroplasties: Multivariable Cox Regressions With Multiplicative Interaction of Age and Shell Type (England and Wales, 2003–2010).

	Multivariable analysis		
Covariate	HR	95% CI	*P* value
Age (y)			
Category			0.330
≤ 60	1		
61–75	0.79	0.49–1.25	0.307
≥ 76	0.62	0.33–1.17	0.141
Bearing			
Category			0.048
Metal-on-XLPE	1		
Metal-on-standard PE	2.52	1.33–4.78	0.005
Ceramic-on-standard PE	2.99	1.50–7.78	0.025
Ceramic-on-XLPE	1.74	0.68–4.45	0.252
Ceramic-on-ceramic	1.86	0.97–3.56	0.061
Shell			
Solid back	1		
Multi-hole	1.37	0.91–2.07	0.135
Age * shell			
Category			0.022
≤ 60 y	1		
61–75	0.80	0.33–1.94	0.628
≥ 76	0.23	0.08–0.70	0.010

HR, hazards ratio; CI, confidence intervals; ASA, American Society of Anaesthesiologists; XLPE, highly cross-linked polyethylene; PE, polyethylene.

fit. This potentially poorer method of fixation, the reduced surface area for bony in-growth, or wear debris migrating through the holes, may contribute to the higher revision seen in these multi-hole shells in younger patients. Conversely, in older patients with poorer bone quality, reliance on press fit alone may not be adequate in any patients, and supplementary fixation with screws may provide greater fixation. Of note, no difference in revision was found between PSL and Hemispherical shells.

Previous reports have shown that increasing age is associated with lower revision rates after cemented THA [10,19]. We found an interaction with shell type, which may explain the lower revision rates in older patients in this study. However, it is important to remember that patients aged ≥ 76 years have lower functional demands, and fewer patients requiring revision surgery will be fit enough in this age group, limiting the conclusions that can be drawn when patient-reported functional and general health data are unavailable. Furthermore, 10-year patient survival following THA performed in older patients (aged ≥ 80 years) is less than 25% according to Norwegian Registry data [20]. The literature reports no superiority of cementless over cemented cups at 10 years [21] and, given costs are generally higher than cemented, we question the cost-effectiveness of the use of cementless cups in 3976 (25%) patients aged ≥ 76 years in this current analysis.

As expected, the overall revision presented here at 5 years (1.56%; 95% CI 1.23–1.89) was similar to reports from the NJR 8th Annual Report for 18 358 Exeter V40/Trident THAs (1.69%; 95% CI 1.39–2.07) [7]. However, revision at 5 years when the commonest bearing (CoC) was used in combination with a solid-back shell in patients ≤ 75 - years was only 1.13% (95% CI 0.43–1.83). Although the follow-up time is shorter, the data presented here suggest that MoXLPE, in combination with a solid shell has even lower revision. Overall revision, as described in the analyses of brands alone in the NJR 8th Annual Report, is therefore skewed by longer follow-up data from poorer performing components (historical higher use of standard PE). Components that are now most commonly used in current practice (MoXLPE, CoC bearings) have lower revision rates than those reported by the NJR.

Increasing femoral head size is thought to contribute to lower dislocation [22] and revision [11]. However, in this study there were no differences in revision rates across head sizes. Of note, surgical approach did not influence revision after adjustment for other factors. Although BMI appeared to have an influence on the model, with the degree of missing data it was felt that excluding this parameter was the most appropriate solution. Efforts to improve BMI recording to allow for appropriate adjustment in future explanatory analysis are required.

The commonest primary reason for revision was infection (27.0%); dislocation accounted for 25.5% of revisions. This study reports mid-

Table 7
Revision Rates Following Exeter/Trident Hybrid Hip Arthroplasty By Bearing and Shell Type in Patients Aged ≤ 75 Years (95% Confidence Intervals) (England and Wales, 2003–2010).

	Revision Rates By Bearing				Overall Revision Rates
	MoXLP	MoSP	CoXLP	CoC	
1 y					
All	0.33% (0.07–0.60)	0.73% (0.39–1.08)	0.65% (0.08–1.21)	0.54% (0.35–0.74)	0.57% (0.43–0.71)
Solid shell	0.24% (0.00–0.72)	0.79% (0.21–1.37)	–	0.25% (0.03–0.46)	0.40% (0.20–0.59)
Multi-hole shell	0.36% (0.05–0.68)	0.70% (0.27–1.13)	0.67% (0.00–1.42)	0.73% (0.44–1.02)	0.67% (0.47–0.86)
3 y					
All	0.72% (0.26–1.18)	1.36% (0.87–1.86)	1.49% (0.10–2.87)	1.10% (0.79–1.41)	1.14% (0.92–1.37)
Solid shell	0.24% (0.00–0.72)	1.35% (0.55–2.16)	–	0.42% (0.13–0.71)	0.64% (0.37–0.91)
Multi-hole shell	0.86% (0.28–1.44)	1.37% (0.74–2.00)	2.15% (0.00–4.51)	1.57% (1.08–2.06)	1.46% (1.13–1.79)
5 y					
All	–	2.01% (1.25–2.78)	–	1.66% (1.15–2.16)	1.74% (1.35–2.13)
Solid shell	–	1.78% (0.63–2.92)	–	1.13% (0.43–1.83)	1.21% (0.67–1.76)
Multi-hole shell	–	2.17% (1.14–3.19)	–	1.99% (1.30–2.67)	2.07% (1.52–2.62)
Total number					
All	2193	2476	937	5831	11 764
Solid shell	504	957	375	2202	4180
Multi-hole shell	1689	1519	562	3629	7584

Inadequate numbers of CoSP for analysis. For sub-analysis of data, where numbers were inadequate, no figures are reported.

term data: as expected, only a small number of implants (23.4%) were revised for aseptic loosening/lysis. Excluding dislocation, cup-related failures (aseptic loosening/lysis, malalignment, dissociation of liner, and liner wear) were cited in 39.7% (56) of revisions, compared with 9.9% [14] for stems. Of note, previous concerns regarding high rates of mal-seating of the Trident ceramic liners (8%–16.4% of all procedures) [23,24] do not appear to translate into liner dissociation and subsequent revision procedures (3.5% of revisions were attributable to ceramic liner dissociations in this series).

In summary, there were significant differences in implant failure between bearing surface materials and acetabular shell fixation types, after adjustment for a range of covariates in a large cohort of single-brand hybrid THAs. In this study, standard polyethylene liners and multi-hole Trident shells were associated with significantly higher revision rates overall. Metal-on-highly-cross-linked polyethylene in a shell with no holes appears to be the best choice in patients aged ≤ 75 years, in short- to medium-term analysis of this popular hybrid brand combination. CoC bearings may have a role in the youngest patients. This study demonstrates that multiple factors can influence revision risk; registry data analyses may mislead if they fail to adjust for all relevant covariates when comparing across brands and types. For surgeons using hybrid THA, the findings presented may help guide their practice. Findings may also provide a useful reference for comparison with future analyses comparing implant types.

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Appendix A. Supplementary material

The reliability of the Cox model was explored by alternative stepwise procedures using the likelihood ratio test. Covariates found not to be statistically significant were excluded from the model, based on statistical entry ($P < 0.05$) and rejection ($P > 0.10$) criteria. The same covariates were fitted forward and reverse stepwise to ensure that findings were not qualitatively affected in the final model, with any inconsistency reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring two-way interactions between covariates and for the constant proportionality over time assumption. In order to improve efficiency of the final models, where no differences were found within subcategories (e.g. shell geometry type) during preliminary modeling, these were combined. All models were fitted using SPSS version 19.0 (SPSS Inc, IBM Corporation, Armonk, NY).

On univariable analysis, age as a continuous covariate was a significant influence (HR = 0.98, 95% CI 0.96–1.00, $P = 0.016$). We therefore created separate multivariable models to test age selection (as continuous or categorical data). As a continuous covariate, age did not affect selection within the model, nor the influence of the other significant covariates (multi-hole shell: HR = 1.69, MoSP bearing: HR = 2.65, CoSP: HR = 3.15, CoXLP: HR = 1.89, CoC: HR = 1.94). The final model was therefore reported with age as categorical data.

High BMI (≥ 30 kg/m^2) was associated with an increased risk of revision compared to BMI < 30 kg/m^2 on univariable analysis (≥ 30 kg/m^2: HR = 2.03, 95% CI 1.15–3.58, $P = 0.015$). This inclusion of BMI in the preliminary multivariable modeling resulted in the loss of 58% of available procedures from the analysis, and while the HRs for individual bearings where not qualitatively affected by this, shell type and age were not selected within the model (Supplementary Table 1). This substantial data loss was accompanied by stepwise selection instability, and so BMI was therefore removed from the final analysis.

Tests for time dependency of covariates were not statistically significant. Forward and reverse stepwise model construction led to the same final model.

References

1. Morshed S, Bozic KJ, Ries MD, et al. Comparison of cemented and uncemented fixation in total hip replacement: a meta-analysis. Acta Orthop 2007;78(3):315.
2. No-authors-listed. Annual Report 2008, 8 year report. New Zealand National Joint Registry. 2008 [23/03/2012]; Available from: http://www.cdhb.govt.nz/njr/reports/A2D65CA3.pdf.
3. Annual Report 2006. Finnish National Arthroplasty Register. 2006; Available from: http://www.nam.fi/english/publications.
4. Annual Report 2008. Norwegian Arthroplasty Register. 2008 [23/03/2012]; Available from: http://www.haukeland.no/nrl/eng/default.htm.
5. Annual report 2010. Swedish Hip Registry. 2010; Available from: http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sflb.ashx.
6. Corbett KL, Losina E, Nti AA, et al. Population-based rates of revision of primary total hip arthroplasty: a systematic review. PLoS One 2010;5(10):e13520.
7. National Joint Registry for England and Wales 8th Annual Report. 2011 [25/03/2012]; Available from: http://www.njrcentre.org.uk/NjrCentre/LinkClick.aspx?fileticket=1TQ%2bEiNejm0%3d&tabid=86&mid=523.
8. Australian Orthopaedic Association, National Joint Replacement Register. 2010 [13th June 2011]; Available from: http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp.
9. National Joint Registry for England and Wales. 2012 [02/04/2012]; Available from: http://www.njrcentre.org.uk/njrcentre/default.aspx.

10. Roder C, Bach B, Berry DJ, et al. Obesity, age, sex, diagnosis, and fixation mode differently affect early cup failure in total hip arthroplasty: a matched case–control study of 4420 patients. J Bone Joint Surg Am 2010;92(10):1954.
11. Smith AJ, Dieppe P, Vernon K, et al. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. Lancet 2012;379(9822):1199.
12. Johnsen SP, Sorensen HT, Lucht U, et al. Patient-related predictors of implant failure after primary total hip replacement in the initial, short- and long-terms. A nationwide Danish follow-up study including 36,984 patients. J Bone Joint Surg Br 2006;88(10):1303.
13. Wylde V, Blom AW. The failure of survivorship. J Bone Joint Surg Br 2011;93(5):569.
14. Jacobs CA, Christensen CP, Greenwald AS, et al. Clinical performance of highly cross-linked polyethylenes in total hip arthroplasty. J Bone Joint Surg Am 2007;89(12):2779.
15. Kuzyk PR, Saccone M, Sprague S, et al. Cross-linked versus conventional polyethylene for total hip replacement: a meta-analysis of randomised controlled trials. J Bone Joint Surg Br 2011;93(5):593.
16. Howard JL, Kremers HM, Loechler YA, et al. Comparative survival of uncemented acetabular components following primary total hip arthroplasty. J Bone Joint Surg Am 2011;93(17):1597.
17. Hannouche D, Zaoui A, Zadegan F, et al. Thirty years of experience with alumina-on-alumina bearings in total hip arthroplasty. Int Orthop 2011;35(2):207.
18. Sexton SA, Walter WL, Jackson MP, et al. Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg Br 2009;91(11):1448.
19. Chandler HP, Reineck FT, Wixson RL, et al. Total hip replacement in patients younger than thirty years old. A five-year follow-up study. J Bone Joint Surg Am 1981;63(9):1426.
20. Lie SA, Engesaeter LB, Havelin LI, et al. Mortality after total hip replacement: 0–10-year follow-up of 39,543 patients in the Norwegian Arthroplasty Register. Acta Orthop Scand 2000;71(1):19.
21. Hailer NP, Garellick G, Karrholm J. Uncemented and cemented primary total hip arthroplasty in the Swedish Hip Arthroplasty Register. Acta Orthop 2010;81(1):34.
22. Jameson SS, Lees D, James P, et al. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. J Bone Joint Surg Br 2011;93(7):876.
23. Howcroft DW, Qureshi A, Graham NM. Seating of ceramic liners in the uncemented trident acetabular shell: is there really a problem? Clin Orthop Relat Res 2009;467(10):2651.
24. Langdown AJ, Pickard RJ, Hobbs CM, et al. Incomplete seating of the liner with the Trident acetabular system: a cause for concern? J Bone Joint Surg Br 2007;89(3):291.

Supplementary Table 1
Independent Predictors of Revision Following 15 740 Exeter/Trident Hybrid Hip Arthroplasties, Including Body Mass Index Data: Simple and Multivariable Cox Regressions (England and Wales, 2003–2010).

	Simple Analysis			Multivariable Analysis[a]		
Covariate	HR	95% CI	*P* value	HR	95% CI	*P* value
Gender						
Female	1					
Male	1.04	0.74–1.45	0.829			
Age						
Category			0.033			
≤ 60	1					
61–75	0.79	0.54–1.14	0.201			
≥ 76	0.50	0.30–0.84	0.009			
ASA grade						
1/2	1					
≥ 3	1.08	0.66–1.77	0.766			
Body mass index						
< 30 kg/m^2	1			1		
≥ 30 kg/m^2	2.03	1.15–3.58	0.015	2.00	1.13–3.54	0.017
Stem offset						
Category			0.613			
35.5 mm	0.73	0.34–1.59	0.429			
37.5 mm	1.01	0.70–1.46	0.943			
44 mm	1					
50 mm	1.38	0.74–2.60	0.316			
Stem taper						
≤ 2	1					
≥ 3	0.63	0.32–1.24	0.180			
Head size						
Category			0.152			
28 mm	1.28	0.89–1.84	0.176			
32 mm	1					
≥ 36 mm	0.82	0.51–1.33	0.421			
Neck offset						
Category			0.139			
Standard	1		0.152			
Plus	1.38	0.89–2.15				
Minus	1.41	0.95–2.10	0.085			
Bearing						
Category			0.050			0.159
Metal-on-XLPE	1			1		
	2.46	1.30–4.65	0.006	1.97	0.71–5.45	0.194
Ceramic-on-standard PE	3.51	1.37–9.00	0.009	5.44	1.08–27.36	0.040
Ceramic-on-XLPE	1.98	0.78–5.04	0.150	3.16	1.02–9.81	0.046
Ceramic-on-ceramic	2.29	1.23–4.26	0.009	2.50	1.02–6.15	0.046
Shell						
Solid back	1					
Multi-hole	1.54	1.06–2.24	0.024			
Cement						
Category			0.169			
Palacos HV antibiotic	1					
Simplex P antibiotic	0.97	0.67–1.41	0.876			
Other	1.55	0.95–2.52	0.082			
Surgical approach						
Category			0.036			
Posterior	1					
Anterolateral	1.53	1.09–2.15	0.015			
Other	0.51	0.07–3.63	0.497			
Year of procedure	1.06	0.94–1.19	0.341			
Operator						
Consultant	1					
Other	1.28	0.85–1.91	0.237			
Consultant Exeter/Trident volume						
Category			0.273			
Low (≤ 50)	1.14	0.71–1.83	0.597			
Medium (51–200)	1.40	0.91–2.13	0.130			
High (≥ 201)	1					

HR, hazards ratio; CI, confidence intervals; ASA, American Society of Anaesthesiologists; XLPE, highly cross-linked polyethylene; PE, polyethylene.
[a] Based on 6637 procedures with body mass index data.

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■ HIP

Independent predictors of revision following metal-on-metal hip resurfacing

A RETROSPECTIVE COHORT STUDY USING NATIONAL JOINT REGISTRY DATA

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Modern metal-on-metal hip resurfacing has been widely performed in the United Kingdom for over a decade. However, the literature reports conflicting views of the benefits: excellent medium- to long-term results with some brands in specific subgroups, but high failure rates and local soft-tissue reactions in others. The National Joint Registry for England and Wales (NJR) has collected data on all hip resurfacings performed since 2003. This retrospective cohort study recorded survival time to revision from a resurfacing procedure, exploring risk factors independently associated with failure. All patients with a primary diagnosis of osteoarthritis who underwent resurfacing between 2003 and 2010 were included in the analyses. Cox's proportional hazard models were used to analyse the extent to which the risk of revision was related to patient, surgeon and implant covariates.

A total of 27 971 hip resurfacings were performed during the study period, of which 1003 (3.59%) underwent revision surgery. In the final adjusted model, we found that women were at greater risk of revision than men (hazard ratio (HR) = 1.30, p = 0.007), but the risk of revision was independent of age. Of the implant-specific predictors, five brands had a significantly greater risk of revision than the Birmingham Hip Resurfacing (BHR) (ASR: HR = 2.82, p < 0.001, Conserve: HR = 2.03, p < 0.001, Cormet: HR = 1.43, p = 0.001, Durom: HR = 1.67, p < 0.001, Recap: HR = 1.58, p = 0.007). Smaller femoral head components were also significantly more likely to require revision (≤ 44 mm: HR = 2.14, p < 0.001, 45 to 47 mm: HR = 1.48, p = 0.001) than medium or large heads, as were operations performed by low-volume surgeons (HR = 1.36, p < 0.001). Once these influences had been removed, in 4873 male patients < 60 years old undergoing resurfacing with a BHR, the five-year estimated risk of revision was 1.59%.

In summary, after adjustment for a range of covariates we found that there were significant differences in the rate of failure between brands and component sizes. Younger male patients had good five-year implant survival when the BHR was used.

Metal-on-metal (MoM) resurfacing of the hip remains a contentious issue despite its evolution over more than 50 years. Uncertainties include the use of resurfacing as opposed to total hip replacement (THR) and the choice of resurfacing arthroplasty. Part of the concern may be historical: early resurfacing designs were flawed and had high failure rates.[1,2] Modern resurfacing is based on learning experiences from the McKee–Farrar hip replacement, a pioneer MoM THR that provided reasonable long-term survival in some patients.[3] The first of the current generation of resurfacing arthroplasties was introduced in the late 1990s with the evolution of the Birmingham Hip Resurfacing (BHR; Smith & Nephew, Memphis, Tennessee) in the United Kingdom. Encouraging early to mid-term results[4] prompted many manufacturers to exploit the concept and introduce their own versions, each with subtly differing interpretations of the fundamental design characteristics. Excellent ten-year results for the BHR have been reported from the designers' series and from independent units.[5-7]

At the peak of usage (2007) more than 6000 hip resurfacings were being implanted in England and Wales annually.[8] The implant was intended for younger, more active patients for whom longevity was essential. Perceived benefits included low dislocation risk and preservation of femoral bone, permitting an uncomplicated revision when required.[9] However, there are reports of excessive wear, high levels of circulating metal ions, local soft-tissue reactions and persistent pain in some patients.[10-13]

In 2010 the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) issued an alert, warning of problems with MoM implants and the need for regular

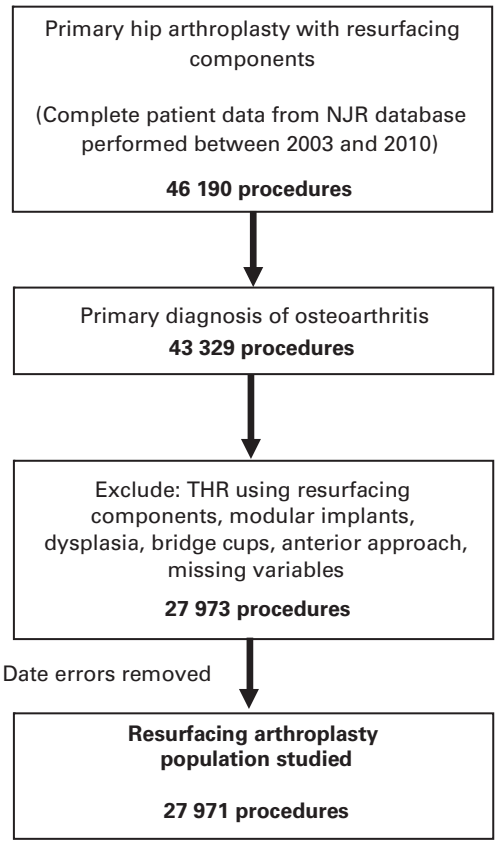


Fig. 1

Flowchart describing the inclusion criteria for this study (NJR, National Joint Registry for England and Wales; THR, total hip replacement).

follow-up.[14] Later that year, the Articular Surface Replacement (ASR; DePuy, Leeds, United Kingdom) was withdrawn from distribution in the United Kingdom amid concerns regarding high failure rates, initially described in single-surgeon series and subsequently corroborated in registry data.[8,15,16] Although specific design characteristics associated with the ASR may be important, other brands also perform poorly.[17] Potentially, a range of surgical, patient and implant factors may contribute to the high rates of failure: implant position, component size, and female gender have all been implicated as risks for failure.[18,19]

The aim of this study was to explore the risk factors for revision in a national cohort of patients who have undergone hip resurfacing, using data from the National Joint Registry for England and Wales (NJR).[20]

Materials and Methods

This was a retrospective cohort study assessing NJR data for the survival time to revision from a first resurfacing procedure and exploring the risk factors independently associated with failure.

The NJR has assimilated data on patients, surgeons and implants performed in both the private sector and the NHS in England and Wales since 2003. Data were extracted for all hip resurfacings for patients with a primary diagnosis of osteoarthritis (OA) submitted to the NJR until December 2010. Resurfacing components used with a femoral stem, modular resurfacing components, and complex resurfacings such as those using dysplasia or bridge acetabular components were excluded. The anterior approach was used for < 100 procedures and these were also excluded. A summary of the inclusion criteria is shown in Figure 1.

Covariate categories examined were patient age at the time of resurfacing, gender, American Society of Anesthesiology (ASA) grade,[21] body mass index (BMI), brand of prosthesis, the size of the femoral component, the grade of the surgeon, the surgical approach and the volume of resurfacing procedures undertaken in the consultant's practice. Covariates used are summarised in Table I.

For an implant to have been recorded as revised (where one implant is exchanged for another, or removed as part of a staged procedure) on the NJR dataset, a complete record of the revision procedure (including the side of operation) is submitted from the treating hospital and linked to the original procedure by matching unique patient identifiers. A number of causes of revision can be recorded for each operation. In order to summarise these data effectively, infection or peri-prosthetic fracture were taken to be the primary reason when recorded. Soft-tissue reaction to metal debris and metallosis (including other free text terms such as the acronym ALVAL – aseptic lymphocytic vasculitis-associated lesions[22]) were grouped together. Pain was only taken as a cause when no other reason was provided.

Information regarding the duration and severity of symptoms, radiological appearance and activity levels prior to and following the resurfacing procedure was not available in the NJR data, but may be available in due course as patient-reported outcome measures (PROMs) become linked to the NJR.

Statistical analysis. A revision procedure was considered to be a 'failure event', and the time between the index procedure and revision was a measurement of survival of the joint. Survival times for patients who had not undergone revision were censored at the study census date (31 December 2010). Event analysis was used to investigate the time to failure.[23] In this model, the contribution of potential factors to the risk of failure can be quantified. Cox's proportional hazard models were used to assess the extent to which the timing of failure could be explained in terms of the patient, surgeon and implant covariates. The Cox model assumes that there is an underlying unspecified baseline hazard that stays constant through time and which is influenced by covariates that mitigate or enhance the risk of failure.

Age and consultant volume were analysed as categorical data because of the greater clinical relevance of group comparisons. Age was partitioned into four groups based approximately on standard deviations from the mean. Consultant volume was partitioned into three groups, informed by spread of the data. As the distribution of head sizes differs between genders, the data were analysed in order to

Table I. Covariates used in the event analyses

Category	Variable type	Covariate
Age	Continuous	Age at time of surgery
	Ordinal	≤ 45 years
		46 to 55
		56 to 65
		≥ 66 years
Gender	Binary	Male
		Female
American Society of Anesthesiologists grade	Ordinal	Grade 1
		Grade 2
		Grade ≥ 3
Body mass index (BMI)	Continuous	BMI at time of surgery
	Ordinal	Underweight (< 19 kg/m^2)
		Normal (19 < 25 kg/m^2)
		Overweight (25 < 30 kg/m^2)
		Obese (≥ 30 kg/m^2)
Brand	Nominal	Birmingham Hip Resurfacing (Smith & Nephew)
		Articular Surface Replacement (DePuy)
		Adept (Finsbury Orthopaedics Limited)
		Cormet (Corin Group plc)
		Conserve Plus (Wright Medical Technology Inc.)
		Durom (Zimmer Inc.)
		Mitch (Stryker Orthopaedics)
		Recap (Biomet Inc.)
Head size category	Continuous	
	Ordinal	Very small (≤ 44 mm)
		Small (45 mm to 47 mm)
		Medium (48 mm to 50 mm)
		Large (≥ 51 mm)
Surgical approach	Binary	Posterior
		Anterolateral
Primary surgeon	Binary	Consultant
		Other
Consultant resurfacing volume	Continuous	
	Ordinal	Low (≤ 50 cases throughout study period)
		Medium (51 to 200)
		High (≥ 201)

partition into four groups containing both male and female patients in each. The categories for surgical approach on the data forms have evolved over the period of the study. For the purposes of this analysis the anterolateral, direct lateral, lateral and Hardinge[24] surgical approaches were grouped together ('anterolateral') and compared with the posterior approach. For categorical covariate hazard ratios (HR) the most frequent category was used as the baseline against which to compare hazards associated with other categories in that covariate; for example, the BHR was used as the baseline against which all other brands were compared. Exceptions to this were age (where the youngest group was used as the baseline) and head size (where the largest implant group was used). Kaplan-Meier survival graphs were generated to display visual differences in unadjusted covariates. The log-rank (Mantel-Cox) test was used to perform paired comparisons between each of the covariates and the reference covariate in each of the following categories: gender, ASA grade, brand, femoral head size and consultant volume. Life tables were included to describe numbers in each covariate entering each year of the study.

All models were fitted using SPSS version 19.0 (SPSS Inc., IBM Corporation, Armonk, New York). When modelling determinants, any covariates found to have a non-statistically significant association were excluded from the model, based on statistical entry ($p < 0.05$) and rejection ($p > 0.1$) criteria. Results are presented as HR with 99% confidence

Table II. Demographic information on the hip resurfacing patients (England and Wales, 2003 to 2010)

Characteristic	Hip resurfacing (n = 27 971)
Mean (SD) age (yrs)	55.1 (8.48)
Age by category (n, %)	
≤ 45 years	3383 (*12.1*)
46 to 55	9540 (*34.1*)
56 to 65	12 215 (*43.7*)
≥ 66 years	2833 (*10.1*)
Gender (n, %)	
Male	19 335 (*69.1*)
Female	8636 (*30.9*)
American Society of Anesthesiologists (ASA) grade (n, %)	
1	13 767 (*49.2*)
2	13 381 (*47.8*)
≥ 3	823 (*2.9*)
Mean (SD) body mass index (BMI) (kg/m^2)	28.3 (4.60)
BMI by category (n, %)	
Underweight (< 20 kg/m^2)	95 (*0.3*)
Normal (20 < 25 kg/m^2)	1634 (*5.8*)
Overweight (25 < 30 kg/m^2)	4088 (*14.6*)
Obese (≥ 30 kg/m^2)	3021 (*10.8*)
No data	19 131 (*68.4*)
Approach (n, %)	
Posterior	20 048 (*71.7*)
Anterolateral	5578 (*19.9*)
No data	2345 (*8.4*)
Brand (n, %)	
BHR	15 459 (*55.3*)
ASR	2631 (*9.4*)
Adept	2466 (*8.8*)
Conserve	1173 (*4.2*)
Cormet	3193 (*11.4*)
Durom	1381 (*4.9*)
Mitch	339 (*1.2*)
Recap	1329 (*4.8*)
Head size (n, %)	
Very small (≤ 44 mm)	3928 (*14.0*)
Small (45 mm to 47 mm)	5295 (*18.9*)
Medium (48 mm to 50 mm)	10 720 (*38.3*)
Large (≥ 51 mm)	8028 (*28.7*)
Operator (n, %)	
Consultant	26 166 (*93.5*)
Other	1805 (*6.5*)
Number of consultants (n)	722
Consultant resurfacing volume (n, %)	
Low (≤ 50 cases over study period)	7202 (*25.7*)
Medium (51 to 200)	11 910 (*42.6*)
High (≥ 201)	8859 (*31.7*)
Number of surgical units (n)	376

intervals (CI); ratios > 1 indicate that risk is higher than the reference covariate category. Owing to the statistical methods used and the large population size, only covariates fitting models with $p < 0.01$ were considered significant influences, to ensure that the chance of a type 1 error was reduced. The reliability of the models was explored by alternative stepwise procedures using the likelihood ratio test. The same covariates were fitted forward and reverse stepwise to ensure that findings were not qualitatively affected in the final model, and any inconsistency was reported. The final model was re-evaluated as a directly entered model (non-stepwise) to provide unconditional estimates, and was assessed by exploring two-way interactions between covariates and for the constant proportionality over time assumption. In addition, baseline entry and rejection criteria for the model were reduced to $p < 0.01$ and $p > 0.05$, respectively, to test covariate selection within the model.

Further analysis was then performed to compare brand differences in men < 60 years old. Operations were excluded if previously identified significant influences for implant failure were present. One-, three-, five- and seven-year revision rates (with 95% CIs) were then calculated for each brand and in total for the subgroup. Those brands with < 200 operations registered were excluded. Data were compared to the estimated revision rates for all patients in the study.

Results

A total of 27 971 hip resurfacings were available for analysis. The majority were in men (19 335, 69.1%), almost all had an ASA grade ≤ 2 (27 148, 97.1%) and the mean age was 55 years (15 to 108). The posterior approach was used in 20 048 cases (71.7%) and the BHR was the most commonly implanted prosthesis (15 459, 55.3%). Small or very small femoral components (≤ 47 mm) were used in 9223 hips (33%). Patients were under the care of 722 different consultants in 376 different surgical units, and most operations had been performed by a consultant (26 166 operations, 93.5%). A total of 7202 procedures (25.7%) were performed under the care of a consultant who had recorded < 50 resurfacing procedures during the study period. Demographic information is shown in Table II.

In all, 1003 patients (3.59%) underwent a revision procedure. The most common reason was aseptic loosening in 264cases (26.3%), followed by peri-prosthetic fracture in 213 (21.2%) and pain without a recorded cause in 183 (18.2%). Revision due to a soft-tissue reaction to metal debris was undertaken in 71 patients (7.1%). Revision data are summarised in Table III. The 90-day mortality rate was 0.08%.[25] As of December 2010, 346 patients (1.24%) had died.

Patient-specific predictors of implant failure in the unadjusted data were female gender and ASA grades > 2. After risk adjustment using Cox's proportional hazards model, female gender (HR = 1.30 (99% CI 1.01 to 1.76); $p = 0.007$) and ASA grade ≥ 3 (HR = 1.74 (99% CI 1.17 to 2.61); $p < 0.001$) remained statistically significant (Table IV).

There were 19 133 entries (68.4%) without BMI data and 2345 (8.4%) without surgical approach data. Patient age, BMI, surgical approach and grade of operator did not significantly influence the risk of revision.

Table III. Reason recorded for revision following hip resurfacing (England and Wales, 2003 to 2010)

Reason for failure (n, %)	Revision (n = 1003)
Aseptic component loosening/lysis	264 (*26.3*)
Femoral	112
Acetabular	132
Both	20
Peri-prosthetic fracture	213 (*21.2*)
Femoral neck	203
Acetabulum	6
Both	4
Unexplained pain	183 (*18.2*)
Technical error	90 (*9.0*)
Component mismatch	9
Component malalignment	81
Adverse soft-tissue reaction to metal debris*	71 (*7.1*)
Infection	71 (*7.1*)
Dislocation/subluxation	45 (*4.5*)
Component fracture	37 (*3.7*)
Acetabular wear	10 (*1.0*)
Other	11 (*1.1*)
Avascular necrosis of the femoral head	9
Heterotrophic ossification	1
Leg-length discrepancy	1
No cause described	60 (*6.0*)

* including free text terms: metallosis, aseptic lymphocyte-dominated vasculitis associated lesion (ALVAL)

When the unadjusted data were analysed for brand, ASR, Cormet (Corin Group PLC, Cirencester, United Kingdom), Conserve (Wright Medical Technology Inc., Arlington, Tennessee), Durom (Zimmer Inc., Warsaw, Indiana) and Recap (Biomet Orthopedics LLC, Warsaw, Indiana) all had significantly higher revision rates than the BHR (Fig. 2). After risk adjustment, the same five brands were found to have a greater revision hazard than the BHR (ASR: HR = 2.82 (99% CI 2.24 to 3.54), $p < 0.001$; Conserve: HR = 2.03 (99% CI 1.42 to 2.91), $p < 0.001$; Cormet: HR = 1.43 (99% CI 1.10 to 1.86), $p = 0.001$; Durom: HR = 1.67 (99% CI 1.16 to 2.39), $p < 0.001$; Recap: HR = 1.58 (99% CI 1.03 to 2.42), $p = 0.007$) (Table IV).

Size of the femoral head < 48 mm was found to be a significant predictor of revision in both the unadjusted and the adjusted data (Fig. 3). Small femoral head sizes had significantly higher revision hazards than large heads (≤ 44 mm: HR = 2.14 (99% CI 1.53 to 3.00), $p < 0.001$; 45 to 47 mm: HR = 1.48 (99% CI 1.09 to 2.00), $p = 0.001$). There were no significant differences between the medium and the larger head sizes.

Surgeons who performed ≤ 200 resurfacings during the study period had a higher rate of revision in the unadjusted data. However, after risk adjustment, only patients operated on by low-volume surgeons (< 50 resurfacings) had a higher risk of revision (HR = 1.36 (99% CI 1.09 to 1.71), $p < 0.001$) than high-volume surgeons (Table IV).

Tests for interaction (multiplicative) between covariates and time-dependency were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final model.

When data for younger (< 60 years), fitter (ASA grades 1 and 2) male patients were analysed by brand, following resurfacing performed with head sizes > 48 mm by medium- to high-volume consultants, BHR patients (n = 4873) had a significantly lower five-year estimated revision rate (1.59% (95% CI 1.17 to 2.00)) than the poorest-performing brand (ASR (n = 715): 5.67% (95% CI 3.48 to 7.85)) and the entire subgroup (8172 patients: 2.47% (95% CI 2.04 to 2.91)) (Table V and Fig. 4). The estimated revision rate for the whole study population at five years was 4.76% (95% CI 4.44 to 5.08) (Table V).

Discussion

This retrospective cohort study provides the largest in-depth analysis of hip resurfacings to date. Significantly higher revision rates following resurfacing were independently associated with brand (ASR, Durom, Conserve, Cormet, Recap), female gender, smaller sizes of component, higher ASA grade and lower consultant volume. Increasing age was not associated with a greater risk of revision. This is most likely due to appropriate patient selection for resurfacing surgery across the population, mitigating the increased risk expected in older patients. Despite debate in the literature regarding the most appropriate surgical approach,[26-28] in this analysis there was no significant difference between posterior and anterolateral approaches in terms of the risk of revision.

Although registries provide data from a vast number of patients, there are limitations. Revision is taken as a surrogate marker of failure, as other endpoints are unavailable. This does not take into account patients living with a painful hip, those with high metal ion levels, those with soft-tissue reactions, or those awaiting revision at the time of censoring. Thus the analysis assumes a common spectrum of, and progression to, failure regardless of brand or size of prosthesis. It is also apparent that poor positioning of the components may contribute to early failure.[18,19] This analysis lacks data about positioning, but the relative performance of prostheses is likely to be robust within an analysis of such large numbers unless there are systematic differences in the ease of aligning different prostheses.

Several covariates are known to be associated, for example female gender and smaller prosthetic head size (females generally require smaller sizes than males). We explored multiplicative interactions between covariates and, in the final model, all significant covariate categories were independent of each other. The study design was observational and thus vulnerable to omitted variables, which may confound our findings. However, similarities between the unadjusted and adjusted models, robustness under different model fitting assumptions, and the independence of time support the stability of estimates.

NJR-linked PROMs are unlikely to contribute greatly to this type of analysis, as they report a single point in time (usually at around six months after surgery), and many of

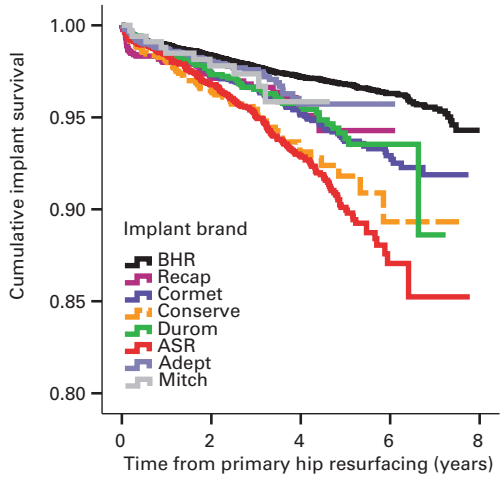
Table IV. Independent predictors of revision. Age of patient, body mass index, operator and surgical approach were not selected for the final model (HR, hazards ratio; CI, confidence interval)

	Simple (unadjusted) analysis		Multiple variable (adjusted) analysis	
Covariate	**HR (99% CI)**	**p-value**	**HR (99% CI)**	**p-value**
Gender				
Male	-		-	
Female	2.04 (1.74 to 2.41)	< 0.001	1.30 (1.01 to 1.67)	0.007
Age category (yrs)		0.368		
≤ 45	-			
46 to 55	0.91 (0.70 to 1.19)	0.375		
56 to 65	0.85 (0.66 to 1.09)	0.091		
≥ 66	0.91 (0.64 to 1.27)	0.452		
ASA* grade		< 0.001		0.001
1	-		-	
2	1.19 (1.00 to 1.40)	0.008	1.14 (0.96 to 1.35)	0.045
≥ 3	1.74 (1.16 to 2.60)	< 0.001	1.74 (1.17 to 2.61)	< 0.001
Body mass index		0.050		
Underweight (< 18.5 kg/m^2)	2.07 (0.70 to 6.11)	0.082		
Normal (18.5 < 25 kg/m^2)	1.46 (0.97 to 2.19)	0.016		
Overweight (25 < 30 kg/m^2)	-			
Obese (≥ 30 kg/m^2)	1.19 (0.83 to 1.73)	0.213		
Approach				
Posterior	-			
Anterolateral	1.26 (1.04 to 1.53)	0.002		
Brand		< 0.001		< 0.001
BHR†	-		-	
ASR‡	2.80 (2.24 to 3.51)	< 0.001	2.82 (2.24 to 3.54)	< 0.001
Adept	1.32 (0.92 to 1.90)	0.047	1.26 (0.87 to 1.81)	0.107
Conserve	2.45 (1.73 to 3.47)	< 0.001	2.03 (1.42 to 2.91)	< 0.001
Cormet	1.74 (1.36 to 2.23)	< 0.001	1.43 (1.10 to 1.86)	0.001
Durom	1.72 (1.20 to 2.45)	< 0.001	1.67 (1.16 to 2.39)	< 0.001
Mitch	1.50 (0.65 to 3.38)	0.222	1.40 (0.61 to 3.20)	0.298
Recap	1.73 (1.14 to 2.64)	0.001	1.58 (1.03 to 2.42)	0.007
Head size category		< 0.001		< 0.001
Very small (≤ 44 mm)	2.46 (1.95 to 3.11)	< 0.001	2.14 (1.53 to 3.00)	< 0.001
Small (45 mm to 47 mm)	1.60 (1.27 to 2.03)	< 0.001	1.48 (1.09 to 2.00)	0.001
Medium (48 mm to 50 mm)	0.87 (0.68 to 1.01)	0.118	0.99 (0.77 to 1.26)	0.907
Large (≥ 51 mm)	-		-	
Operator				
Consultant	-			
Other	1.07 (0.76 to 1.49)	0.624		
Consultant resurfacing volume		< 0.001		0.001
Low (≤ 50)	1.52 (1.22 to 1.88)	< 0.001	1.36 (1.09 to 1.71)	< 0.001
Medium (51 to 200)	1.24 (1.01 to 1.51)	0.007	1.14 (0.92 to 1.41)	0.110
High (≥ 201)	-		-	

* ASA, American Society of Anesthesiologists
† BHR, Birmingham Hip Resurfacing
‡ ASR, Articular Surface Replacement

the problems resulting from a resurfacing procedure emerge over a longer period.

Despite evidence of good long-term survival in younger male patients,[7] the use of hip resurfacing is now decreasing in England and Wales.[8] It is accepted that there are now fewer indications for resurfacing. It has previously been reported that men < 60 years of age undergoing resurfacing for osteoarthritis have a rate of revision at five-years of 6.05% (95% CI 5.55 to 6.60), significantly poorer than with hybrid (2.79% (95% CI 2.30 to 3.37)) and cemented THRs (3.25% (95% CI 2.83 to 3.73)) according to the NJR data.[8] However, our own analysis found a five-year

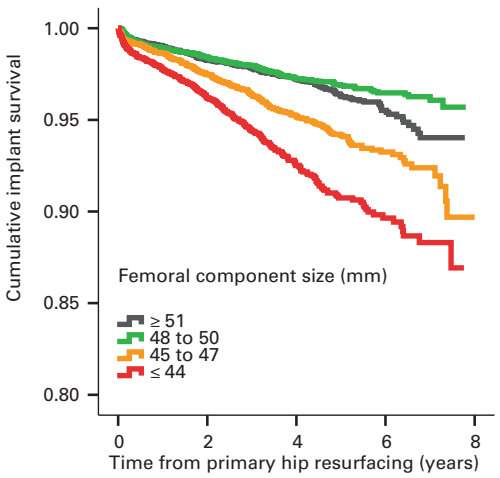


Life table showing numbers at risk in each year

Brand	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
BHR	15 459	14 172	12 314	10 069	7545	5092	2821	989
ASR	2631	2554	2314	1819	1201	586	135	1
Adept	2466	2049	1481	842	296	107	4	0
Conserve	1173	1037	850	610	332	127	52	10
Cormet	3193	3029	2590	1996	1334	883	463	159
Durom	1381	1318	1117	862	595	311	82	10
Mitch	339	314	272	151	39	0	0	0
Recap	1329	1120	818	488	189	44	2	0

Fig. 2

Kaplan-Meier unadjusted cumulative implant survival by resurfacing prosthesis brand (England and Wales, 2003 to 2010) (BHR, Birmingham Hip Resurfacing; ASR, Articulating Surface Replacement).



Life table showing numbers at risk each year

Femoral size (mm)	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
≤ 44	3928	3697	3178	2444	1613	966	474	167
45-47	5295	4075	4368	3522	2492	1534	786	245
48-50	10 720	9674	8124	6166	4186	2644	1362	488
≥ 51	8028	7247	6086	4705	3240	2006	937	269

Fig. 3

Kaplan-Meier unadjusted cumulative implant survival by femoral component size (England and Wales, 2003 to 2010).

Table V. Estimated revision rates by brand of component following resurfacing for male patients aged < 60 years, with American Society of Anesthesiologists grade ≤ 2, using a femoral head size ≥ 48 mm, performed by a mid- to high-volume consultant, compared with the rates of the entire study population

	Revision rates under optimal conditions* (%, 95% CI)							
	Birmingham Hip Resurfacing	Articular Surface Replacement	Adept	Cormet	Durom	Recap	Total	Revision rates for entire study population
1 year	0.65 (0.43 to 0.88)	0.99 (0.26 to 1.72)	0.70 (0.09 to 1.31)	0.26 (0.00 to 0.62)	1.03 (0.03 to 2.03)	0.96 (0.00 to 2.04)	0.71 (0.52 to 0.89)	1.29 (1.15 to 1.42)
3 year	1.18 (0.85 to 1.51)	2.78 (1.51 to 4.04)	1.06 (0.27 to 1.85)	1.21 (0.37 to 2.04)	2.85 (1.10 to 4.61)	2.41 (0.44 to 4.38)	1.51 (1.22 to 1.80)	2.93 (2.72 to 3.25)
5 year	1.59 (1.17 to 2.00)	5.67 (3.48 to 7.85)	2.20 (0.45 to 3.96)	2.79 (1.27 to 4.31)	5.27 (2.33 to 8.22)	-	2.47 (2.04 to 2.91)	4.76 (4.44 to 5.08)
7 year	2.21 (1.51 to 2.91)	6.42 (3.80 to 9.04)	-	5.31 (1.94 to 8.69)	-	-	3.34 (2.62 to 4.06)	6.29 (5.76 to 6.81)
Total number	4873	715	787	783	395	348	8172	27 971

* Conserve and Mitch brands had < 200 operations overall, so were excluded from this analysis

revision rate of 1.59% (95% CI 1.17 to 2.00) in men < 60 years who received a BHR compared with 4.76% (95% CI 4.44 to 5.08) for the entire study population. Thus, previous NJR analysis may have failed to reflect this heterogeneity, and revision rates for the BHR in young men may be considered more acceptable. Further evidence is required from comparison studies with stemmed implants and data from the PROMs project in order to ascertain whether resurfacing is superior to THR in this group.

Femoral neck fracture and reactions to metal debris are the most commonly reported reasons for revision following hip resurfacing.[11,25,29] The major cause of revision in this current study was component loosening or lysis. Metal debris and soft tissue reactions were uncommon, although descriptions of failure associated with debris have only been common in recent years, and the categories of revision in the NJR have evolved through modifications of the data collection forms. Many failures described in the component loosening, pain and infection categories may actually be a result of metal debris. Given these limitations, it is difficult to refute the evidence from in-depth reporting of revision in smaller studies.

Although several studies have found that higher failure rates in women are related to component size and

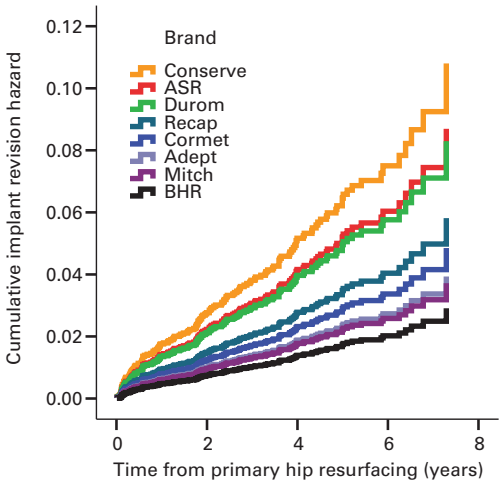


Fig. 4

Cumulative implant revision chart by brand (male patients < 60 years with American Society of Anesthesiologists grade ≤ 2, using head size ≥ 48 mm by mid- to high-volume consultant (8172 procedures)) (England and Wales data, 2003 to 2010) (BHR, Birmingham Hip Resurfacing; ASR, Articulating Surface Replacement).

independent of gender,[30,31] this current study identified that women have an increased risk of revision of 31% compared with men. A combination of factors may contribute to this, such as lower bone density (resulting in decreased cement penetration[32] or an increase in risk of fracture), anatomical differences (leading to implant malalignment and impingement[33]) and immunological responses.[34] It is not clear why higher ASA grade would result in greater implant failure, but there may be an association with poorer bone quality or immunological reserve.

Five brands have a significantly higher risk of revision than the most widely used device in the United Kingdom (BHR). There appears to be a brand influence after risk adjustment, suggesting that there are specific design features of some brands that may predispose to failure. This may relate to the characteristics of the acetabular component, such as its thickness and the ability to prevent deflection or lower head coverage, which has been implicated in the ASR and other sub-hemispherical designs.[35,36] Lower clearance, as seen with the ASR, may also increase wear and subsequent failure. The BHR currently holds an Orthopaedic Device Evaluation Panel (ODEP) 10a rating in the United Kingdom – good evidence that this implant has > 90% survival at ten years.[37] However, these latest data show that smaller implants have significantly higher revision rates across all resurfacing brands, including the BHR. Smaller resurfacing components may function in boundary lubrication rather than mixed or fluid-film as intended, resulting in increased wear and reactions to metal debris, and this may explain the poorer results with these sizes. Even in patients with a BHR, survival will drop < 90% at ten years, based on current data. For resurfacing femoral components < 47 mm a 10a rating may not be appropriate. Restricted to medium and large head sizes only (femoral head size > 48 mm) all resurfacing brands have an eight-year survival > 90% according to these current data.

Consultant volume conflates the number of years a surgeon has been working with their rate of surgery. Thus low-volume long-serving surgeons are grouped with higher-volume but less experienced surgeons. However, many authors have described a learning curve in hip resurfacing surgery related simply to the number of procedures performed.[38,39] Our findings support the expert opinions from surgeons at the Ghent hip resurfacing meeting.[40]

Female patients, those patients who require small components and surgeons performing low numbers of resurfacing procedures are associated with significantly higher failure rates. After adjustment for these covariates, there remain differences in the rates of failure between different brands of resurfacing prosthesis. For surgeons who undertake hip resurfacing, these data should guide their practice. However, further evidence is required to establish whether there is a true benefit of resurfacing devices over THR.

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References

1. **Howie DW, Cain CM, Cornish BL.** Pseudo-abscess of the psoas bursa in failed double-cup arthroplasty of the hip. *J Bone Joint Surg [Br]* 1991;73-B:29–32.
2. **Freeman MA, Bradley GW.** ICLH surface replacement of the hip: an analysis of the first 10 years. *J Bone Joint Surg [Br]* 1983;65-B:405–411.
3. **August AC, Aldam CH, Pynsent PB.** The McKee-Farrar hip arthroplasty: a long-term study. *J Bone Joint Surg [Br]* 1986;68-B:520–527.
4. **Daniel J, Pynsent PB, McMinn DJ.** Metal-on-metal resurfacing of the hip in patients under the age of 55 years with osteoarthritis. *J Bone Joint Surg [Br]* 2004;86-B:177–184.
5. **Daniel J, Ziaee H, Kamali A, et al.** Ten-year results of a double-heat-treated metal-on-metal hip resurfacing. *J Bone Joint Surg [Br]* 2010;92-B:20–27.
6. **Treacy RB, McBryde CW, Shears E, Pynsent PB.** Birmingham hip resurfacing: a minimum follow-up of ten years. *J Bone Joint Surg [Br]* 2011;93-B:27–33.
7. **Grammatopoulos G, Pandit H, McLardy-Smith P, et al.** The ten-year survival of the Birmingham Hip Resurfacing in men: an independent series. *J Bone Joint Surg [Br]* 2011;Suppl:In press.
8. **Ellams D, Forsyth O, Hindley P, et al.** National Joint Registry for England and Wales: 8th Annual Report, 2011. http://www.njrcentre.org.uk/NjrCentre/Portals/0/Documents/NJR%208th%20Annual%20Report%202011.pdf (date last accessed 28 February 2012).
9. **Spencer RF.** Evolution in hip resurfacing design and contemporary experience with an uncemented device. *J Bone Joint Surg [Am]* 2011;93-A(Suppl):84–88.
10. **Langton DJ, Jameson SS, Joyce TJ, et al.** Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: a consequence of excess wear. *J Bone Joint Surg [Br]* 2010;92-B:38–46.
11. **Langton DJ, Joyce TJ, Jameson SS, et al.** Adverse reaction to metal debris following hip resurfacing: the influence of component type, orientation and volumetric wear. *J Bone Joint Surg [Br]* 2011;93-B:164–171.

12. **Haddad FS, Thakrar RR, Hart AJ, et al.** Metal-on-metal bearings: the evidence so far. *J Bone Joint Surg [Br]* 2011;93-B:572–579.
13. **Kwon YM, Glyn-Jones S, Simpson DJ, et al.** Analysis of wear of retrieved metal-on-metal hip resurfacing implants revised due to pseudotumours. *J Bone Joint Surg [Br]* 2010;92-B:356–361.
14. **No authors listed.** Medicines and Healthcare Regulatory Agency (MHRA). Medical Device Alert: all metal-on-metal (MoM) hip replacements, 2010 (MDA/2010/033). http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON079157 (date last accessed 28 February 2012).
15. **Jameson SS, Langton DJ, Nargol AV.** Articular surface replacement of the hip: a prospective single-surgeon series. *J Bone Joint Surg [Br]* 2010;92-B:28–37.
16. **Graves S, Davidson D, de Steigher R, et al.** Australian Orthopaedic Assosciation. National Joint Replacement Registry: Annual Report 2011. http://www.dmac.adelaide.edu.au/aoanjrr/documents/AnnualReports2011/AnnualReport_2011_WebVersion.pdf (date last accessed 28 February 2012).
17. **Naal FD, Pilz R, Munzinger U, Hersche O, Leunig M.** High revision rate at 5 years after hip resurfacing with the Durom implant. *Clin Orthop Relat Res* 2011;469:2598–2604.
18. **Grammatopoulos G, Pandit H, Glyn-Jones S, et al.** Optimal acetabular orientation for hip resurfacing. *J Bone Joint Surg [Br]* 2010;92-B:1072–1078.
19. **Langton DJ, Jameson SS, Joyce TJ, Webb J, Nargol AV.** The effect of component size and orientation on the concentrations of metal ions after resurfacing arthroplasty of the hip. *J Bone Joint Surg [Br]* 2008;90-B:1143–1151.
20. **No authors listed.** National Joint Registry website, 2012 http://www.njrcentre.org.uk/ (date last accessed 29 February 2012).
21. **American Society of Anesthesiologists**. New classification of physical status. *Anesthesiology* 1963;24:111.
22. **Willert HG, Buchhorn GH, Fayyazi A, et al.** Metal-on-metal bearings and hypersensitivity in patients with artificial hip joints: a clinical and histomorphological study. *J Bone Joint Surg [Am]* 2005;87-A:28–36.
23. **Therneau TM, Grambsch PM.** *Modelling survival data: extending the Cox Model.* Berlin: Springer, 2000.
24. **Hardinge K.** The direct lateral approach to the hip. *J Bone Joint Surg [Br]* 1982;64-B:17–19.
25. **Amstutz HC, Le Duff MJ, Campbell PA, Wisk LE, Takamura KM.** Complications after metal-on-metal hip resurfacing arthroplasty. *Orthop Clin North Am* 2011;42:207–230.
26. **Khan A, Yates P, Lovering A, Bannister GC, Spencer RF.** The effect of surgical approach on blood flow to the femoral head during resurfacing. *J Bone Joint Surg [Br]* 2007;89-B:21–25.
27. **McBryde CW, Revell MP, Thomas AM, Treacy RB, Pynsent PB.** The influence of surgical approach on outcome in Birmingham hip resurfacing. *Clin Orthop Relat Res* 2008;466:920–926.
28. **Griffiths DE, Acton K, Hull JB.** Hip resurfacing with preservation of femoral head blood supply. *Surgeon* 2008;6:115–119.
29. **Glyn-Jones S, Pandit H, Kwon YM, et al.** Risk factors for inflammatory pseudotumour formation following hip resurfacing. *J Bone Joint Surg [Br]* 2009;91-B:1566–1574.
30. **McBryde CW, Theivendran K, Thomas AM, Treacy RB, Pynsent PB.** The influence of head size and sex on the outcome of Birmingham hip resurfacing. *J Bone Joint Surg [Am]* 2010;92-A:105–112.
31. **Graves S, Davidson D, de Steigher R, et al.** Australian Orthopaedic Assosciation. National Joint Replacement Registry: Annual Report 2008. http://www.dmac.adelaide.edu.au/aoanjrr/documents/aoanjrrreport_2008.pdf (date last accessed 28 February 2012).
32. **Graham J, Ries M, Pruitt L.** Effect of bone porosity on the mechanical integrity of the bone-cement interface. *J Bone Joint Surg [Am]* 2003;85-A:1901–1908.
33. **Nevelos J, Ingham E, Doyle C, et al.** Microseparation of the centers of alumina-alumina artificial hip joints during simulator testing produces clinically relevant wear rates and patterns. *J Arthroplasty* 2000;15:793–795.
34. **Hallab NJ, Anderson S, Caicedo M, et al.** Immune responses correlate with serum-metal in metal-on-metal hip arthroplasty. *J Arthroplasty* 2004;19(Suppl):88–93.
35. **Campbell P, Beaulé PE, Ebramzadeh E, et al.** The John Charnley Award: a study of implant failure in metal-on-metal surface arthroplasties. *Clin Orthop Relat Res* 2006;453:35–46.
36. **Fisher J.** Bioengineering reasons for the failure of metal-on-metal hip prostheses: an engineer's perspective. *J Bone Joint Surg [Br]* 2011;93-B:1001–1004.
37. **No authors listed.** NHS Supply Chain. Orthopaedic Device Evaluation Panel Rating, 2011. http://www.supplychain.nhs.uk/odep (date last accessed 28 February 2012).
38. **Nunley RM, Zhu J, Brooks PJ, et al.** The learning curve for adopting hip resurfacing among hip specialists. *Clin Orthop Relat Res* 2010;468:382–391.
39. **Siebel T, Maubach S, Morlock MM.** Lessons learned from early clinical experience and results of 300 ASR hip resurfacing implantations. *Proc Inst Mech Eng H* 2006;220:345–353.
40. **De Smet K, Campbell PA, Gill HS.** Metal-on-metal hip resurfacing: a consensus from the Advanced Hip Resurfacing Course, Ghent, June 2009. *J Bone Joint Surg [Br]* 2010;92-B:335–336.

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The Impact of Body Mass Index on Patient Reported Outcome Measures (PROMs) and Complications Following Primary Hip Arthroplasty

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ABSTRACT

Influence of BMI upon patient outcomes and complications following THA was examined across a national cohort of patients. Outcomes were compared by BMI groups (19.0–29.9 kg/m^2 [reference], 30.0–34.9 kg/m^2 [obese class I], 35.0 kg/m^2+ [obese class II/III]), adjusted for case-mix differences. Obese class I patients had a significantly smaller improvement in OHS (18.9 versus 20.5, $P < 0.001$) and a greater risk of wound complications (odds ratio [OR] = 1.57, $P = 0.006$). For obese class II/III patients, there were significantly smaller improvements in OHS and EQ-5D index ($P < 0.001$), and greater risk of wound complications ($P = 0.006$), readmission ($P = 0.001$) and reoperation ($P = 0.003$). Large improvements in patient outcomes were seen irrespective of BMI, although improvements were marginally smaller and complication rates higher in obese patients.

Body mass index (BMI) and rates of obesity within the population are increasing across the developed world [1], resulting in poorer general health and greater risk of lower limb osteoarthritis (OA) [2,3]. The National Joint Registry (NJR) in England and Wales has noted a year-on-year increase in total hip arthroplasties (THAs) performed overall and in obese patients, with 38% having a BMI over 30 kg/m^2 in 2011 compared with less than 30% in 2003 [4].

There is some evidence that lower limb arthroplasty in obese patients is more technically demanding (due to instrumentation issues), takes longer to perform [5], is associated with higher surgical and medical complications in the early post-operative period [6,7], and outcomes such as function and implant longevity may be poorer [8–10]. Thus, raised BMI might be used to ration primary THA in a public funded health service, in effect denying patients' access to surgical intervention [11]. Restrictions might apply to BMIs >35 kg/m^2, although lower cut-off limits have been proposed [12]. However, the evidence for denying access to a hip surgeon for patients with a high BMI is limited, and may be inappropriate [13,14].

Patient reported outcome measures (PROMs) offer patient-centred evidence of the benefit of a procedure, and supplement clinical measures traditionally used to assess the success of joint arthroplasty such as risk of revision [15]. PROMs have been routinely collected by the Department of Health (DoH) for National Health Service (NHS) patients undergoing THA in England and Wales since 2008. PROMs include a joint specific score, a general health measure and self-reported complication data. These can now be linked to the NJR dataset in order to compare early outcomes for specific patient and implant groups at a national level. This analysis explores the impact of BMI on PROMs and complications following primary THA.

Methods

Design

A retrospective cohort study was conducted using prospectively collected patient-level NJR and PROMs-linked data to compare general and joint specific outcome scores and self-reported

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complications at a minimum 6 months following primary THA in patients with varying BMI.

Data

Data on hip arthroplasty patients, their surgeons and implants used are collected by the NJR across England and Wales. The national PROMs study collects joint-specific and general health scores pre-operatively and six months post-operatively. Self-reported post-operative complications are also available. By linking the two datasets at the level of the patient we were able to combine PROMs with the corresponding demographic and operative details held in the NJR. In order to link the two datasets a number of linkage criteria were used. Firstly, to ensure correct matching, two unique identifiers (NJR and procedure numbers) recorded in both datasets were used. Secondly, the operation date recorded by the patient in the PROMs data had to be within ± 30 days of the operation date recorded on the NJR record, to ensure the patient was scoring the same procedure.

We chose to perform the analysis using the single most commonly used brand of cemented and cementless THA, in order to control for any implant influences whilst providing widely applicable results for THAs performed in England and Wales. According to the NJR 8th Annual Report, the commonest cemented THA brand used since 2003 is the Exeter V40 hip and Contemporary socket (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 23.2% of all cemented THAs (37,995 of 163,981) [16]. The Corail stem/Pinnacle cup (DePuy Ltd, Leeds, United Kingdom) is the most commonly used cementless THA (31.2% [40,879] of 130,920 cementless THAs).

There were a number of exclusion criteria. For the NJR data these were: all procedures with an indication other than OA, procedures with missing implant or patient data, and procedures with missing or outlying BMI (<19 kg/m^2 or >65 kg/m^2) data were excluded. Procedures with PROMs data that were missing, undated, dated more than 12 months prior to or following the operation, or non-identical duplicates were excluded; for identical duplicates the first record was retained for analysis. Where the presence of a co-morbidity or complication was sought in the questionnaire but left blank by the patient, it was assumed to be absent. The study population is summarised in Fig. 1. The demographic, surgical and implant-related variables available for analysis are listed in Table 1.

The national PROMs project uses validated measures of hip-specific (Oxford hip score [OHS]) [17] and general health outcomes (EuroQol [EQ-5D-3L]) [18]. For this analysis the outcomes of interest were improvements between the pre-operative and post-operative scores (the 'change scores') and self-reported post-operative complications (bleeding, wound problems, readmission and reoperation). Change scores, being approximately normally distributed, are analytically preferable to post-operative scores [19]. The OHS (scored 0 lowest to 48 highest) has previously been shown to be a reliable, valid and responsive outcome measure and can be used for the clinical assessment of large hip arthroplasty databases in a cross-sectional population [20]. The EQ-5D-3L consists of 2 parts – the EQ-5D descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system evaluates five different aspects of general health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension has 3 levels: no problems, some problems, extreme problems. The respondent indicates his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. General population weightings are then applied to these scores to produce a single summary index value for health status (zero for death and one for full health, with some health states being worse than dead [−0.59]) [18]. The EQ VAS records the respondent's self-rated health on a visual analogue scale where the endpoints are 'best imaginable health state' and 'worst imaginable health state'. This information can be used as a quantitative measure of health outcome; variations over time can be used for clinical and economic appraisal. The EQ-5D-3L is commonly used throughout Europe for assessment in a variety of different

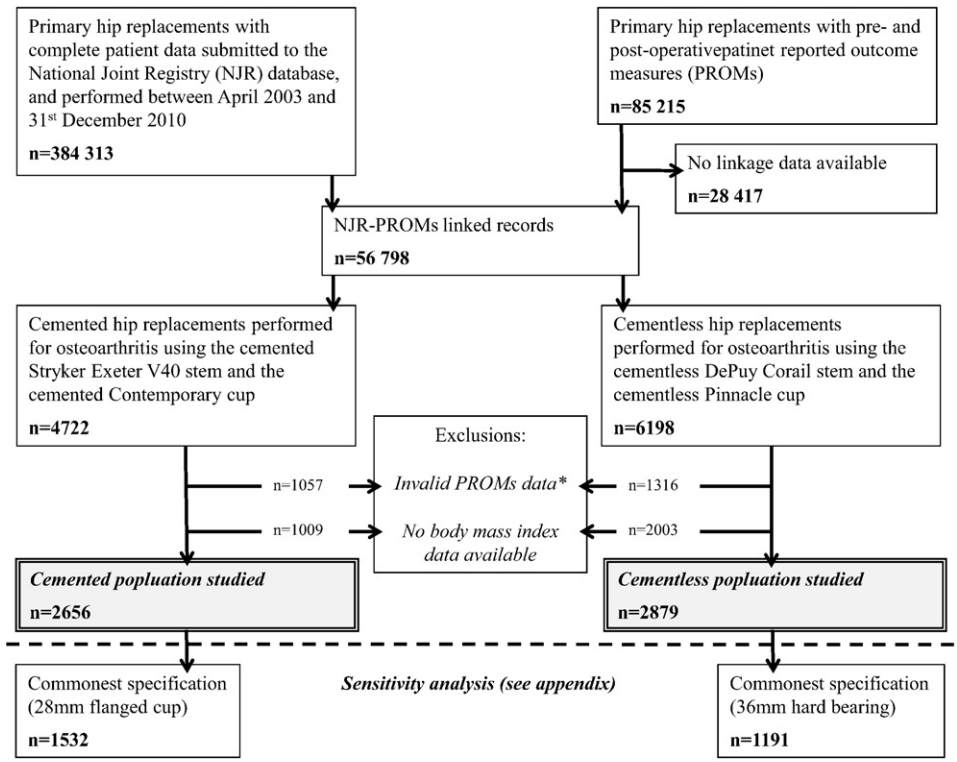

Fig. 1. Flowchart describing study cohort.

Table 1
Patient Demographics and Proms Data for Cemented Stryker Exeter V40 Contemporary Hip Replacement, by Body Mass Index.

		Body Mass Index			Differences Between BMI Groups[a]
	All Patients	19–29.9 kg/m^2 (Reference Group)	30–34.9 kg/m^2 (Obese Class I)	35 kg/m^2+ (Obese Class II/III)	
Number (%)	2656	1640 (61.7)	695 (26.2)	321 (12.1)	
Patient factors					
Age, mean years (standard deviation [sd], range)	73.3 (7.7, 36.7–93.7)	74.3 (7.6, 36.7–93.7)	72.3 (7.4, 45.1–92.9)	70.7 (7.4, 46.4–92.1)	$P < 0.001$
Females	1687 (63.5)	1025 (62.5)	430 (61.9)	232 (72.3)	$P = 0.002$
ASA					
1	274 (10.3)	195 (11.9)	67 (9.6)	12 (3.7)	$P < 0.001$
2	1912 (72.0)	1186 (72.3)	500 (71.9)	226 (70.4)	
3+	470 (17.7)	259 (15.8)	128 (18.4)	83 (25.9)	
Co-morbidities					
Heart disease	268 (10.1)	149 (9.1)	83 (11.9)	36 (11.2)	$P = 0.086$
Stroke	32 (1.2)	16 (1.0)	12 (1.7)	4 (1.3)	$P = 0.314$
Diabetes	270 (10.2)	120 (7.3)	102 (14.7)	48 (15.0)	$P < 0.001$
Hypertension	1219 (45.9)	682 (41.6)	360 (51.8)	177 (55.1)	$P < 0.001$
Circulation	220 (8.3)	117 (7.1)	68 (9.8)	35 (10.9)	$P = 0.020$
Lung	187 (7.0)	119 (7.3)	40 (5.8)	28 (8.7)	$P = 0.196$
Depression	132 (5.0)	71 (4.3)	41 (5.9)	20 (6.2)	$P = 0.151$
Preoperative general health					
Excellent	94 (3.6)	65 (4.0)	23 (3.4)	6 (1.9)	$P < 0.001$
Very good	767 (29.4)	517 (32.1)	184 (26.9)	66 (20.9)	
Good	1207 (46.3)	727 (45.2)	328 (47.9)	152 (48.1)	
Fair	470 (18.0)	259 (16.1)	126 (18.4)	85 (26.9)	
Poor	72 (2.8)	41 (2.6)	24 (3.5)	7 (2.2)	
Preoperative disability	1548 (58.3)	901 (58.9)	425 (66.4)	222 (75.3)	$P < 0.001$
Patient reported outcome scores					
Oxford Hip scores					
Pre-operative, mean (sd, range)	18.2 (8.1, 0–48)	19.2 (8.1, 0–44)	17.4 (7.9, 0–48)	15.3 (7.4, 1–40)	$P < 0.001$
Post-operative, mean (sd, range)	38.3 (8.9, 2–48)	39.4 (8.3, 6–48)	36.8 (9.4, 2–48)	35.7 (9.6, 4–48)	$P < 0.001$
EQ5D visual analogue score					
Pre-operative, mean (sd, range)	67.1 (19.8, 0–100)	68.3 (19.2, 0–100)	67.2 (20.4, 0–100)	60.8 (20.7, 4–100)	$P < 0.001$
Post-operative, mean (sd, range)	75.2 (17.8, 0–100)	76.6 (17.4, 0–100)	74.0 (18.1, 0–100)	70.7 (18.6, 0–100)	$P < 0.001$
EQ5D index					
Pre-operative, mean (sd, range)	0.368 (0.313, −0.484 to 1)	0.392 (0.307, −0.429 to 1)	0.345 (0.322, −0.484 to 1)	0.305 (0.315, −0.349 to 0.796)	$P < 0.001$
Post-operative, mean (sd, range)	0.779 (0.225, −0.239 to 1)	0.799 (0.217, −0.239 to 1)	0.756 (0.232, −0.239 to 1)	0.728 (0.235, −0.074 to 1)	$P < 0.001$
Time from operation to PROMs completion, mean days (sd, range)	209.2 (29.1, 183–358)	209.1 (29.0, 183–358)	209.6 (29.4, 183–358)	209.0 (29.3, 184–337)	$P = 0.636$

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures.
[a] Analysis of variance test (continuous data variables) or Chi squared (categorical data variables).

clinical settings, including joint replacement [21,22], and was chosen by the Department of Health in the United Kingdom as the most suitable generic health measure for the PROMs project because reliable UK population weighting values were available [23] (for more information on EuroQol assessment visit http://www.euroqol.org). Patients are also asked about comorbidities, general health and self-reported disability as part of the pre-operative PROMs questionnaire. These can be used to understand and match the differences in health status between patient groups. Sample sizes for all the BMI groups were in excess of the minimum numbers identified in the PROMs feasibility pilot to identify meaningful differences (more than 150/group) [19].

Statistical Analysis

The variables available for the analyses are shown in Appendix Table 1. To align with its clinical application, BMI was grouped into three categories: 19.0–29.9 kg/m^2 (normal and overweight – reference group), 30.0–34.9 kg/m^2 (obese class I), 35.0 kg/m^2+ (obese class II and III). BMI was also assessed as a continuous variable to ensure BMI categorisation did not qualitatively alter the findings. Differences in baseline characteristics across the BMI groups were analysed using analysis of variance test (ANOVA, continuous data variables) or Chi-square test (categorical data variables). Analyses of cemented and cementless procedures were performed independently as no attempt was made to adjust for baseline differences between types of implants.

Univariable analysis was performed initially to identify variables potentially influencing each outcome, based on statistical rejection criteria of $P > 0.10$; these variables were then included in the multivariable models. Analysis of covariance (ANCOVA) was used for testing differences in OHS and EQ5D index change scores across BMI groups. Multi-variable logistic regression was used to analyse differences in the risk of each of the complications across BMI groups. Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Pre-operative scores were included within all models, as recommended by the Oxford group [20].

Reflecting analysis of a large dataset, statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values (including 99% confidence intervals) for each of the BMI categories. *P*-values are provided as statistical tests of the differences between the reference and other BMI categories. For complication risks, results are presented as odds ratios (ORs) with 99% CIs: ratios greater than one indicate that risk is higher when compared with the reference BMI category. Due to the statistical methods employed, and the large population size, only covariates fitting models with $P < 0.01$ were considered significant influences, to reduce the risk of Type 1 error. All models were fitted using STATA 12 (StataCorp LP, Texas, USA).

In order to provide 'real-world' clinical scenarios, predicted changes in OHS were produced for the cemented model using the margins function in STATA. This demonstrated the differences in hip

Table 2
Patient Demographics and PROMs Data for Cementless DePuy Corail Pinnacle Hip Replacement, by Body Mass Index.

		Body Mass Index			Differences Between BMI Groups[a]
	All Patients	19–29.9 kg/m^2 (Reference Group)	30–34.9 kg/m^2 (Obese Class I)	35 kg/m^2+ (Obese Class II/III)	
Number (%)	2879	1738 (60.4)	713 (24.8)	428 (14.9)	
Patient factors					
Age, mean years (standard deviation [sd], range)	65.8 (9.5, 25.2–94.0)	66.7 (9.6, 26.2–94.0)	65.3 (9.2, 25.2–90.2)	62.9 (9.1, 28.7–88.2)	$P < 0.001$
Females	1602 (55.6)	979 (56.3)	374 (52.5)	249 (58.2)	$P = 0.112$
ASA					
1	554 (19.2)	417 (24.0)	106 (14.9)	31 (7.2)	$P < 0.001$
2	2057 (71.5)	1202 (69.2)	541 (75.9)	226 (73.4)	
3+	268 (9.3)	119 (6.9)	66 (9.3)	83 (19.4)	
Co-morbidities					
Heart disease	226 (7.8)	130 (7.5)	51 (7.2)	45 (10.5)	$P = 0.082$
Stroke	35 (1.2)	22 (1.3)	8 (1.1)	5 (1.2)	$P = 0.953$
Diabetes	219 (7.6)	81 (4.7)	76 (10.7)	62 (14.5)	$P < 0.001$
Hypertension	1123 (39.0)	582 (33.5)	300 (42.1)	241 (56.3)	$P < 0.001$
Circulation	136 (4.7)	74 (4.3)	34 (4.8)	28 (6.5)	$P = 0.136$
Lung	158 (5.5)	88 (5.1)	36 (5.0)	34 (7.4)	$P = 0.054$
Depression	172 (6.0)	96 (5.5)	36 (5.0)	40 (9.3)	$P = 0.006$
Preoperative general health					
Excellent	150 (5.4)	110 (6.6)	26 (3.8)	14 (3.4)	$P < 0.001$
Very good	870 (31.5)	582 (35.0)	206 (30.0)	82 (19.8)	
Good	1210 (43.8)	698 (42.0)	321 (46.7)	191 (46.1)	
Fair	473 (17.1)	241 (14.5)	121 (17.6)	111 (26.8)	
Poor	61 (2.2)	31 (1.9)	14 (2.0)	16 (3.7)	
Preoperative disability	1405 (53.9)	783 (50.1)	350 (53.9)	272 (68.9)	$P < 0.001$
Patient reported outcome scores					
Oxford Hip scores					
Pre-operative, mean (sd, range)	18.8 (8.1, 1–43)	19.9 (8.1, 2–43)	18.5 (7.8, 2–43)	15.1 (7.3, 1–39)	$P < 0.001$
Post-operative, mean (sd, range)	40.1 (8.6, 0–48)	40.8 (8.1, 6–48)	40.0 (8.3, 8–48)	37.0 (10.1, 1–48)	$P < 0.001$
EQ5D visual analogue score					
Pre-operative, mean (sd, range)	66.7 (20.9, 0–100)	68.5 (20.1, 0–100)	66.5 (21.0, 0–100)	60.1 (22.7, 4–100)	$P < 0.001$
Post-operative, mean (sd, range)	77.1 (18.4, 0–100)	78.6 (17.3, 0–100)	77.3 (17.3, 0–100)	70.9 (20.6, 0–100)	$P < 0.001$
EQ5D index					
Pre-operative, mean (sd, range)	0.381 (0.313, −0.349 to 1)	0.414 (0.306, −0.349 to 1)	0.379 (0.310, −0.239 to 1)	0.253 (0.316, −0.349 to 0.796)	$P < 0.001$
Post-operative, mean (sd, range)	0.799 (0.246, −0.594 to 1)	0.823 (0.228, −0.594 to 1)	0.800 (0.231, −0.074 to 1)	0.705 (0.306, −0.319 to 1)	$P < 0.001$
Time from operation to PROMs completion, mean days (sd, range)	208.5 (27.8, 183–363)	208.5 (27.8, 183–363)	207.6 (27.1, 183–363)	2010.0 (28.6, 183–362)	$P = 0.985$

ASA – American Society of Anaesthesiologists score, PROMs – Patient reported outcomes measures.
[a] Analysis of variance test (continuous data variables) or Chi squared (categorical data variables).

specific improvement when sex, differences in pre-existing health status and disability, and level of pre-operative OHS were specified within the model, in addition to BMI.

Results

There were 8547 NJR-PROMs linked primary procedures, of which 65% had BMI data. Of the remaining 5535, 2656 were cemented Exeter Contemporary and 2879 were cementless Corail Pinnacle.

Cemented Hip Arthroplasty Baseline Characteristics

There were 1640 patients (61.7%) with a BMI of 19–29.9 kg/m^2, 695 (26.2%) 30–34.9 kg/m^2 and 321 (12.1%) 35 kg/m^2 and over (Table 1). Obese patients were more likely to be younger ($P < 0.001$), female ($P = 0.002$) and have a higher ASA grade ($P < 0.001$). Similarly, diabetes ($P < 0.001$) and hypertension ($P < 0.001$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health ($P < 0.001$) was poorer and self-reported disability ($P < 0.001$) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: $P < 0.001$, EuroQol VAS: $P < 0.001$, EQ5D index: $P < 0.001$); time from operation to post-operative questionnaire completion was similar across groups (209.0–209.6 days, $P = 0.636$) (Table 1).

Cementless Hip Arthroplasty Baseline Characteristics

There were 1738 patients (60.4%) with a BMI of 19–29.9 kg/m^2, 713 (24.8%) 30–34.9 kg/m^2 and 428 (14.9%) 35 kg/m^2 and over (Table 2). Similarly to the cemented group, obese patients were more likely to be younger ($P < 0.001$) and have a higher ASA grade ($P < 0.001$), but there were no differences in proportions of females. Diabetes ($P < 0.001$), hypertension ($P < 0.001$) and depression ($P = 0.006$) were more prevalent in patients with higher BMI, but proportions of other comorbidities were not significantly different. Pre-operative general health ($P < 0.001$) was poorer and self-reported disability ($P < 0.001$) more common in obese patients.

Pre-operative scores were significantly lower in obese patients (OHS: $P < 0.001$, EuroQol VAS: $P < 0.001$, EQ5D index: $P < 0.001$); time from operation to post-operative questionnaire completion was similar across groups (207.6–210.0 days, $P = 0.985$) (Table 2).

Surgical Factors

The majority of operations were performed through the posterior approach (cemented: 55.4% [1471]; cementless: 63.6% [1830]), with the patient in a lateral position (79.1% [2102]; 78.4% [2256]), by a consultant (64.0% [1700]; 77.0% [2216]), and using regional anaesthesia (78.8% [1792]; 80.4% [1923]). Low molecular weight heparin (53.6% [1218]; 66.2% [1593]) and mechanical methods (80.3% [2133]; 89.9% [2636]) were used as venous thromboembolic prophylaxis in the majority of cases (Table 3).

Table 3
Surgical Factors for Populations Studied.

	Cemented (Exeter Contemporary)	Cementless (Corail Pinnacle)
Number	2656	2879
Approach		
Posterior	1471 (55.4)	1830 (63.6)
Direct lateral	1117 (42.1)	888 (30.8)
Other	68 (2.6)	161 (5.6)
Chemical VTE prophylaxis		
LMWH only	1218 (53.6)	1593 (66.2)
Aspirin only	233 (10.2)	208 (8.7)
Other	701 (30.8)	379 (15.8)
None	122 (5.4)	225 (9.4)
Mechanical VTE prophylaxis		
GCS	747 (28.1)	912 (37.9)
GCS/mechanical pump combination	663 (25.0)	662 (27.5)
Foot pump only	413 (15.6)	221 (9.2)
Mechanical calf pump only	280 (10.5)	350 (14.6)
Other	30 (1.1)	17 (0.7)
None	523 (19.7)	243 (10.1)
Anaesthesia		
Regional	1085 (47.7)	1369 (57.2)
General	481 (21.2)	470 (19.6)
Regional and general	708 (31.1)	554 (23.2)
Grade		
Consultant	1700 (64.0)	2216 (77.0)
Other	956 (36.0)	663 (23.0)
Position		
Lateral	2102 (79.1)	2256 (78.4)
Supine	172 (6.5)	149 (5.2)
Unknown	382 (14.4)	474 (16.5)

VTE – Venous thromboembolism, LMWH – Low molecular weight heparin, GCS – Graduated compression stockings.

Oxford Hip Score Improvement

For the cemented procedure, univariable analysis showed no differences in OHS improvement across the BMI groups. However, after adjusting for other influential variables, when compared with the reference BMI group (20.5, 99% CI 20.0–21.1), both obese class I (18.9, 99% CI 18.1–19.8, $P < 0.001$) and class II/III patients (18.7, 99% CI 17.5–19.9, $P < 0.001$) had a significantly lower improvement in OHS (Table 4).

For cementless procedure, there was no difference in OHS improvement between BMI groups in univariable analysis. After risk adjusting, when compared with the reference BMI group (21.5, 99% CI 21.1–22.1), obese class II/III patients (20.0, 99% CI 18.9–21.0, $P < 0.001$) had a significantly lower improvement in OHS (Table 5).

In the 'real-world' scenarios, when a male patient with a BMI between 19 and 29.9 kg/m^2 reporting a pre-operative OHS of 10, no disability, very good preoperative health and minimal comorbidities undergoes a cemented THA, they should expect an improvement in OHS of 32. A female patient with a BMI of 35 kg/m^2+, self-reported fair health, presence of disability and co-morbidities and a pre-operative OHS of 25, an improvement in OHS of only 9 was predicted. Self reported disability, pre-operative function and health scores, and comorbidities were greater influences on OHS change than BMI. A lower pre-operative OHS predicts a greater improvement, whilst presence of a disability and comorbidities, poorer health and higher BMI predict lower improvements in OHS (Table 6).

EQ5D Index Improvement

For the cemented procedure, there were no differences in EQ5D index improvement between BMI groups in univariable analysis. After risk adjusting, both obese class I (0.394, 99% CI 0.372–0.416, $P = 0.036$) and class II/III patients (0.387, 99% CI 0.353–0.420, $P = 0.043$) had lower improvement in EQ5D index when compared with the reference BMI group (0.416, 99% CI 0.401–0.431), but neither was significant at the threshold value (Table 4).

For the cementless procedure and univariable analysis, the EQ5D index improvement was actually higher in obese class II/III patients (0.453, 99% CI 0.410–0.497, $P = 0.016$) when compared with the reference group (0.408, 99% CI 0.386–0.429), but this failed to reach the significance threshold specified. However, after risk adjustment obese class II/III patients (0.371, 99% CI 0.341–0.401, $P < 0.001$) had a significantly lower improvement in EQ5D index compared with the reference BMI group (0.425, 99% CI 0.410–0.441) (Table 5).

Risk of Complications

In the cemented group there was a significantly increased risk of complications in obese class II/III patients compared to the reference group, adjusted for other variables: wound complications, OR = 2.06, 99% CI 1.25–3.40, $P < 0.001$; readmission, OR = 1.99, 99% CI 1.17–3.39, $P = 0.001$; and, reoperation, (OR = 2.73, 99% CI 1.14–6.53, $P = 0.003$). Complications were less pronounced in obese class I patients with only wound complications being significant at the 1% level ($P < 0.01$), OR = 1.57, 99% CI 1.03–2.38, $P = 0.006$. Bleeding risk was similar across all groups (Table 7).

For the cementless group, wound complications were significantly higher in obese class II/III patients (OR = 2.39, 99% CI 1.52–3.75, $P < 0.001$) when compared to the reference group, after risk adjusting. Complication risk between the reference and other BMI groups for bleeding, readmission and reoperation was similar (Table 8).

Discussion

This retrospective cohort study using NJR-PROMs linked data provides evidence of large improvements in OHS and EQ5D index at 6 months following surgery irrespective of BMI, although improvements were marginally smaller and complication rates higher in obese patients, after adjusting for other influences. Our key finding was that joint specific and general health gains were lower and the

Table 4
Patient Reported Outcome Scores Following Primary Cemented Stryker Exeter V40 Contemporary Hip Arthroplasty, by Body Mass Index (Simple and Multivariable Analyses).

	Simple			Multivariable		
	Value	99% CI	*P* Value	Value	99% CI	*P* Value
Change in OHS						
BMI 19–29.9 kg/m^2 (n = 1640)	20.2	19.5–20.8	Reference	20.5	20.0–21.1	Reference
BMI 30–34.9 kg/m^2 (n = 695)	19.5	18.5–20.4	0.116	18.9	18.1–19.8	<0.001
BMI 35 kg/m^2+ (n = 321)	20.4	19.0–21.8	0.708	18.7	17.5–19.9	<0.001
Change EQ5D index						
BMI 19–29.9 kg/m^2 (n = 1640)	0.408	0.386–0.431	Reference	0.416	0.401–0.431	Reference
BMI 30–34.9 kg/m^2 (n = 695)	0.410	0.376–0.444	0.928	0.394	0.372–0.416	0.036
BMI 35 kg/m^2+ (n = 321)	0.418	0.367–0.468	0.669	0.387	0.353–0.420	0.043

OHS – Oxford Hip Score, BMI – Body mass index.

Table 5
Patient Reported Outcome Scores Following Primary Cementless DePuy Corail Pinnacle Hip Arthroplasty, by Body Mass Index (Simple and Multivariable Analyses).

	Simple			Multivariable		
	Value	99% CI	*P* Value	Value	99% CI	*P* Value
Change in OHS						
BMI 19–29.9 kg/m^2 (n = 1738)	20.9	20.3–21.5	Reference	21.5	21.1–22.1	Reference
BMI 30–34.9 kg/m^2 (n = 713)	21.5	20.5–22.4	0.188	21.3	20.5–22.1	0.532
BMI 35 kg/m^2+ (n = 428)	21.9	20.7–23.1	0.065	20.0	18.9–21.0	<0.001
Change EQ5D index						
BMI 19–29.9 kg/m^2 (n = 1738)	0.408	0.386–0.429	Reference	0.425	0.410–0.441	Reference
BMI 30–34.9 kg/m^2 (n = 713)	0.420	0.386–0.454	0.422	0.419	0.395–0.442	0.527
BMI 35 kg/m^2+ (n = 428)	0.453	0.410–0.497	0.016	0.371	0.341–0.401	<0.001

OHS – Oxford Hip Score, BMI – Body mass index.

complication risks higher as BMI increased from obesity class I to II/III. These findings were similar for both cemented and cementless implants. We also found that a number of other variables influence outcome scores in addition to BMI including self reported disability, pre-operative function and health scores, and comorbidities. This finding is clinically important as it can be used to describe the potential benefit in function, together with the risks of complications, to individual patients. It also provides evidence that BMI in isolation should not be the sole determinant of restrictions in referral to orthopaedic services.

Whilst this is the largest study to date to report the affect of BMI on functional outcome within single THA brands, there are some potential limitations for the findings. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Some data were unavailable for analysis; for example, radiological data on cup positioning (which may be more difficult in patients with higher BMI). Moreover, there were large numbers of procedures that could not be analysed, either because of dataset linkage issues, missing NJR or PROMs data fields or absent BMI data (35% of the linked NJR-PROMs data). Despite these limitations, the data available for analysis were extensive and adjustments for differences in the baseline characteristics of BMI groups (where available) were performed. In addition, similarities between the unadjusted and adjusted models, and robustness under different model fitting assumptions support the stability of estimates.

It could be argued that all THA brands should be examined to increase numbers for analysis and broaden the scope of findings of the study. By restricting the implants to only the most commonly used from each

Table 6
Predicted OHS Improvement for Specific Self-Reported Patient Factors, Based on Cemented Hip Replacement Model.

	Preoperative Very Good Health				Preoperative Fair Health			
	No Disability		Disability		No Disability		Disability	
	Minimal Co-Morbidity[a]	Co-Morbidity Present[b]	Minimal Co-Morbidity	Co-Morbidity Present	Minimal Co-Morbidity	Co-Morbidity Present	Minimal Co-Morbidity	Co-Morbidity Present
Females								
BMI 19–29.9 kg/m^2								
Pre-op OHS 10	30.4	26.0	28.4	23.9	29.6	25.1	26.2	23.1
Pre-op OHS 15	26.4	21.9	24.3	19.9	25.5	21.1	22.1	19.1
Pre-op OHS 20	22.4	17.9	20.3	15.9	21.5	17.1	18.1	15.0
Pre-op OHS 25	18.3	13.9	16.3	11.9	17.5	13.1	14.1	11.0
BMI 30–34.9 kg/m^2								
Pre-op OHS 10	28.9	24.5	26.9	22.4	28.1	23.6	24.7	21.6
Pre-op OHS 15	24.9	20.4	22.8	18.4	24.1	19.6	20.6	17.6
Pre-op OHS 20	20.9	16.4	18.8	14.4	20.0	15.6	16.6	13.5
Pre-op OHS 25	16.9	12.4	14.8	10.4	16.0	11.6	12.6	9.5
BMI 35 kg/m^2+								
Pre-op OHS 10	28.8	24.4	26.8	22.3	28.0	23.5	24.6	21.5
Pre-op OHS 15	24.8	20.4	22.8	18.3	24.0	19.5	20.6	17.5
Pre-op OHS 20	20.8	16.3	18.7	14.3	19.9	15.5	16.5	13.5
Pre-op OHS 25	16.8	12.3	14.7	10.3	15.9	11.5	12.5	9.4
Males								
BMI 19–29.9 kg/m^2								
Pre-op OHS 10	32.2	27.8	30.2	25.7	31.4	26.9	28.0	24.9
Pre-op OHS 15	28.2	23.8	26.2	21.7	27.4	22.9	24.0	20.9
Pre-op OHS 20	24.2	19.8	22.1	17.7	23.4	18.9	19.9	16.9
Pre-op OHS 25	20.2	15.7	18.1	13.7	19.3	14.9	15.9	12.8
BMI 30–34.9 kg/m^2								
Pre-op OHS 10	30.7	26.3	28.7	24.2	29.9	25.5	26.5	23.4
Pre-op OHS 15	26.7	22.3	24.7	20.2	25.9	21.4	22.5	19.4
Pre-op OHS 20	22.7	18.3	20.7	16.2	21.9	17.4	18.5	15.4
Pre-op OHS 25	18.7	14.2	16.6	12.2	17.8	13.4	14.4	11.4
BMI 35 kg/m^2+								
Pre-op OHS 10	30.7	26.2	28.6	24.2	29.8	25.4	26.4	23.3
Pre-op OHS 15	26.6	22.2	24.6	20.1	25.8	21.4	22.4	19.3
Pre-op OHS 20	22.6	18.2	20.6	16.1	21.8	17.3	18.4	15.3
Pre-op OHS 25	18.6	14.2	16.6	12.1	17.8	13.3	14.4	11.3

BMI – Body mass index, ASA – American Society of Anaesthesiologists, Regional anaesthesia and posterior approach used in model.
[a] Minimal co-morbidity – ASA 2, no depression, no circulatory problems.
[b] Co-morbidity present – ASA 3, depression, circulatory problems.

Table 7
Patient Reported Complications Following Primary Cemented Stryker Exeter V40 Contemporary Hip Arthroplasty, by Body Mass Index (Simple and Multivariable Analyses).

			Simple			Multivariable		
	%	n	OR	99% CI	*P* Value	OR	99% CI	*P* Value
Bleeding complications								
BMI 19–29.9 kg/m^2 (n = 1640)	3.7	(61)	1			1		
BMI 30–34.9 kg/m^2 (n = 695)	5.3	(37)	1.46	0.84–2.52	0.079	1.47	0.83–2.60	0.083
BMI 35 kg/m^2+ (n = 321)	4.4	(14)	1.18	0.54–2.58	0.584	1.16	0.52–2.57	0.633
Wound complications								
BMI 19–29.9 kg/m^2 (n = 1640)	7.2	(118)	1			1		
BMI 30–34.9 kg/m^2 (n = 695)	10.8	(75)	1.56	1.04–2.33	0.004	1.57	1.03–2.38	0.006
BMI 35 kg/m^2+ (n = 321)	15.0	(48)	2.27	1.41–3.64	<0.001	2.06	1.25–3.40	<0.001
Readmission								
BMI 19–29.9 kg/m^2 (n = 1640)	6.2	(102)	1			1		
BMI 30–34.9 kg/m^2 (n = 695)	8.8	(61)	1.45	0.94–2.24	0.027	1.45	0.94–2.24	0.028
BMI 35 kg/m^2+ (n = 321)	11.2	(36)	1.90	1.13–3.22	0.002	1.99	1.17–3.39	0.001
Reoperation								
BMI 19–29.9 kg/m^2 (n = 1640)	1.6	(26)	1			1		
BMI 30–34.9 kg/m^2 (n = 695)	2.7	(19)	1.74	0.79–3.83	0.068	1.67	0.76–3.68	0.095
BMI 35 kg/m^2+ (n = 321)	4.4	(14)	2.83	1.19–6.75	0.002	2.73	1.14 to 6.53	0.003

OR – Odds ratio, BMI – Body mass index.

group we were able to remove difficulties adjusting for the performance of different brands, which may be used in far smaller numbers and propensity in different sub-groups of patients. The two implants analysed represent 29% (100,803) of all cemented and cementless implants (344,185) used in England and Wales since 2003. The remaining 71% are made up of 140 femoral stem brands and 117 acetabular components [4]. Despite the exclusion of other brands, the study cohort provided adequate numbers of procedures for analysis according to recommendations for sample size arising from the PROMs feasibility study [19] and by the Oxford score design group [20]. Additionally, our sensitivity analyses, based on commonly used component sets in each type of hip, provided similar results, suggesting our findings may generalise across different bearings, head sizes and fixation methods.

Pre-operative health scores were included in our multi-variable analyses; it might be argued that these should not be included since patients with higher BMI are likely to have poorer function, potentially creating a flaw in the study findings, as multi-variable testing adjusts for the effect of pre-operative function. However, demographic data support this; whilst different BMI groups were not exactly matched in terms of pre-operative scores, the differences were clinically small. Moreover, by providing predicted OHS improvements for different clinical situations, this study has confirmed that BMI is only one of several important variables influencing outcome, and its (independent) influence on change score is small. Interestingly, the differences in OHS improvement across groups are less than the threshold of 3 points suggested by the OHS designers to demonstrate a clinical important difference [20].

Previous work has demonstrated that risk of revision is significantly (1.5 times) higher in patients with a BMI >30 kg/m^2 following cementless hip arthroplasty with a Corail/Pinnacle [10], although BMI was not found to influence implant survival in analyses of the cemented Exeter Contemporary [24]. This could be a result of greater subsidence risk with cementless implants in patients with a higher BMI, or may be an erroneous finding, as previously published work has proposed that weight rather than BMI directly influences implant survival [25].

Other studies suggest that arthroplasty patients with a high BMI may have more complications [7], including a greater risk of infection [26] and dislocation [9,27], slower recovery [28], and poorer function [9] after THA. However, several studies have found consistently good improvement irrespective of BMI with comparable satisfaction and implant survival [29–31]. A study of 3290 THA patients found that morbidly obese (BMI >40 kg/m^2) patients had a similar change in outcome scores postoperatively to those with lower BMIs. Although final outcome scores were found to be lower (as in this current study) and complications higher, the authors concluded that morbidly obese patients may have as much to gain from THA as patients with a lower BMI [13]. This view was supported by an analysis of 1421 THAs by Andrew et al, in which no difference in OHS was found at 5 years

Table 8
Patient Reported Complications Following Primary Cementless DePuy Corail Pinnacle Hip Arthroplasty, by Body Mass Index (Simple and Multivariable Analyses).

			Simple			Multivariable		
	%	n	OR	99% CI	*P* Value	OR	99% CI	*P* Value
Bleeding complications								
BMI 19–29.9 kg/m^2 (n = 1738)	5.1	(89)	1			1		
BMI 30–34.9 kg/m^2 (n = 713)	6.3	(45)	1.25	0.77–2.03	0.240	1.10	0.64–1.90	0.647
BMI 35 kg/m^2+ (n = 428)	5.8	(25)	1.15	0.63–2.10	0.550	1.15	0.59–2.25	0.595
Wound complications								
BMI 19–29.9 kg/m^2 (n = 1738)	6.6	(115)	1			1		
BMI 30–34.9 kg/m^2 (n = 713)	9.5	(68)	1.49	0.99–2.25	0.013	1.43	0.93–2.21	0.032
BMI 35 kg/m^2+ (n = 428)	14.5	(62)	2.39	1.55–3.68	<0.001	2.39	1.52–3.75	<0.001
Readmission								
BMI 19–29.9 kg/m^2 (n = 1738)	6.3	(110)	1			1		
BMI 30–34.9 kg/m^2 (n = 713)	5.5	(39)	0.86	0.52–1.40	0.419	0.87	0.50–1.50	0.503
BMI 35 kg/m^2+ (n = 428)	7.0	(30)	1.12	0.64–1.93	0.608	1.32	0.72–2.41	0.233
Reoperation								
BMI 19–29.9 kg/m^2 (n = 1738)	2.0	(35)	1			1		
BMI 30–34.9 kg/m^2 (n = 713)	1.4	(10)	0.69	0.27–1.76	0.309	0.69	0.27–1.76	0.309
BMI 35 kg/m^2+ (n = 428)	2.3	(10)	1.16	0.46–2.96	0.675	1.16	0.46–2.96	0.675

OR – Odds ratio, BMI – Body mass index.

between BMI groups [14]. In addition, they found little difference in change of OHS between 3 months and 5 years following arthroplasty, suggesting that the results at 6–12 months post-operatively in our current study are a reliable indication of longer-term outcome. Interestingly, a similar study on TKA patients (without separate brand analysis) found no difference in change scores across different BMIs in 13,673 procedures [32].

In summary, patients experience a good improvement in outcome following THA irrespective of BMI. However, improvements were slightly smaller and complication rates higher in obese patients, after adjusting for other influences. A number of other patient variables also influence outcome scores in addition to BMI. In terms of improvement in health and function, a high BMI in isolation should not be a justifiable reason for denying surgery within a public funded health service. This sub-group of patients should be counselled that improvement following hip arthroplasty is likely to be less than that for an equivalent normal weight individual. Strategies to lower BMI, such as pre-operative weight loss programmes (including bariatric intervention [33]), should be considered.

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Appendix A

Appendix Table 1
Summary of Demographic and Surgical Variables Available for Analysis (Those Found to Have a Significant Influence on Specific Statistical Models and Therefore Included in Final Models Are Shown).

	Source	Description	Included in Final Models*
Patient factors			
Age (years)	NJR/PROMs		7
Sex	NJR/PROMs		A,E,1,3
American Society of Anaesthesiology grade	NJR	Grades 1 to 4	E
Body mass index (BMI) (kg/m^2)	NJR	Only BMI within 15 kg/m^2 to 65 kg/m^2 included	All
Comorbidities	PROMs	Recorded by patients as part of the pre-operative PROMs questionnaire. Ten co-morbidities: i) ischaemic heart disease, ii) respiratory disease, iii) diabetes, iv) hypertension, v) kidney disease, vi) liver disease, vii) circulatory problems, viii) cancer, ix) depression, x) stroke	A (vii), B (vii,ix), C (vii,ix), D (vii, ix, x), E (vii,ix), F (i,vii,ix) G (vii,ix,x), H (vii, ix, x), 6 (iii), 4(v)
Pre-operative general health	PROMs	Indicates the patient's perception of their own general health with five options: i) excellent, ii) very good, iii) good, iv) fair, v) poor	A,B,C,D,E,F,G,H
Pre-operative disability	PROMs	Indicates whether the patient considers themselves to have a disability	A,B,C,D,E,F,G,H, 1
Pre-operative Oxford Hip Score	PROMs	Derived from adding the points (0 to 4) together from the response to hip symptom-specific questions on a scale of 0 to 48 (0 worst, 48 best)	A,C,E,F,G
Pre-operative EQ5D Visual Analogue Score	PROMs	Indicates how well the patient feels on the day of completing the questionnaire on a scale of 0-100 (0 worst, 100 best)	2
Pre-operative EQ5D index	PROMs	Single summary score derived from EQ5D profile (based on response to 5 questions) by applying a formula with appropriate operation specific weightings (0 to 1)	B,D,F,H
Surgical factors			
Lead surgeon grade	NJR	Consultant or other	No
Hospital funding	NJR	NHS or other	
Approach	NJR	Posterior or direct lateral	A,B,C,D,E,F,G,H, 1,5
Patient position	NJR	Lateral or supine	No
Anaesthesia	NJR	i) Regional only, ii) general only, iii) general and regional	E
Chemical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) aspirin only, ii) LMWH only, iii) other, iv) none	7
Mechanical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) TEDS only, ii) combination TEDS/mechanical pump, iii) foot pump only, iv) intermittent calf pump only, v) other, and vi) none	6
Time from operation to post-operative PROMs completion	PROMs	Calculated from the date of operation as recorded on the NJR database to the date of post-operative PROMs as recorded on the questionnaire	No

PROMS outcome scores for:
commonest cemented implants: A. OHS change, B. EQ5D index change
commonest cementless implants: C. OHS change, D. EQ5D index change
all cemented implants: E. OHS change, F. EQ5D index change
all cementless implants: G. OHS change, H. EQ5D index change
PROMS patient reported complications for:
cemented implants: 1. wound, 2. bleeding, 3. readmission, 4. further surgery
cementless implants: 5. wound, 6. bleeding, 7. readmission, 8. further surgery

Appendix Table 2
Demographics for Sensitivity Analysis.

	Cemented (Exeter Contemporary 28 mm Flanged Polyethylene)	Cementless (Corail Pinnacle 36 mm Hard Bearing)
Number	1532	1191
Patient factors		
Age, mean years (standard deviation [sd], range)	72.8 (7.7, 36.7 to 92.9)	63.0 (9.7, 25.2 to 89.0)
Females	1036 (67.6)	540 (45.3)
ASA		
1	165 (10.8)	282 (23.7)
2	1106 (72.2)	814 (68.4)
3	252 (16.5)	94 (7.9)
4/5	9 (0.6)	1 (0.1)
Body mass index (kg/m^2)		
BMI 19 to 29.9	924 (60.3)	712 (59.8)
30 to 34.9	417 (27.2)	285 (23.9)
35 +	191 (12.5)	194 (16.3)
Co-morbidities		
Heart disease	137 (8.9)	95 (8.0)
Stroke	19 (1.2)	12 (1.0)
Diabetes	164 (10.7)	78 (6.6)
Hypertension	706 (46.1)	438 (36.8)
Circulation	122 (8.0)	37 (4.0)
Lung	112 (7.3)	69 (5.8)
Liver	6 (0.4)	5 (0.4)
Kidney	21 (1.4)	13 (1.1)
Nervous	13 (0.9)	7 (0.6)
Cancer	88 (5.7)	39 (3.3)
Depression	76 (5.0)	82 (6.9)
Preoperative general health		
Excellent	57 (3.8)	62 (5.3)
Very good	467 (31.0)	375 (32.3)
Good	686 (45.5)	477 (41.1)
Fair	265 (17.6)	220 (19.0)
Poor	34 (2.3)	27 (2.3)
Preoperative disability	868 (56.7)	553 (46.4)
Preoperative OHS, mean score (sd, range)	18.4 (8.1, 0 to 44)	19.2 (8.1, 2 to 42)
Pre-op EQ5D VAS, mean score (sd, range)	67.6 (19.7, 0 to 100)	66.2 (20.6, 0 to 100)
Pre-op EQ5D index, mean (sd, range)	0.374 (0.311, -0.429 to 1)	0.387 (0.317, -0.349 to 1)
Time from operation to PROMs completion, mean days (sd, range)	208.9 (29.1, 183 to 358)	209.6 (29.0, 183 to 362)
Surgical factors		
Provider		
NHS	1313 (85.7)	1029 (86.4)
Other	3 (0.2)	4 (0.3)
Unknown	216 (14.1)	162 (13.6)
Approach		
Posterior	866 (56.5)	765 (64.2)
Direct lateral	628 (40.1)	337 (28.3)
Other	38 (2.5)	89 (7.5)
Chemical VTE prophylaxis		
LMWH only	623 (47.3)	625 (60.5)
Aspirin only	153 (11.6)	126 (12.2)
Other	438 (33.3)	193 (18.7)
None	102 (7.8)	89 (8.6)
Mechanical VTE prophylaxis		
GCS	431 (28.1)	400 (38.7)
GCS/mechanical pump combination	335 (21.9)	342 (33.1)
Foot pump only	253 (16.5)	64 (6.2)
Mechanical calf pump only	204 (12.3)	133 (12.9)
Other	23 (1.5)	12 (1.2)
None	286 (18.7)	82 (7.9)
Anaesthesia		
Regional	708 (53.8)	562 (54.5)
General	238 (18.1)	229 (22.2)
Regional and general	370 (28.1)	241 (23.4)
Grade		
Consultant	943 (61.6)	920 (77.3)
Other	589 (38.5)	271 (22.8)
Position		
Lateral	1211 (79.0)	964 (80.9)
Supine	105 (6.9)	69 (5.8)
Unknown	216 (14.1)	158 (13.3)

OHS – Oxford hip score, VAS – Visual analogue score, NHS – National Health Service, VTE – Venous thromboembolism, LMWH – Low molecular weight Heparin, GCS – Graduated compression stockings.

Appendix Table 3
Patient Reported Outcome Scores Following Primary Cemented Stryker Exeter V40 Contemporary Hip Replacement, by Body Mass Index (Simple and Multivariable Analyses).

	Simple			Multivariable		
	Value	99% CI	*P* Value	Value	99% CI	*P* Value
Change in OHS (commonest implant specification[a])						
BMI 19 to 29.9 kg/m^2 (n = 924)	20.4	19.5 to 21.2	Reference	20.7	19.9 to 21.4	Reference
BMI 30 to 34.9 kg/m^2 (n = 417)	19.8	18.5 to 21.1	0.331	19.2	18.2 to 20.3	0.005
BMI 35 kg/m^2+ (n = 191)	20.0	18.1 to 21.9	0.643	18.6	17.0 to 20.1	0.002
Change EQ5D index ([a])						
BMI 19 to 29.9 kg/m^2 (n = 924)	0.406	0.376 to 0.436	Reference	0.410	0.390 to 0.431	Reference
BMI 30 to 34.9 kg/m^2 (n = 417)	0.414	0.370 to 0.457	0.722	0.392	0.363 to 0.422	0.190
BMI 35 kg/m^2+ (n = 191)	0.408	0.343 to 0.474	0.945	0.377	0.334 to 0.421	0.082

OHS – Oxford Hip Score, BMI – Body mass index.
[a] Commonest implant specification: *Exeter V40 Contemporary flanged polyethylene cup (internal diameter 28 mm).*

Appendix Table 4
Patient Reported Outcome Scores Following Primary Cementless DePuy Corail Pinnacle Hip Replacement, by Body Mass Index (Simple and Multivariable Analyses).

	Simple			Multivariable		
	Value	99% CI	*P* Value	Value	99% CI	*P* Value
Change in OHS (commonest implant specification[a])						
BMI 19 to 29.9 kg/m^2 (n = 712)	21.2	20.3 to 22.2	Reference	21.7	20.9 to 22.6	Reference
BMI 30 to 34.9 kg/m^2 (n = 285)	20.7	19.2 to 22.3	0.481	21.0	19.7 to 22.3	0.218
BMI 35 kg/m^2+ (n = 194)	22.0	20.1 to 23.8	0.369	19.9	18.3 to 21.5	0.009
Change EQ5D index ([a])						
BMI 19 to 29.9 kg/m^2 (n = 712)	0.413	0.379 to 0.448	Reference	0.440	0.416 to 0.465	Reference
BMI 30 to 34.9 kg/m^2 (n = 285)	0.404	0.350 to 0.459	0.722	0.406	0.367 to 0.445	0.059
BMI 35 kg/m^2+ (n = 194)	0.449	0.383 to 0.515	0.217	0.358	0.312 to 0.405	<0.001

OHS – Oxford Hip Score, BMI – Body mass index.
[a] Commonest implant specification: *Corail Pinnacle ceramic-on-ceramic or metal-on-metal with 36 mm head.*

References

1. Finucane MM, Stevens GA, Cowan MJ, et al. National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9.1 million participants. Lancet 2011;377(9765):557.
2. Jia H, Lubetkin EI. The impact of obesity on health-related quality-of-life in the general adult US population. J Public Health (Oxf) 2005;27(2):156.
3. Lohmander LS, Gerhardsson de Verdier M, Rollof J, et al. Incidence of severe knee and hip osteoarthritis in relation to different measures of body mass: a population-based prospective cohort study. Ann Rheum Dis 2009;68(4):490.
4. No-authors-listed , National Joint Registry for England and Wales 9th Annual Report; 2012 [Available from: http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR9thAnnualReport2012.pdf].
5. Vasarhelyi EM, MacDonald SJ. The influence of obesity on total joint arthroplasty. J Bone Joint Surg (Br) 2012;94(11 Suppl A):100.
6. Namba RS, Paxton L, Fithian DC, et al. Obesity and perioperative morbidity in total hip and total knee arthroplasty patients. J Arthroplasty 2005;20(7 Suppl 3):46.
7. Jain NB, Guller U, Pietrobon R, et al. Comorbidities increase complication rates in patients having arthroplasty. Clin Orthop Relat Res 2005;435:232.
8. Busato A, Roder C, Herren S, et al. Influence of high BMI on functional outcome after total hip arthroplasty. Obes Surg 2008;18(5):595.
9. Davis AM, Wood AM, Keenan AC, et al. Does body mass index affect clinical outcome post-operatively and at five years after primary unilateral total hip replacement performed for osteoarthritis? A multivariate analysis of prospective data. J Bone Joint Surg (Br) 2011;93(9):1178.
10. Jameson SS BP, Mason JM, Rymaszewska M, et al. Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements. Bone Joint J 2013 [In press].
11. Lacobucci G. CCGs ration care for obese and smokers with new wave of restrictions; 2012 [from: http://www.pulsetoday.co.uk/ccgs-ration-care-for-obese-and-smokers-with-new-wave-of-restrictions/13569559.article#.UP3dUKWSJpI].
12. Ewan M. guidance 32 - hip referral and surgery thresholds updated 2009 [cited 2012 01/12/2012]. Available from: http://67.18.16.98/~hertford/images/stories/ResourceCentre/BHPrioritiesForum/Guidance32HipReferralandSurgeryThresholdsUpdatedNov09.pdf.
13. McCalden RW, Charron KD, MacDonald SJ, et al. Does morbid obesity affect the outcome of total hip replacement?: an analysis of 3290 THRs. J Bone Joint Surg (Br) 2011;93(3):321.
14. Andrew JG, Palan J, Kurup HV, et al. Obesity in total hip replacement. J Bone Joint Surg (Br) 2008;90(4):424.
15. Devlin NJ, Parkin D, Browne J. Patient-reported outcome measures in the NHS: new methods for analysing and reporting EQ-5D data. Health Econ 2010;19(8):886.
16. No-authors-listed, National Joint Registry for England and Wales 8th Annual Report; 2011 [[25/03/2012]; Available from: http://www.njrcentre.org.uk/NjrCentre/LinkClick.aspx?fileticket=1TQ%2bEiNejm0%3d&tabid=86&mid=523].
17. Dawson J, Fitzpatrick R, Carr A, et al. Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg (Br) 1996;78(2):185.
18. No-authors-listed. EuroQol (EQ5D Score); 2009 [[29/08/2012]; Available from: http://www.euroqol.org/].
19. Browne J, Jamieson L, Lewsey J, et al. Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health; 2007 [2007 [29/08/2012]].
20. Murray DW, Fitzpatrick R, Rogers K, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg (Br) 2007;89(8):1010.
21. Judge A, Cooper C, Arden NK, et al. Pre-operative expectation predicts 12-month post-operative outcome among patients undergoing primary total hip replacement in European orthopaedic centres. Osteoarthritis Cartilage 2011;19(6):659.
22. Lawless BM, Greene M, Slover J, et al. Does age or bilateral disease influence the value of hip arthroplasty? Clin Orthop Relat Res 2012;470(4):1073.
23. Smith SC, Cano S, Lamping DL, et al. Patient-Reported Outcome Measures (PROMs) for routine use in Treatment Centres: recommendations based on a review of the scientific evidence: Health Services Research Unit. London, UK: London School of Hygiene & Tropical Medicine; 2005.
24. Jameson SS, Baker PN, Mason J, et al. The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements: a retrospective cohort study of medium-term data from a National Joint Registry. J Bone Joint Surg (Br) 2012;94(12):1611.
25. Traina F, Bordini B, De Fine M, et al. Patient weight more than body mass index influences total hip arthroplasty long term survival. Hip Int 2011;21(6):694.
26. Namba RS, Inacio MC, Paxton EW. Risk factors associated with surgical site infection in 30,491 primary total hip replacements. J Bone Joint Surg (Br) 2012;94(10):1330.
27. Chee YH, Teoh KH, Sabnis BM, et al. Total hip replacement in morbidly obese patients with osteoarthritis: results of a prospectively matched study. J Bone Joint Surg (Br) 2010;92(8):1066.
28. Jones CA, Cox V, Jhangri GS, et al. Delineating the impact of obesity and its relationship on recovery after total joint arthroplasties. Osteoarthritis Cartilage 2012;20(6):511.
29. Collins RA, Walmsley PJ, Amin AK, et al. Does obesity influence clinical outcome at nine years following total knee replacement? J Bone Joint Surg (Br) 2012;94(10):1351.
30. Yeung E, Jackson M, Sexton S, et al. The effect of obesity on the outcome of hip and knee arthroplasty. Int Orthop 2011;35(6):929.
31. McLaughlin JR, Lee KR. The outcome of total hip replacement in obese and non-obese patients at 10- to 18-years. J Bone Joint Surg (Br) 2006;88(10):1286.
32. Baker P, Petheram T, Jameson S, et al. The association between body mass index and the outcomes of total knee arthroplasty. J Bone Joint Surg Am 2012;94(16):1501.
33. Kulkarni A, Jameson SS, James P, et al. Does bariatric surgery prior to lower limb joint replacement reduce complications? Surgeon 2011;9(1):18.

No functional benefit of larger femoral heads and alternative bearings at 6 months following primary hip replacement

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Background and purpose — There has been a recent trend towards the use of greater femoral head sizes in an attempt to improve function and enhance stability after primary hip replacement. This has been associated with the use of alternative bearings, theoretically to reduce wear and improve implant longevity.

Methods — We examined the influence of these variables on patient-reported outcome measures (PROMs) for a consecutive series of primary hip replacements using National Joint Registry (NJR) and PROMs-linked data. To minimize the confounding influence of implant design factors, the single most commonly used brand in England and Wales (DePuy Corail Pinnacle) was examined. Improvement in patient hip-specific outcomes (Oxford hip score, OHS), general health outcomes (Euroqol, EQ-5D), and rates of self-reported complications (bleeding, wound problems, readmission, and reoperation) were compared for different head sizes (28-mm, 32-mm, and 36-mm) and bearings (metal-on-polyethylene (MoP), ceramic-on-polyethylene (CoP), and ceramic-on-ceramic (CoC)), adjusting for differences in case mix.

Results — At a mean follow-up of 7 months, improvements in OHS and EQ5D index were similar for 28-mm and 36-mm heads. A 32-mm head was associated with poorer function (OHS: 20, 99% CI: 19–21, p = 0.002; EQ5D index: 0.39, 99% CI: 0.36–0.42, p = 0.004), although these small differences may not be of clinical importance. There were no statistically significant benefits of either CoP or CoC bearings compared to a MoP bearing. Complication rates were similar within comparisons of head sizes or bearings.

Interpretation — In this short-term study, we did not find any functional benefits of larger head sizes or alternative bearings, after adjusting for other influences. We question their use in routine primary hip replacement given the lack of evidence of improved long-term survival in the literature.

Greater femoral head size may improve function and enhance stability after primary total hip replacement (THR) (Bartz et al. 2000, Cuckler et al. 2004, Hummel et al. 2009). Previous studies have shown a greater range of movement with increasing head size (Amstutz et al. 1975, Matsushita et al. 2009). Use of a larger head size is an attractive option in younger patients who require stability at higher levels of function, and in older patients in order to reduce dislocation risk. However, greater surface area may also increase wear rates, irrespective of bearing materials (Charnley et al. 1969, Dowling et al. 1978, Livermore et al. 1990, Bragdon et al. 2013, Jack et al. 2013), and there have been reports of excessive taper load with large-diameter bearings (Langton et al. 2012, Meyer et al. 2012). Larger heads have been associated with the use of alternative bearings, in order to reduce wear and improve implant longevity. The National Joint Registry (NJR) in England and Wales has described an increase in the use of larger femoral head sizes (over 28 mm)—from 5% to 50% between 2005 and 2010 (England and Wales National Joint Registry 2012). Over the same period, the use of ceramic-on-polyethylene (CoP) and ceramic-on-ceramic (CoC) bearings has increased.

Medium-term revision rates are higher with CoC bearings than with metal-on-polyethylene (MoP) bearings generally, across registry data, and specifically, when the most commonly used implant in England and Wales (Corail stem/Pinnacle cup; DePuy Ltd., Leeds, UK) was analyzed (Sexton et al. 2009, Jameson et al. 2013). Larger femoral sizes using hard-bearing technology did not give any functional improvement over 28-mm MoP (Hanna et al. 2012) in a small randomized trial, and larger head sizes have not been found to offer any gait-related benefits (Zagra et al. 2013). The functional benefits of increasing head size and alternative bearings have yet to fully assessed.

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Patient-reported outcome measures (PROMs) supplement revision risk in the assessment of success after joint replacement (Devlin et al. 2010). PROMs are routinely collected on National Health Service (NHS) patients undergoing THR in England. Data on hip replacement patients, their surgeons, and the implants used are collected by the NJR. These datasets can be linked in order to compare early outcomes for specific patient and implant groups at the national level. The present analysis explored the effect of bearing surface and femoral head size on PROMs and complications following THR. We hypothesized that larger heads and alternative bearings would have no functional benefit over standard (28-mm MoP) bearings.

Material and methods

Design

We conducted a cohort study using prospectively collected patient-level NJR and PROMs-linked data to compare outcome scores and self-reported complications after primary THR for different head sizes and different bearings.

Data

The national PROMs study collects joint-specific and general health scores preoperatively and around 6 months postoperatively, and self-reported complications. By linking databases at the patient level, PROMs data can be combined with the corresponding demographic and operative details held in the NJR. To link them, a number of criteria were used: firstly, to ensure correct matching, 2 unique identifiers (NJR and procedure numbers) recorded in both datasets were used; secondly, the operation date recorded by the patient in the PROMs data had to be within ± 30 days of the operation date recorded on the NJR record, to ensure that the patient was scoring the same procedure.

We chose to perform the analysis using the single most commonly used brand of THR used in England and Wales (Corail stem/Pinnacle cup; DePuy Ltd., Leeds, UK), in order to control for any implant-related influences (England and Wales National Joint Registry 2012).

There were a number of exclusion criteria. For the NJR data, these were: all procedures with an indication other than OA, procedures with missing implant or patient data, head sizes smaller than 28 mm and larger than 36 mm, and rarely used bearings (ceramic-on-metal and metal-on-ceramic). Metal-on-metal bearings were also excluded, as few of these are now implanted (England and Wales National Joint Registry 2012). Procedures with PROMs data that were missing, undated, dated more than 12 months prior to or following the operation, or that had non-identical duplicates were excluded; for identical duplicates, the first record was retained for analysis. Where the presence of a co-morbidity or complication was asked for in the questionnaire but left blank by the patient, it was assumed to be absent. The study population is summarized in Figure 1. The PROMs project was introduced in April 2008. Linkage of NJR data to PROMs was possible between this date and December 2010 (the limit of our access to NJR data). Details regarding the delivery and return of PROMs questionnaires were not available for this study. The demographic, surgical, and implant-related variables available for analysis are listed in Table 1 (see Supplementary data).

The national PROMs project uses validated measures of hip-specific outcomes (Oxford hip score (OHS)) (Dawson et al. 1996) and general health outcomes (EuroQol (EQ-5D)) (EuroQol group 2009). For this analysis, the outcomes of interest were improvements between preoperative and postoperative scores (the "change scores") and self-reported postoperative complications (bleeding, wound problems, re-admission, and reoperation). Change scores, being approximately normally distributed, are analytically preferable to postoperative scores (Browne et al. 2007). The OHS (score 0–48) has

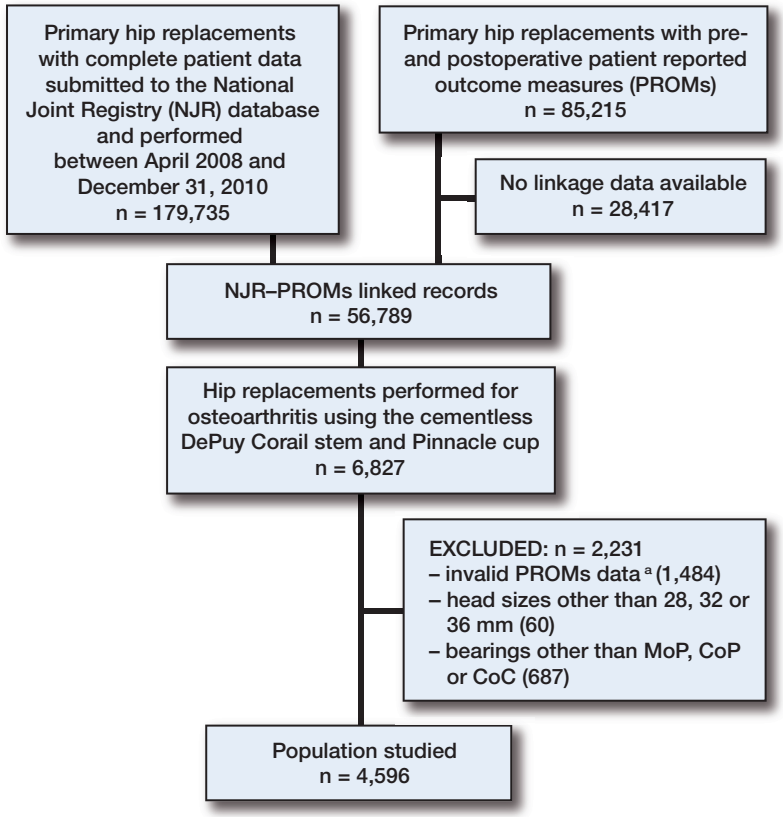

Figure 1. Flow chart describing the study cohort. MoP – metal-on-polyethylene, CoP – ceramic-on-polyethylene, CoC –ceramic-on-ceramic. [a] Invalid PROMs data includes records with missing outcome score rccords, preoperative scores dated more than 12 months prior to operation, postoperative records without a date or dated < 6 months or > 12 months following the primary hip replacement, non-identical duplicates (all excluded) and identical duplicates (only one record retained).

previously been shown to be a reliable, valid, and responsive outcome measure (Murray et al. 2007). A threshold of 3 points has been proposed to demonstrate a clinically important difference (Murray et al. 2007). The EQ-5D index (score –0.59 to 1.00) is a generic measure of health used for clinical and economic appraisal. It evaluates 5 different aspects of general health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) that are scored and combined using population weightings to produce a single index value for health status (group 2009). Patients are also asked about comorbidities, general health, and self-reported disability as part of the preoperative PROMs questionnaire. These can be used to adjust for differences in health status between patient groups. Sample sizes for all the head-size and bearing groups were in excess of the minimum numbers identified in the PROMs feasibility pilot for identification of meaningful differences (more than 150 per group) (Browne et al. 2007).

Patients are also asked to indicate their satisfaction with the outcome following surgery (excellent, very good, good, fair, or poor), and whether they deem surgery to have been a success (much better, a little better, about the same, a little worse, or much worse). While unadjusted values have been provided for information, no attempt was made to adjust for baseline differences in either success or satisfaction, as previous analyses have demonstrated that the variables available within the NJR and PROMs databases are insufficient to explain these differences (i.e. the influence of unmeasured variables has a greater effect than the effect of the measured variables) (Browne et al. 2007, Hamilton et al. 2013).

Statistics

The variables available for the analyses are shown in Table 1 (see Supplementary data). The head sizes analyzed were 28 mm, 32 mm, and 36 mm. The bearings were MoP, CoP, and CoC. Differences in baseline characteristics across the groups would be a source of confounding in any comparative analysis. Thus, to test the hypothesis that there were no differences between groups, the following tests were employed: 1-way analysis of variance (ANOVA, parametric continuous data variables), the Kruskal-Wallis test (non-parametric continuous data variables), or the chi-square test (categorical data variables).

Univariable analysis was performed initially to identify variables that possibly influenced each outcome, based on statistical rejection criteria of $p > 0.1$; these variables were then included in the multivariable models. Analysis of covariance (ANCOVA) was used for testing of differences in OHS and EQ5D index change scores across head size and bearing groups. Multivariable logistic regression was used to analyze differences in the risk of each of the complications across groups. Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Preoperative scores were included in all models, as recommended by the designers of the Oxford hip score (Murray et al. 2007).

Reflecting analysis of a large dataset, statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values (including 99% confidence intervals (CIs)) separately for each of the head-size and bearing categories. p-values are provided as statistical evaluation of the differences between the reference (head size of 28 mm and MoP bearing) and other variables within the category. For complication risks, results are presented as odds ratios (ORs) with CIs: ratios greater than 1 indicate that risk is higher when compared with the reference category. Due to the statistical methods employed and the large population size, only covariates fitting models with $p < 0.01$ were retained in final models as significant influences, to reduce the risk of type-1 error. All models were fitted using STATA 12.

For more information on the statistical techniques used, see Supplementary data.

Ethics

Explicit patient consent was taken for both the NJR and PROMs data collection. Further ethics approval is not required for registry studies in the UK.

Results

There were 4,596 NJR-PROMs linked primary procedures. MoP accounted for 47% (2,171), CoC for 45% (2,064), and CoP for 7.9% (361). A standard (28-mm) head size was used in 41% of procedures (1,864), the 36-mm in 41% (1,863), and the 32-mm in 19% (869). When the demographics were compared across bearing groups, patients with a CoC bearing were generally younger and in better health, but there were comparable numbers of women in each group and mean BMI was similar. Patients who had a larger head size implanted were generally younger and in better health (Table 2). Patients fitted with a 32-mm head generally had a higher ASA grade and higher BMI, and poorer general health. Although there were statistically significant differences between categories of bearing and head size for each of the surgical covariates as a result of the large study population, the groups were qualitatively similar and therefore broadly comparable (Tables 2 and 3).

In the unadjusted PROMs data, patients with a CoC bearing and a larger head size generally had higher preoperative and postoperative OHS and EQ5D indices. Patient-reported levels of satisfaction and success were similar across the bearing groups and the 28-mm and 36-mm head size groups, although the 32-mm head size group had poorer scores (Tables 4 and 5).

Improvement in outcome score

Improvements in OHS and EQ5D index were similar for MoP, CoP, and CoC bearings (Table 6, see Supplementary data).

Improvements in OHS and EQ5D index were similar for a 28-mm and a 36-mm head. Although the difference was small,

Table 2. Patient demographics for the population studied, by head size

	All patients	Head size 28 mm (Reference)	32 mm	36 mm	p-value [a]
Number (%)	4,596	1,864 (40.6)	869 (18.9)	1,863 (40.5)	
Patient factors					
Age, mean (SD) range	66.0 (9.7) 25.2–95.1	68.0 (8.9) 31.0–95.1	68.2 (10.1) 26.2– 94.1	62.9 (9.5) 25.2–90.2	< 0.001
Females, n (%)	2,620 (57.0)	1,303 (69.9)	535 (61.6)	782 (42.0)	< 0.001
ASA, n (%)					< 0.001
1	804 (17.5)	286 (15.3)	93 (10.7)	425 (22.8)	
2	3,360 (73.1)	1,410 (75.6)	644 (74.1)	1,306 (70.1)	
3+	432 (9.4)	168 (9.0)	132 (15.2)	132 (7.1)	
BMI (SD) range [b]	29.0 (5.4) 15–65	28.7 (5.2) 15–56	29.1 (5.6) 16–50	29.5 (5.4) 16–65	0.03
Comorbidities, n (%)					
Heart disease	388 (8.4)	152 (8.2)	91 (10.5)	145 (7.8)	0.05
Stroke	67 (1.5)	29 (1.6)	13 (1.5)	25 (1.3)	0.9
Diabetes	355 (7.7)	158 (8.5)	70 (8.1)	127 (6.8)	0.2
Hypertension	1,764 (38.4)	739 (39.7)	366 (42.1)	659 (35.4)	0.001
Circulation	221 (4.8)	102 (5.5)	45 (5.2)	74 (4.0)	0.09
Lung	270 (5.9)	112 (6.0)	42 (4.8)	116 (6.2)	0.3
Depression	309 (6.7)	126 (6.8)	44 (5.1)	139 (6.7)	0.07
Preoperative general health					0.02
Excellent	265 (5.8)	100 (5.4)	53 (6.1)	114 (6.1)	
Very good	1,413 (30.7)	566 (30.4)	235 (27.0)	611 (32.8)	
Good	2,008 (43.7)	862 (46.2)	394 (45.3)	755 (40.5)	
Fair	781 (17.0)	285 (15.3)	165 (19.0)	330 (17.7)	
Poor	129 (2.9)	51 (2.7)	22 (2.5)	53 (2.8)	
Preoperative disability	2,229 (48.5)	928 (50.0)	448 (51.6)	853 (45.8)	0.007
Surgical factors					
Chemical VTE prophylaxis					< 0.001
LMWH only	2,583 (56.2)	1,115 (59.8)	518 (59.6)	950 (51.0)	
Aspirin only	415 (9.0)	146 (7.8)	50 (5.8)	219 (11.8)	
Other	544 (11.8)	163 (8.7)	98 (11.3)	283 (15.2)	
None	304 (6.6)	133 (7.1)	36 (4.1)	135 (7.3)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	
Mechanical VTE prophylaxis					< 0.001
Compression stockings (CS)	1,249 (27.2)	500 (26.8)	222 (25.6)	527 (28.3)	
CS + mechanical pump	918 (20.0)	296 (15.9)	134 (15.4)	488 (26.2)	
Foot pump only	523 (11.4)	278 (14.9)	86 (9.9)	159 (8.5)	
Mechanical calf pump only	756 (16.5)	312 (16.7)	173 (19.9)	271 (14.6)	
Other	22 (0.5)	7 (0.4)	0 (0.0)	15 (1.0)	
None	378 (8.2)	164 (8.8)	87 (6.8)	127 (6.8)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	
Bearing					< 0.001
Metal-on-polyethylene	2,171 (47.2)	1,423 (76.3)	510 (58.7)	238 (12.8)	
Ceramic-on-polyethylene	361 (7.9)	198 (10.6)	100 (11.5)	63 (3.4)	
Ceramic-on-ceramic	2,064 (44.9)	243 (13.0)	259 (29.8)	1,562 (83.8)	
Anesthesia					< 0.001
Regional	2,077 (45.2)	871 (46.7)	303 (34.9)	903 (48.5)	
General	827 (18.0)	312 (16.7)	168 (19.3)	347 (18.6)	
Regional and general	906 (19.7)	357 (19.2)	224 (25.8)	325 (17.4)	
Not recorded	786 (17.1)	324 (17.4)	174 (20.0)	288 (15.5)	
Lead surgeon grade					< 0.001
Consultant	3,475 (75.6)	1,484 (79.6)	618 (71.1)	1,373 (73.7)	
Other	1,121 (24.4)	380 (20.4)	251 (28.9)	490 (26.3)	
Position					0.02
Lateral	3,598 (78.3)	1,449 (77.7)	666 (76.6)	1,483 (79.6)	
Supine	248 (5.4)	108 (5.8)	36 (4.1)	104 (5.6)	
Not recorded	750 (16.3)	307 (16.5)	167 (19.2)	276 (14.8)	

ASA: American Society of Anaesthesiologists score; PROMs: patient-reported outcomes measures.
[a] Difference between groups with 1-way ANOVA (continuous data variables) or chi-squared test (categorical data variables).
[b] BMI (body mass index) data on 2,726.

the 32-mm head was associated with a poorer outcome (OHS: 20, 99% CI: 19–21, p = 0.002; EQ5D index: 0.39, 99% CI: 0.36–0.42, p = 0.004) (Table 7, see Supplementary data).

Risk of complications

There were no statistically significant differences in risk of

Table 3. Patient demographics for the population studied, by bearing

	All patients	Bearing: Metal-on-polyethylene (Reference)	Ceramic-on-polyethylene	Ceramic-on-ceramic	p-value [a]
Number (%)	4,596	2,171 (47.2)	361 (7.9)	2,064 (44.9)	
Patient factors					
Age, mean (SD) range	66.0 (9.7) 25.2–95.1	70.8 (8.0) 31.0–95.1	64.6 (8.3) 39.0–87.2	61.1 (9.1) 25.2–91.5	< 0.001
Females, n (%)	2,620 (57.0)	1,259 (58.0)	220 (60.9)	1,141 (55.3)	0.06
ASA, n (%)					< 0.001
1	804 (17.5)	246 (11.3)	64 (17.7)	494 (23.9)	
2	3,360 (73.1)	1,673 (77.1)	249 (69.0)	1,438 (69.7)	
3+	432 (9.4)	252 (11.6)	48 (13.3)	132 (6.4)	
BMI (SD) range [b]	29.0 (5.4) 15–65	28.7 (5.2) 15–56	29.3 (5.3) 18–54	29.2 (5.6) 18–65	0.09
Comorbidities, n (%)					
Heart disease	388 (8.4)	233 (10.7)	28 (7.8)	127 (6.2)	< 0.001
Stroke	67 (1.5)	42 (1.9)	4 (1.1)	21 (1.0)	0.04
Diabetes	355 (7.7)	201 (9.3)	27 (7.5)	127 (6.2)	0.001
Hypertension	1,764 (38.4)	960 (44.2)	136 (37.7)	668 (32.4)	< 0.001
Circulation	221 (4.8)	132 (6.1)	25 (6.9)	64 (3.1)	< 0.001
Lung	270 (5.9)	122 (5.6)	21 (5.8)	127 (6.2)	0.8
Depression	309 (6.7)	123 (5.7)	25 (6.9)	161 (7.8)	0.02
Preoperative general health					0.001
Excellent	265 (5.8)	104 (4.8)	20 (5.5)	137 (6.6)	
Very good	1,413 (30.7)	649 (29.9)	93 (25.8)	669 (32.4)	
Good	2,008 (43.7)	1,004 (46.2)	184 (51.0)	819 (39.7)	
Fair	781 (17.0)	363 (16.7)	53 (14.7)	380 (18.4)	
Poor	129 (2.9)	51 (2.3)	11 (3.0)	59 (2.9)	
Preoperative disability	2,229 (48.5)	1,117 (51.5)	192 (53.2)	920 (44.6)	< 0.001
Surgical factors					
Chemical VTE prophylaxis					< 0.001
LMWH only	2,583 (56.2)	1,322 (60.9)	211 (49.0)	1,050 (50.9)	
Aspirin only	415 (9.0)	179 (8.3)	21 (5.8)	215 (10.4)	
Other	544 (11.8)	189 (8.7)	45 (12.5)	310 (15.0)	
None	304 (6.6)	115 (5.3)	27 (7.5)	62 (7.8)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	327 (15.8)	
Mechanical VTE prophylaxis					< 0.001
Compression stockings (CS)	1,249 (27.2)	644 (29.7)	98 (27.2)	507 (24.6)	
CS + mechanical pump	918 (20.0)	342 (15.8)	79 (21.9)	497 (24.1)	
Foot pump only	523 (11.4)	324 (14.9)	10 (2.8)	189 (9.2)	
Mechanical calf pump only	756 (16.5)	311 (14.3)	70 (19.4)	375 (18.2)	
Other	22 (0.5)	4 (0.2)	1 (0.3)	17 (0.8)	
None	378 (8.2)	180 (8.3)	46 (12.7)	152 (7.4)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	327 (15.4)	
Head size					< 0.001
28 mm	1,864 (40.6)	1,423 (65.6)	198 (54.9)	243 (11.8)	
32 mm	869 (18.9)	510 (23.5)	100 (27.7)	869 (18.9)	
36 mm	1,863 (40.5)	238 (11.0)	63 (17.5)	1,562 (40.5)	
Anesthesia					0.01
Regional	2,077 (45.2)	987 (45.5)	153 (42.4)	937 (45.4)	
General	827 (18.0)	344 (15.9)	72 (19.9)	411 (19.9)	
Regional and general	906 (19.7)	454 (20.9)	77 (18.2)	375 (18.2)	
Not recorded	786 (17.1)	386 (17.8)	59 (16.3)	341 (16.5)	
Lead surgeon grade					0.002
Consultant	3,475 (75.6)	1,600 (73.7)	294 (81.4)	1,581 (76.6)	
Other	1,121 (24.4)	571 (26.3)	67 (18.6)	483 (23.4)	
Position					0.1
Lateral	3,598 (78.3)	1,708 (78.7)	284 (78.7)	1,606 (77.8)	
Supine	248 (5.4)	97 (4.5)	20 (5.5)	131 (6.4)	
Not recorded	750 (16.3)	366 (16.9)	57 (15.8)	327 (15.8)	

ASA: American Society of Anaesthesiologists score; PROMs: patient-reported outcomes measures.
[a] Difference between groups with 1-way ANOVA (continuous data variables) or chi-squared test (categorical data variables).
[b] BMI (body mass index) data on 2,726.

bleeding, wound complications, re-admission, or reoperation after case-mix adjustment when the bearing groups were compared (Table 8, see Supplementary data). Bleeding risk was higher in the 32-mm head-size group (OR = 1.8, 99% CI: 1.2–2.8, $p < 0.001$) but not in the 36-mm head-size group (OR 1.3, CI 0.9 to 2.0, 0.063) when compared with the 28-mm group.

Table 4. Patient-reported outcomes for populations studied, by bearing

	Metal-on-polyethylene	Ceramic-on-polyethylene	Ceramic-on-ceramic	p-value [a]
Number (%)	2,171 (47.2)	361 (7.9)	2,064 (44.9)	
Oxford hip score				
Preoperative, mean (SD) range	18.4 (8.0) 1–43	18.5 (8.4) 0–43	19.2 (8.1) 1–46	0.003
Postoperative, median (range)	42 (0–48)	41 (7–48)	43 (2–48)	< 0.001
EQ5D index				
Preoperative, mean (SD)	0.368 (0.314)	0.375 (0.331)	0.394 (0.311)	0.01
range	-0.349 to 1	-0.484 to 0.883	-0.594 to 1	
Postoperative, median (range)	0.815 (-0.319 to 1)	0.796 (-0.319 to 1)	0.848 (-0.594 to 1)	0.008
Satisfaction, n (%)				0.3
Excellent	882 (40.6)	144 (39.9)	887 (43.0)	
Very good	804 (37.0)	123 (34.1)	728 (35.3)	
Good	364 (16.8)	66 (18.3)	321 (15.6)	
Fair	90 (4.2)	23 (6.4)	89 (4.3)	
Poor	31 (1.4)	5 (1.4)	39 (1.9)	
Success, n (%)				0.05
Much better	1,936 (89.2)	303 (83.9)	1,828 (88.6)	
A little better	157 (7.2)	46 (12.7)	158 (7.7)	
About the same	33 (1.5)	3 (0.8)	35 (1.7)	
A little worse	26 (1.2)	6 (1.7)	29 (1.4)	
Much worse	19 (0.9)	3 (0.8)	14 (0.7)	
Time from operation to PROMs completion, mean days (SD) range	208 (28) 183–363	207 (23) 183–333	210 (29) 183–361	0.002

PROMs: patient-reported outcome measures.
[a] 1-way ANOVA was used for parametric data, Kruskal-Wallis test for non-parametric data, and chi-squared test for proportions.

Table 5. Patient-reported outcomes for populations studied, by head size

	28 mm	32 mm	36 mm	p-value [a]
Number (%)	1,864 (40.6)	869 (18.9)	1,863 (40.5)	
Oxford hip score				
Preoperative, mean (SD) range	18.2 (8.0) 1–44	18.3 (7.9) 2–43	19.6 (8.2) 0–46	< 0.001
Postoperative, median (range)	43 (0–48)	41 (4–48)	48 (2–48)	< 0.001
EQ5D index				
Preoperative, mean (SD)	0.366 (0.315)	0.365 (0.316)	0.401 (0.311)	0.001
range	-0.484 to 1	-0.319 to 1	-0.594 to 1	
Postoperative, median (range)	0.848 (-0.319 to 1)	0.796 (-0.126 to 1)	0.850 (-0.594 to 1)	< 0.001
Satisfaction, n (%)				< 0.001
Excellent	791 (42.4)	319 (36.7)	803 (43.1)	
Very good	683 (36.6)	299 (34.4)	673 (36.1)	
Good	288 (15.5)	190 (21.9)	273 (14.7)	
Fair	77 (4.1)	46 (5.3)	79 (4.2)	
Poor	25 (1.3)	15 (1.7)	35 (1.9)	
Success, n (%)				0.001
Much better	1,673 (89.8)	736 (84.7)	1,658 (89.0)	
A little better	124 (6.7)	103 (11.9)	134 (7.2)	
About the same	27 (1.5)	14 (1.6)	30 (1.6)	
A little worse	22 (1.2)	10 (1.2)	29 (1.6)	
Much worse	18 (1.0)	6 (0.7)	12 (0.6)	
Time from operation to PROMs completion, mean days (SD) range	207 (26) 183–361	209 (28) 184–357	210 (29) 183–363	0.002

PROMs: patient-reported outcome measures.
[a] 1-way ANOVA was used for parametric data, Kruskal-Wallis test for non-parametric data, and chi-squared test for proportions.

Risk of wound complications was higher in the 36-mm group (OR = 1.7, 99% CI: 1.1–2.6, p = 0.002). Re-admission and reoperation risks were similar when the different head sizes were compared (Table 9, see Supplementary data).

Discussion

This large cohort study using NJR-PROMs linked data from a single hip system showed no functional benefit when femoral

head sizes greater than 28 mm and bearings other than MoP were used for primary THR. These findings are important for clinicians attempting to determine the most suitable hip implants for patients with osteoarthritis.

While this is the largest study to date to report the effects of head size and bearing type on functional outcome for a single hip replacement brand, there are some potential limitations to our findings. The study design was observational and thus vulnerable to omitted variables, which may have confounded the findings. Some data were unavailable for analysis; for example, radiological data on cup positioning. There were also large numbers of procedures that could not be analyzed, either because the datasets could not be linked (for example, due to missing patient identification details) or because there were specific data fields with incomplete data. Moreover, any bias in completion and return of PROMs cannot be assessed, as no details were available regarding the number of questionnaires sent out or returned. Non-responders are more likely to be younger patients (and therefore more likely to have larger head sizes and alternative bearings). However, previous PROMs analyses have demonstrated that non-responders generally perform more poorly (Ostendorf et al. 2004). Irrespective of these issues, similarities between the unadjusted and adjusted models and robustness under different model fitting assumptions support the stability of estimates.

By restricting the implants to the most commonly used brand only, we were able to remove the problems associated with adjusting for multiple brands (differing implant design characteristics and bearing surface manufacturing processes). The Corail Pinnacle constitutes 14% of all hip implants used in England and Wales since 2003. Cementless components now predominate, and around 40% of those implanted in 2011 were Corail Pinnacle (England-and-Wales-National-Joint-Registry 2012). [Ann-Britt: v.v. ta bort bindestrecken] This implant combination also offers a wide range of bearing options and head sizes, making it a good choice for analysis, and sample sizes of each of the comparison groups were in excess of the minimum numbers required to identify meaningful differences (Browne et al. 2007). False-negative results are therefore unlikely, especially as OHS and EQ5D indices for each of the groups were qualitatively similar, irrespective of confidence intervals.

As with all NJR-PROMs studies, the design of the study was constrained by the data available. In particular, this limited the length of follow-up available and the measures of hip function used. Although functional outcome at 6 months can be described as early, the follow-up in this study was adequate for group comparisons. The literature shows little improvement in change in OHS between 6 months and 5 years following hip replacement, suggesting that the results in our short-term study are a reliable indication of longer-term outcome (Andrew et al. 2008, Judge et al. 2013).

Greater femoral head size may reduce dislocation risk. In a randomized trial of patients undergoing metal-on-highly-crosslinked polyethylene hip replacements, Howie et al. (2012) found that a head size of 36 mm reduced the 1-year dislocation risk compared to 28 mm in 533 primary procedures—from 4.4% to 0.8%. In addition, a large cohort study of over 240,000 THRs performed in England and Wales found a reduction in 1-year dislocation risk from 1.4% to 1.1% over a period of 5 years, during which the use of large femoral head sizes increased. However, there was no change in the 12-month revision rate (Jameson et al. 2011). Lower dislocation rates with larger femoral head sizes have also been found in Australian and Norwegian registry data (Bystrom et al. 2003, ANJRR 2013). Without radiographic data, dislocation risk is difficult to analyze. The 1-year risk in the study by Howie et al. (2012) is high compared to others; Stroh et al. (2013) reported dislocation with head sizes less than 36 mm of only 1.8% (10 in 559) at 5 years, which is similar to the English NHS data (taking into account that most dislocations occur in the first year after surgery) (Jameson et al. 2011). Before larger head sizes are recommended, the incidence of late dislocation, wear, periprosthetic osteolysis, and liner fracture should also be established (Howie et al. 2012). Importantly, revision risk did not decrease in the English NHS data, suggesting that most early dislocations are relatively benign and do not require a revision procedure. Although dislocation data were unavailable in the current study, other outcomes were used as surrogate endpoints. The majority of dislocations following primary THR occur within the first 5 weeks after surgery (Bourne and Mehin 2004); therefore, patient-reported complications associated with a dislocation, such as re-admission and reoperation, should demonstrate a difference if, for example, one head size had a lower risk than another. Increasing femoral head size may also increase range of movement, but several studies have shown that it is the patient's bony anatomy that causes impingement, and therefore limits this range irrespective of head size (Bunn et al. 2012, Klingenstein et al. 2012). Interestingly, PROMs were poorer and bleeding risk was higher in patients implanted with a 32-mm head. This may be explained by the patient demographics, which showed a slightly greater mean BMI and relatively more patients with higher ASA grade and poorer health. In these patients, a surgeon may choose to increase head size from 28 mm in an attempt to increase stability, thereby potentially reducing a need for further revision surgery. Differences in unmeasured patient variables across groups (which cannot be controlled) may also account for this finding. However, it must be stressed that the statistically significant OHS change difference of 1.4 between 28-mm and 32-mm femoral heads is unlikely to be clinically significant.

Medium- to long-term risk of revision is lowest in MoP bearings across worldwide registries and published trials, and no functional benefit of alternative bearings has so far been found (Sedrakyan et al. 2011). When implant survival of 35,386 Corail Pinnacle THRs was examined in the NJR cohort, hard bearings had a higher revision risk than MoP (MoM: HR =

1.9, p < 0.001; CoC: HR = 1.6, p = 0.003) (Jameson et al. 2013). In a randomized trial of 49 patients who received either large-head MoM articulations or standard (28- to 32-mm) MoP THRs, no statistically significant benefits were found in function, dislocation, or implant failure (Hanna et al. 2012), although the numbers are small and this could be a consequence of type-II statistical error.

Metal-on-metal bearings were not included in this study. Although a large number of Corail Pinnacle THRs have been implanted in England and Wales with these bearings, their use is now low due to high revision rates and concerns regarding the systemic effects of excessive metal wear debris.

In summary, no functional benefits of larger head sizes or alternative bearings were found in this national analysis of NJR-PROMs linked THRs, after adjusting for other influences. Given the lack of evidence in the literature of improved implant survival with these implant options, we question their use in routine primary THR.

Supplementary data

Tables 1 and 6–9 are available at Acta's website (www.actaorthop.org), identification number 7059.

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SJ developed the idea, analyzed the data, and mainly wrote the paper. JM provided extensive advice on data analysis and co-wrote the paper. PB co-developed the idea, assisted with statistical issues, and edited the paper. PG developed the idea and edited the paper. DD co-developed the idea and edited the paper. MR co-developed the idea, co-wrote the paper, and supervised the project.

Amstutz H C, Lodwig R M, Schurman D J, Hodgson A G. Range of motion studies for total hip replacements. A comparative study with a new experimental apparatus. Clin Orthop Relat Res 1975; (111): 124-30.

Andrew J G, Palan J, Kurup H V, Gibson P, Murray D W, Beard D J. Obesity in total hip replacement. J Bone Joint Surg Br 2008; 90 (4): 424-9.

Bartz R L, Nobel P C, Kadakia N R,Tullos H S. The effect of femoral component head size on posterior dislocation of the artificial hip joint. J Bone Joint Surg Am 2000; 82 (9): 1300-7.

Bourne R B, Mehin R. The dislocating hip: what to do, what to do. J Arthroplasty 2004; 19 (4 Suppl 1): 111-4.

Bragdon C R, Doerner M, Martell J, Jarrett B, Palm H, Malchau H. The 2012 John Charnley Award: Clinical multicenter studies of the wear performance of highly crosslinked remelted polyethylene in THA. Clin Orthop Relat Res 2013; 471 (2): 393-402.

Browne J, Jamieson L, Lewsey J. "Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health, 2007." 2007. Retrieved 29/08/2012, from http:// www.lshtm.ac.uk/php/hsrp/research/proms_report_12_dec_07.pdf.

Bunn A, Colwell C W, Jr., D'Lima D D. Bony impingement limits design-related increases in hip range of motion. Clin Orthop Relat Res 2012; 470 (2): 418-27.

Bystrom S, Espehaug B, Furnes O, Havelin L I. Femoral head size is a risk factor for total hip luxation: a study of 42,987 primary hip arthroplasties from the Norwegian Arthroplasty Register. Acta Orthop Scand 2003; 74 (5): 514-24.

Charnley J, Kamangar A, Longfield M D. The optimum size of prosthetic heads in relation to the wear of plastic sockets in total replacement of the hip. Med Biol Eng 1969; 7 (1): 31-9.

Cuckler J M, Moore K D, Lombardi A V, Jr., McPherson E, Emerson R. Large versus small femoral heads in metal-on-metal total hip arthroplasty. J Arthroplasty 2004; 19 (8 Suppl 3): 41-4.

Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg Br 1996; 78 (2): 185-90.

Devlin N J, Parkin D, Browne J. Patient-reported outcome measures in the NHS: new methods for analysing and reporting EQ-5D data. Health Econ 2010; 19 (8): 886-905.

Dowling J M, Atkinson J R, Dowson D, Charnley J. The characteristics of acetabular cups worn in the human body. J Bone Joint Surg Br 1978; 60-B (3): 375-82.

England and Wales National Joint Registry. "National Joint Registry for England and Wales 9th Annual Report." 2012. from http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf.

group E. "EuroQol (EQ5D Score)." 2009. Retrieved 29/08/2012, from http://www.euroqol.org/.

Hamilton D F, Lane J V, Gaston P, Patton J T, Macdonald D, Simpson A H, Howie C R. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. BMJ Open 2013; 3 (4): e002525.

Hanna S A, Sewell M D, Sri-Ram K, Miles J, Aston W J, Pollock R C, Carrington R W, Briggs T W. The effect of femoral head size on functional outcome in primary total hip arthroplasty: a single-blinded randomised controlled trial. Hip Int 2012; 22 (6): 592-7.

Howie D W, Holubowycz O T, Middleton R. Large femoral heads decrease the incidence of dislocation after total hip arthroplasty: a randomized controlled trial. J Bone Joint Surg Am 2012; 94 (12): 1095-102.

Hummel M T, Malkani A L, Yakkanti M R, Baker D L. Decreased dislocation after revision total hip arthroplasty using larger femoral head size and posterior capsular repair. J Arthroplasty 2009; 24 (6 Suppl): 73-6.

Jack C M, Walter W L, Shimmin A J, Cashman K, de Steiger R N. Large diameter metal on metal articulations. Comparison of total hip arthroplasty and hip resurfacing arthroplasty. J Arthroplasty 2013; 28 (4): 650-3.

Jameson S S, Lees D, James P, Serrano-Pedraza I, Partington P F, Muller S D, Meek R M, Reed M R. Lower rates of dislocation with increased femoral head size after primary total hip replacement: a five-year analysis of NHS patients in England. J Bone Joint Surg Br 2011; 93 (7): 876-80.

Jameson S S, Baker P N, Mason J M, Rymaszewska M, Gregg P J, Deehan D J, Reed M R. Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements. Bone Joint J 2013; 95-B(6): 747-57.

Judge A, Arden N K, Batra R N, Thomas G, Beard D, Javaid M K, Cooper C, Murray D. The association of patient characteristics and surgical variables on symptoms of pain and function over 5 years following primary hip-replacement surgery: a prospective cohort study. BMJ Open 2013; 3 (3): e002453.

Klingenstein G G, Yeager A M, Lipman J D, Westrich G H. Increased range of motion to impingement with large head total hip arthroplasty: point of diminishing returns. Hip Int 2012; 22 (3): 261-5.

Langton D J, Sidaginamale R, Lord J K, Nargol A V, Joyce T J. Taper junction failure in large-diameter metal-on-metal bearings. Bone Joint Res 2012; 1 (4): 56-63.

Livermore J, Ilstrup D, Morrey B. Effect of femoral head size on wear of the polyethylene acetabular component. J Bone Joint Surg Am 1990; 72 (4): 518-28.

Matsushita A, Nakashima Y, Jingushi S, Yamamoto T, Kuraoka A, Iwamoto Y. Effects of the femoral offset and the head size on the safe range of motion in total hip arthroplasty. J Arthroplasty 2009; 24 (4): 646-51.

Meyer H, Mueller T, Goldau G, Chamaon K, Ruetschi M, Lohmann C H. Corrosion at the cone/taper interface leads to failure of large-diameter metal-on-metal total hip arthroplasties. Clin Orthop Relat Res 2012; 470 (11): 3101-8.

Murray D W, Fitzpatrick R, Rogers K, Pandit H, Beard D J, Carr A J, Dawson J. The use of the Oxford hip and knee scores. J Bone Joint Surg Br 2007; 89 (8): 1010-4.

ANJRR. "Australian National Joint Replacement Registry." 2013. Retrieved 08/03/2014, from https://aoanjrr.dmac.adelaide.edu.au/documents/10180/127202/Annual%20Report%202013?version=1.2&t=1385685288617.

Ostendorf M, van Stel H F, Buskens E, Schrijvers A J, Marting L N, Verbout A J, Dhert W J. Patient-reported outcome in total hip replacement. A comparison of five instruments of health status. J Bone Joint Surg Br 2004; 86 (6): 801-8.

Sedrakyan A, Normand S L, Dabic S, Jacobs S, Graves S, Marinac-Dabic D. Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. BMJ 2011; 343: d7434.

Sexton S A, Walter W L, Jackson M P, De Steiger R, Stanford T. Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg Br 2009; 91 (11): 1448-53.

Stroh D A, Issa K, Johnson A J, Delanois R E, Mont M A. Reduced dislocation rates and excellent functional outcomes with large-diameter femoral heads. J Arthroplasty 2013; 28(8): 1415-20.

Zagra L, Anasetti F, Bianchi L, Licari V, Giacometti Ceroni R. No difference in gait recovery after THA with different head diameters: a prospective randomized study. Clin Orthop Relat Res 2013; 471(12): 3830-7.

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A Comparison of Surgical Approaches for Primary Hip Arthroplasty: A Cohort Study of Patient Reported Outcome Measures (PROMs) and Early Revision Using Linked National Databases

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ABSTRACT

The posterior and lateral approaches to primary hip arthroplasty were compared using national data from England and Wales. Specific component combinations of the most commonly used cemented and cementless implant brands were analysed separately. There was no significant difference between the approaches for all-cause revision risk (cemented: $P = 0.726$, cementless: $P = 0.295$) and revision for dislocation ($P = 0.176$, $P = 0.695$) at 12 months following 37,593 procedures, after adjusting for patient and surgical variables. Analysis of 3881 linked episodes found the posterior approach was associated with significantly higher improvement in function (Oxford Hip Score: 20.8 versus 18.9, $P < 0.001$ (cemented procedures); 21.7 versus 20.2, $P = 0.008$ (cementless), EQ5D index: 0.416 versus 0.383, $P = 0.003$; 0.431 versus 0.384, $P = 0.003$). The posterior approach may offer a functional benefit (albeit small clinically), without increased revision risk.

The most appropriate surgical approach for primary total hip arthroplasty (THA) continues to stimulate debate. The two most commonly used techniques are the posterior approach, where the joint capsule is approached through the external rotator muscles on the posterior aspect of the femoral neck [1], and the lateral approach [2], where the abductor muscles are divided mid-tendon and reflected from the anterior aspect of the femoral neck. Post-operative limping secondary to abductor weakness occurs in 4% to 20% of procedures performed through a lateral approach [3]. Proponents of the posterior approach cite the benefits of less tissue damage, more rapid functional recovery and lower incidence of limp, and recommend this in younger patients. However, dislocation rates following a posterior approach may be higher due to the inherent weakness of the posterior capsular and soft tissue structures following surgery.

The 9th Annual Report of the National Joint Registry for England and Wales states that 59% (42,566 of 71,642) of primary THAs are currently implanted via the posterior approach compared to 35% (25,244) through the lateral approach [4]. Other approaches account for around 5% (3882). In previous analyses of the NJR dataset, surgical approach was not found to significantly affect mid-term implant survival of the most commonly implanted cemented and cementless THAs [5,6]. However, functional outcome and early revision may differ depending on surgical approach. Patient-reported outcome measures (PROMs) are increasingly being used to supplement risk of revision in the assessment of joint arthroplasty [7]. A single unit study demonstrated a functional benefit of the posterior approach at one to three years following THA [8], but a multi-centre study found no differences in improvement of Oxford hip score (OHS) and dislocation or revision rates between surgical approaches at five years [9]. However, these analyses are limited by modest numbers of procedures and the heterogeneity of implants used.

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Since 2008 the Department of Health (DoH) has routinely collected PROMs for NHS-funded elective THA performed in England and Wales. Outcome scores and self-reported complications following the THA can be linked to the NJR dataset in order to compare early PROMs for specific patient groups on a national level.

This analysis therefore aims to identify a benefit, if any, of the posterior approach in the first 12 months after primary THA using fixed implant characteristics, in terms of PROMs and revision risk, and after adjustment for a range of patient and surgical factors.

Methods

Design

A retrospective cohort study was conducted using patient-level NJR-PROMs-linked primary THA data to compare outcome scores and early revision risk for the posterior and lateral surgical approaches.

Data

Data on hip arthroplasty patients, their surgeons and implants used are collected by the NJR across England and Wales. Revision risk can be determined as primary procedures are linked within the database to any subsequent revision procedure on the same hip. The national PROMs study collects functional scores pre-operatively and six months post-operatively, together with self-reported post-operative complications. By linking the NJR and the PROMs datasets at the level of the patient, function and complication data can be determined for a specific subset of the NJR data. In order to link the two datasets a number of linkage criteria were used. Firstly, to ensure correct matching, two unique identifiers (NJR and procedure numbers) recorded in both datasets were used. Secondly, the operation date recorded by the patient in the PROMs data had to be within ± 30 days of the operation date recorded on the NJR record, to ensure the patient was scoring the same procedure.

We chose to perform this analysis using specific component combinations of the commonest cemented and cementless brands, in order to control for any implant influences. According to the NJR 8th Annual Report, the commonest cemented THA brand used since 2003 is the Exeter V40 hip and Contemporary cup (Stryker Orthopaedics, Mahwah, New Jersey, United States), accounting for 23% of all cemented THAs (37,995 of 163,981) [10]. Femoral head size and type of Contemporary cup (hooded or flanged) have previously been shown to independently influence revision risk [6]. For this analysis we therefore choose to examine all procedures performed with a 28-mm head and a flanged cup design (representing 70% of all Exeter V40-Contemporary THAs implanted in 2010). The Corail stem/Pinnacle cup (DePuy Ltd, Leeds, United Kingdom) is the most commonly used cementless THA (31% [40,879] of 130,920 cementless THAs). We analysed procedures that employed a 36-mm hard bearing (ceramic-on-ceramic [CoC] and metal-on-metal [MoM]) as these represent almost half of components implanted (48%), and provide a suitable contrast with the cemented implants to ensure the results from this study can be applied generally across different surgeons' practice.

There were a number of exclusion criteria. For the NJR data these were: all procedures with an indication other than osteoarthritis (OA)

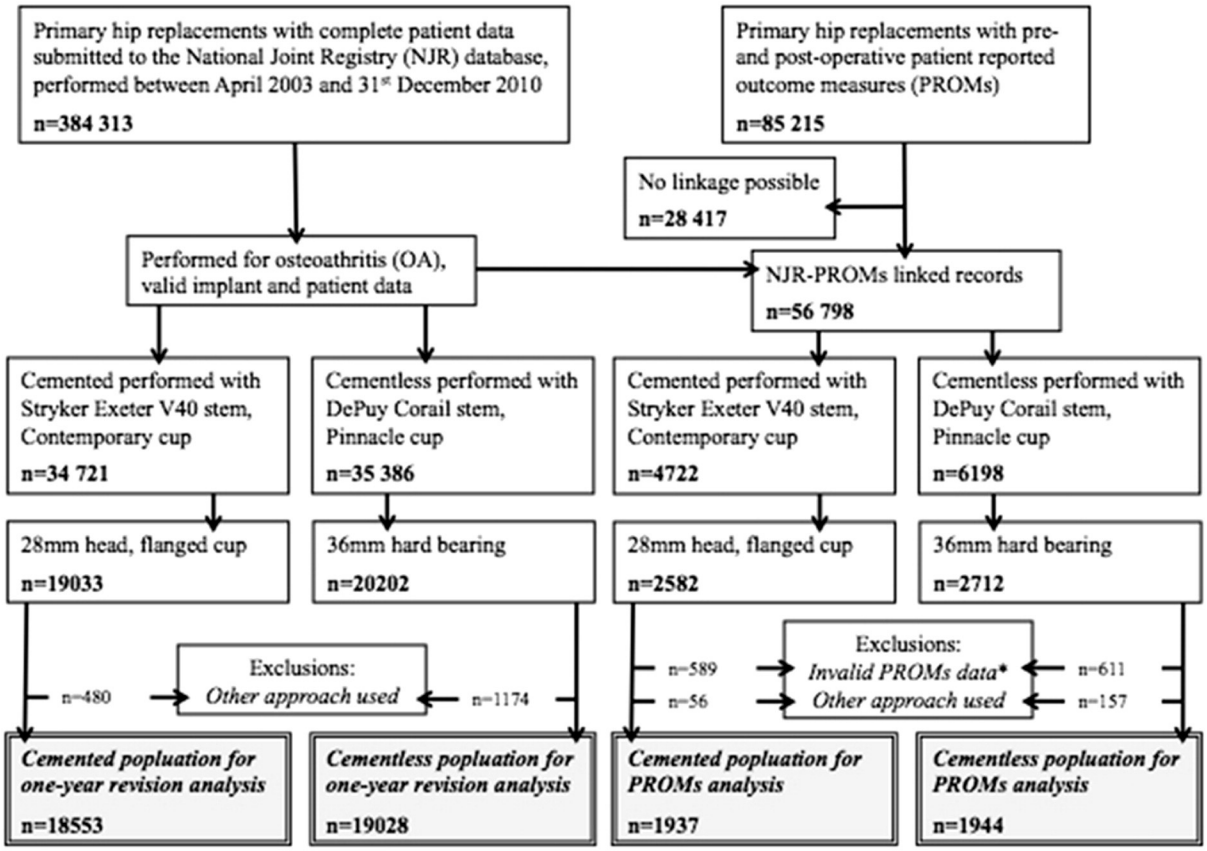

Fig. 1. Flow chart showing study inclusion criteria.

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and procedures with missing implant or patient data were excluded. As several stem and cup options were used rarely, these were also excluded from analyses. Procedures with PROMs data that were missing, undated, dated more than 12 months prior to or following the operation, or non-identical duplicates were excluded; for identical duplicates the first record was retained for analysis. Where the presence of a co-morbidity or complication was sought in the questionnaire but left blank by the patient, it was assumed to be absent. A summary of the population studied is shown in Fig. 1. The demographic, surgical and implant-related variables available for analysis are listed in Table 1.

The national PROMs project uses validated measures of hip-specific (Oxford Hip Score, OHS) [11] and general quality of life outcomes (EuroQol EQ-5D) [12]. For this analysis the outcomes of interest were improvements between the pre-operative and post-operative scores (the 'change scores') and self-reported post-operative complications (bleeding, wound problems, readmission and reoperation). Change scores, being approximately normally distributed, are analytically preferable to post-operative scores [13]. The OHS (scored 0 lowest to 48 highest) has previously been shown to be a reliable, valid and responsive outcome measure and can be used for the clinical assessment of large hip arthroplasty databases in a cross-sectional population [14]. The EQ-5D index (scored −0.59 to 1.00) is a generic measure of health used for clinical and economic appraisal. It evaluates five different aspects of general health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) that are scored and combined using population weightings to produce a single index value for health status [12]. For post-operative complications, patients were specifically asked if they were readmitted as a consequence of a problem with the operated hip, or if

Table 1
Demographics for NJR-PROMS linked Populations Studied, by Surgical Approach.

	Cemented (Exeter V40/Contemporary Flanged 28 mm)			Cementless (Corail/Pinnacle MoM/CoC 36 mm)		
	Posterior	Lateral	*P* Value	Posterior	Lateral	*P* Value
Number (%)	1121 (57.9)	816 (42.1)		1266 (65.1)	678 (34.9)	
Patient factors						
Age, mean years (standard deviation [sd], range)	72.6 (8.1, 36.7 to 93.5)	73.2 (7.2, 47.8 to 92.9)	0.945	63.2 (9.9, 25.2 to 96.2)	64.3 (8.9, 37.2 to 87.9)	0.994
Females, n (%)	765 (68.2)	523 (64.1)	0.056	585 (46.2)	284 (41.9)	0.068
ASA grade						
1	112 (10.1)	90 (11.0)	0.003	273 (21.6)	133 (19.6)	0.583
2	831 (74.8)	551 (67.5)		895 (70.7)	489 (72.1)	
3+	178 (15.1)	175 (21.5)		98 (7.7)	56 (8.3)	
BMI, mean kg/m^2 (sd, range)[a]	28.6 (4.9, 16 to 52)	28.9 (5.1, 18 to 59)	0.285	29.0 (5.3, 16 to 58)	29.7 (5.9, 18 to 65)	0.058
Co-morbidities						
Heart disease	87 (7.8)	94 (11.5)	0.005	98 (7.7)	62 (9.1)	0.283
Stroke	12 (1.1)	17 (2.1)	0.070	15 (1.2)	9 (1.3)	0.786
Diabetes	109 (9.7)	94 (11.5)	0.203	80 (6.3)	50 (7.4)	0.375
Hypertension	527 (47.0)	368 (45.1)	0.404	478 (37.8)	228 (33.6)	0.071
Circulation	90 (8.0)	67 (8.2)	0.885	45 (3.6)	34 (5.0)	0.120
Lung	63 (5.6)	67 (8.2)	0.024	79 (6.2)	50 (7.4)	0.338
Depression	49 (4.4)	53 (6.5)	0.039	81 (6.4)	62 (9.1)	0.027
Preoperative general health						
Excellent	56 (5.0)	25 (3.1)	0.001	73 (5.8)	38 (5.6)	0.818
Very good	361 (32.2)	211 (25.9)		408 (32.2)	201 (29.6)	
Good	506 (45.1)	393 (48.2)		514 (40.6)	288 (42.5)	
Fair	172 (15.3)	162 (19.9)		235 (18.6)	132 (19.5)	
Poor	26 (2.4)	25 (3.1)		36 (2.8)	19 (2.8)	
Preoperative disability	608 (54.2)	482 (59.1)	0.002	580 (45.8)	322 (47.5)	0.576
Surgical factors						
Chemical VTE prophylaxis						
LMWH only	470 (49.0)	355 (50.8)	<0.001	637 (57.8)	409 (71.3)	<0.001
Aspirin only	115 (12.0)	57 (8.2)		179 (16.2)	24 (4.2)	
Other	355 (37.0)	178 (25.5)		186 (16.9)	104 (18.1)	
None	19 (2.0)	109 (15.6)		101 (9.2)	37 (6.5)	
Mechanical VTE prophylaxis						
Compression stockings (CS)	260 (23.2)	261 (32.0)	<0.001	401 (36.4)	207 (36.1)	0.003
CS/mechanical pump combination	235 (20.1)	210 (25.7)		364 (33.0)	178 (31.0)	
Foot pump only	276 (24.6)	38 (4.7)		107 (9.7)	32 (5.6)	
Mechanical calf pump only	140 (12.5)	128 (15.7)		148 (13.4)	104 (18.1)	
Other	21 (1.9)	1 (0.1)		14 (1.3)	4 (0.7)	
None	189 (16.9)	178 (21.8)		69 (6.3)	49 (8.5)	
Anaesthesia						
Regional	502 (44.8)	379 (46.4)	0.607	625 (49.4)	341 (50.3)	0.433
General	195 (17.4)	129 (15.8)		246 (19.4)	119 (17.6)	
Regional and general	262 (23.4)	191 (19.0)		230 (18.2)	108 (15.9)	
Not recorded	162 (14.5)	117 (11.6)		165 (13.0)	110 (16.2)	
Lead surgeon grade						
Consultant	731 (65.2)	515 (63.1)	0.341	977 (77.2)	494 (72.7)	0.035
Other	390 (34.8)	301 (36.9)		289 (22.8)	184 (27.1)	
Position						
Lateral	933 (83.2)	600 (73.5)	<0.001	1096 (86.6)	500 (73.7)	<0.001
Supine	26 (2.3)	99 (12.1)		7 (0.6)	74 (10.9)	
Not recorded	162 (14.5)	117 (14.3)		163 (12.9)	104 (15.3)	

MoM, metal-on-metal; CoC, ceramic-on-ceramic; ASA, American Society of Anaesthesiologists; BMI, body mass index; VTE, venous thromboembolism; LMWH, low molecular weight heparin.
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, Chi squared test for proportions.
[a] BMI data available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%).

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they underwent a further operation on the hip in question. Patients are also asked about comorbidities, general health and self-reported disability as part of the pre-operative PROMs questionnaire. These can be used to understand and match the differences in health status between patient groups. Sample sizes for the two groups were in excess of the minimum numbers identified in the PROMs feasibility pilot to identify meaningful differences (more than 150/group) [13].

Patients are also asked to indicate a perception of their health pre-operatively and post-operatively on a visual analogue score (VAS, 0 poorest health, 100 best), their satisfaction with the outcome following surgery (excellent, very good, good, fair, poor), and whether they deem surgery to have been a success (much better, a little better, about the same, a little worse, much worse). Whilst unadjusted values have been provided for information, no attempt was made to adjust for baseline differences. Previous analyses have demonstrated that the variables available within the NJR and PROMs databases are insufficient to explain differences in the VAS, patient satisfaction and success of the procedure (i.e. the influence of unmeasured variables is much greater) [13].

Statistical Analysis

The variables available for the analyses are shown in Appendix Table 1. Differences in baseline characteristics between the two surgical approach groups were analysed using the two-tailed independent t-test with assumed equal variance (continuous parametric data variables), the two sample Wilcoxon rank-sum (Mann–Whitney) test (continuous non-parametric data variables) or Chi-square test (categorical data variables). Analyses of cemented and cementless procedures were performed independently; no attempt was made to adjust for baseline differences between types of implants.

Univariable analysis was performed initially to identify variables potentially influencing each outcome; these were then subsequently included in the multivariable models. Multivariable linear regression was used for testing differences in OHS and EQ5D index change scores between the approach groups. Multivariable logistic regression was used to analyse differences in the risk of each of the self-reported complications available within the PROMs data, and revision risk at one-year (using data from the unlinked NJR cohort). Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Pre-operative scores were included within all models, as recommended by the designers of the Oxford score [14]. Body mass index (BMI) is known to have an influence on PROMs and was therefore included in models where its influence was significant, despite a reduction in numbers as a consequence of incomplete recording of BMI. For the revision analysis NJR data unlinked to PROMs were preferred due to the larger population size.

Reflecting analysis of a large dataset, statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values (including 99% confidence intervals) for the posterior and the lateral approach groups. *P* values are provided as statistical tests of the differences between the two groups. For complication risks, results are presented as odds ratios (ORs) with 99% CIs: ratios greater than one indicate that risk is higher with the lateral approach. Due to the statistical methods employed, and the large population size, only covariates fitting models with $P < 0.01$ were considered significant influences, to reduce the risk of Type 1 error. All models were fitted using STATA 12 (StataCorp LP, Texas, USA).

In order to provide 'real-world' clinical scenarios, predicted changes in OHS were produced for both the cemented and cementless models using the margins function in STATA. This demonstrated the differences in hip specific improvement when gender, pre-existing health status, disability, and comorbidities were specified within the model, in addition to surgical approach.

Results

There were 37,593 primary procedures on the NJR database which met the inclusion criteria. Of these, 3881 could be linked to PROMs data; 1937 were cemented Exeter Contemporary with a flanged cup design and a 28-mm head, and 1944 were cementless Corail Pinnacle

Table 2
Patient Reported Outcomes for Populations Studied, by Surgical Approach.

	Cemented (Exeter V40/Contemporary Flanged 28 mm)			Cementless (Corail/Pinnacle MoM/CoC 36 mm)		
	Posterior	Lateral	*P* Value	Posterior	Lateral	*P* Value
Number (%)	1121 (57.9)	816 (42.1)		1266 (65.1)	678 (34.9)	
Oxford Hip scores						
Pre-operative, mean (sd, range)	18.9 (8.0, 0 to 44)	17.4 (7.8, 2 to 43)	<0.001	19.3 (8.1, 0 to 46)	18.6 (8.2, 1 to 42)	0.078
Post-operative, median (range)	42 (4 to 48)	39 (0 to 48)	<0.001	44 (2 to 48)	43 (5 to 48)	0.004
EQ5D visual analogue score						
Pre-operative, mean (sd, range)	68.7 (19.3, 4 to 100)	65.9 (20.2, 0 to 100)	0.003	66.8 (20.3, 0 to 100)	66.6 (21.0, 0 to 100)	0.848
Post-operative, mean (sd, range)	77.4 (16.7, 0 to 100)	73.0 (19.3, 0 to 100)	<0.001	78.5 (17.9, 0 to 100)	76.4 (17.6, 15 to 100)	0.015
EQ5D index						
Pre-operative, mean (sd, range)	0.393 (0.307, −0.358 to 1)	0.341 (0.313, −0.429 to 0.883)	<0.001	0.390 (0.316, −0.594 to 1)	0.377 (0.318, −0.239 to 1)	0.401
Post-operative, median (range)	0.815 (−0.003 to 1)	0.760 (−0.016 to 1)	<0.001	0.883 (−0.074 to 1)	0.812 (−0.077 to 1)	0.010
Satisfaction						
Excellent	454 (40.5)	249 (30.5)	<0.001	595 (47.0)	273 (40.3)	<0.001
Very good	395 (35.2)	290 (35.5)		442 (34.9)	228 (29.6)	
Good	212 (18.9)	192 (23.5)		160 (12.6)	121 (17.8)	
Fair	46 (4.1)	65 (8.0)		45 (3.6)	43 (6.3)	
Poor	14 (1.2)	20 (2.5)		25 (2.0)	13 (1.9)	
Success						
Much better	1003 (89.5)	669 (82.0)	<0.001	1136 (89.7)	584 (86.1)	0.131
A little better	86 (7.7)	102 (12.5)		81 (6.4)	60 (8.8)	
About the same	19 (1.7)	20 (2.5)		29 (3.6)	16 (2.4)	
A little worse	10 (0.9)	15 (1.8)		12 (1.5)	12 (1.8)	
Much worse	3 (0.3)	10 (1.2)		8 (1.0)	6 (0.9)	
Time from operation to PROMs completion, mean days (sd, range)	208.5 (28.2, 183 to 358)	209.0 (30.0, 183 to 363)	0.729	209.9 (30.3, 183 to 362)	208.7 (27.7, 183 to 343)	0.410

MoM, metal-on-metal; CoC, ceramic-on-ceramic; PROMs, patient reported outcome measures.
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, two sample Wilcoxon rank-sum (Mann–Whitney) test for non parametric data, Chi squared test for proportions.

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Table 3
Demographics for NJR Populations Studied, by Surgical Approach.

	Cemented (Exeter V40/Contemporary Flanged 28 mm)			Cementless (Corail/Pinnacle MoM/CoC 36 mm)		
	Posterior	Lateral	*P* Value	Posterior	Lateral	*P* Value
Number (%)	9345 (50.4)	9208 (49.6)		11995 (63.0)	7033 (37.0)	
Patient factors						
Age, mean years (standard deviation [sd], range)	73.8 (8.1, 26.2 to 99.5)	73.9 (7.8, 26.7 to 97.0)	0.418	64.2 (10.2, 19.4 to 106.2)	65.1 (10.0, 17.9 to 95.5)	<0.001
Females, n (%)	6277 (67.2)	5981 (65.0)	0.001	6033 (50.3)	3230 (45.9)	0.001
ASA grade						
1	1037 (11.1)	1496 (16.3)	<0.001	2615 (21.8)	1326 (18.8)	<0.001
2	6754 (72.3)	6126 (66.5)		8128 (67.7)	4878 (69.3)	
3+	1554 (16.6)	1586 (17.2)		1260 (10.5)	833 (11.8)	
BMI, mean kg/m^2 (sd, range)[a]	28.2 (5.0, 16 to 63)	28.5 (5.3, 16 to 63)	0.025	28.9 (5.4, 16 to 62)	29.1 (5.3, 15 to 65)	0.116
Surgical factors						
Chemical VTE prophylaxis						
LMWH only	3910 (46.6)	4386 (52.7)	<0.001	5986 (55.7)	3962 (62.6)	<0.001
Aspirin only	1169 (13.9)	970 (11.7)		1960 (18.2)	294 (4.7)	
Other	2900 (34.6)	2230 (26.8)		1284 (12.0)	1171 (18.5)	
None	409 (4.9)	736 (8.8)		1513 (14.1)	899 (14.2)	
Mechanical VTE prophylaxis						
Compression stockings (CS)	1624 (17.4)	3132 (34.0)	<0.001	2650 (24.7)	1765 (27.9)	<0.001
CS/mechanical pump combination	2628 (28.1)	2865 (31.1)		3846 (35.8)	1917 (30.3)	
Foot pump only	1973 (21.1)	383 (4.2)		1152 (10.7)	249 (3.9)	
Mechanical calf pump only	1421 (15.2)	831 (9.0)		1406 (13.1)	1260 (19.9)	
Other	534 (5.7)	762 (8.3)		119 (1.1)	18 (0.3)	
None	1165 (12.5)	1235 (13.4)		1570 (14.6)	1117 (17.7)	
Anaesthesia						
Regional	4261 (45.6)	4031 (43.8)	<0.001	5512 (45.9)	3740 (53.2)	<0.001
General	1283 (13.7)	1275 (13.9)		2461 (20.5)	1098 (15.6)	
Regional and general	2760 (29.5)	2698 (29.3)		2524 (21.0)	1225 (17.4)	
Not recorded	1041 (11.1)	1204 (13.1)		1498 (12.6)	970 (13.4)	
Lead surgeon grade						
Consultant	6972 (74.6)	6650 (72.2)	<0.001	10231 (85.2)	5563 (79.1)	<0.001
Other	2373 (25.4)	2558 (27.8)		1772 (14.8)	1474 (21.0)	
Position						
Lateral	8275 (88.6)	6916 (75.1)	<0.001	10584 (88.2)	5208 (74.0)	<0.001
Supine	119 (1.3)	1409 (15.3)		159 (1.3)	1118 (15.9)	
Not recorded	951 (10.2)	883 (9.6)		1260 (10.5)	711 (10.1)	

MoM, metal-on-metal; CoC, ceramic-on-ceramic; ASA, American Society of Anaesthesiologists; BMI, body mass index; VTE, venous thromboembolism; LMWH, low molecular weight heparin.
Statistical notes: two tailed independent t-test with assumed equal variance used for parametric data, Chi squared test for proportions.
[a] BMI data available for 7570 cemented implants (40.8%) and 8609 cementless implants (45.2%).

with a hard bearing (MoM or CoC) with a 36-mm head (Table 1). PROMs questionnaires were completed at a mean of 7 months following surgery (Table 2).

Cemented Hip Arthroplasty Baseline Characteristics

The majority of procedures were performed through a posterior approach (57.9%, 1121) (Table 1). These patients were more likely to have a lower ASA grade ($P = 0.003$), fewer comorbidities ($P = 0.002$), better pre-operative general health ($P = 0.001$) and less self reported disability (0.002).

Pre-operative and post-operative scores were significantly higher in hip arthroplasties performed through a posterior approach (OHS: $P < 0.001$ and <0.001, EuroQol VAS: $P = 0.003$ and <0.001, EQ5D index: $P < 0.001$ and <0.001); time from operation to post-operative questionnaire completion was equivalent to arthroplasties performed through a lateral approach (Table 2). Levels of satisfaction ($P < 0.001$) and perceived success ($P < 0.001$) were higher with the posterior approach.

Cementless Hip Arthroplasty Baseline Characteristics

The majority of procedures were performed through a posterior approach (65.1%, 1266) (Table 1). There were no significant differences in patient baseline characteristics across the two approach groups.

Post-operative scores were significantly higher in cementless hip arthroplasties performed through a posterior approach (OHS: $P = 0.004$, EuroQol VAS: $P = 0.015$, EQ5D index: $P = 0.010$); time from operation to post-operative questionnaire completion was equivalent

Table 4
Change in Patient Reported Outcome Scores at 7 Months Following Primary Total Hip Arthroplasty Through Either a Posterior or a Lateral Approach (Simple and Multivariable Analyses).

	Simple			Multivariable		
	Posterior	Lateral	*P* Value	Posterior	Lateral	*P* Value
Change in Oxford hip score (99% confidence intervals)						
Cemented	20.4 (19.6 to 21.2)	19.8 (18.9 to 20.6)	0.156	20.8 (20.0 to 21.5)	18.9 (18.0 to 19.7)	<0.001
Cementless	21.2 (20.5 to 22.0)	20.7 (19.7 to 21.8)	0.336	21.7 (20.9 to 22.4)	20.2 (19.1 to 21.4)	0.008
Change in EQ5D index						
Cemented	0.407 (0.380 to 0.434)	0.405 (0.374 to 0.436)	0.903	0.416 (0.397 to 0.434)	0.383 (0.361 to 0.404)	0.003
Cementless	0.418 (0.392 to 0.445)	0.398 (0.362 to 0.434)	0.231	0.431 (0.409 to 0.454)	0.384 (0.350 to 0.419)	0.003

Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28-mm cup*
Cementless: *DePuy Corail stem with Pinnacle shell and 36-mm metal-on-metal or ceramic-on-ceramic bearing*

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Table 5
Predicted Change in Oxford Hip Score at 7 Months Following Primary THA Performed Through a Posterior or Lateral Approach for Specific Patient Groups.

	Oxford Hip Score Change (99% CIs)	
	Posterior Approach	Lateral Approach
Good health		
Male		
Cemented	27.3 (24.7 to 29.9)	25.9 (23.2 to 28.5)
Cementless	26.9 (24.6 to 29.3)	26.0 (23.6 to 28.4)
Female		
Cemented	25.6 (23.1 to 28.2)	24.2 (21.6 to 26.8)
Cementless	26.2 (23.9 to 28.5)	25.2 (22.9 to 27.6)
Intermediate health		
Male		
Cemented	23.8 (22.4 to 25.1)	22.3 (21.0 to 23.7)
Cementless	23.7 (22.4 to 24.9)	22.7 (21.4 to 24.1)
Female		
Cemented	22.1 (21.0 to 23.2)	20.7 (19.5 to 21.9)
Cementless	22.9 (21.6 to 24.2)	22.0 (20.6 to 23.4)
Poor health		
Male		
Cemented	11.4 (7.9 to 14.9)	10.0 (6.5 to 13.5)
Cementless	10.2 (6.4 to 14.1)	9.3 (5.5 to 13.1)
Female		
Cemented	9.8 (6.3 to 13.2)	8.3 (4.9 to 11.8)
Cementless	9.5 (5.6 to 13.3)	8.5 (4.6 to 12.4)

CI, confidence interval.
Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28-mm cup.*
Cementless: *DePuy Corail stem with Pinnacle shell and 36-mm metal-on-metal or ceramic-on-ceramic bearing.*
Good health: self-reported excellent health, no disability, no circulatory problems, *Intermediate health*: self-reported good health, no disability, no circulatory problems, *Poor health*: self-reported poor health and disability, circulatory problems. Pre-op Oxford hip score taken as the mean for the cohort.

to arthroplasties performed through a lateral approach (Table 2). Levels of satisfaction ($P < 0.001$) were higher with the posterior approach but there was no significant difference in perceived success ($P = 0.131$).

The NJR-PROMs linked data subgroups were representative of the entire unlinked NJR populations (18,553 cemented and 19,040 cementless procedures) (Table 3).

Surgical Factors

The most commonly used chemical venous thromboembolic (VTE) prophylaxis agent was low molecular weight heparin (LMWH, used in 49.0% to 71.3%). Patterns of chemical and mechanical venous thromboembolic prophylaxis differed across the approaches for both cemented (both $P < 0.001$) and cementless hip arthroplasties ($P < 0.001$ and $P = 0.003$ respectively). The most common anaesthesia regime was regional (46.4% to 50.3%, depending on study subgroup). Type of anaesthesia and grade of lead surgeon were equivalent. The majority of patients were in the lateral position (73.5% to 86.6%), with procedures performed through a posterior approach more likely to utilise this position (cemented and cementless $P < 0.001$) (Table 1). Other than approach, surgical factors did not influence any of the multivariable models.

Oxford Hip Score Improvement

For both cemented and cementless procedures, univariable analysis showed no differences in OHS improvement between the posterior and the lateral approaches. However, after adjusting for influential variables, when compared with the posterior approach (cemented: 20.8, 99% CI 20.0 to 21.5, cementless: 21.7, 99% CI 20.9 to 22.4), the lateral approach was associated with a significantly lower improvement in OHS (cemented: 18.9, 99% CI 18.0 to 19.7, $P < 0.001$, cementless: 20.2, 99% CI 19.1 to 21.4, $P = 0.008$) (Table 4).

By fixing the pre-operative OHS to its mean value we have demonstrated the effect other influential variables have on change in OHS (Table 5). Males, those in good health with no disability and no comorbidities, and those who have a hip arthroplasty through a posterior approach have the greatest predicted improvement in OHS, irrespective of implant type.

EQ5D Index Improvement

For both cemented and cementless procedures, univariable analysis showed no differences in EQ5D index improvement between the posterior and the lateral approaches. However, after adjusting for influential variables, when compared with the posterior approach

Table 6
Patient Reported Complications and Revision Rates at One-Year Following Primary Total Hip Arthroplasty Through a Posterior or a Lateral Approach (Simple and Multivariable Analyses).

	Posterior	Lateral	Simple Analysis OR (99% CI, *P* Value)	Multivariable OR (99% CI, *P* Value)
Bleeding complications				
Cemented, % (n)	4.2 (47)	5.0 (49)	1.20 (0.67 to 2.14, 0.415)	1.20 (0.67 to 2.17, 0.424)
Cementless	6.4 (81)	6.8 (46)	1.06 (0.64 to 1.76, 0.766)	1.02 (0.60 to 1.75, 0.913)
Wound complications				
Cemented	8.6 (96)	11.5 (94)	1.33 (0.88 to 2.01, 0.074)	1.02 (0.62 to 1.69, 0.916)
Cementless	9.6 (121)	13.6 (92)	1.41 (0.95 to 2.10, 0.026)	1.44 (0.97 to 2.17, 0.017)
Readmission				
Cemented	7.7 (86)	8.8 (72)	1.15 (0.73 to 1.79, 0.434)	1.16 (0.73 to 1.85, 0.405)
Cementless	5.8 (73)	7.3 (49)	1.26 (0.76 to 2.10, 0.236)	1.16 (0.68 to 1.99, 0.463)
Reoperation				
Cemented	2.6 (29)	2.5 (20)	0.98 (0.46 to 2.10, 0.948)	0.94 (0.44 to 2.02, 0.833)
Cementless	1.6 (20)	2.1 (14)	1.31 (0.53 to 3.25, 0.438)	1.26 (0.48 to 3.32, 0.546)
One-year all-cause revision rate				
Cemented	0.3 (26)	0.2 (21)	0.82 (0.38 to 1.75, 0.497)	0.89 (0.37 to 2.12, 0.726)
Cementless	0.8 (101)	0.9 (61)	1.03 (0.68 to 1.57, 0.854)	0.82 (0.50 to 1.34, 0.295)
One-year revision rate for dislocation				
Cemented	0.1 (12)	0.1 (6)	0.51 (0.14 to 1.84, 0.176)	0.51 (0.14 to 1.84, 0.176)
Cementless	0.2 (22)	0.2 (15)	1.16 (0.49 to 2.77, 0.644)	0.85 (0.30 to 2.41, 0.695)

OR, odds ratio; CI, confidence interval.
An odds ratio >1 indicates that the risk of a complication is greater in the lateral approach group if the confidence intervals do not cross 1.
Analyses are based on the NJR-PROMs linked dataset (1937 cemented and 1944 cementless procedures) for the self reported complications and the unlinked NJR database (18553 cemented and 19040 cementless procedures) for one-year revision. Patients revised for other reasons were excluded from the revision for dislocation analysis.
Cemented: *Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28-mm cup.*
Cementless: *DePuy Corail stem with Pinnacle shell and 36-mm metal-on-metal or ceramic-on-ceramic bearing.*

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(cemented: 0.416, 99% CI 0.397 to 0.434, cementless: 0.431, 99% CI 0.409 to 0.454), the lateral approach was associated with a significantly lower improvement in EQ5D index (cemented: 0.383, 99% CI 0.361 to 0.404, $P = 0.003$, cementless: 0.384, 99% CI 0.350 to 0.419, $P = 0.003$) (Table 4).

Risk of Complications

There were no significant differences after multivariable testing between surgical approaches with either a cemented or cementless hip arthroplasty in terms of bleeding, wound complications, readmission, reoperation or one-year revision risk (Table 6).

Discussion

This large cohort study using NJR-PROMs linked data provides evidence that the posterior approach may offer a functional benefit to patients compared with the lateral, whilst appearing not to confer an additional risk of dislocation or requirement for revision during the first post-operative year. These findings were similar for both cemented and cementless implants and are clinically important as they identify a modifiable surgical parameter that may result in improved patient outcome.

Whilst these data are the largest to date reporting functional outcome following different surgical approaches, we accept that there are limitations. The study design is observational and thus vulnerable to omitted variables, which may have confounded our findings. Published dislocation rates are between 1% and 3% [15]. True first-time dislocation rates (without subsequent revision) were unavailable in this analysis; revision rates (all cause and revision for dislocation) at one-year were therefore used as a surrogate endpoint. Around half of all first-time dislocations ultimately require revision [16], and the majority occur within the first few months following surgery [15]; revision for recurrent early dislocation would be captured within the one-year revision data. Moreover, patient reported complications associated with a dislocation, such as readmission and reoperation, were reported in our current study. Patients are likely to report complications associated with the operated hip, irrespective of whether they underwent closed reduction in the emergency department or open reduction in theatre. Differences in dislocation risk for the two approach groups may therefore be apparent from these outcome measures, although we accept the limitations with this methodology.

Radiographic findings are currently unavailable within the NJR dataset. Cup positioning and femoral anteversion may influence risk of dislocation and subsequent revision. However, both approaches afford good exposure to the acetabulum so poorly positioned implants are unlikely to influence the results of one approach more than the other. In addition, previous studies have found no radiographic predictors of patient reported pain, function or satisfaction at 1–3 years following THA [17].

Despite these limitations, similarities between the unadjusted and adjusted models and robustness under different model fitting assumptions support the stability of estimates. Additionally, similar results were produced when BMI data were removed from the analyses to increase numbers available within statistical models, suggesting our findings are robust.

In this study the implants analysed were limited to the commonest component specification of the most popular brands in England and Wales. This ensured control over certain variables, such as bearings and head size, which may influence risk of dislocation, revision and functional outcome.

Although a statistically significant benefit of the posterior approach was found, this difference may not be clinically important. The Oxford score design group has previously described the minimum clinically important difference to be between 2 and 5 points [9,14]. The difference found in this study was only 1.9 in the cemented analysis. Nevertheless, it would seem prudent to explore all avenues of benefit to optimize patient outcome, especially in the immediate post-operative phase. Although these are early outcome data, previous analyses have shown the functional benefits of the posterior approach may persist for up to three years [8]. Comparison of OHS improvement following primary THA is now possible between surgical units in England (DoH Hospital Episode Statistics (HES) online website) [18], and the data presented here may prompt practicing surgeons to reconsider their choice of surgical approach in order to improve their patient scores. Whilst this should not be discouraged, it is important to appreciate that the benefits are small, and complications may be higher in the learning curve period associated with perfecting a surgical approach.

Other published studies demonstrate mixed findings when surgical approaches to the hip are compared. A single unit analysis of PROMs data in 911 patients demonstrated a functional benefit of the posterior approach at 1–3 years following THA [8], whilst a multicentre study of 1035 patients found there were no differences in change in OHS and in dislocation or revision rates between surgical approaches at 5 years [9]. Both of these analyses are limited by the heterogeneity of implants used.

In summary, greater improvements in outcome scores were found when a posterior approach was employed, after adjusting for patient and surgical factors. A larger effect was found with the cemented implant. Although these differences are small and may not be clinically important, the posterior approach offered significantly better early functional outcome scores to patients without an increased risk of revision or other complications.

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References

1. Gibson A. Posterior exposure of the hip joint. J Bone Joint Surg Br 1950;32-B(2):183.
2. Hardinge K. The direct lateral approach to the hip. J Bone Joint Surg Br 1982;64(1):17.
3. Masonis JL, Bourne RB. Surgical approach, abductor function, and total hip arthroplasty dislocation. Clin Orthop Relat Res 2002;405:46.
4. No-authors-listed. National Joint Registry for England and Wales 9th annual report. 2012; Available from: http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf.
5. Jameson SS, Baker PN, Mason JM, et al. Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements. Bone and Joint Jounal 2013 In press.
6. Jameson SS, Baker PN, Mason J, et al. The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements: a retrospective cohort study of medium-term data from a National Joint Registry. J Bone Joint Surg Br 2012;94(12):1611.
7. Devlin NJ, Parkin D, Browne J. Patient-reported outcome measures in the NHS: new methods for analysing and reporting EQ-5D data. Health Econ 2010;19(8):886.
8. Smith AJ, Wylde V, Berstock JR, et al. Surgical approach and patient-reported outcomes after total hip replacement. Hip Int 2012;7.
9. Palan J, Beard DJ, Murray DW, et al. Which approach for total hip arthroplasty: anterolateral or posterior? Clin Orthop Relat Res 2009;467(2):473.
10. No-authors-listed. National Joint Registry for England and Wales 8th annual report. 2011 [25/03/2012]; Available from: http://www.njrcentre.org.uk/NjrCentre/LinkClick.aspx?fileticket=1TQ%2bEiNejm0%3d&tabid=86&mid=523.
11. Dawson J, Fitzpatrick R, Carr A, et al. Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg Br 1996;78(2):185.
12. No-authors-listed. EuroQol (EQ5D Score). 2009 [29/08/2012]; Available from: http://www.euroqol.org/.
13. Browne J JL, Lewsey J, et al. Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health, 2007. 2007 [29/08/2012]; Available from: http://www.lshtm.ac.uk/php/hsrp/research/proms_report_12_dec_07.pdf.
14. Murray DW, Fitzpatrick R, Rogers K, et al. The use of the Oxford hip and knee scores. J Bone Joint Surg Br 2007;89(8):1010.

15. Bourne RB, Mehin R. The dislocating hip: what to do, what to do. J Arthroplasty 2004;19(4 Suppl 1):111.
16. Devane PA, Wraighte PJ, Ong DC, et al. Do joint registries report true rates of hip dislocation? Clin Orthop Relat Res 2012;470(11):3003.
17. Wylde V, Maclean A, Blom AW. Post-operative radiographic factors and patient-reported outcome after total hip replacement. Hip Int 2012;22(2):153.
18. Health-and-Social-Care-Information-centre. Patient reported outcome measures. 2013 [27/04/2013]; Available from: http://www.hscic.gov.uk/proms.

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Appendix

Univariable analysis to identify variables potentially influencing each outcome was based on statistical rejection criteria of $P > 0.10$. The reliability of the multivariable statistical models was explored in a number of ways: covariates found not to be statistically significant were excluded from the model, based on statistical entry ($P < 0.05$) criteria; the same covariates were fitted forward and reverse stepwise manually to ensure findings were not qualitatively affected in the final model, with any inconsistency reported; the final models were re-evaluated as a directly entered model (non-stepwise), and were assessed by exploring 2-way interactions between covariates.

The purpose of the analysis was hypothesis generating rather than hypothesis testing, consequently the choice of level of statistical significance is somewhat arbitrary.

Tests for interaction (multiplicative) between covariates were not statistically significant. Forward and reverse stepwise model construction and varying significance thresholds led to the same final models. BMI data were available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%); therefore final OHS and EQ5D index change models analysed fewer procedures than available in the entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels. Variables included in the change score models, and their significance levels within the final models, are shown in Appendix Table 2.

Appendix Table 1
Summary of the Demographic and Surgical Variables Available for Analysis.

	Source	Description
Patient factors		
Age (years)	NJR/PROMs	
Gender	NJR/PROMs	
American Society of Anaesthesiology (ASA) grade	NJR	Grades 1 to 4
Body mass index (BMI) (kg/m^2)	NJR	Only BMI within 15 kg/m^2 to 60 kg/m^2 included
Comorbidities	PROMs	Recorded by patients as part of the pre-operative PROMs questionnaire. Nine co-morbidities: i) ischaemic heart disease, ii) respiratory disease, iii) diabetes, iv) hypertension, v) kidney disease, vi) liver disease, vii) circulatory problems, viii) cancer, ix) depression
Pre-operative general health	PROMs	Indicates the patient's perception of their own general health with five options: i) excellent, ii) very good, iii) good, iv) fair, v) poor
Pre-operative disability	PROMs	Indicates whether the patient considers themselves to have a disability
Pre-operative Oxford Hip Score (OHS)	PROMs	Derived from adding the points (0 to 4) together from the response to hip symptom-specific questions on a scale of 0 to 48 (0 worst, 48 best)
Pre-operative EQ5D Visual Analogue Score	PROMs	Indicates how well the patient feels on the day of completing the questionnaire on a scale of 0–100 (0 worst, 100 best)
Pre-operative EQ5D index	PROMs	Single summary score derived from EQ5D profile (based on response to 5 questions) by applying a formula with appropriate operation specific weightings
Surgical factors		
Lead surgeon grade	NJR	Consultant or other
Approach	NJR	Posterior or direct lateral
Patient position	NJR	Lateral or supine
Anaesthesia	NJR	i) Regional only, ii) general only, iii) general and regional
Chemical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) aspirin only, ii) LMWH only, iii) other, iv) none
Mechanical venous thromboembolism prophylaxis	NJR	Intended prophylaxis as recorded at time of operation: i) Compression stockings (CS) only, ii) combination CS/mechanical pump, iii) foot pump only, iv) intermittent calf pump only, v) other, and vi) none
Time from operation to post-operative PROMs completion	PROMs	Calculated from the date of operation as recorded on the NJR database to the date of post-operative PROMs as recorded on the questionnaire

NJR, National Joint Registry; PROMs, patient reported outcome measures; LMWH, low molecular weight heparin.

Appendix Table 2
Variables Included in the Change Score Multivariable Linear Regression Models.

	Oxford Hip Score Change		EQ5D Index Change	
	Cemented Model	Cementless Model	Cemented Model	Cementless Model
Approach	<0.001	0.008	0.003	0.003
Preoperative Oxford hip score	<0.001	<0.001	0.002	–
Preoperative EQ5D index	–	–	<0.001	<0.001
Preoperative general health	<0.001	<0.001	<0.001	<0.001
Preoperative disability	0.003	0.001	<0.001	<0.001
Circulatory problems	<0.001	<0.001	<0.001	0.002
History of depression	–	0.001	<0.001	<0.001
BMI[a]	<0.001	0.040	–	0.001
Gender	<0.001	–	–	
Goodness of fit of model (adjusted R^2)	36%	41%	58%	60%

BMI, body mass index.
Cemented: Stryker Exeter V40 stem with Flanged Contemporary internal diameter 28-mm cup.
Cementless: DePuy Corail stem with Pinnacle shell and 36-mm metal-on-metal or ceramic-on-ceramic bearing.
[a] BMI data available for 1501 cemented implants (77.5%) and 1104 cementless implants (56.8%) therefore final change models analyse fewer procedures than entire cohort. Despite this, testing with BMI excluded from the model did not qualitatively affect the change scores or significance levels.

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Have cementless and resurfacing components improved the medium-term results of hip replacement for patients under 60 years of age?

Patient-reported outcome measures, implant survival, and costs in 24,709 patients

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Background and purpose — The optimal hip replacement for young patients remains unknown. We compared patient-reported outcome measures (PROMs), revision risk, and implant costs over a range of hip replacements.

Methods — We included hip replacements for osteoarthritis in patients under 60 years of age performed between 2003 and 2010 using the commonest brand of cemented, cementless, hybrid, or resurfacing prosthesis (11,622 women and 13,087 men). The reference implant comprised a cemented stem with a conventional polyethylene cemented cup and a standard-sized head (28- or 32-mm). Differences in implant survival were assessed using competing-risks models, adjusted for known prognostic influences. Analysis of covariance was used to assess improvement in PROMs (Oxford hip score (OHS) and EQ5D index) in 2014 linked procedures.

Results — In males, PROMs and implant survival were similar across all types of implants. In females, revision was statistically significantly higher in hard-bearing and/or small-stem cementless implants (hazard ratio (HR) = 4) and resurfacings (small head sizes (< 48 mm): HR = 6; large head sizes (≥ 48 mm): HR = 5) when compared to the reference cemented implant. In component combinations with equivalent survival, women reported significantly greater improvements in OHS with hybrid implants (22, p = 0.006) and cementless implants (21, p = 0.03) (reference, 18), but similar EQ5D index. For men and women, National Health Service (NHS) costs were lowest with the reference implant and highest with a hard-bearing cementless replacement.

Interpretation — In young women, hybrids offer a balance of good early functional improvement and low revision risk. Fully cementless and resurfacing components are more costly and do not provide any additional benefit for younger patients.

Implants in young patients must perform to a higher level while lasting longer. Literature from the 1980s described high rates of early loosening and implant failure following cemented hip replacement in younger patients (Chandler et al. 1981, Dorr et al. 1983, Collis 1984, Ranawat et al. 1984, Sharp and Porter 1985). These problems drove the development of cementless implants; larger, more anatomical head sizes; and hard bearings (Lord et al. 1979, Sedel et al. 1990, Cuckler et al. 2004, Delaunay et al. 2008). It was hoped that these advances would reduce rates of aseptic revision by addressing the main causes of failure (polyethylene (PE) debris and polymethylmethacrylate-bone interface loosening) and reduce early dislocation rates. Resurfacing devices were also introduced to provide an anatomical solution, providing a lower risk of dislocation, a perceived greater function, and "easier" revision if required (Spencer 2011). Implant failures remain, however, but the mode of failure has changed: high dislocation rates with ceramic-on-ceramic (CoC) bearings and metal wear-related failures with large-head metal-on-metal (MoM) bearings (Sexton et al. 2009, Haddad et al. 2011, Smith et al. 2012b).

Findings from worldwide registry data show that cemented implants outperform all others, in terms of implant survival (Finnish National Arthoplasty Registry 2006, New Zealand National Joint Registry 2008, Norwegian Arthroplasty Registry 2008, Australian National Joint Registry 2010, Swedish Hip Registry 2010, England and Wales National Joint Registry 2012). Following their analysis of the literature, Sedrakyan et al. (2011) found that there were no benefits of using hard bearings instead of PE bearings.

Of the primary hip replacements performed in 2011 in England and Wales with patient data available, 20% (13,871

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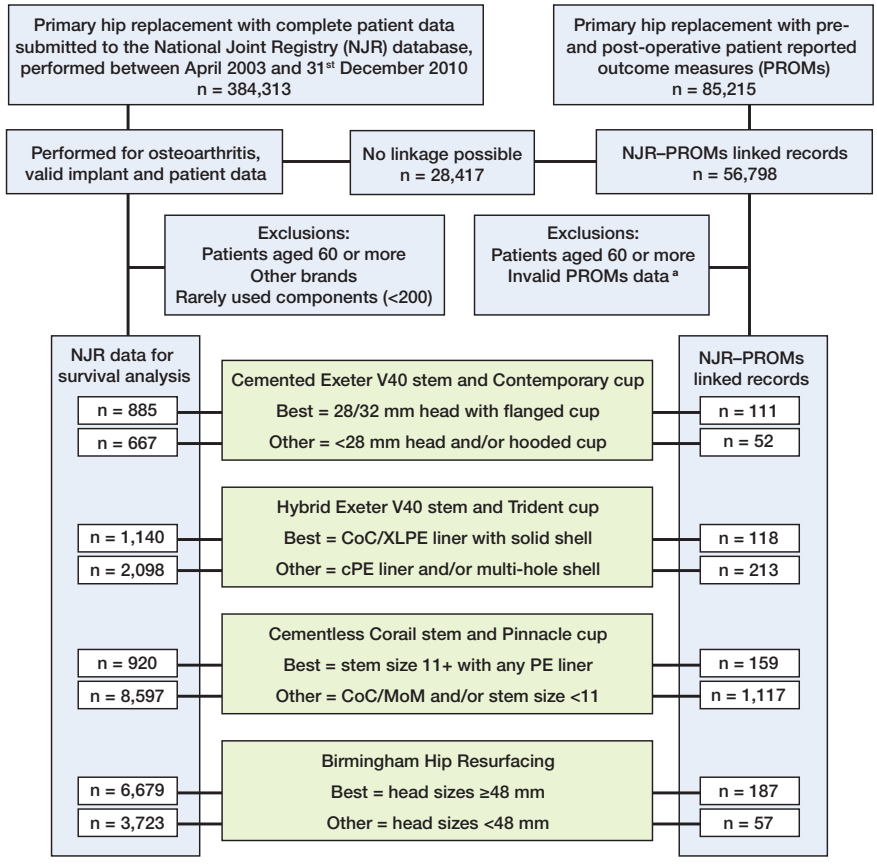
of 68,331; 7,249 women and 6,622 men) were implanted in patients under 60 years of age. The majority of these replacements used cementless fixation (either fully cementless (60%, 8,372 of 13,871) or hybrid (15%, 2,064)), or used a resurfacing device (8.4%, 1,159). The evidence for this practice therefore remains elusive. It may be that some combinations improve implant survival or function, but the subtleties of brand differences may be lost when implants are analyzed within groups, as in joint registry analyses.

Implant survival data and patient functional outcome can now be assessed by using linked data from the Patient-Reported Outcomes Measures (PROMs) project and the National Joint Registry (NJR) in England and Wales. Hypothesizing that no implants offer superior functional outcome and survival, we compared different types of replacements to identify optimal combinations for young patients, employing the most commonly used standard cemented hip replacement as the reference case.



Flow chart describing inclusion criteria.

Methods

Design

We conducted a cohort study using prospectively collected patient-level NJR and PROMs data to compare implant survival and patient-reported outcomes in different primary hip replacements. Material costs were analyzed using National Health Service (NHS) procurement data.

Data

We chose the single most commonly used brand of each type of hip replacement performed in England and Wales for the analysis, in order to control for brand heterogeneity within groups: (1) cemented (taper slip design), Exeter V40 stem/Contemporary cup (Stryker Orthopaedics, Mahwah, NJ) (23% of cemented implants); (2) cementless, Corail stem/Pinnacle cup (DePuy Ltd., Leeds UK) (31% of cementless); (3) hybrid, Exeter V40 stem/Trident cup (Stryker Orthopaedics) (33% of hybrids); and (4) resurfacing, Birmingham Hip Resurfacing (BHR) (Smith and Nephew, Memphis, TN) (55% of resurfacings) (England and Wales National Joint Registry 2012). These implants have been separately stratified into 2 groups based on revision risk of component options (Jameson et al. 2012a, b, 2013b, c). The "best"-performing component sets were: cemented Exeter with the Contemporary flanged cup and a 28-mm or 32-mm femoral head (metal or ceramic); hybrid Exeter with solid shell Trident cup and either a CoC bearing or a highly crosslinked PE liner (with either a metal head or a ceramic head); cementless Corail stem (size 11 or greater) with a Pinnacle cup and a PE liner (metal or ceramic head); and BHR using components with a head size of 48 mm or greater. All the remaining options had statistically significantly higher revision risk and were separately grouped as "others": cemented Exeter with the Contemporary hooded cup and/or a head size less than 28 mm; hybrid Exeter with Trident multi-hole shell and/or a conventional PE liner; cementless small-stem Corail (less than size 11) and/or a Pinnacle cup with any hard-bearing liner; and BHR using head sizes of less than 48 mm (Figure).

The NJR has collected patient, implant, and surgeon data on all hip replacements performed in the public and private health systems in England and Wales since 2003. Submission of private health system data was mandatory from 2003, but public health providers were not obliged to submit data during the period of study. Despite this, compliance (the number of procedures recorded by the NJR compared with the number recorded by the NHS) rose from 60% in 2003 to 100% in 2010 (England and Wales National Joint Registry 2012).

In this study, all primary hip replacements were included if performed using the specified implants on patients under 60 years of age and submitted to the NJR between April 1,

Table 2. Patient demographics for the National Joint Registry population studied, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		
	Best	Others	Best	Others	Best	Others	Best	Others	p-value [a]
Number (%)	885 (4)	667 (3)	1,140 (5)	2,098 (9)	920 (4)	8,597 (35)	6,679 (27)	3,723 (15)	
Age, median (range)	56 (23–60)	57 (26–60)	54 (18–60)	55 (20–60)	57 (27–60)	54 (16–60)	52 (19–60)	52 (19–60)	< 0.001
Females, n (%)	548 (62)	412 (62)	642 (56)	1,340 (64)	454 (49)	4,880 (57)	432 (7)	2,914 (78)	< 0.001
ASA, n (%) [b]									
1	263 (30)	193 (29)	430 (38)	677 (32)	252 (27)	2,815 (33)	3,750 (56)	1,969 (53)	< 0.001
2	543 (61)	421 (63)	664 (58)	1,246 (59)	603 (66)	5,233 (61)	2,748 (41)	1,677 (45)	
3+	79 (9)	53 (8)	46 (4)	175 (8)	65 (7)	549 (6)	181 (3)	77 (2)	
BMI, mean (SD)	30 (6)	30 (5)	30 (5)	30 (6)	30 (5)	30 (5)	29 (4)	28 (5)	< 0.001
(range) [c]	(18–59)	(16–50)	(18–56)	(16–54)	(17–52)	(16–65)	(16–51)	(16–63)	

[a] Differences between groups. Statistical notes: 1-way analysis of variance (ANOVA) was used for normally distributed data, Kruskal-Wallis test for non-normally distributed data, and chi-squared test for proportions;
[b] ASA: American Society of Anaesthesiologists;
[c] BMI: body mass index, kg/m^2 (data based on 9,544 procedures (39%)).

2003 and December 31, 2010. There were a number of other exclusion criteria: all procedures with an indication other than OA (which represents only 7% of procedures (England and Wales National Joint Registry 2012); procedures with missing implant or patient data; and rarely used implant options. From data described in the original studies, between 4.0% and 14% of correctly specified procedures on patients with OA were excluded due to rarely used implant components or missing component data fields.

The national PROMs project was introduced in 2008 and uses validated measures of hip-specific function (Oxford hip score (OHS)) (Dawson et al. 1996) and general health status (EuroQol (EQ-5D-3L)) (group E 2009), collected preoperatively and around 6 months postoperatively (public health system patients only). By linking databases at the patient level, PROMs data can be combined with the corresponding demographic and operative details held in the NJR. To carry out linkage, we used a number of criteria: firstly, to ensure correct matching, 2 unique identifiers (NJR and procedure numbers) recorded in both datasets were used; secondly, the operation date recorded by the patient in the PROMs data had to be within ± 30 days of the operation date recorded in the NJR record, to ensure the patient was scoring the same procedure. Procedures with PROMs data that were missing, undated, dated more than 12 months prior to or following the operation, or non-identical duplicates were excluded; for identical duplicates, the first record was retained for analysis. Where the presence of a comorbidity was sought in the questionnaire but left blank by the patient, it was assumed to be absent. The study population is summarized in the Figure. The demographic, surgical, and implant-related variables available for analysis are listed in Table 1 (Supplementary data).

For this analysis, the patient-reported outcomes of interest were improvements between the preoperative and postoperative scores (the "change scores"). Change scores, being approximately normally distributed, are analytically preferable to postoperative scores (Browne et al. 2007). The OHS (score 0–48) has been shown to be a reliable, valid, and responsive outcome measure (Murray et al. 2007). A clinically relevant improvement in OHS is considered to be greater than 3 (Murray et al. 2007). The EQ-5D-3L index (where 0 is death, 1 is perfect health, and < 1 is "worse than death") is a measure of health status that is used widely in clinical and economic evaluations. Patients are asked about comorbidities, general health, and self-reported disability as part of the preoperative PROMs questionnaire. These can be used to adjust for differences in health status between patient groups.

In the PROMs after surgery, patients are also requested to indicate their satisfaction with the outcome (excellent, very good, good, fair, or poor), and whether they deem surgery to have been a success (much better, a little better, about the same, a little worse, or much worse). While unadjusted values of success and satisfaction have been provided for information in this study, we made no attempt to adjust for baseline differences in these measures, as previous analyses have shown that the variables available in the NJR and PROMs databases are insufficient to explain any differences (i.e. the influence of unmeasured variables has a greater effect than the effect of the measured variables) (Browne et al. 2007, Hamilton et al. 2013).

24,709 procedures were available for analysis in the NJR dataset, comprising the most commonly used brands of cemented (1,552, 6.3%), hybrid (3,238, 13%), cementless (9,517, 39%), and resurfacing (10,402, 42%) replacements (Figure). Due to relatively poor compliance and fewer hip replacements performed in the early years of the registry, mean follow-up time was 2.7 years (median 2.4) despite the fact that the range was 0–8 years. Numbers of patients with 6-year survival data were: 153 best cemented, 212 other cemented, 212 best hybrid, 244 other hybrid, 107 best cementless, 381 other cementless, 1,573 best resurfacing, and 2,223 other resurfacing. Resurfacing procedures were more likely to have been performed in younger, fitter patients (Table 2). The majority of smaller (< 48-mm head size) resurfacing procedures ("other")

Table 3. Patient demographics for the National Joint Registry-PROMs [a] linked population studied, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		
	Best	Others	Best	Others	Best	Others	Best	Others	p-value [b]
Number (%)	111 (6)	52 (3)	118 (6)	213 (11)	159 (8)	1,117 (56)	187 (9)	57 (3)	
Age, median (range)	56 (37–60)	57 (48–60)	54 (30–60)	56 (28–60)	57 (39–60)	54 (25–60)	52 (32–60)	54 (35–60)	< 0.001
Females, n (%)	70 (63)	37 (72)	73 (62)	147 (69)	82 (52)	671 (60)	8 (4)	41 (72)	< 0.001
ASA [c]									
1	34 (31)	11 (21)	44 (37)	75 (35)	40 (25)	377 (34)	84 (45)	24 (42)	< 0.001
2	63 (57)	33 (64)	67 (57)	123 (58)	109 (69)	687 (62)	101 (54)	31 (54)	
3+	14 (13)	8 (15)	7 (6)	15 (7)	10 (6)	53 (5)	2 (1)	2 (4)	
BMI, mean (SD)	29 (6)	30 (6)	30 (5)	30 (6)	31 (5)	30 (6)	29 (4)	29 (6)	
(range) [d]	(19–59)	(19–49)	(20–47)	(18–50)	(17–46)	(18–65)	(18–45)	(19–43)	0.7

[a] PROMs: patient-reported outcome measures;
[b] Statistical notes: 1-way ANOVA was used for normally distributed data, Kruskal-Wallis test for non-normally distributed data, and chi-squared test for proportions;
[c] ASA: American Society of Anaesthesiologists;
[d] BMI: body mass index, kg/m^2 (data based on 1,293 procedures (64%)).

were performed in women (78%). Across the total hip replacement groups, patient variables were clinically very similar, although the "best" hybrid procedures were more likely to be performed in younger, fitter patients. The entire NJR population demographics profile was qualitatively similar to that of the smaller NJR-PROMs linked population (Tables 2 and 3).

Statistics

Implants were analyzed based on previously stratified revision risk; thus, we compared 8 groups (the optimal implant options were defined as "best", while the remaining options were grouped as "other" for each of the 4 types of replacement) (Figure). Differences in baseline characteristics across the groups would be a source of confounding in any comparative analysis. Therefore, to test the hypothesis that there were no differences between groups, we employed the following tests: 1-way analysis of variance (ANOVA, normally distributed continuous data variables), the Kruskal-Wallis test (non-normally distributed continuous data variables), and the chi-squared test (categorical data variables).

Bivariable analysis was performed initially to identify variables potentially influencing each outcome, based on statistical rejection criteria of $p > 0.1$; these variables were then included in the multivariable models.

We used competing-risks regression models (CRR) to test adjusted differences in survival across the implant groups, where patient death prior to either revision or censoring was the competing risk. In contrast to Cox proportional hazards (CPH) models, death is treated as a permanent condition that prevents future revision from occurring (and so is a competing event to revision) rather than merely a censoring event. CPH analysis tends to overestimate the risk of revision, which progressively worsens over time, particularly when the risk of death is higher than the risk of revision (for example, in elderly patients). Although it could be argued that a young population is not particularly susceptible to this inaccuracy at medium-term follow-up, we felt this approach was the most suitable. We used the 'stcrreg' command in STATA to implement the competing-risks regression based on the proportional sub-hazards model of Fine and Gray (1999). CRR is semi-parametric in that the baseline sub-hazard of the event of interest is left unspecified, and the effects of covariates are assumed to be proportional. Although it is possible to allow the same covariate to have a different effect on the main risk and the competing risk, we felt that this was unnecessary given that the risk of death and revision was unlikely to vary greatly across the age range analyzed. Survival times for patients who had not undergone revision or had not died were censored at the study census date (December 31, 2010).

We used analysis of covariance (ANCOVA) for testing of differences in OHS and EQ5D index change scores. Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Preoperative scores were included within all models, as recommended by the designers of the OHS (Murray et al. 2007).

The reliability of the multivariable statistical models was explored in a number of ways: covariates found not to be statistically significant were excluded from the model, based on statistical entry criteria ($p < 0.1$); the same covariates were fitted forward and reverse stepwise manually to ensure that findings were not qualitatively affected in the final model, with any inconsistency reported. We then re-evaluated the final models as a directly entered model (non-stepwise), assessed by exploring 2-way interactions between covariates and, for the survival analysis, assessed for the assumption of constant proportionality over time. Clustering of data may have an adverse effect on the results of one particular group, especially in registry studies where comparison groups are relatively small. For example, if a poorly performing hospital or surgeon contributes disproportionally to one group, the results of that group may be incorrectly poor. We did not

Table 4. Patient-reported outcomes for populations studied, by implant group

	Cemented		Hybrid		Cementless		Resurfacing		
	Best	Others	Best	Others	Best	Others	Best	Others	p-value [a]
Number (%)	111 (6)	52 (3)	118 (6)	213 (11)	159 (8)	1,117 (56)	187 (9)	57 (3)	
Oxford hip scores									
Preoperative									
mean (SD)	19 (9)	16 (7)	19 (8)	18 (8)	17 (7)	18 (8)	22 (8)	19 (8)	0.02
range	3–40	3–33	4–37	1–36	2–39	2–46	4–43	4–37	0.02
Postoperative,									
median (range)	41 (0–48)	40 (4–48)	43 (8–48)	43 (7–48)	42 (4–48)	43 (2–48)	46 (2–48)	43 (5–48)	< 0.001
EQ5D index									
Preoperative,									
mean (SD)	0.40 (0.30)	0.28 (0.32)	0.41 (0.32)	0.35 (0.33)	0.32 (0.31)	0.35 (0.32)	0.47 (0.31)	0.38 (0.34)	0.3
range	-0.24–0.85	-0.18–0.80	-0.24–0.80	-0.59–0.81	-0.35–0.73	-0.25–1	-0.24–1	-0.24–0.81	
Postoperative,									
median	0.81	0.73	0.81	0.82	0.80	0.82	1.00	0.81	< 0.001
range	-0.59–1	-0.02–1	-0.24–1	-0.35–1	-0.07–1	-0.24–1	-0.35–1	-0.24–1	< 0.001
Satisfaction (n, %)									
Good to excellent	99 (89)	44 (85)	110 (93)	198 (93)	150 (94)	1,033 (93)	170 (91)	50 (88)	0.3
Poor/fair	12 (11)	8 (15)	8 (7)	15 (7)	9 (6)	84 (8)	17 (9)	7 (12)	
Success (n, %)									
Better	105 (95)	47 (90)	113 (96)	207 (98)	155 (98)	1,072 (96)	181 (97)	53 (93)	0.3
About the same									
or worse	6 (5)	5 (10)	5 (4)	6 (3)	4 (3)	45 (4)	6 (3)	4 (7)	
Time from op. to									
PROMs complete,									
mean days (SD)	213 (32)	219 (37)	211 (26)	210 (28)	210 (30)	210 (28)	272 (45)	269 (49)	< 0.001
range	188–343	186–329	186–315	183–332	187–350	183– 361	186–360	186–353	

PROMs: patient-reported outcome measures.
[a] Statistical notes: 1-way ANOVA was used for normally distributed data, Kruskal-Wallis test for non-normally distributed data, and chi-squared test for proportions.

adjust for clustering. However, previous registry analyses have found little difference in results when attempting this adjustment (Smith et al. 2012b).

The results of survival analysis are presented as hazard ratios (HRs). Statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values separately for each of the implant groups. The p-values refer to statistical tests of the differences between the reference implant (cemented Exeter with a Contemporary flanged PE cup and 28- or 32-mm metal or ceramic head) and the 7 others. Significance was assumed at $p < 0.05$. Estimates are reported with 95% confidence intervals (CIs). All models were fitted using STATA software version 12. For the purpose of identification, parameter estimates with probabilities < 5% were considered significant, with further consideration of the clinical importance of magnitude of estimates.

Costs for specific implant combinations were provided by NHS Wales (all 7 units within Wales) and an NHS supply chain (buyers on behalf of 30 units within the English NHS). The highest and lowest prices paid for implants during 2012 were analyzed and a modal cost was provided for each of the implant components. These costs represent actual prices paid, after discounts but excluding value-added tax (VAT) at 20% and the NJR levy fee (£20, which is included in the cost of each implant). Costs presented also include acetabular screws (for cementless cup fixation) when used, the commonest cement used for each implant type, femoral cement restrictors, and all the equipment required to mix and perform pressurized cementation. For the purposes of this analysis, we assumed that theater use and length of stay were similar for all types of replacement; thus, differences between implant combination costs approximate to differences in NHS costs. £1 is equivalent to 1.22 and to $1.70 (correct as of May 7, 2014).

Explicit patient consent was taken for both the NJR and PROMs data collection. Further ethics approval is not required for registry studies in the UK.

Results

Patient-reported outcomes were available for 2014 procedures (8.2%), comprising cemented (163, 11% of NJR data), hybrid (331, 10%), cementless (1,276, 13%), and resurfacing (244, 2.3%) replacements (Table 4). Preoperative OHS and EQ5D indices were similar across implant groups, except the large-head resurfacing group ("best") where patients had a 3.3 to 6.0 times higher preoperative OHS. Postoperative OHS values were generally lower in the cemented group, but postoperative EQ5D indices were similar in all groups. There were no statistically significant differences between groups regarding those who reported their satisfaction with the procedure and those who reported that the operation had been successful (Table 4).

Table 5. Risk of revision following hip replacement in patients aged < 60 years of age (simple and multivariable analyses)

	Simple			Multivariable		
	HR	95% CI	p-value	HR	95% CI	p-value
Females (n = 11,622)						
Best cemented (n = 548)	1			1		
Other cemented (n = 412)	3.06	0.81–11.5	0.1	3.12	0.83–11.8	0.1
Best hybrid (n = 642)	1.42	0.34–5.94	0.6	1.39	0.33–5.78	0.7
Other hybrid (n = 1,340)	2.87	0.85–9.65	0.1	2.78	0.83–9.35	0.1
Best cementless (n = 454)	1.47	0.30–7.24	0.6	1.50	0.30–7.38	0.6
Other cementless (n = 4,880)	3.45	1.10–10.9	0.03	3.35	1.06–10.6	0.04
Best resurfacing (n = 432)	5.12	1.50–17.5	0.009	4.95	1.45–16.9	0.01
Other resurfacing (n = 2,914)	6.57	2.09–20.6	0.001	6.36	2.02–30.0	0.002
Males (n = 13,087)						
Best cemented (n = 337)	1			1		
Other cemented (n = 255)	0.78	0.17–3.46	0.7	0.77	0.17–3.45	0.7
Best hybrid (n = 498)	0.48	0.11–2.16	0.3	0.48	0.11–2.16	0.3
Other hybrid (n = 758)	1.40	0.45–4.35	0.6	1.34	0.43–4.17	0.6
Best cementless (n = 466)	0.62	0.14–2.79	0.5	0.62	0.14–2.78	0.5
Other cementless (n = 3,717)	1.51	0.55–4.18	0.4	1.46	0.53–4.05	0.4
Best resurfacing (n = 6,247)	1.01	0.37–2.76	1.0	1.02	0.37–2.78	1.0
Other resurfacing (n = 809)	2.08	0.72–6.00	0.2	2.06	0.71–5.97	0.2

Table 6. Patient-reported outcome change scores following hip replacement in female patients < 60 years of age (simple and multivariable analyses)

	Simple			Multivariable		
	Value	95% CI	p-value	Value	95% CI	p-value
Change in Oxford hip score (n = 1,129)						
Best cemented (n = 70)	18.0	15.6–20.4	Ref.	18.2	16.1–20.3	Ref.
Other cemented (n = 37)	22.2	18.8–25.5	0.051	21.7	18.8–24.6	0.052
Best hybrid (n = 73)	21.2	18.8–23.6	0.06	22.3	20.2–24.3	0.006
Other hybrid (n = 147)	22.2	20.5–23.9	0.006	21.9	20.4–23.3	0.005
Best cementless (n = 82)	23.1	20.8–25.3	0.003	21.3	19.4–23.3	0.03
Other cementless (n = 671)	22.1	21.3–22.9	0.002	22.2	21.6–22.9	< 0.001
Best resurfacing (n = 8)	29.4	22.2–36.5	0.003	26.6	20.2–33.0	0.01
Other resurfacing (n = 41)	22.0	18.8–25.2	0.05	21.0	18.1–24.0	0.1
Change in EQ5D index (n = 1,129)						
Best cemented (n = 70)	0.367	0.280–0.453	Ref.	0.407	0.347–0.466	Ref.
Other cemented (n = 37)	0.458	0.334–0.581	0.2	0.432	0.348–0.517	0.6
Best hybrid (n = 73)	0.462	0.375–0.548	0.1	0.486	0.428–0.545	0.06
Other hybrid (n = 147)	0.462	0.401–0.523	0.1	0.453	0.411–0.495	0.2
Best cementless (n = 82)	0.453	0.372–0.535	0.2	0.430	0.372–0.487	0.6
Other cementless (n = 671)	0.440	0.412–0.468	0.1	0.438	0.418–0.457	0.3
Best resurfacing (n = 8)	0.623	0.377–0.870	0.054	0.517	0.338–0.696	0.2
Other resurfacing (n = 41)	0.454	0.341–0.567	0.2	0.421	0.338–0.503	0.8

In women, revision was higher in "other" (hard-bearing or small-stem) cementless implants (HR = 3.4, CI: 1.1–11) and resurfacings ("best", large head: HR = 5.0, CI: 1.5–17; "other", small head: HR = 6.7, CI: 2–30) when compared to the reference (cemented) group. The "best" hybrid group (solid shell with a CoC or metal/ceramic on highly crosslinked PE) had similar implant survival (HR = 1.4, CI: 0.3–6) (Table 5). Greater improvements in OHS were seen in the hybrid groups ("best": 22, CI: 20–24; "other", multi-hole shells or standard PE liner: 22, CI: 20–24) and the cementless groups ("best", PE liners: 21, CI: 19–23; "other": 22, CI: 22–23) when compared with the "best" cemented (18, CI: 16–20). The "best" resurfacing procedures showed good results, but this was based on only 8 procedures (Table 6). EQ5D indices were similar in all groups.

In men, improvements in revision (Table 5) and PROMs were equivalent in all groups when compared to the reference (Table 7).

Tests for interaction (multiplicative) between covariates and for time-dependency were not statistically significant. Forward and reverse stepwise model construction led to the same final models. Body mass index (BMI) was selected as a variable within the competing-risks survival model for men. However, this approach excluded 63% of data. BMI was therefore excluded and the model was constructed with age and ASA group. The output from these models (simple and multivariable with either BMI or age and ASA group included) is shown in Table 8 (Supplementary data). Variables included in the statistical models, and their significance levels within the final models, are shown in Tables 9 and 10 (Supplementary data).

Implant cost data showed the standard cemented replacement in this analysis to be the cheapest (median and modal price: £928, with a range from £899 to £1,250). Resurfacing implants ranged from £1,662.01 to £2,472.34. A cementless 36-mm CoC implant cost the NHS between £2,064 and £3,551 (Table 11). Cost data were obtained from units across England and Wales.

Discussion

This large cohort study using medium-term stratified revision-risk NJR-PROMs linked data comparing types of hip replacement in patients below 60 years of age showed no advantage of resurfacing or cementless implants over standard cemented hip replacement in male patients. For women, functional

Table 7. Patient-reported outcome scores following hip replacement in male patients < 60 years of age (simple and multivariable analyses)

	Simple			Multivariable		
	Value	95% CI	p-value	Value	95% CI	p-value
Change in Oxford hip score (n = 885)						
Best cemented (n = 41)	18.4	15.4–21.4	Ref.	20.1	17.6–22.7	Ref.
Other cemented (n = 15)	17.9	12.9–22.9	0.8	17.9	13.7–22.1	0.4
Best hybrid (n = 45)	21.0	18.1–23.8	0.2	21.0	18.5–23.4	0.6
Other hybrid (n = 66)	21.6	19.2–24.0	0.1	20.8	18.8–22.8	0.7
Best cementless (n = 77)	20.4	18.2–22.6	0.3	19.8	17.9–21.6	0.8
Other cementless (n = 446)	20.9	19.9–21.7	0.1	20.3	19.6–21.1	0.9
Best resurfacing (n = 179)	19.7	18.3–21.2	0.5	20.8	19.5–22.1	0.6
Other resurfacing (n = 16)	18.4	13.6–23.3	1.0	20.0	15.8–24.2	1.0
Change in EQ5D index (n = 885)						
Best cemented (n = 41)	0.368	0.262–0.475	Ref.	0.392	0.318–0.467	Ref.
Other cemented (n = 15)	0.397	0.219–0.574	0.8	0.336	0.212–0.459	0.4
Best hybrid (n = 45)	0.255	0.157–0.354	0.1	0.325	0.255–0.394	0.2
Other hybrid (n = 66)	0.419	0.340–0.498	0.5	0.413	0.357–0.469	0.7
Best cementless (n = 77)	0.395	0.320–0.470	0.7	0.388	0.335–0.442	0.9
Other cementless (n = 446)	0.410	0.379–0.441	0.5	0.396	0.374–0.417	0.9
Best resurfacing (n = 179)	0.370	0.321–0.419	1.0	0.398	0.361–0.435	0.9
Other resurfacing (n = 16)	0.307	0.142–0.472	0.5	0.357	0.238–0.476	0.6

Table 11. Cost of specific hip implants (NHS costs 2011/12). The figures are based on actual implant costs paid to manufacturers by NHS Wales (7 Trusts) and NHS supply chain (30 Trusts in England), excluding value-added tax (VAT, 20%) and NJR levy costs (£20). £1 is equivalent to 1.22 and to $1.70 (correct as of May 7, 2014)

	Costs (£)		
	Modal	Low	High
Best cemented			
Exeter stem / 28-mm metallic head / flanged Contemporary cup [a]	928	899	1,250
Exeter stem / 32-mm ceramic head / flanged Contemporary cup [a]	1,343	1,183	1,580
Other cemented			
Exeter stem / 26-mm metallic head / hooded Contemporary cup [a]	928	899	1,250
Best hybrid			
Exeter stem / 32-mm metallic head / highly crosslinked polyethylene liner / solid-back Trident shell [a]	1,465	1,440	2,092
Exeter stem / 36-mm ceramic head / ceramic liner / solid-back Trident shell [a]	1,780	1,780	2,619
Other hybrid			
Exeter stem / 28-mm metallic head / conventional polyethylene liner / multi-hole Trident shell [a]	1,405	1,405	2,040
Best cementless			
Corail stem / 28-mm metallic head / conventional polyethylene liner / Pinnacle shell	1,587	1,587	2,722
Other cementless			
Corail stem / 36-mm metallic head / metallic liner / Pinnacle shell	1,791	1,703	2,924
Corail stem / 36-mm ceramic head / ceramic liner / Pinnacle shell	2,210	2,064	3,551
Best resurfacing			
Birmingham Hip Resurfacing using head size ≥ 48 mm [a]	1,944	1,662	2,472
Other resurfacing			
Birmingham Hip Resurfacing using head size < 48 mm [a]	1,944	1,662	2,472

[a] Including cement (cemented implants, 4 mixes of Heraeus Palacos R+G at £26.75 per mix; hybrid, 2 mixes of Palacos R+G; resurfacing, 1 mix of Stryker Antibiotic Simplex at £27.72), mixing set (Optivac £44.29, 2 sets for fully cemented), cement restrictor (Hardinge £22.00, not resurfacing). For multi-hole Trident shells, costs of 2 Stryker screws are included (£40 per screw). For Pinnacle shells, the cost of 2 screws for half of the implants is included (£54.05 per screw).
Note: Exeter stems 44/5, 44/6, and all 50 offsets increase cost by £614.27 (< 5% Exeter stems) (Jameson et al. 2012).

outcome was better with hybrid and cementless implants. Although revision risk was similar to that of cemented for the best cementless and hybrid implants, the risk was 3.5 times higher with the commonly used hard-bearing cementless implants. Material costs, approximating to NHS costs, were lowest with a standard cemented hip replacement and highest with hard-bearing cementless implants. These findings are important for clinicians and healthcare providers to determine the most suitable and cost-effective hip implants for young patients with osteoarthritis.

We have not found any previous analyses describing stratified implant revision-risk data, patient-reported outcomes, and material costs for specific implants in young patients requiring hip replacement. However, the findings may have some limitations. As with all database analyses, the study design was observational and therefore vulnerable to omitted variables, which may have confounded our findings. Potentially important variables such as race, socioeconomic status, patient experiences, and levels of perioperative pain were unavailable, yet they are known to influence certain patient outcomes such as satisfaction (Hamilton et al. 2013). In addition, important clinical information such as radiological data was not available.

A decision about a particular patient's surgical treatment is based on patient-related, surgical, and unit factors, and is not randomly determined. Patients who receive cementless or resurfacing implants may be more aware of implant choice and they may be more highly educated. Although statistical adjustment can help, a large proportion of variation within the models remains unexplained. There is also the possibility of over-adjustment, which may influence the precision of the results. However, despite the inherent limitations of statistical adjustment in cohort studies, the variables we selected in the models appear logical. Some surgical factors such as volume, grade of surgeon, and approach have been included in analyses, but analysis of the effects of data clustering (in terms of surgeon and unit) was not possible.

As a result of limiting the study to specific brands and stratifying implant options, the numbers in some groups were low and there may have been bias. The PROMs feasibility pilot indicated that the minimum numbers of PROMs required within each comparison group were in the order of 150 for identification of meaningful differences (Browne et al. 2007). The analyses were possibly underpowered to detect differences between implants, and this might—in isolation—explain the lack of significant findings in men. However, similar numbers gave clearly significant findings in women. Qualitatively, this is unlikely to have occurred by chance given the consistent interaction with gender, although this analysis could usefully be replicated in other future database analyses to correlate theses findings.

The NJR currently only covers medium-term survival; many procedures have short follow-up. Polyethylene wear-associated revision may occur in greater numbers beyond 10 years, and hard bearings may ultimately have greater longevity, but there is currently no evidence to support this. A systematic review of worldwide registry and cohort study data failed to show any benefit of other bearings over metal-on-PE (MoP) bearings (Sedrakyan et al. 2011). Furthermore, Australian joint registry data suggest that metal on highly crosslinked PE has the lowest 10-year revision risk (Australian National-Joint Registry 2012) and dislocation rates are higher with CoC bearings (Sexton et al. 2009). In England and Wales, the use of MoM has declined dramatically over the last 5 years due to concerns about metal wear debris reactions (Medicines and Healthcare products Regulatory Agency 2011, England and Wales National Joint Registry 2012).

The validity of NJR data has been questioned, with loss of data or under-reporting of revision numbers a possibility, although this should affect each group equally. The PROMs data are recorded at 6 months only. This may be too early for determination of the success of a joint replacement. However, the Oxford group has published data showing that PROMs improve to 12 months, with the greatest improvement in the first 3 months. No improvements were seen between 12 months and 5 years, suggesting that the results of our short-term study are a reliable indication of longer-term outcome (Andrew et al. 2008, Judge et al. 2013). There may be selection bias in the PROMs data, as response rates may be differ in patients of different ages, different socioeconomic groups, and different races. However, we could not assess whether there was any bias in completion and return of PROMs, as no details were available regarding the number of questionnaires sent out or returned. The point at which a patient undergoes a hip procedure may also be different (reflecting the need to adjust for preoperative scores) depending on age, expectations, and occupation. Patients undergoing resurfacing tended to have higher preoperative scores. This may in turn limit their ability to improve after joint replacement, due to the ceiling effect in the OHS and EQ5D index.

The discrepancy between the ratio of NJR-PROMS linked episodes to total NJR episodes across implants (1:10 for cemented vs. 1:50 for resurfacing) is difficult to explain, but may be due to a generally younger resurfacing population, or because there was a higher proportion of resurfacings in the private sector (for which PROMs are not available). This may limit the conclusions that can be drawn from the resurfacing data.

Pennington et al. (2013) recently published a paper on cost effectiveness using NJR, PROMs, and implant cost data, which compared types of hip replacement. Hybrid implants were found to have the most cost-effective profile. As in our study, the authors found that cementless implants offered no net advantage while being more costly. However, there were a number of limitations, which may have influenced the reliability of their results: resurfacings were not included; all brands within each group were analyzed together, with no adjustment for the heterogeneity of implants; and analyses were limited to MoP bearings only.

Although hybrid implants appeared to offer a balance between implant survival and functional benefit for young women in the present study, it must be stressed that this requires adequate fixation with a solid acetabular shell. Analysis of the hybrid data previously demonstrated that multi-hole shell (with screw fixation) had poorer survival (Jameson et al. 2013b). The risk of revision in women with this combination was 3 times greater than for the best cemented implant in our data, which approached significance ($p = 0.1$). While a cemented procedure will have reproducible results, the suc-

cess of a cementless cup is reliant on adequacy of the press-fit. In addition, there is no obvious explanation for the difference in the effect of implant type on men and women in our study. It is reasonable to suggest, therefore, that a surgeon using cemented implants in the majority of patients could also use the same implants in young women with acceptable and reproducible results.

Despite the poor results of cemented implants during the 1980s, more contemporary analyses have shown equivalent or better survival compared to cementless implants (Busch et al. 2010, Pakvis et al. 2011, Schmitz et al. 2013, Toossi et al. 2013), supporting the encouraging results of registry data. The findings from the earlier studies may have been influenced by previous generations of implants and poor cementation techniques. Data from our previous study suggest that the Exeter Contemporary system using the flanged cup design and a head size of 28 mm or greater had good and reproducible results in all patients, from all surgeons across England and Wales (Jameson et al. 2012a). Moreover, no additional survival benefit was seen when 32-mm and/or ceramic heads were used in place of 28-mm metal heads. In addition, head size and bearing type appear to have no influence on PROMs and complications across a range of implant options (Jameson et al. 2014).

Although our study found no benefit of a resurfacing procedure in young men over a standard cemented replacement (despite inclusion of only the best-performing brand and use of large femoral head sizes), there may be long-term implant survival benefit. However, it is known that high-volume surgeons have lower revision rates in complex procedures (Jameson et al. 2012b, Baker et al. 2013), and there remain concerns regarding the local and systemic complications associated with MoM bearings (Haddad et al. 2011); the regulatory body in the United Kingdom currently stipulates that all MoM implants should be reviewed on an annual basis (Medicines and Healthcare products Regulatory Agency 2011). In addition, Costa et al. (2012) found no evidence of benefit at 12 months when patients were randomized to resurfacing or hip replacement. A cost analysis performed on the same cohort found that resurfacing offered only very short-term efficiency benefits over THA in a selected patient group (Edlin et al. 2012). A dramatic fall in the use of resurfacings, with clustered use predominantly in the young male group during 2011, would suggest that surgeons in England and Wales are responding to the evidence (England and Wales National Joint Registry 2012).

Cementless implants with mid/large stems and MoP or CoP performed well in young women with equivalent survival and better improvement in OHS compared to cemented implants. However, this group represented only 8.5% of cementless implants used in women (454 of 5,334). Moreover, 39% of females required a small stem size (7,932 of 20,166) in a previous analysis (Jameson et al. 2013a) and implant failure increased with higher BMI, suggesting that the group of women that could benefit is small. Proponents of fully cementless procedures argue that operative time is also shorter, increasing patient turnover and theater use. However, there is no good evidence of this. Such an efficiency benefit is relevant only when implants offer equivalent clinical benefit and material costs, a finding that is not supported by our analysis. The use of cement on the femoral side has many advantages that outweigh the disadvantage of a slightly longer operating time (Murray 2011).

We found no advantage in the use of fully cementless or resurfacing implants in young patients when compared with a standard cemented hip replacement. For young women, hybrid implants that employ adequate press-fit acetabular fixation and either highly crosslinked PE or ceramic bearings may provide the best balance of early improvement in outcome, revision risk, and cost.

Supplementary data

Tables 1 and 8–10 are available at Acta's website (www.actaorthop.org), identification number 6590.

SJ, MR, and MP developed the concept. SJ analyzed the data with assistance from JM and PB. SJ wrote the first draft of the paper, with contributions and editing from PB, JM, PG, DD, and MR.

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Andrew J G, Palan J, Kurup H V, Gibson P, Murray D W, Beard D J. Obesity in total hip replacement. J Bone Joint Surg (Br) 2008; 90 (4): 424-9.

Australian National Joint Registry. "Australian Orthopaedic Association, National Joint Replacement Register." 2010. Retrieved 13th June 2011, from http://www.dmac.adelaide.edu.au/aoanjrr/index.jsp

Australian National Joint Registry. "Australian National Joint Replacement Registry Annual Report 2012." 2012. from https://aoanjrr.dmac.adelaide.edu.au/documents/10180/60142/Annual%20Report%202012?version=1.3&t=1361226543157.

Baker P, Jameson S, Critchley R, Reed M, Gregg P, Deehan D. Center and surgeon volume influence the revision rate following unicondylar knee replacement: an analysis of 23,400 medial cemented unicondylar knee replacements. J Bone Joint Surg (Am) 2013; 95 (8): 702-9.

Browne J, Jamieson L, Lewsey J. "Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health, 2007." 2007. Retrieved 29/08/2012, from http:// www.lshtm.ac.uk/php/hsrp/research/proms_report_12_dec_07.pdf.

Busch V, Klarenbeek R, Slooff T, Schreurs B W, Gardeniers J. Cemented hip designs are a reasonable option in young patients. Clin Orthop 2010; (468) (12): 3214-20.

Chandler H P, Reineck F T, Wixson R L, McCarthy J C. Total hip replacement in patients younger than thirty years old. A five-year follow-up study. J Bone Joint Surg (Am) 1981; 63 (9): 1426-34.

Collis D K. Cemented total hip replacement in patients who are less than fifty years old. J Bone Joint Surg (Am) 1984; 66 (3): 353-9.

Costa M L, Achten J, Parsons N R, Edlin R P, Foguet P, Prakash U, Griffin D R. Total hip arthroplasty versus resurfacing arthroplasty in the treatment of patients with arthritis of the hip joint: single centre, parallel group, assessor blinded, randomised controlled trial. BMJ 2012; 344 e2147.

Cuckler J M, Moore K D, Lombardi A V, Jr., McPherson E, Emerson R. Large versus small femoral heads in metal-on-metal total hip arthroplasty. J Arthroplasty (Suppl 3) 2004; 19 (8): 41-4.

Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg (Br) 1996; 78 (2): 185-90.

Delaunay C P, Bonnomet F, Clavert P, Laffargue P, Migaud H. THA using metal-on-metal articulation in active patients younger than 50 years. Clin Orthop 2008; (466) (2): 340-6.

Dorr L D, Takei G K, Conaty J P. Total hip arthroplasties in patients less than forty-five years old. J Bone Joint Surg (Am) 1983; 65 (4): 474-9.

Edlin R, Tubeuf S, Achten J, Parsons N, Costa M. Cost-effectiveness of total hip arthroplasty versus resurfacing arthroplasty: economic evaluation alongside a clinical trial. BMJ Open 2012; 2 (5): e001162.

England and Wales National Joint Registry. "National Joint Registry for England and Wales 9th Annual Report." (2012). from http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf.

Fine J, Gray R. A proportional hazards model for the subdistribution of a competing risk. J Am Stat Assoc 1999; 94: 496-509.

Finnish National Arthoplasty Registry. "Annual Report 2006. Finnish National Arthroplasty Register." 2006. from http://www.nam.fi/english/publications.

group E. "EuroQol (EQ5D Score)." 2009. Retrieved 29/08/2012, from http://www.euroqol.org/.

Haddad F S, Thakrar R R, Hart A J, Skinner J A, Nargol A V, Nolan J F, Gill H S, Murray D W, Blom A W, Case C P. Metal-on-metal bearings: the evidence so far. J Bone Joint Surg (Br) 2011; 93 (5): 572-9.

Hamilton D F, Lane J V, Gaston P, Patton J T, Macdonald D, Simpson A H, Howie C R. What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. BMJ Open 2013; 3 (4): e002525.

Jameson S S, Baker P N, Mason J, Gregg P J, Brewster N, Deehan D J, Reed M R. The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements: A retrospective cohort study of medium-term data from a National Joint Registry. J Bone Joint Surg (Br) 2012a; 94 (12): 1611-7.

Jameson S S, Baker P N, Mason J, Porter M L, Deehan D J, Reed M R. Independent predictors of revision following metal-on-metal hip resurfacing: a retrospective cohort study using National Joint Registry data. J Bone Joint Surg (Br) 2012b; 94 (6): 746-54.

Jameson S S, Baker P N, Mason J M, Rymaszewska M, Gregg P J, Deehan D J, Reed M R. Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements. Bone Joint J 2013a; 95-B(6): 747-57.

Jameson S S, Mason J M, Baker P N, Jettoo P, Deehan D J, Reed M R. Factors influencing revision risk following 15 740 single-brand hybrid hip arthroplasties: A cohort study from a National Joint Registry. J Arthroplasty 2013b; 28(7): 1152-9.

Jameson S S, Baker P N, Mason J M, Gregg P J, Deehan D J, Reed M R. No functional benefit of larger femoral heads and alternative bearings in primary hip replacement: A cohort study using linked National Joint Registry and Patient Reported Outcome Measures (PROMs) data. Acta Orthop 2014 [Epub ahead of print]

Judge A, Arden N K, Batra R N, Thomas G, Beard D, Javaid M K, Cooper C, Murray D. The association of patient characteristics and surgical variables on symptoms of pain and function over 5 years following primary hip-replacement surgery: a prospective cohort study. BMJ Open 2013; 3 (3): e002453.

Lord G A, Hardy J R, Kummer F J. An uncemented total hip replacement: experimental study and review of 300 madreporique arthroplasties. Clin Orthop 1979; (141): 2-16.

Medicines and Healthcare products Regulatory Agency. "Medical Device Alert: All metal-on-metal (MoM) hip replacements (MDA/2012/008)." 2011. Retrieved 21/03/2012, from http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON143782.

Murray D W. Cemented femoral fixation: the North Atlantic divide. Orthopedics 2011; 34 (9): e462-3.

Murray D W, Fitzpatrick R, Rogers K, Pandit H, Beard D J, Carr A J, Dawson J. The use of the Oxford hip and knee scores. J Bone Joint Surg (Br) 2007; 89 (8): 1010-4.

New Zealand National Joint Registry. "Annual Report 2008, 8 year report. New Zealand National Joint Registry." 2008. Retrieved 23/03/2012, from http://www.cdhb.govt.nz/njr/reports/A2D65CA3.pdf.

Norwegian Arthroplasty Registry. "Annual Report 2008. Norwegian Arthroplasty Register." 2008. Retrieved 23/03/2012, from http://www.haukeland.no/nrl/eng/default.htm.

Pakvis D, van Hellemondt G, de Visser E, Jacobs W, Spruit M. Is there evidence for a superior method of socket fixation in hip arthroplasty? A systematic review. Int Orthop 2011; 35 (8): 1109-18.

Pennington M, Grieve R, Sekhon J S, Gregg P, Black N, van der Meulen J H. Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis. BMJ 2013; 346: f1026.

Ranawat C S, Atkinson R E, Salvati E A, Wilson P D, Jr. Conventional total hip arthroplasty for degenerative joint disease in patients between the ages of forty and sixty years. J Bone Joint Surg (Am) 1984; 66 (5): 745-52.

Schmitz M W, Busch V J, Gardeniers J W, Hendriks J C, Veth R P, Schreurs B W. Long-term results of cemented total hip arthroplasty in patients younger than 30 years and the outcome of subsequent revisions. BMC Musculoskelet Disord 2013; 14: 37.

Sedel L, Kerboull L, Christel P, Meunier A, Witvoet J. Alumina-on-alumina hip replacement. Results and survivorship in young patients. J Bone Joint Surg (Br) 1990; 72 (4): 658-63.

Sedrakyan A, Normand S L, Dabic S, Jacobs S, Graves S, Marinac-Dabic D. Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. BMJ 2011; 343: d7434.

Sexton S A, Walter W L, Jackson M P, De Steiger R, Stanford T. Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg (Br) 2009; 91 (11): 1448-53.

Sharp D J, Porter K M. The Charnley total hip arthroplasty in patients under age 40. Clin Orthop 1985; (201): 51-6.

Smith A J, Dieppe P, Howard P W, Blom A W. Failure rates of metal-on-metal hip resurfacings: analysis of data from the National Joint Registry for England and Wales. Lancet 2012a; 380 (9855): 1759-66.

Smith A J, Dieppe P, Vernon K, Porter M, Blom A W. Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales. Lancet 2012b; 379(9822): 1199-204.

Spencer R F. Evolution in hip resurfacing design and contemporary experience with an uncemented device. J Bone Joint Surg (Am) (Suppl 2) 2011; 93: 84-8.

Swedish Hip Registry. "Annual report 2010. Swedish Hip Registry." 2010. from http://www.shpr.se/Libraries/Documents/AnnualReport-2010-2-eng.sflb.ashx.

Toossi N, Adeli B, Timperley A J, Haddad F S, Maltenfort M, Parvizi J. Acetabular components in total hip arthroplasty: is there evidence that cementless fixation is better? J Bone Joint Surg (Am) 2013; 95 (2): 168-74.

PLOS ONE

RESEARCH ARTICLE

Implant Optimisation for Primary Hip Replacement in Patients over 60 Years with Osteoarthritis: A Cohort Study of Clinical Outcomes and Implant Costs Using Data from England and Wales

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Abstract

Background

Hip replacement is one of the most commonly performed surgical procedures worldwide; hundreds of implant configurations provide options for femoral head size, joint surface material and fixation method with dramatically varying costs. Robust comparative evidence to inform the choice of implant is needed. This retrospective cohort study uses linked national databases from England and Wales to determine the optimal type of replacement for patients over 60 years undergoing hip replacement for osteoarthritis.

Methods and Findings

Implants included were the commonest brand from each of the four types of replacement (cemented, cementless, hybrid and resurfacing); the reference prosthesis was the cemented hip procedure. Patient reported outcome scores (PROMs), costs and risk of repeat (revision) surgery were examined. Multivariable analyses included analysis of covariance to assess improvement in PROMs (Oxford hip score, OHS, and EQ5D index) (9159 linked episodes) and competing risks modelling of implant survival (79,775 procedures). Cost of implants and ancillary equipment were obtained from National Health Service procurement data.

Results

EQ5D score improvements (at 6 months) were similar for all hip replacement types. In females, revision risk was significantly higher in cementless hip prostheses (hazard ratio,

levy is set by the NJR Steering Committee. The NJR Steering Committee is responsible for data collection. This work was funded by a fellowship from the National Joint Registry.

Competing Interests: All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: The authors have conformed to the NJR's standard protocol for data access and publication. The views expressed represent those of the authors and do not necessarily reflect those of the National Joint Register Steering committee or the Health Quality Improvement Partnership (HQIP) who do not vouch for how the information is presented. No financial relationships with any organisations that might have an interest in the submitted work in the previous three years. No other relationships or activities that could appear to have influenced the submitted work. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. Following analysis and presentation of this data at national meetings, Stryker funded travel to four Stryker sponsored hip meetings where this data was presented.

HR = 2.22, p<0.001), when compared to the reference hip. Although improvement in OHS was statistically higher (22.1 versus 20.5, p<0.001) for cementless implants, this small difference is unlikely to be clinically important. In males, revision risk was significantly higher in cementless (HR = 1.95, p = 0.003) and resurfacing implants, HR = 3.46, p<0.001), with no differences in OHS. Material costs were lowest with the reference implant (cemented, range £1103 to £1524) and highest with cementless implants (£1928 to £4285).

Limitations include the design of the study, which is intrinsically vulnerable to omitted variables, a paucity of long-term implant survival data (reflecting the duration of data collection), the possibility of revision under-reporting, response bias within PROMs data, and issues associated with current outcome scoring systems, which may not accurately reflect level of improvement in some patients.

Conclusions

Cement fixation, using a polyethylene cup and a standard sized head offers good outcomes, with the lowest risks and at the lowest costs. The most commonly used cementless and resurfacing implants were associated with higher risk of revision and were more costly, while perceptions of improved function and longevity were unsupported.

Introduction

Management of osteoarthritis (OA) of the hip is a significant global health burden. Hip replacement is an established and successful treatment of end-stage OA, with excellent quality of life improvement and cost-effectiveness [1,2]. Over 270,000 hip replacements are performed in the United States (US) annually, and almost 90,000 within the United Kingdom (UK) [3,4,5]. The national tariff for a hip replacement is £5280 in England. This equates to approximately £475million in annual UK healthcare costs. These costs are expected to triple over the next five years, whilst annual volume is expected to double within ten [6].

Cemented hip replacements (which utilise a polymer known as 'cement' to secure the implant in place) with a metal-on-polyethylene (MoP) articulating ('bearing') surface account for one third of all hip replacements implanted in England and Wales since 2003. These devices show consistently good implant survival in long-term cohort studies and worldwide joint replacement registries [3,6,7,8,9,10,11,12,13,14,15,16,17,18]. They utilise tried and tested technology, and are inexpensive. However, concerns of early loosening and implant failure during the 1980s [19,20,21,22,23] drove the development of cementless implants, which rely on press-fit stability and bone integration for fixation rather than cement [24]. Advances in engineering also led to a proliferation of implant options available within brands; larger, more anatomical femoral head sizes in an attempt to reduce dislocation risk, and 'hard' articulations, where highly engineered metal-on-metal (MoM) or ceramic-on-ceramic (CoC) bearings are employed in an effort to minimise long-term wear and subsequent failure [25,26,27]. Cementless implants now account for the majority of replacements in North America and Australia, and their use in England and Wales has recently surpassed cemented implants [3,28,29]. Resurfacing devices, which resurface the femoral head and preserve bone (rather than excising femoral head/neck and replacing with a ball and stem, as in standard hip replacement), provide near anatomically-sized components and were introduced in the 1990s with the aim of reducing dislocation risk, improving function and allowing an 'easier' revision if required [30]. These were

designed predominantly for younger patients, but surgeons widened their indications as good early results encouraged use in older patients. Although there is little data on implant costs in the literature, there is a logical perception that implants with modular components (providing numerous options), modern technologies and complex, highly engineered components are more costly. Despite this, thorough evaluation of the evidence for different types of hip replacement is absent from the literature.

Some patients with hip replacements will require a revision procedure to replace a failed or worn implant. The National Joint Registry (NJR) was established in 2003 to provide a record of hip replacements and any subsequent revisions performed in the pubic and private health systems in England and Wales. Patient Reported Outcomes Measures (PROMs) have been collected on hip replacement patients in the public system since 2008. Linkage of these national datasets allows the analysis of patient functional outcome following hip replacement and subsequent implant failure rates for specific implants. Taking the most commonly used cemented hip replacement as the reference implant for comparison, the objective of this study was to provide a summative evaluation of different implant types in order to determine the most cost-effective components for hip replacement, referencing patient reported outcomes and risk of implant revision. This study examines the eighty percent of all primary hip replacements that are performed in patients 60 years and over [3]. Younger patients (under 60 years is arbitrarily a reasonable threshold) may have differing demands of their prostheses, and as such have been analysed elsewhere [31].

Methods

Design

A retrospective cohort study design assessed prospectively collected patient-level PROMs and NJR data to compare outcomes and implant survival across different primary hip replacements, with supplementary material costs for specific implant combinations obtained through National Health Service (NHS) procurement.

Data

The single most commonly used brands of each type of hip replacement performed in England and Wales were chosen for the analysis, in order to control for brand heterogeneity within each type (the NJR annual report provides adequate analysis of the entire breadth of replacements available–our intention was to specifically analyse component options within brands, which would be impossible across all brands). Individual analyses of the same data on each individual hip replacement type have already defined component options within brand that confer the lowest revision risk (i.e. the longest survival) [32,33,34,35]. For this current analysis we stratified each hip replacement type based on these previously established component revision risks into 'optimal' component sets (with significantly lower revision risk) and 'sub-optimal' (all remaining component options) (**Table 1**).

All primary hip replacements performed using the specified implants on patients over 60 years and submitted to the NJR between 1st April 2003 and 31st December 2010 were initially included. Subsequently, exclusion criteria were employed as follows: all procedures with an indication other than OA; procedures with missing implant or patient data; and rarely used implant options [32,33,34,35].

The national PROMs project uses validated measures of hip-specific (Oxford hip score [OHS]) [36] and general health status outcomes (EuroQol [EQ-5D-3L]) [37] collected pre- and around six months post-operatively. By linking databases at the patient level, PROMs data can be combined with the corresponding demographic and operative details held in the NJR.

Table 1. Implants studied by type of hip replacement, with descriptions of optimal and sub-optimal component configurations.

Type	Brand combination	Manufacturer	Market share, by type (England & Wales)
Cemented	Exeter V40 stem	Stryker Orthopaedics, Mahwah, New Jersey, United States	23%
	Contemporary polyethylene cup		
	Optimal component set:		
	Any Exeter stem		
	Flanged version of Contemporary cup		
	28mm or 32mm femoral head (metal or ceramic*)		
	Sub-optimal component set:		
	Small heads (<28mm)		
	Hooded version of Contemporary cup		
Cementless	Corail stem	DePuy Ltd, Leeds, United Kingdom	31%
	Pinnacle modular (shell and liner) cup		
	Optimal component set:		
	Medium/large Corail stem (size 11 or greater)		
	Pinnacle cup / polyethylene liner (metal or ceramic head*)		
	Sub-optimal component set:		
	Small Corail stems (<size 11)		
	Pinnacle metal and ceramic liners*		
Hybrid	Exeter V40 stem	Stryker Orthopaedics, Mahwah, New Jersey, United States	33%
	Trident modular (shell and liner) cup		
	Optimal component set:		
	Any Exeter stem		
	Solid shell Trident cup		
	Ceramic bearing or a XLPE liner (metal or ceramic head*)		
	Sub-optimal component set:		
	Cluster hole Trident shell		
	Conventional polyethylene liner		
Resurfacing	Birmingham Hip Resurfacing (BHR)	Smith & Nephew, Memphis, Tennessee, United States	55%
	Optimal component set:		
	Components with head size of 48mm or greater		
	Sub-optimal component set:		
	Components with head size <48mm		

*grouped together as no significant benefit of options was identified, XLPE–highly cross-linked polyethylene

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The study population is summarised in Fig 1. The demographic, surgical and implant-related variables available for analysis are listed in S1 Table.

For this analysis PROMs of interest were improvements between the pre- and post-operative scores (the 'change scores') and self-reported readmission and reoperation in the post-operative period. Change scores, being approximately normally distributed, are analytically preferable to post-operative scores [38]. The OHS (scored 0 lowest to 48 highest) has previously been shown to be a reliable, valid and responsive outcome measure for patients with hip OA undergoing replacement surgery [39]. The EQ-5D index (scored 0 to 1, where 0 is no health [i.e. dead] and 1 is perfect health) is a measure of health status used for clinical and economic appraisal. It evaluates five different aspects of general health (mobility, self-care, usual activities, pain/ discomfort and anxiety/depression) that are scored and combined using

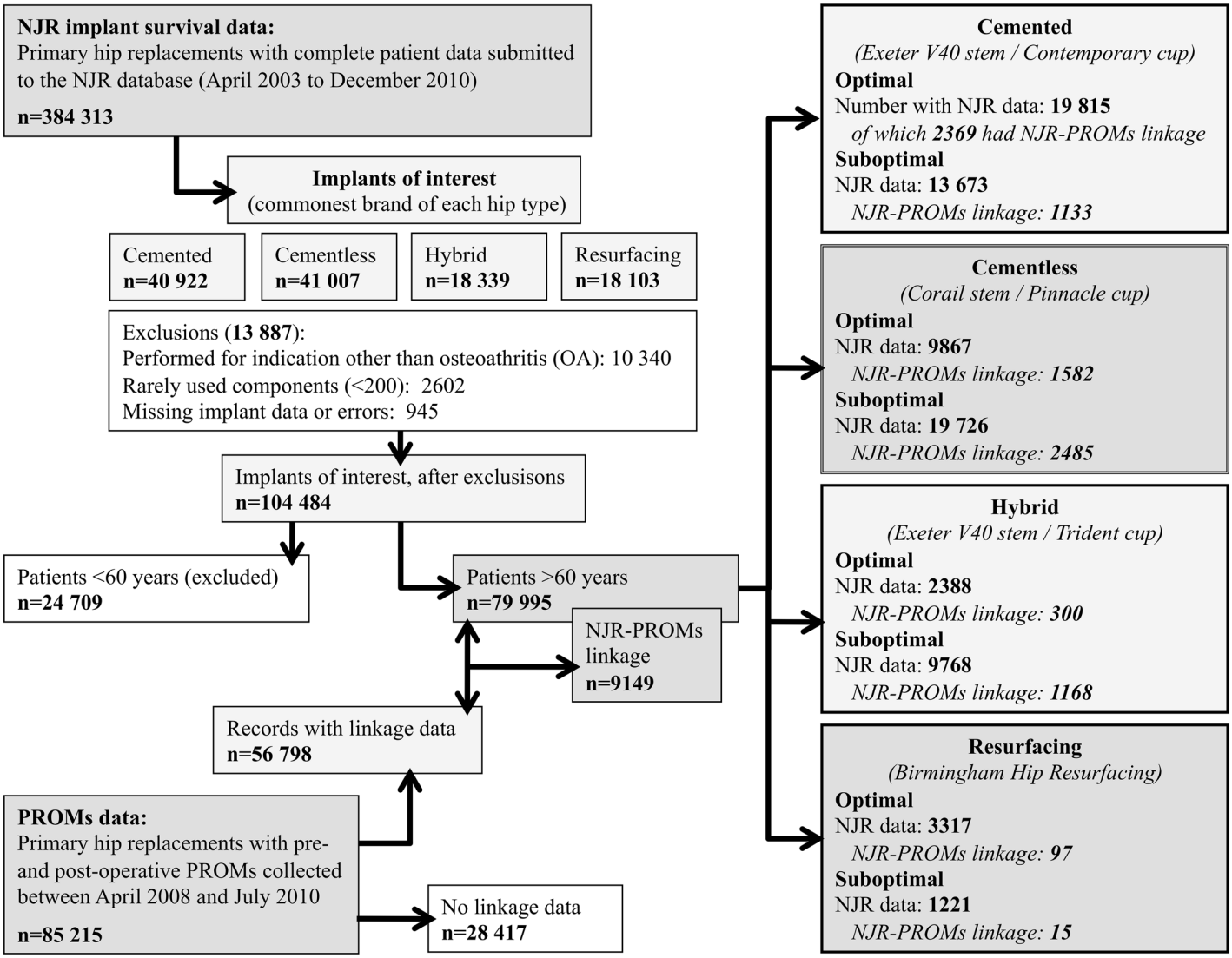

Fig 1. Flowchart describing inclusion criteria and study populations.

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population weightings to produce a single index value for health status [37]. In this context, readmission and reoperation are used as a crude surrogate marker for hip dislocation. Dislocation occurs when the femoral component disarticulates from within the acetabular component. This is an acute event that requires readmission and manipulation under anaesthesia to restore normal component positions. Unfortunately this data is not captured by the NJR, but may vary depending on head size and bearing material. Thus, to provide a summative evaluation, it is reasonable to include these measures, despite the limitations. Within the pre-operative PROMs questionnaire, patients are also asked about comorbidities, general health and self-reported disability. These can be used to adjust for differences in health status between patient groups.

Statistical Analysis

Implants were compared based on previously stratified revision risk within prosthesis types. Therefore, eight groups were compared (four 'optimal' groups and four 'sub-optimal' groups)

(Fig 1). Differences in baseline characteristics across the groups were analysed using one-way analysis of variance test (ANOVA, parametric continuous data variables), the Kruskal-Wallis test (non-parametric continuous data variables) or the Chi-square test (categorical data variables).

Univariable analysis was performed initially to identify variables potentially influencing each outcome, based on statistical rejection criteria of $p>0.10$; these variables were then included in the multivariable models (see supplementary material for complete statistical methods). Due to the large population sizes and the questionable merits of statistically adjusting for gender, we chose to analyse data on males and females separately.

Implant survival times for patients who had not undergone revision were censored on the 31st December 2010. Competing risks models were used to adjust for potential differences in mortality across the implant groups, where patient death prior to either revision or censoring was the competing risk [40]. Cumulative incidence charts were then produced for each type of implant and by gender. Analysis of covariance (ANCOVA) was used for testing differences in OHS and EQ5D index change scores. Multivariable logistic regression was used to analyse differences in the risk of readmission and reoperation. Time from implantation to questionnaire completion was included in models to evaluate whether differences in duration of follow-up influenced findings. Pre-operative scores were included within all models, as recommended by the designers of the OHS [39].

Results of the survival analysis were presented as hazard ratios (HRs). Statistical models for the change scores were evaluated with the margins function in STATA in order to provide predicted values separately for each of the implant groups. P-values are provided as statistical tests of the differences between the reference implant and the seven others. Significance was taken as $p<0.05$. All values are provided with 95% confidence intervals (CIs): ratios greater than one indicate that risk is higher when compared with the reference category. All models were fitted using STATA 12 (StataCorp LP, Texas, USA). Further supplementary information is available in **S1 Text** and **S2 to S5 Tables**.

Costs for specific implant combinations were provided by NHS Wales (all seven hospital Trusts) and NHS supply chain (buyers on behalf of 30 hospital Trusts within the English NHS). Highest and lowest prices paid for implants during 2012 are provided for each of the implant components. A mode cost was also produced at source and provided. These costs represent actual prices paid, after discounts. In addition, the NJR levy fee (£20, which is included in the amount paid for each implant) and Value Added Tax (VAT, at 20%) were added for the total costs. The costs presented in this study also include acetabular screws (for cementless cup fixation) when used, the commonest cement used for each implant type, femoral cement restrictors and all equipment required to mix and perform pressurised cementation. Although it is acknowledged that hip replacement with cementless implants may result in slightly shorter operative time, for the purposes of this analysis it is assumed that theatre utilisation and length of stay was similar for all types of replacement, and that differences in specific implant costs approximated to incremental costs.

Ethics

The National Joint Registry (England and Wales) Research Committee approved this study. Explicit patient consent is taken at the time of data collection for both the NJR and PROMs. Further ethical approval was not required for this study. Patient records/information was anonymized and de-identified prior to receipt of data and analysis.

Table 2. Patient demographics for National Joint Registry population studied, by implant group.

	Cemented		Hybrid		Cementless		Resurfacing		Difference
	Optimal	Sub-opt.	Optimal	Sub-opt.	Optimal	Sub-opt.	Optimal	Sub-opt.	
Number (%)	19815 (24.8)	13673 (17.1)	2388 (3.0)	9768 (12.2)	9867 (12.4)	19726 (24.7)	3317 (4.2)	1221 (1.5)	
Age, median years (range)	74.8 (60 to 100)	74.8 (60 to 97)	67.6 (60 to 97)	71.7 (60 to 103)	72.2 (60 to 98)	68.7 (60 to 106)	63.8 (60 to 89)	63.3 (60 to 88)	p<0.001
Female	12788 (64.5)	9163 (67.0)	1238 (51.8)	6142 (62.9)	5303 (53.7)	11559 (58.6)	166 (5.0)	872 (71.4)	p<0.001
ASA									
1	2461 (12.4)	1822 (13.3)	508 (21.3)	1336 (13.7)	1219 (12.4)	2921 (14.8)	1343 (40.5)	542 (44.4)	p<0.001
2	13835 (69.8)	9496 (69.5)	1637 (68.6)	6888 (70.5)	7186 (72.8)	14280 (72.4)	1833 (55.3)	644 (52.7)	
3+	3519 (17.8)	2355 (17.2)	243 (10.2)	1544 (15.8)	1462 (14.8)	2525 (12.8)	141 (4.3)	35 (2.9)	
BMI, mean kg/m^2(sd, range)	28.3 (5.0, 15 to 63)	27.9 (5.0, 15 to 65)	28.4 (5.1 16 to 56)	28.1 (5.1, 15 to 61)	28.4 (5.1, 15 to 64)	28.5 (5.2, 15 to 64)	27.8 (4.3, 18 to 64)	27.3 (4.2, 18 to 40)	p = 0.015

ASA–American Society of Anesthesiologists, BMI–body mass index (data based on 34756 procedures [44%])

Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

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Results

There were 79,775 procedures available for implant survival analysis within the NJR dataset. Significant baseline differences were seen in age, ASA grade, proportions of females and BMI for the type of implant received (Table 2). Linkage of PROMs data with data stored in the NJR dataset was possible in 9159 procedures. The demographics of patients and implants for the linked procedures were qualitatively similar to the NJR population (Table 3). Unadjusted pre-operative OHS and EQ5D index scores were clinically similar across the cemented, cementless

Table 3. Patient demographics for National Joint Registry-PROMs linked population studied, by implant group.

	Cemented		Hybrid		Cementless		Resurfacing		Difference
	Optimal	Sub-opt.	Optimal	Sub-opt.	Optimal	Sub-opt.	Optimal	Sub-opt.	
Number (%)	2369 (25.9)	1133 (12.4)	300 (3.3)	1168 (12.8)	1582 (17.3)	2485 (27.2)	97 (1.1)	15 (0.2)	
Age, median years (range)	74.0 (60 to 93)	75.2 (60 to 94)	68.1 (60 to 91)	71.6 (60 to 93)	72.0 (60 to 95)	67.8 (60 to 96)	64.2 (60 to 75)	62.8 (60 to 67)	p<0.001
Female	1463 (61.8)	747 (65.9)	164 (54.7)	744 (63.7)	776 (49.1)	1425 (57.3)	1 (1.0)	13 (86.7)	p<0.001
ASA									
1	213 (9.0)	96 (8.5)	53 (17.7)	122 (10.5)	162 (10.2)	345 (13.9)	35 (36.1)	5 (33.3)	p<0.001
2	1709 (72.1)	829 (73.2)	217 (72.3)	888 (76.0)	1201 (75.9)	1897 (76.3)	59 (60.8)	10 (66.6)	
3+	447 (18.9)	208 (18.4)	30 (10.0)	158 (13.5)	219 (13.8)	243 (9.8)	3 (3.1)	0 (0)	
BMI, mean kg/m (sd, range)	28.6 (5.0, 16 to 55)	28.1 (4.7, 15 to 46)	28.4 (4.6 17 to 44)	28.2 (4.8, 17 to 43)	28.5 (4.9, 16 to 56)	28.6 (5.2, 15 to 50)	28.0 (4.0, 20 to 38)	27.8 (2.9, 23 to 32)	p = 0.679

PROMs–patient reported outcome measures, ASA–American Society of Anesthesiologists, BMI–body mass index (data based on 5843 procedures [64%])

Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

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Table 4. Patient reported outcomes for populations studied, by implant group and gender.

	Cemented		Hybrid		Cementless		Resurfacing		p value
	Optimal	Sub-optimal	Optimal	Sub-optimal	Optimal	Sub-optimal	Optimal	Sub-optimal	
Females (n, %)	1463 (27.4)	747 (14.0)	164 (3.1)	744 (14.0)	776 (14.6)	1425 (26.7)	1 (0.0)	13 (0.2)	
Oxford Hip scores									
Pre-operative, mean (sd, range)	17.4 (8.0, 0 to 44)	16.8 (8.0, 0 to 42)	19.7 (7.8, 4 to 37)	18.3 (8.0, 1 to 38)	17.3 (7.7, 1 to 43)	18.5 (8.1, 0 to 44)	13	25.9 (4.5,18 to 33)	<0.001
Post-operative, median (range)	40 (4 to 48)	38 (2 to 48)	43 (13 to 48)	42 (5 to 48)	42 (6 to 48)	42 (2 to 48)	48	46 (21 to 48)	<0.001
EQ5D index									
Pre-operative, mean (sd, range)	0.342 (0.313, -0.43 to 1)	0.319 (0.325, -0.48 to 1)	0.432 (0.301, -0.24 to 0.88)	0.356 (0.323, -0.59 to 1)	0.346 (0.317, -0.35 to 1)	0.366 (0.318, -0.59 to 1)	0.516	0.586 (0.192, 0.09 to 0.76)	0.008
Post-operative, median (range)	0.796 (-0.24 to 1)	0.760 (-0.24 to 1)	0.850 (-0.18 to 1)	0.814 (-0.24 to 1)	0.812 (-0.13 to 1)	0.796 (-0.32 to 1)	1	1 (0.52 to 1)	<0.001
Time from op to PROMs complete, mean days (sd, range)	208.8 (29.0, 183 to 358)	209.5 (29.2, 183 to 358)	209.5 (30.6, 184 to 360)	209.4 (28.5, 183 to 364)	207.2 (25.8, 185 to 357)	208.3 (28.4, 183 to 360)	193	258.8 (46.8, 192 to 316)	0.323
Males (n, %)	906 (23.7)	386 (10.1)	136 (3.6)	424 (11.1)	806 (21.1)	1060 (27.8)	96 (2.5)	2 (0.1)	
Oxford Hip scores									
Pre-operative, mean (sd, range)	19.8 (7.9, 0 to 44)	19.1 (8.1, 2 to 48)	22.1 (7.9, 4 to 41)	20.4 (8.5, 2 to 42)	19.9 (8.0, 2 to 42)	20.4 (8.3, 3 to 44)	25.7 (8.2, 4 to 43)	21.5 (0.7,21 to 22)	0.001
Post-operative, median (range)	43 (7 to 48)	41 (12 to 48)	44 (14 to 48)	43 (11 to 48)	43 (2 to 48)	44 (1 to 48)	45 (13 to 48)	48	<0.001
EQ5D index									
Pre-operative, mean (sd, range)	0.425 (0.300, -0.32 to 1)	0.439 (0.288, -0.48 to 0.88)	0.439 (0.288, -0.07 to 0.80)	0.422 (0.302, -0.35 to 1)	0.418 (0.301, -0.35 to 1)	0.425 (0.311, -0.35 to 1)	0.551 (0.253, -0.18 to 81)	0.516	0.016
Post-operative, median (range)	0.814 (-0.18 to 1)	0.814 (-0.18 to 1)	0.883 (0.88 to 1)	1 (-0.24 to 1)	0.850 (-0.18 to 1)	0.883 (-0.59 to 1)	1 (-0.02 to 1)	1	<0.001
Time from op to PROMs complete, mean days (sd, range)	208.2 (28.5, 183 to 363)	207.6 (27.2, 183 to 355)	208.5 (27.1, 183 to 336)	205.0 (22.3, 184 to 355)	207.9 (28.7, 183 to 363)	207.2 (27.5, 183 to 362)	272.4 (44.3, 184 to 336)	195.5 (3.5, 193 to 198)	0.192

SD–standard deviation, PROMs–patient reported outcome measures

Statistical notes: one-way analysis of variance (ANOVA) used for parametric data, Kruskal-Wallis test for non parametric data, Chi squared test for proportions

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and hybrid replacements, but higher prior to resurfacings (Table 4). Post-operative scores were lowest in the sub-optimal cemented group and highest after any resurfacing.

Patient Reported Outcome Measures

In females OHS change was significantly higher (22.1 versus 20.5, $p<0.001$) in the optimal cementless group when compared with the reference implant. No other implant combination had a significantly better OHS improvement. There were no significant OHS improvement benefits across the implant types in males. No implant combination displayed an EQ5D index improvement significantly greater than the reference, in either sex (Table 5). For OHS, 40% to 42% of variation within the models could be explained by known variables; for EQ5D index

Table 5. Patient reported outcome scores following hip replacement in patients aged 60 years and over (simple and multivariable analyses).

	Simple			Multivariable		
	Value	95% CI	P value	Value	95% CI	P value
Females (n = 5333)						
Change in OHS						
Optimal cemented (n = 1463)	20.2	19.7 to 20.7	Reference	20.5	20.1 to 21.0	Reference
Sub-optimal cemented (n = 747)	19.2	18.4 to 19.9	0.029	19.7	19.0 to 20.5	0.075
Optimal hybrid (n = 164)	20.4	18.9 to 21.9	0.773	21.7	20.0 to 23.4	0.207
Sub-optimal hybrid (n = 744)	20.7	20.0 to 21.4	0.227	20.9	20.1 to 21.6	0.463
Optimal cementless (n = 776)	21.9	21.2 to 22.6	<0.001	22.1	21.3 to 22.8	<0.001
Sub-optimal cementless (n = 1425)	20.7	20.2 to 21.2	0.169	21.0	20.4 to 21.5	0.270
Change in EQ5D index						
Optimal cemented (n = 1463)	0.421	0.402 to 0.439	Reference	0.426	0.414 to 0.439	Reference
Sub-optimal cemented (n = 747)	0.429	0.403 to 0.454	0.619	0.418	0.398 to 0.439	0.502
Optimal hybrid (n = 164)	0.373	0.320 to 0.427	0.103	0.452	0.404 to 0.499	0.312
Sub-optimal hybrid (n = 744)	0.433	0.408 to 0.459	0.421	0.436	0.416 to 0.457	0.430
Optimal cementless (n = 776)	0.446	0.421 to 0.471	0.100	0.447	0.427 to 0.467	0.086
Sub-optimal cementless (n = 1425)	0.417	0.398 to 0.435	0.765	0.420	0.404 to 0.435	0.182
Males (n = 3826)						
Change in OHS						
Optimal cemented (n = 906)	20.1	19.5 to 20.7	Reference	20.3	19.7 to 20.9	Reference
Sub-optimal cemented (n = 386)	20.4	19.5 to 21.4	0.553	19.9	18.9 to 20.9	0.521
Optimal hybrid (n = 136)	20.0	18.3 to 21.6	0.882	18.9	17.2 to 20.6	0.140
Sub-optimal hybrid (n = 424)	20.5	19.6 to 21.4	0.488	20.6	19.7 to 21.5	0.603
Optimal cementless (n = 806)	20.7	20.0 to 21.3	0.222	20.6	19.9 to 21.3	0.521
Sub-optimal cementless (n = 1060)	20.2	19.6 to 20.8	0.820	19.8	19.1 to 20.5	0.295
Optimal resurfacing (n = 96)	17.1	15.2 to 19.0	0.004	19.1	17.2 to 21.1	0.282
Change in EQ5D index						
Optimal cemented (n = 906)	0.379	0.357 to 0.401	Reference	0.390	0.374 to 0.407	Reference
Sub-optimal cemented (n = 386)	0.417	0.384 to 0.450	0.060	0.391	0.364 to 0.418	0.988
Optimal hybrid (n = 136)	0.377	0.322 to 0.432	0.941	0.364	0.316 to 0.411	0.302
Sub-optimal hybrid (n = 424)	0.419	0.387 to 0.450	0.044	0.415	0.389 to 0.441	0.121
Optimal cementless (n = 806)	0.395	0.371 to 0.418	0.345	0.401	0.381 to 0.421	0.428
Sub-optimal cementless (n = 1060)	0.390	0.370 to 0.410	0.482	0.358	0.340 to 0.377	0.011
Optimal resurfacing (n = 96)	0.340	0.273 to 0.406	0.270	0.398	0.343 to 0.453	0.790

OHS–Oxford Hip Score, CI–confidence interval

Note: No predicted values are available for resurfacings in females (14 PROMs available only) and others resurfacing in males (2 PROMs only)

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this was 61% to 63% (S4 Table). There were no significant differences in readmission or further surgery (**Table 6**).

Implant Revision Risk

When compared to the reference hip in females, the following had significantly higher revision risks: sub-optimal cemented (HR = 1.85, p<0.001), sub-optimal hybrid (HR = 1.68, p = 0.012), optimal cementless (HR = 2.22, p<0.001), sub-optimal cementless (HR = 3.60, p<0.001), and sub-optimal resurfacing (HR = 8.74, p<0.001). Optimal hybrid and optimal resurfacing had similar implant survival, but confidence intervals were wide for resurfacing (**Table 7**).

Table 6. Risk of readmission and reoperation following hip replacement in patients aged 60 years and over (simple and multivariable analyses).

		Simple			Multivariable		
	Number (%)	OR	95% CI	P value	OR	95% CI	P value
Females (n = 5333)							
Readmission							
Optimal cemented (n = 1463)	92 (6.3)	1			1		
Sub-opt. cemented (n = 747)	67 (8.9)	1.47	1.06 to 2.04	0.022	1.67	1.11 to 2.51	0.013
Optimal hybrid (n = 164)	8 (4.9)	0.76	0.36 to 1.60	0.477	1.76	0.23 to 2.50	0.651
Sub-optimal hybrid (n = 744)	47 (6.3)	1.00	0.70 to 1.44	0.979	1.24	0.77 to 2.00	0.379
Optimal cementless (n = 776)	56 (7.2)	1.16	0.82 to 1.64	0.401	1.25	0.79 to 1.98	0.340
Sub-opt cementless (n = 1425)	82 (5.8)	0.91	0.67 to 1.24	0.547	1.18	0.78 to 1.78	0.423
Reoperation							
Optimal cemented (n = 1463)	29 (2.0)	1			1		
Sub-opt. cemented (n = 747)	20 (2.7)	1.36	0.76 to 2.42	0.296	1.22	0.67 to 2.22	0.522
Optimal hybrid (n = 164)	3 (1.8)	0.92	0.28 to 3.06	0.894	0.99	0.29 to 3.31	0.982
Sub-optimal hybrid (n = 744)	15 (2.0)	1.02	0.54 to 1.91	0.957	0.95	0.50 to 1.82	0.879
Optimal cementless (n = 776)	6 (0.8)	0.39	0.16 to 0.93	0.034	0.46	0.16 to 1.35	0.156
Sub-opt cementless (n = 1425)	27 (1.9)	0.96	0.56 to 1.62	0.865	0.83	0.47 to 1.46	0.519
Males (n = 3826)							
Readmission							
Optimal cemented (n = 906)	88 (9.7)	1			1		
Sub-opt. cemented (n = 386)	32 (8.3)	0.84	0.55 to 1.28	0.420	0.97	0.57 to 1.63	0.894
Optimal hybrid (n = 136)	14 (4.5)	1.07	0.59 to 1.93	0.832	0.74	0.29 to 1.93	0.542
Optimal cementless (n = 806)	69 (8.6)	0.87	0.63 to 1.21	0.410	0.82	0.53 to 1.27	0.381
Sub-opt cementless (n = 1060)	68 (6.4)	0.64	0.46 to 0.87	0.007	0.77	0.50 to 1.19	0.238
Optimal resurfacing (n = 96)	4 (4.2)	0.40	0.15 to 1.13	0.083	0.60	0.18 to 2.03	0.411
Reoperation							
Optimal cemented (n = 906)	21 (2.3)	1			1		
Sub-opt. cemented (n = 386)	6 (1.6)	0.67	0.27 to 1.66	0.383	0.85	0.31 to 2.34	0.749
Optimal hybrid (n = 136)	5 (3.7)	1.61	0.59 to 4.34	0.348	1.34	0.37 to 4.83	0.658
Sub-optimal hybrid (n = 424)	6 (1.4)	0.60	0.24 to 1.51	0.281	0.55	0.18 to 1.68	0.297
Optimal cementless (n = 806)	17 (2.1)	0.91	0.48 to 1.73	0.770	0.47	0.18 to 1.21	0.116
Sub-opt cementless (n = 1060)	18 (1.7)	0.73	0.39 to 1.37	0.328	0.72	0.33 to 1.56	0.409
Optimal resurfacing (n = 96)	1 (1.0)	0.44	0.06 to 3.33	0.430	1		-

OR–odds ratio, CI–confidence interval

Note: No predicted values are available for resurfacings in females (14 PROMs available only) and others resurfacing in males (2 PROMs only)

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For males, all implants except hybrids had significantly higher revision risk: sub-optimal cemented (HR = 2.09, p = 0.001), optimal cementless (HR = 1.95, p = 0.003), sub-optimal cementless (HR = 2.53, p<0.001), optimal resurfacing (HR = 3.46, p<0.001) and sub-optimal resurfacing (HR = 6.21, p<0.001) (Table 7).

Material Costs

The reference (cemented) replacement in this analysis was the cheapest (most commonly paid total price £1138). Resurfacing implants ranged in total cost from £2018 to £2991. A cementless 36mm CoC implant cost the NHS between £2500 and £4285 (Table 8).

Table 7. Risk of revision following hip replacement in patients aged 60 years and over (simple and multivariable analyses).

	Simple			Multivariable		
	HR	95% CI	P value	HR	95% CI	P value
Females (n = 47231)						
Optimal cemented (n = 12788)	1			1		
Sub-optimal cemented (n = 9163)	1.77	1.28 to 2.44	0.001	1.85	1.31 to 2.61	<0.001
Optimal hybrid (n = 1238)	1.30	0.60 to 2.85	0.507	1.26	0.56 to 2.81	0.578
Sub-optimal hybrid (n = 6142)	1.73	1.19 to 2.52	0.004	1.68	1.12 to 2.52	0.012
Optimal cementless (n = 5303)	2.15	1.47 to 3.14	<0.001	2.22	1.48 to 3.34	<0.001
Sub-optimal cementless (n = 11559)	3.62	2.70 to 4.85	<0.001	3.60	2.63 to 4.94	<0.001
Optimal resurfacing (n = 166)	1.98	0.49 to 8.07	0.339	2.31	0.57 to 9.41	0.244
Sub-optimal resurfacing (n = 872)	7.66	5.21 to 11.3	<0.001	8.74	5.81 to 13.2	<0.001
Males (n = 32544)						
Optimal cemented (n = 7027)	1			1		
Sub-optimal cemented (n = 4510)	2.03	1.36 to 3.04	0.001	2.09	1.37 to 3.18	0.001
Optimal hybrid (n = 1150)	0.94	0.40 to 2.21	0.882	0.68	0.26 to 1.76	0.425
Sub-optimal hybrid (n = 3626)	1.47	0.92 to 2.37	0.108	1.28	0.78 to 2.11	0.327
Optimal cementless (n = 4564)	2.08	1.36 to 3.16	0.001	1.95	1.25 to 3.05	0.003
Sub-optimal cementless (n = 8167)	2.79	1.95 to 3.98	<0.001	2.53	1.74 to 3.68	<0.001
Optimal resurfacing (n = 3151)	3.30	2.23 to 4.88	<0.001	3.46	2.28 to 5.26	<0.001
Sub-optimal resurfacing (n = 349)	6.13	3.37 to 11.2	<0.001	6.21	3.36 to 11.5	<0.001

HR–hazard ratio, CI–confidence interval

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Discussion

The reference implant (fully cemented, standard head size and conventional polyethylene cup) offered the lowest risk of implant failure at the lowest cost in patients over 60 years. No functional benefit of any implant was found in males relative to the reference implant; some differences for females were statistically significant but of unclear clinical importance. Readmission and reoperation rates were similar across all groups, suggesting there are no large variations in dislocation risk across implants. Notably higher costs and poorer implant survival was found when resurfacing and cementless implants were used. The findings of this summative evaluation of a range of hip replacements are contrary to current trends in surgery and may be useful for healthcare providers, surgeons and those commissioning hip replacement services.

As with all database analyses, the study design is observational and thus vulnerable to omitted variables. Implant choices in this cohort result from the interplay of patient, surgical and provider factors, and are not assigned randomly. Potentially important variables that were unavailable, such as radiological data, race, socioeconomic status, patient experiences, levels of perioperative pain and preoperative expectations, are known to influence outcome [41,42]; a large proportion of variation within the models in this study therefore remains unexplained.

The numbers within comparison groups were adequate in order to identify meaningful differences in PROMs, despite limiting to specific brands (to reduce the confounding effect of implant heterogeneity) [38]. Additionally, raw data from the NJR annual report suggests no other brands afford better implant survival than the commonest brands as used here [3]. Whilst the NJR only describes mid-term implant survival, there is currently no evidence to support the assertion that polyethylene-wear associated revision may occur in greater numbers beyond ten years, as other national registries established many decades ago show good

Table 8. Cost of specific hip implant combinations (NHS costs 2011/12).

Implant description		Stem		Femoral head		Cup		Ancillary items		Cost, mode / range (£)	Total cost* (£)
		Description	Cost (£)	Description	Cost (£)	Description	Cost (£)	Description	Cost (£)		
CEMENTED Stryker Exeter V40 Contemporary											
Most commonly used 'optimal' component set	Flanged cup / 28mm metal head	44/size 1	397.90 to 547.40	Stainless steel (Orthinox) V40 standard offset 28mm	145.00 to 257.60	Flanged cup	138.40 to 227.50	Heraeus Palacos R +Gentamycin antibiotic cement (4 mixes required)	26.75 /mix	**928.41** (898.88 to 1250.08)	**1138.09**
Alternative 'optimal'	Flanged cup / 32mm ceramic head	44/size 1	397.90 to 547.40	Ceramic (Alumina) V40 standard offset 32mm	415.00 to 588.00	Flanged cup	138.40 to 227.50	DePuy Hardinge restrictor	22.00	**1343.41** (951.30 to 1580.48)	**1636.09**
Most commonly used 'sub-optimal'	Hooded cup/ 26mm head	44/ size 1	397.90 to 547.40	Stainless steel (Orthinox) standard offset 26mm	138.40 to 227.50	Hooded cup	138.40 to 227.50	Biomet Optivac vacuum mixing and delivery system (2 required)	44.29 /kit	**928.41** (898.88 to 1250.08)	**1138.09**
HYBRID Stryker Exeter V40 Trident											
Most commonly used 'optimal' component set	Solid shell/ 36mm CoC	44/ size 1	397.90 to 547.40	Ceramic (Alumina) V40 standard offset 36mm	415.00 to 588.00	Ceramic 36mm liner plus PSL solid back shell	415.00 to 717.50 plus 432.40 to 646.10	Heraeus Palacos R +Gentamycin antibiotic cement (2 mixes required) DePuy Hardinge restrictorBiomet Optivac vacuum mixing and delivery system (1 required)	26.75 /mix22.0044.29	**1780.09** (1780.09 to 2618.79)	**2160.11**
Alternative 'optimal'	Solid shell/ 32mm MoXLP	44/ size 1	397.90 to 547.40	Cobalt-chrome (Vitallium) V40 standard offset 32mm	145.00 to 271.60	X3 XLPE 32mm 10 degree liner plus PSL solid back shell	345.14 to 506.80 plus 432.40 to 646.10			**1465.00** (1440.23 to 2091.69)	**1782.00**
Most commonly used 'sub-optimal'	Multi-hole shell/ 28mm MoP	44/ size 1	397.90 to 547.40	Cobalt-chrome (Vitallium) V40 standard offset 28mm	145.00 to 271.60	Conventional Polyethylene 28mm liner plus PSL 5-hole	230.09 to 375.20 plus 432.40 to 646.10	As above, plus 2 Stryker acetabular screws	40.00 to 51.10	**1405.18** (1405.18 to 2051.19)	**1710.22**
RESURFACING Smith & Nephew Birmingham Hip Resurfacing											
Optimal	Head size ≥48mm	-	-	BHR head	540.00 to 865.52	BHR cup	1050.00 to 1534.81	Stryker Antibiotic Simplex cement (1 mix required)	27.72	**1943.71** (1662.01 to 2472.34)	**2356.45**
Sub-optimal	Head size <48mm	-	-	BHR head	540.00 to 865.52	BHR cup	1050.00 to 1534.81				
CEMENTLESS DePuy Corail Pinnacle											

(*Continued*)

Table 8. (*Continued*)

Implant description		Stem		Femoral head		Cup		Ancillary items		Cost, mode / range (£)	Total cost* (£)
		Description	Cost (£)	Description	Cost (£)	Description	Cost (£)	Description	Cost (£)		
Most commonly used 'optimal' component set	28mm MoP	Size 11 KS	642.85 to 1118	Metal standard offset 28mm	130.53 to 227.00	Marathon 28mm PE neutral lip liner plus cluster-hole Duofix	252.43 to 439.00 plus 510.03 to 887.00	1 DePuy acetabular screw included	54.05	**1586.94** (1586.94 to 2722.10)	**1928.33**
Commonly used 'sub-optimal'	36mm MoM	Size 11 KS	642.85 to 1118	Ultamet standard offset 36mm	249.55 to 434.00	Metal liner plus Sector cluster-hole Duofix	249.55 to 434.00 plus 510.03 to 887.00			**1790.78** (1703.08 to 2924.10)	**2172.94**
Commonly used 'sub-optimal'	36mm CoC	Size 11 KS	642.85 to 1118	Ceramic 36mm standard offset	431.25 to 750.00	Ceramic liner plus Sector cluster-hole Duofix	428.38 to 745.00 plus 510.03 to 887.00			**2209.95** (2063.61 to 3551.10)	**2675.94**

CoC–ceramic-on-ceramic, MoXLP–metal-on-highly cross-linked polyethylene, MoP–metal-on polyethylene, MoM–metal-on-metal, PE–polyethylene. Figures based on actual implant costs paid to manufacturers by NHS Wales (seven Trusts) and NHS Supply chain (30 Trusts in England). *Total cost is calculated using the mode cost plus NJR levy costs (£20) and Value Added Tax (20%). Note–very large Exeter stems (offset 44 sizes 4 and 5, and all 50 offset stems) increase cost by £614.27 (this represents less than 5% of all Exeter stems used) [32]

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long-term survival of cemented implants with polyethylene bearings (cemented polyethylene cup 90% survival at 16 years, compared with 85% for cementless, Swedish Annual Report 2011) [11]. A systematic review of world wide registry and cohort study data failed to show a benefit of other bearings when compared with MoP [6]. Furthermore, dislocation risk has been shown to be higher with CoC [43] and there are concerns surrounding metal wear debris reactions in patients with MoM implants, which has prompted a dramatic reduction in their use over the last five years [3,44].

This analysis covers an entire nation of surgeons and surgical units providing hip replacement, and therefore provides strong external validity. However, NJR data validity has been questioned; data loss and under-reporting of revision numbers remains a concern (although this should affect comparison groups equally). PROMs data are currently recorded only once post-operatively, at around six months following surgery, which may be too early to determine success of a joint replacement. Nevertheless, the greatest improvement in OHS occurs in the first three months, with no improvements seen beyond 12 months; results from this current study are therefore a reliable indication of longer-term outcome [45,46]. There may also be selection bias within the PROMs data; questionnaire response rates may vary across different ages, socioeconomic groups or race. The point at which a patient undergoes a hip procedure may also be different (reflecting the need to adjust for pre-operative scores), depending on age, expectations and occupation. Patients undergoing resurfacing tend to have higher pre-operative scores. This may in turn limit their ability to improve within the constraints of the current scoring systems, due to a ceiling effect of both the OHS and EQ5D index.

Pennington et al recently published a cost effectiveness paper using NJR, PROMs and implant cost data to compare types of hip replacement [47]. Hybrid implants were found to

have the most cost-effective profile. Corroborating the findings presented in this current study, the authors found that cementless implants offered no benefit whilst being more costly. However, all brands within each hip replacement type were analysed collectively (using only MoP bearings), with no adjustment for the heterogeneity of implants. This limits the implications of their findings as pooling brands and configurations (when comparing procedures) may mask important differences between brand, configuration and procedure. However, Pulikottil-Jacob et al took this a step further by examining different types of hip replacement fixation and bearing, and found that available evidence does not support recommending a particular device on cost effectiveness grounds alone, although the authors did not examine PROMs or complication data [48].

Although hybrid implants have good implant survival in this current study, it must be stressed these results rely on rigid press-fit of the acetabular component into the bony socket without the need for supplementary screws to aid fixation. The use of multi-hole shells to allow supplementary screw fixation (as apposed to 'solid' shells, without holes) have a 37% higher risk of revision [34]. Whilst a cemented procedure will have reproducible results, adequate cementless cup fixation may be more difficult to achieve.

The fully cementless implant analysed here has a 1.9 to 3.6 times higher revision risk than the standard cemented implant. Although there was a higher OHS improvement (1.6 points) in females, this is below the clinical important threshold of 3 to 5 points suggested by the OHS designers [39,49]. Proponents of fully cementless procedures argue that the costs may actually be lower than those of cemented implants, as cementation requires greater operative time [50]. Although we chose to analyse the commonest cementless implant, we acknowledge that others may have lower costs. We have assumed that implant specific costs approximate to the incremental costs of different implants. There remains no good evidence of improved theatre efficiency for cementless implants in the literature; savings of 15 to 20 minute per case have been suggested [50,51,52], but equating this to monetary savings is only credible when extra replacements are actually performed within an operating schedule. Additionally, our analysis is likely to understate the true incremental costs of implants: subsequent revision surgery (which occurs more commonly with cementless and resurfacing procedures) would increase the overall costs of these types relative to cemented implants. One study found that annual hip replacement costs in the US (where cementless implants are used almost exclusively) could be reduced by $2billion if there was a joint registry comparable to the Swedish registry (enabling reductions in revision rates) [53]. The use of cement on the femoral side has many advantages that outweigh the disadvantage of a slightly longer operative time [28], and the available literature suggests that cemented fixation of acetabular components is more reliable than cementless beyond the first postoperative decade [14].

This study demonstrates no benefit of a resurfacing procedure in patients over 60 years across any of the domains studied in this analysis. Given the high failure rates, the risks of local and systemic complications, and the long-term concerns surrounding these implants, including a medical device warning and mandatory annual follow-up, there appears to be no routine place for a resurfacing procedure in patients over 60 years [44,54]. Even in the ideal resurfacing patient (a young male), Heintzbergen et al showed that absolute differences in cost-utility were small when a BHR was compared to conventional hip replacement [55]. A dramatic fall in the use of resurfacings, with use predominantly in young males during 2011 suggests surgeons practising in England and Wales are responding to the evidence [3].

Long-term observational studies of mortality after hip replacement suggest a higher risk of death when cement is used, but these fail to account for the confounding effect of true patient differences and provide no logical reason for the increased death rate many years after cementation [56,57]. However, an analysis of over 400,000 hip replacements performed in England

and Wales between 2003 and 2011, using a combination of NJR and hospital episodes data (allowing for extensive patient and provider variable adjustment) found the use of hip replacement type to have no impact on mortality at 90 days following surgery [58], implying that cement pressurisation at the time of surgery does not influence surgery-associated mortality.

In the past decade hip surgeons have been guilty of using implants with limited long-term evidence at great expense to the NHS and other healthcare providers (as a result of costs incurred initially and at revision surgery), and with significant adverse impact on patient outcomes [59]. Fordham et al stated that the most cost-effective implants are those with the best survival rates (and hence the fewest revisions), with the best patient outcomes and the least cost [1]. Within this multi-outcome study of national data, a cemented stem with a cemented polyethylene cup and a standard sized head offered similar outcomes to other implants, but with lower revision risk and at the lowest costs. This category of implant should be the gold standard for hip replacement, and used for comparisons with new implants within future robust, randomised clinical trials. Uptake of new implants should depend upon evidence of reduced revisions, patient morbidity and healthcare resource use.

The proliferation of hip replacement options has meant that any analysis aiming to determine 'optimal' hip replacement is inherently complex. However, the intention of this study was to provide a summative evaluation of a range of hip replacements for the patient over 60 years with hip OA. This type of evaluation is crucial to inform commissioning decisions by helping to answer the question 'what is the most cost-effective hip replacement?' We believe the findings of this paper will appeal to commissioners, surgeons, healthcare management and the broader medical community striving to delivery high quality and cost effective healthcare.

Supporting Information

S1 Table. Summary of the demographic and surgical variables available for analysis.
(PDF)

S2 Table. Variables included in the competing risks survival model.
(PDF)

S3 Table. Competing risks survival modelling of hip type using different variable sets.
(PDF)

S4 Table. Variables included in the change score analysis of covariance models.
(PDF)

S5 Table. Variables included in the complications multivariable logistic regression models.
(PDF)

S1 Text. Supplementary methodology.
(PDF)

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STROBE Statement

This study was carried out in accordance with the STROBE checklist.

Author Contributions

Conceived and designed the experiments: SJ MR PG. Performed the experiments: SJ. Analyzed the data: SJ. Contributed reagents/materials/analysis tools: PB JM. Wrote the paper: SJ JM MR PB DD PG.

References

1. Fordham R, Skinner J, Wang X, Nolan J (2012) The economic benefit of hip replacement: a 5-year follow-up of costs and outcomes in the Exeter Primary Outcomes Study. BMJ Open 2.
2. Jenkins PJ, Clement ND, Hamilton DF, Gaston P, Patton JT, Howie CR (2013) Predicting the cost-effectiveness of total hip and knee replacement: a health economic analysis. Bone Joint J 95-B: 115–121. doi: 10.1302/0301-620X.95B1.29835 PMID: 23307684
3. England-and-Wales-National-Joint-Registry (2012) National Joint Registry for England and Wales 9th Annual Report.
4. No-authors-listed (2012) Scottish Arthroplasty Project Biennial Report 2012.
5. Kurtz S, Ong K, Lau E, Mowat F, Halpern M (2007) Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 89: 780–785. PMID: 17403800
6. Sedrakyan A, Normand SL, Dabic S, Jacobs S, Graves S, Marinac-Dabic D (2011) Comparative assessment of implantable hip devices with different bearing surfaces: systematic appraisal of evidence. BMJ 343: d7434. doi: 10.1136/bmj.d7434 PMID: 22127517
7. Australian-National-Joint-Registry (2010) Australian Orthopaedic Association, National Joint Replacement Register.
8. New-Zealand-National-Joint-Registry (2008) Annual Report 2008, 8 year report. New Zealand National Joint Registry.
9. Norwegian-Arthroplasty-Registry (2008) Annual Report 2008. Norwegian Arthroplasty Register.
10. Finnish-National-Arthoplasty-Registry (2006) Annual Report 2006. Finnish National Arthroplasty Register.
11. Swedish-Hip-Registry (2011) Annual report 2011. Swedish Hip Registry.
12. Busch V, Klarenbeek R, Slooff T, Schreurs BW, Gardeniers J (2010) Cemented hip designs are a reasonable option in young patients. Clin Orthop Relat Res 468: 3214–3220. doi: 10.1007/s11999-010-1355-z PMID: 20405346
13. Schmitz MW, Busch VJ, Gardeniers JW, Hendriks JC, Veth RP, Schreurs BW (2013) Long-term results of cemented total hip arthroplasty in patients younger than 30 years and the outcome of subsequent revisions. BMC Musculoskelet Disord 14: 37. doi: 10.1186/1471-2474-14-37 PMID: 23339294
14. Toossi N, Adeli B, Timperley AJ, Haddad FS, Maltenfort M, Parvizi J (2013) Acetabular components in total hip arthroplasty: is there evidence that cementless fixation is better? J Bone Joint Surg Am 95: 168–174. doi: 10.2106/JBJS.K.01652 PMID: 23324965
15. Pakvis D, van Hellemondt G, de Visser E, Jacobs W, Spruit M (2011) Is there evidence for a superior method of socket fixation in hip arthroplasty? A systematic review. Int Orthop 35: 1109–1118. doi: 10.1007/s00264-011-1234-6 PMID: 21404024
16. Berry DJ, Harmsen WS, Cabanela ME, Morrey BF (2002) Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components. J Bone Joint Surg Am 84-A: 171–177. PMID: 11861721
17. Callaghan JJ, Bracha P, Liu SS, Piyaworakhun S, Goetz DD, Johnston RC (2009) Survivorship of a Charnley total hip arthroplasty. A concise follow-up, at a minimum of thirty-five years, of previous reports. J Bone Joint Surg Am 91: 2617–2621. doi: 10.2106/JBJS.H.01201 PMID: 19884436
18. Wroblewski BM, Siney PD, Fleming PA (2007) Charnley low-friction arthroplasty: survival patterns to 38 years. J Bone Joint Surg Br 89: 1015–1018. PMID: 17785737
19. Chandler HP, Reineck FT, Wixson RL, McCarthy JC (1981) Total hip replacement in patients younger than thirty years old. A five-year follow-up study. J Bone Joint Surg Am 63: 1426–1434. PMID: 7320033

20. Dorr LD, Takei GK, Conaty JP (1983) Total hip arthroplasties in patients less than forty-five years old. J Bone Joint Surg Am 65: 474–479. PMID: 6833321
21. Sharp DJ, Porter KM (1985) The Charnley total hip arthroplasty in patients under age 40. Clin Orthop Relat Res: 51–56.
22. Ranawat CS, Atkinson RE, Salvati EA, Wilson PD Jr. (1984) Conventional total hip arthroplasty for degenerative joint disease in patients between the ages of forty and sixty years. J Bone Joint Surg Am 66: 745–752. PMID: 6725322
23. Collis DK (1984) Cemented total hip replacement in patients who are less than fifty years old. J Bone Joint Surg Am 66: 353–359. PMID: 6699050
24. Lord GA, Hardy JR, Kummer FJ (1979) An uncemented total hip replacement: experimental study and review of 300 madreporique arthroplasties. Clin Orthop Relat Res: 2–16.
25. Sedel L, Kerboull L, Christel P, Meunier A, Witvoet J (1990) Alumina-on-alumina hip replacement. Results and survivorship in young patients. J Bone Joint Surg Br 72: 658–663. PMID: 2380223
26. Delaunay CP, Bonnomet F, Clavert P, Laffargue P, Migaud H (2008) THA using metal-on-metal articulation in active patients younger than 50 years. Clin Orthop Relat Res 466: 340–346. doi: 10.1007/s11999-007-0045-y PMID: 18196415
27. Cuckler JM, Moore KD, Lombardi AV Jr., McPherson E, Emerson R (2004) Large versus small femoral heads in metal-on-metal total hip arthroplasty. J Arthroplasty 19: 41–44.
28. Murray DW (2011) Cemented femoral fixation: the North Atlantic divide. Orthopedics 34: e462–463. doi: 10.3928/01477447-20110714-25 PMID: 21902131
29. Australian-National-Joint-Registry (2012) Australian National Joint Replacement Registry Annual Report 2012.
30. Spencer RF (2011) Evolution in hip resurfacing design and contemporary experience with an uncemented device. J Bone Joint Surg Am 93 Suppl 2: 84–88. doi: 10.2106/JBJS.J.01716 PMID: 21543695
31. Jameson SS MJ, Baker PN, Gregg PJ, Porter M, Deehan DJ, Reed MR (2013) HAVE CEMENTLESS AND RESURFACING COMPONENTS IMPROVED HIP REPLACEMENT FOR PATIENTS UNDER 60 YEARS? AN ANALYSIS OF PATIENT REPORTED OUTCOME MEASURES, IMPLANT SURVIVAL AND COSTS. Submitted to Acta Orthop.
32. Jameson SS, Baker PN, Mason J, Gregg PJ, Brewster N, Deehan DJ, et al. (2012) The design of the acetabular component and size of the femoral head influence the risk of revision following 34 721 single-brand cemented hip replacements: A retrospective cohort study of medium-term data from a National Joint Registry. J Bone Joint Surg Br 94: 1611–1617. doi: 10.1302/0301-620X.94B12.30040 PMID: 23188900
33. Jameson SS BP, Mason JM, Rymaszewska M, Gregg PJ, Deehan DJ, Reed MR (2013) Independent predictors of failure up to 7.5 years after 35 386 single-brand cementless total hip replacements. Bone and Joint Jounal In press.
34. Jameson SS, Mason JM, Baker PN, Jettoo P, Deehan DJ, Reed MR (2013) Factors Influencing Revision Risk Following 15 740 Single-Brand Hybrid Hip Arthroplasties: A Cohort Study From a National Joint Registry. J Arthroplasty.
35. Jameson SS, Baker PN, Mason J, Porter ML, Deehan DJ, Reed MR (2012) Independent predictors of revision following metal-on-metal hip resurfacing: a retrospective cohort study using National Joint Registry data. J Bone Joint Surg Br 94: 746–754. doi: 10.1302/0301-620X.94B6.29239 PMID: 22628587
36. Dawson J, Fitzpatrick R, Carr A, Murray D (1996) Questionnaire on the perceptions of patients about total hip replacement. J Bone Joint Surg Br 78: 185–190. PMID: 8666621
37. No-authors-listed (2009) EuroQol (EQ5D Score).
38. Browne J JL, Lewsey J, et al. (2007) Patient reported outcome measures (PROMs) in elective surgery: report to the Department of Health, 2007.
39. Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, et al. (2007) The use of the Oxford hip and knee scores. J Bone Joint Surg Br 89: 1010–1014. PMID: 17785736
40. Fine J, Gray R. (1999) A proportional hazards model for the subdistribution of a competing risk. Journal of the American Statistical Association 94: 496–509.
41. Hamilton DF, Lane JV, Gaston P, Patton JT, Macdonald D, Simpson AH, et al. (2013) What determines patient satisfaction with surgery? A prospective cohort study of 4709 patients following total joint replacement. BMJ Open 3.
42. Clement ND, Muzammil A, Macdonald D, Howie CR, Biant LC (2011) Socioeconomic status affects the early outcome of total hip replacement. J Bone Joint Surg Br 93: 464–469. doi: 10.1302/0301-620X.93B4.25717 PMID: 21464483

43. Sexton SA, Walter WL, Jackson MP, De Steiger R, Stanford T (2009) Ceramic-on-ceramic bearing surface and risk of revision due to dislocation after primary total hip replacement. J Bone Joint Surg Br 91: 1448–1453. doi: 10.1302/0301-620X.91B11.22100 PMID: 19880888

44. Medicines-and-Healthcare-products-Regulatory-Agency (2011) Medical Device Alert: All metal-on-metal (MoM) hip replacements (MDA/2012/008).

45. Judge A, Arden NK, Batra RN, Thomas G, Beard D, Javaid MK, et al. (2013) The association of patient characteristics and surgical variables on symptoms of pain and function over 5 years following primary hip-replacement surgery: a prospective cohort study. BMJ Open 3.

46. Andrew JG, Palan J, Kurup HV, Gibson P, Murray DW, Beard DJ (2008) Obesity in total hip replacement. J Bone Joint Surg Br 90: 424–429. doi: 10.1302/0301-620X.90B4.20522 PMID: 18378913

47. Pennington M, Grieve R, Sekhon JS, Gregg P, Black N, van der Meulen JH (2013) Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis. BMJ 346: f1026. doi: 10.1136/bmj.f1026 PMID: 23447338

48. Pulikottil-Jacob R, Connock M, Kandala NB, Mistry H, Grove A, Freeman K, et al. (2015) Cost effectiveness of total hip arthroplasty in osteoarthritis: comparison of devices with differing bearing surfaces and modes of fixation. Bone Joint J 97-B: 449–457. doi: 10.1302/0301-620X.97B4.34242 PMID: 25820881

49. Beard DJ, Harris K, Dawson J, Doll H, Murray DW, Carr AJ, et al. (2015) Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. J Clin Epidemiol 68: 73–79. doi: 10.1016/j.jclinepi.2014.08.009 PMID: 25441700

50. Kallala R. PA, Morris S., Haddad F. S. (2013) The cost analysis of cemented versus cementless total hip replacement operations on the NHS. Bone Joint J 95-B: 874–876. doi: 10.1302/0301-620X.95B7.26931 PMID: 23814235

51. Barrack RL, Castro F, Guinn S (1996) Cost of implanting a cemented versus cementless femoral stem. J Arthroplasty 11: 373–376. PMID: 8792242

52. Yates P, Serjeant S, Rushforth G, Middleton R (2006) The relative cost of cemented and uncemented total hip arthroplasties. J Arthroplasty 21: 102–105. PMID: 16446193

53. Larsson S, Lawyer P, Garellick G, Lindahl B, Lundstrom M (2012) Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Aff (Millwood) 31: 220–227.

54. Haddad FS, Thakrar RR, Hart AJ, Skinner JA, Nargol AV, Nolan JF, et al. (2011) Metal-on-metal bearings: the evidence so far. J Bone Joint Surg Br 93: 572–579. doi: 10.1302/0301-620X.93B4.26429 PMID: 21511920

55. Heintzbergen S, Kulin NA, Ijzerman MJ, Steuten LM, Werle J, Khong H, et al. (2013) Cost-utility of metal-on-metal hip resurfacing compared to conventional total hip replacement in young active patients with osteoarthritis. Value Health 16: 942–952. doi: 10.1016/j.jval.2013.06.021 PMID: 24041344

56. McMinn DJ, Snell KI, Daniel J, Treacy RB, Pynsent PB, Riley RD (2012) Mortality and implant revision rates of hip arthroplasty in patients with osteoarthritis: registry based cohort study. BMJ 344: e3319. doi: 10.1136/bmj.e3319 PMID: 22700782

57. Kendal AR, Prieto-Alhambra D, Arden NK, Carr A, Judge A (2013) Mortality rates at 10 years after metal-on-metal hip resurfacing compared with total hip replacement in England: retrospective cohort analysis of hospital episode statistics. BMJ 347: f6549. doi: 10.1136/bmj.f6549 PMID: 24284336

58. Hunt LP, Ben-Shlomo Y, Clark EM, Dieppe P, Judge A, MacGregor AJ, et al. (2013) 90-day mortality after 409,096 total hip replacements for osteoarthritis, from the National Joint Registry for England and Wales: a retrospective analysis. Lancet 382: 1097–1104. doi: 10.1016/S0140-6736(13)61749-3 PMID: 24075049

59. Cohen D (2011) Out of joint: the story of the ASR. BMJ 342: d2905. doi: 10.1136/bmj.d2905 PMID: 21572134