The Effect of Acetabular Component Geometry on Revision for Instability or Loosening

A study of 427,385 Primary Hip Replacements from the National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey

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Abbreviations

ANOVA – Analysis of variance

ASA – American Society of Anesthesiologists (physical status grade)

AVN – avascular necrosis

BMI – body mass index

BPT – Best practice tariff

CI – Confidence interval

HR – hazard ratio

LPW – long posterior wall

NHS – National Health Service

NICE – National Institute for Health & Care Excellence

NJR – National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey

Nm – Newton metres

OA – osteoarthritis

OHS – Oxford Hip Score

PE – polyethylene

PMMA – polymethylmethacrylate

QALY – quality adjusted life year

RANKL – receptor activator of nuclear kappa B ligand

RRR – relative risk ratio

SAS – Specialty and Associate Specialist doctor

SD – standard deviation

SF-12 – Short Form Health Survey (12 item)

SHR – subhazard ratio

THA – total hip arthroplasty

WOMAC – Western Ontario and McMaster Universities Osteoarthritis index

Abstract

Instability is a potential complication after total hip arthroplasty (THA), and alternative acetabular component designs feature an elevated rim to improve THA stability. It has been reported, however, that these elevated rim designs can increase the risk of prosthetic impingement that can conversely increase the risk of THA instability and may contribute to PE wear and loosening. The published literature remains unclear regarding the influence of acetabular component bearing surface geometry, and in particular the influence of uncemented lip size, on the risk or revision THA surgery for instability or for loosening.

The aim of this study is to examine the influence of acetabular component geometry on the risk of revision THA for instability or for loosening, and how surgical approach and time from surgery can influence revision risk. An observational cohort analysis of 224,874 cemented and 202,511 uncemented acetabular components from the National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey (NJR) dataset was performed, utilising covariate adjusted competing risks survival analyses.

This Registry based study confirms a significantly higher risk of revision THA for instability and for loosening when a cemented hooded or offset reorientating acetabular component is used, compared to an LPW component, regardless of surgical approach.

In uncemented acetabular components, a lower risk of revision for instability in posterior approach THAs with 10- or 15-degree lipped liners compared to neutral liners was found, but no significant difference between these lip sizes. A higher revision risk is seen with offset reorientating liners. The benefit of lipped geometries against revision for instability was not seen in lateral approach THAs. Uncemented liner geometry does not seem to influence the risk of revision for loosening.

Further research is required to clarify the role of offset reorientating cups/ liners and whether certain situations benefit from their use; and if the observed influences of acetabular bearing surface geometry on revision for instability or for loosening persist into the long-term.

Declaration

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Personal

I would like to express my gratitude to my parents for everything they have done for me, without which I wouldn't be who I am today. My only regret dad is that you didn't get to see me become a husband, a father, a surgeon.

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Lastly, to my beautiful children Anya and Nahla. I am eternally blessed to be your father. Thank you for your smiles, laughs, unconditional love and never-ending distractions! Know that you will always be at the centre of everything I do.

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I have been a Consultant Trauma & Orthopaedic Surgeon at Wrightington, Wigan & Leigh NHS Foundation Trust since August 2017. My areas of clinical specialisation are hip and knee arthroplasty including complex revision surgery, hip arthroscopy surgery and the management of metastatic bone disease.

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FRCS (Trauma & Orthopaedics), Royal College of Surgeons of England, 2015

Significant publications

Panchani S, Divecha H, Lafferty R, Pavlou G, Oakley J, Shaw D, Chitre A, Wynn Jones H, Raut V, Smith R, Gambhir A, Board T. Early functional outcomes of evolutionary total knee arthroplasty: A randomised control trial. Is new always better? JBJS Open Access: July-September 2021 - Volume 6 - Issue 3 - e21.00016

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Outputs from thesis

Journal submissions:

1. Paper 1 (chapter 5) submitted to British Joint Journal (BJJ) 14th January 2021. In press
2. Paper 2 (chapter 6) submitted to British Joint Journal (BJJ) 15th March 2021. In press

Conference abstracts:

1. World Arthroplasty Congress (22nd – 24th April 2021). Paper 2 (chapter 6) has been presented as an e-poster (see Appendices – World Arthroplasty Congress).
2. British Hip Society annual meeting (9th – 11th June 2021). Both papers have been presented.
3. European Hip Society Congress (9th – 10th September 2021). Both papers have been presented.

Chapter 1: Introduction

"Walking is Man's best medicine …"
Hippocrates, Greece, 460 – 360 BC

1.1 Summary

This short chapter introduces the topic area including a brief background of hip osteoarthritis (OA) and hip joint replacement surgery. Complications of hip joint surgery are considered including instability and loosening, and the use of different acetabular component geometries, in an attempt to reduce the risk of instability. The chapter closes with a summary of the structure of the thesis.

1.2 Osteoarthritis of the hip

OA is the most common form of arthritis worldwide and a major cause of disability in middle-age and older adults. The hip is one of the most frequently affected sites and hip OA results in pain, restriction of mobility and impaired quality of life. Patients with significant OA of the hip may find simple activities of daily living very difficult and it can also impair their ability to work and support themselves. Apart from the physical symptoms and restrictions, a strong association between the burden of hip OA with cardiovascular risk has been reported (1), even after adjusting for common cardiovascular risk factors. This association seems to be linked to OA-related walking difficulty and highlights the importance of appropriate assessment and management of patients with hip OA.

There are significant economic and societal considerations facing patients with hip OA, from loss of productivity and increased healthcare/ social care dependence. It has been estimated that the worldwide average total annual cost of living with hip OA is €11000 per person, though significant variations are seen (2).

Early OA can often be managed conservatively with activity modification, weight reduction, progressive strengthening regimes, analgesic agents and intra-articular steroid injections. When these options fail to control a patient's symptoms sufficiently, surgery in the form of a hip joint replacement may be required.

1.3 Hip replacement surgery

Total hip replacement (also referred to as total hip arthroplasty (THA)) surgery is a widely used and successful treatment for severe hip OA. Most THAs are performed in patients with hip OA; a minority are undertaken for other indications including hip fracture and avascular necrosis (AVN). The modern day THA traces its origins to Edward Haboush (Hospital for Joint Disease, New York) who used dental acrylic to fix prostheses to bone (3), and to Sir John Charnley who popularised the principle of "low frictional torque arthroplasty", pioneered the use of polyethylene (PE) cups and developed a reproducible cementation technique. He performed the first successful THA at Wrightington Hospital, Wigan, UK in 1962 (4).

A THA (see Figure 1-1) comprises several components including a polyethylene (PE) "cup" (acetabular component) inserted into the patient's acetabulum (socket on the pelvis), and a metal or ceramic "ball" (femoral head) attached to a stem (femoral stem) that is inserted into the thigh bone (femur). These prosthetic components are fixed into the patient's bone either with bone cement (polymethylmethacrylate, PMMA) or without cement, relying on a tight initial press-fit and bone ongrowth onto the roughened/ porous implant surface.

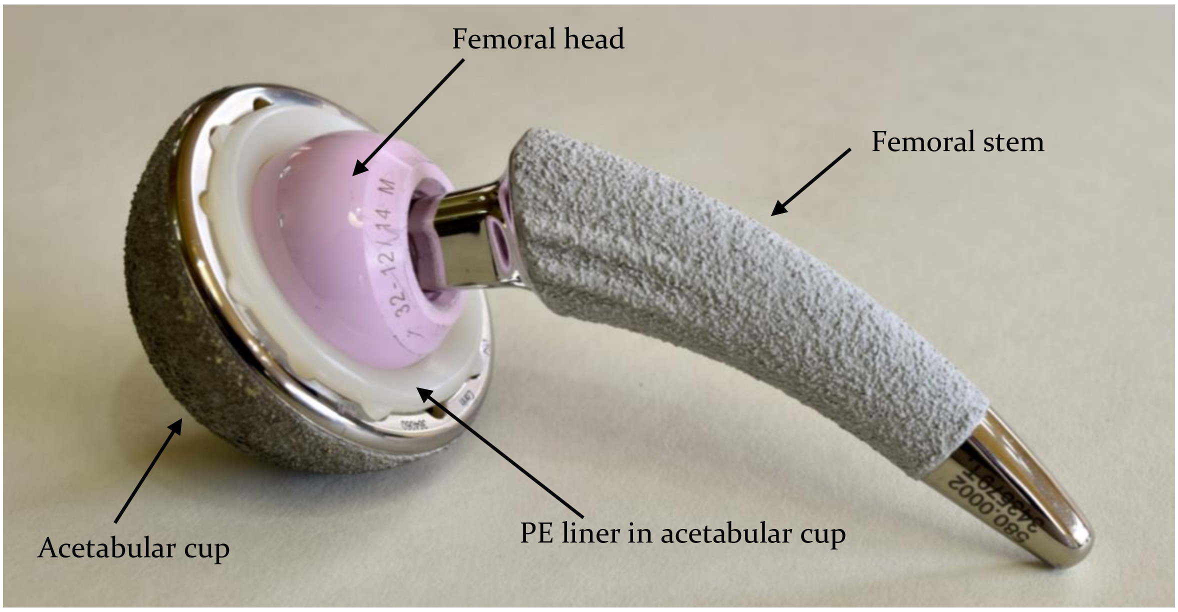

Figure 1-1 Photograph of an uncemented THA

Modern THA surgery is successful and cost-effective in the management of end-stage OA of the hip joint, with estimated costs per QALY (quality adjusted life years) gained after surgery of around £7000 (5), well below the NICE (National Institute for Health & Care Excellence) benchmark of £20,000 per QALY. Long-term, revision free survival estimates at 10 years after surgery are 95.5% and at 15 years, 92.5% (6), indicating excellent long-term survival.

In the UK, 95,677 primary THAs were performed in 2019 (National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey (NJR), 17th Annual Report, 2020, (6)) with an increase expected as populations grow, life expectancy increases and patient functional expectations increase (7).

1.4 Complications of THA

THA surgery, whilst very effective, does have some risks and complications associated with it. These are uncommon but include – infection, bleeding, nerve/ blood vessel injury, venous thromboembolism, intraoperative fracture, leg length discrepancy, instability, ongoing pain/ stiffness, wear, loosening, revision surgery and mortality. Revision THA surgery for instability and loosening are the complications of interest in this thesis.

1.4.1 THA instability

THA instability encompasses two specific conditions – subluxation and dislocation. Subluxation of a THA arises when the prosthetic femoral head begins to lever out of the acetabular component but does not fully come out. Patients are often aware of this and describe sensations of discomfort, clicking or clunking as the femoral head goes back into the socket and a lack of confidence in the THA.

Dislocation of a THA occurs when the prosthetic femoral head comes out fully from the acetabular component, and does not go back in. Dislocations are often very painful with loss of function of the joint, and usually require a general anaesthetic to allow the surgeon to manipulate the femoral head back into the socket.

A range of different acetabular component bearing surface geometries have been developed to try and reduce the risk of THA dislocation, but it remains unclear if these designs are successful in achieving this, and whether these designs could increase the risk of other issues such as THA loosening.

1.4.2 THA loosening

THA loosening occurs when the prosthetic components (acetabular cup or femoral stem) lose their fixation with the host bone in which they are implanted. Most commonly, THA components become loose as a result of PE wear induced osteolysis (bone resorption) at the prosthesis-host bone interface, referred to as aseptic loosening[1]. This eventually results in implant loosening that can generate pain and require revision surgery.

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[1] Septic loosening refers to the process of implant loosening mediated by infection

1.5 Revision hip replacement surgery

Revision THA may be required for complications involving the prosthetic components that cause persisting pain or dysfunction. A revision THA procedure involves the exchange of at least one THA component. In the UK, 123,891 revision THAs have been recorded between 2003 and 2019, with 15% being for instability and 43% for loosening (6).

Revision THA surgery exposes patients to further surgical risks, which may lead to even worse patient outcomes. Data from the NJR (6) shows that the risk of needing further surgery (i.e.: re-revision THA) after a revision THA is increased if the first revision procedure is performed early after the primary THA. Revision THA, for any indication, is associated with increased healthcare costs (8).

Minimising the risk of the first revision surgery following primary THA is therefore paramount to ensuring good patient outcomes and reducing the cost burden on healthcare systems from dislocations and revision THA surgery.

1.6 Thesis structure

Chapter 2 outlines the background to this thesis topic including a description and mechanisms for THA instability and loosening, known risk factors and a description of revision surgery for these complications. The chapter includes an overview of the types of acetabular components in clinical use including both cemented and uncemented components and a summary of the literature concerning their influence on risk of revision for either loosening or instability. Chapter 3 outlines the aims and specific objectives of this study.

Chapter 4 broadly describes the methodology used, including dataset description and variable preparation. The specific methods and analyses performed are fully described within the two results chapters (5 & 6) and are not repeated in this chapter.

Chapter 5 and 6 are presented in journal style. Chapter 5 presents the results of analyses looking at the influence of cemented acetabular component geometry on the risk of revision surgery for instability or for loosening. Chapter 6 presents the results of analyses looking at the influence of uncemented acetabular component geometry on the risk of revision surgery for instability or for loosening.

Chapter 7 summarises the main findings, considers strengths and limitations of the analyses and considers both implications for clinical practice and potential future research directions.

Chapter 2: Background

2.1 Summary

This chapter discusses the concept of prosthetic joint impingement and how this can result in THA instability and loosening. A review of risk factors associated with THA instability is presented. The different acetabular component geometries that are used in clinical practice are described along with how these may influence THA stability and impingement. The main portion of this chapter focuses on reviewing the literature regarding how the acetabular component geometry influences THA stability and the risks of revision surgery specifically for instability, and also for loosening. Gaps in the current knowledge base are highlighted.

2.2 Prosthetic impingement

Prosthetic impingement occurs when two parts of the THA come into contact, that were not intended to have contact (i.e.: surfaces that do not form the bearing couple between the head and the socket). This may occur at the extremes of the safe primary range of motion of the THA, when the femoral neck begins to impinge on the acetabular component rim leading to a levering out effect of the head from the socket.

2.2.1 Impingement and THA instability

Figure 2-1 demonstrates THA impingement between the femoral neck and the acetabular liner rim (upper image), which signifies the limit of the primary arc of movement. In the lower image the femoral neck continues to rotate, pivoting on the acetabular rim at the point of impingement and the femoral head is seen to start levering out, referred to as the secondary arc of movement. This secondary arc of movement is essentially subluxation of the THA as the femoral head is beginning to lever out of the acetabular component and is only in point contact with the acetabular bearing surface. If the femoral head levers out enough past the acetabular liner rim (called the “jumping distance”), it will dislocate fully out of the socket (point of egress).

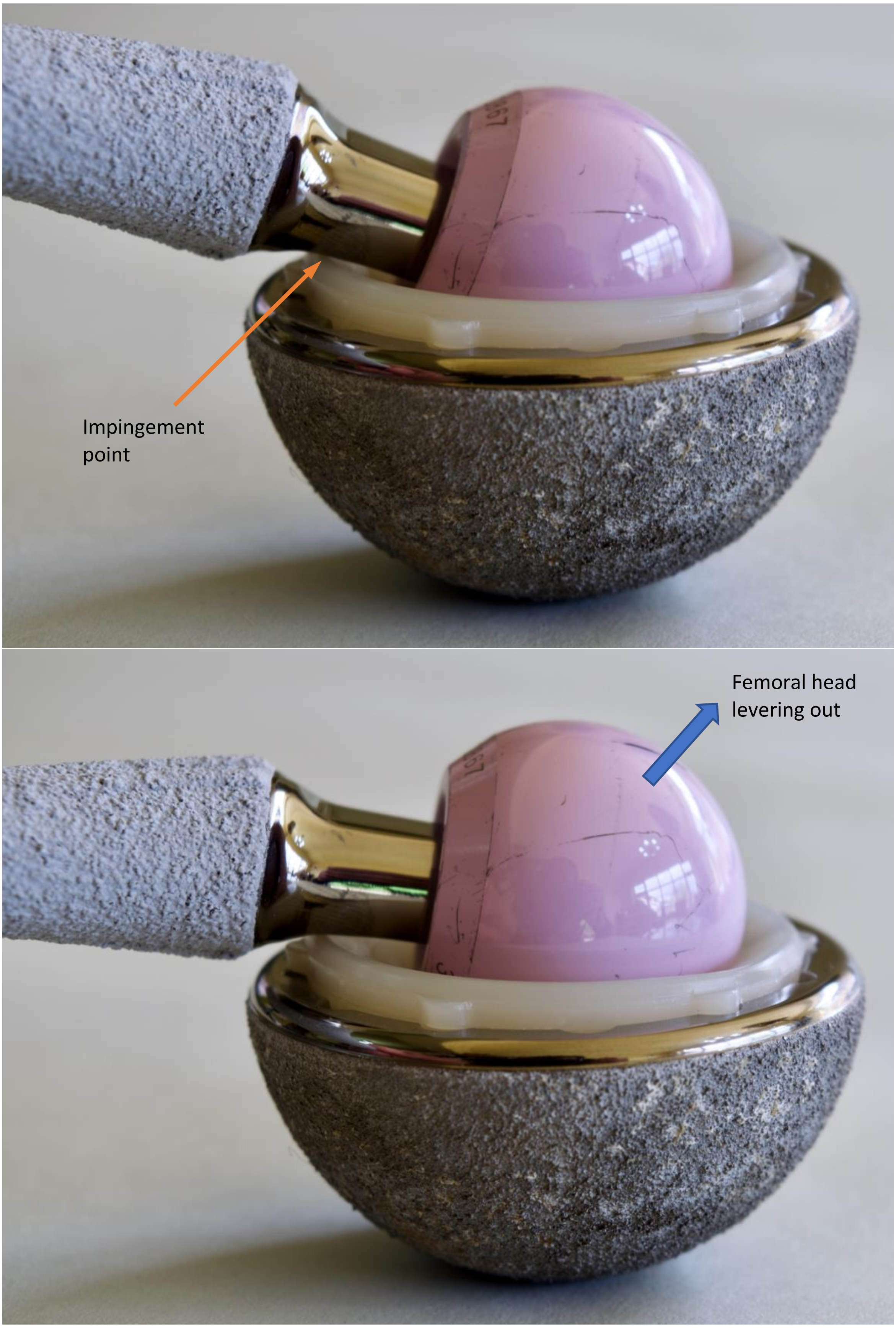

Figure 2-1 Prosthetic THA impingement

2.2.2 Impingement and THA loosening

Prosthetic impingement can result in loosening of THA components through two mechanisms – PE wear driven osteolysis (reviewed in section 1.4.2, page 20) and mechanical transfer of torque to the prosthesis-bone interface. Damage to the PE surface of the acetabular component can arise as a direct result of prosthetic impingement. This can happen at the site of impingement between the femoral neck and the PE rim from mechanical impact and point loading[2] as the femoral neck levers on a small contact point on the PE rim. Additionally, eccentric PE wear can occur opposite the site of impingement from point loading of the femoral head as it begins to lever out of the acetabular component (only in contact over a smaller area as the femoral head begins to subluxate out of contact with the acetabular bearing surface). PE wear induced osteolysis leads to bone resorption around the prosthetic components that can lead to implant loosening. This process is potentially aided by the mechanical transfer of torque from impingement to the prosthesis-bone interface.

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[2] Point loading refers to increased stress concentration due to the load being transferred over a smaller contact area. This can cause increased PE wear in this area

2.3 THA instability

2.3.1 Time to first THA dislocation

The majority of first time THA dislocations seem to occur early after primary THA surgery. Blom et al.(9) found that 64% of dislocations occurred within the first 3 months of surgery. In a review of over 62,000 primary THA's from the Scottish National Arthroplasty Project (SNAP), Meek et al. (10) observed 23% of dislocations happening within the first 3 months and 66% within 12 months of the primary THA. Itokawa's (11) smaller series of 1250 primary THAs had a similar rate, with 69% of dislocations occurring within 12 months of surgery.

2.3.2 Risk factors for THA instability

THA stability is multifactorial with both patient, surgeon and implant factors playing a role (12). Kunutsor et al. (13) performed a systematic review and meta-analysis of 125 studies reporting on risk factors for dislocation after primary THA. This is the largest known study on this topic, and the pooled analysis included 4.6 million primary THAs with 35,000 dislocations. The pooled estimate of risk of dislocation after primary THA was approximately 2%, over a mean follow-up of 6 years. Identified risk factors associated with significant increased risk of dislocation included:

1. Sociodemographic factors
    a. Age at surgery >70 years (compared to <70 years)
    b. BMI (body mass index) > 30 kg/m^2 (compared to <30 kg/m^2)
    c. White ethnicity (only when compared to Asian)
    d. Low-income groups
    e. Increased social deprivation
    f. Nursing home resident (compared to own home)
    g. Drug use disorders
2. Medical history factors
    a. Neurological or psychiatric disorders
    b. ASA (American Society of Anesthesiologists) grade > 3
    c. Previous spinal fusion and abnormal spinopelvic mobility
    d. Previous hip surgery
    e. Frailty
    f. Renal failure
    g. Chronic lung disease

3. Surgical indication for THA
    a. Avascular necrosis (AVN)/ osteonecrosis
    b. Rheumatoid arthritis
    c. Inflammatory arthritis
4. Surgeon related factors
    a. Posterior approach (compared to lateral, anterolateral and anterior approaches)
    b. Posterior approach without soft tissue repair (compared to posterior approach with repair)
    c. Low experience/ low volume surgeon
5. Implant factors
    a. Uncemented THA (compared to cemented THA)
    b. Short or long femoral neck lengths (compared to standard length)
    c. Smaller femoral head diameters
    d. Standard/ neutral acetabular liners (compared to lipped/ elevated rim)
    e. Conventional cups (compared to dual-mobility cups)

As outlined, acetabular bearing surface geometry (factor 5.d. above) is the focus of this thesis and the literature relating to the effect of this on the risk of instability and risk of revision THA surgery will be discussed in a later section. The influence of surgical approach (factor 4.a above) on revision risk related to acetabular component geometry will also be considered in later analyses.

2.3.3 Recurrent THA instability

THAs may dislocate on more than one occasion. Apart from the underlying reason(s) for the first THA dislocation persisting, additional damage to the constraining periarticular soft tissues around a THA (repaired joint capsule, repaired tendons) occurs from the traumatic process of the dislocation. These factors can lead on to further episodes of THA instability that may ultimately necessitate revision THA surgery to rectify.

2.3.3.1 Risk of recurrent THA instability after first dislocation

Blom et al. (9) report on a single centre audit of 1567 consecutive primary THAs with a 3% dislocation rate. They found that 59% of the patients with a first-time dislocation went on to experience recurrent instability. In a smaller case-series, Kotwal et al. (14) followed-up 101 THAs that experienced a first-time dislocation and found the rate of recurrent instability to be 60%. Brennan et al. (15) found a redislocation rate of 69%, of the first time dislocators

(1%) in 6554 primary THAs. Interestingly, they found that the time to the first dislocation probably influenced the risk of becoming a recurrent dislocator. The median time to first dislocation in recurrent dislocators was 13 weeks, whereas in those who did not experience further dislocations it was 3 weeks. The authors proposed that an early dislocation may have the potential for healing of damaged soft tissues, sufficient to reduce the chance of further dislocations.

Itokawa et al. (11) found a similar rate of recurrent THA instability in their review of 1250 THAs with a 2.9% dislocation rate. Of the first time dislocators, 56% become recurrent. They also found the time to first dislocation influenced the risk of recurrent instability, defining "early dislocation" as those occurring within the first 12 months of THA. The rate of recurrent instability in their early dislocators was 40%, whereas in the late dislocators it was 90%.

2.3.3.2 Patient reported outcomes with recurrent THA instability

There is a paucity of published studies examining the effect of THA instability on patient reported outcomes and quality of life (16). Forsythe et al. (17) report the earliest known study looking at patient reported outcomes after dislocation of a primary THA. They compared a cohort of THA patients who experienced dislocation to a control group that did not. Patient satisfaction in the dislocation group was significantly lower than that in the control group. Interestingly though, generic quality of life measures (Short Form health survey 12 item, SF-12) and joint specific outcome measures (Western Ontario and McMaster Universities Osteoarthritis Index, WOMAC) were not significantly different between the groups.

Kotwal et al. (14) found that validated joint specific patient reported outcomes (Oxford Hip Score, OHS), compared to a control group of primary THAs with no dislocation events, were worse in those who experience a single or recurrent dislocation. Additionally, the outcome scores seemed similar in the single and recurrent dislocator groups, highlighting the negative effect on patient reported outcomes from THA instability.

2.3.4 Revision THA for instability

Patients with recurrent THA instability may require revision THA surgery to try to address the causative factors for instability and provide the patient with a stable THA. The reported rate of revision THA for recurrent instability after primary THA varies from 30% (9) to 50% (14). In Itokawa et al.'s series (11), 35% of recurrent dislocators required revision THA surgery. The risk of revision THA surgery also seemed affected by time to first dislocation, being 20% in early dislocators (<12 months after primary THA) and 50% in late dislocators (>12 months after primary THA).

2.3.4.1 Outcomes of revision THA for instability

Kotwal et al. (14) found that patient reported outcome scores were worse after successful revision THA surgery for recurrent instability than the group of recurrent dislocators who had not undergone revision surgery. Failed revision THA surgery for recurrent THA instability led to even worse patient reported outcomes.

2.4 THA loosening

Aseptic loosening of previously well fixed THA components occurs due to PE wear induced osteolysis (bone resorption) (18). As progressive bone at the prosthesis-host interface is resorbed, eventually there will be insufficient supportive bone fixation to the prosthesis to withstand the loading forces across the joint and the component will loosen.

2.4.1 Pathobiology of osteolysis

PE wear occurs mainly from adhesion and abrasion at the bearing couple interface (femoral head against the acetabular component) (19). This generates PE wear particles. The size of PE wear particles seems to be important in stimulating an osteolytic response; histologic analysis of membrane tissue retrieved from the interfaces of loose prosthetic components show that the majority of PE particles are in the submicron range (20). These submicron PE particles are phagocytosed by macrophages and activate a pro-inflammatory foreign body mediated cellular response through pathways involving macrophages, fibroblasts, inflammatory cytokines, osteoblasts and RANKL (receptor activator of nuclear factor kappa B ligand) activation of osteoclasts (21-23). Activated osteoclasts and matrix metalloproteinases (from macrophages) are ultimately responsible for bone resorption.

2.4.2 Risk factors for THA loosening

The common pathway leading to THA loosening is PE wear particle induced osteolysis and there are a number of risk factors that can influence the rate of PE wear. The following risk factors pertain to wear or revision of the acetabular component for loosening.

Patient factors

1. Younger age at surgery is associated with higher wear rates and revision for loosening (24,25)
2. Indication – surgery for sequalae of paediatric hip conditions and for trauma are at higher risk of revision for loosening than surgery for OA (24)
3. Increased body weight (but not BMI) seems to reduce the risk of wear (25) thought to be linked to lower activity levels
4. Greater activity levels after surgery seem to increase the risk of wear – this is probably also linked to age, body weight and preoperative mobility (25)

Prosthesis factors

1. Crosslinked PE[3] has a 40-90% lower wear rate and less observed radiographic osteolysis than non-crosslinked PE (26-28)
2. Ceramic femoral heads have lower wear rates than metal heads when used with non-crosslinked PE (29,30), but no difference is noted when used with cross-linked PE (31)
3. Larger femoral head sizes (>36mm) result in greater wear rates but no observable difference in radiographic osteolysis (32)

Other factors traditionally thought to increase the risk of wear, osteolysis and revision for loosening of acetabular components include male gender and surgeon experience though these have not been found to be significant in two large studies (24,25).

2.4.3 Revision for THA loosening

Loose THA components can cause pain on weightbearing, from motion of the loose components in the host bone, and restriction in mobility. Loose components can cause further bone damage and the components can migrate. This can cause THA instability if the acetabular component migrates significantly out of position. In severe cases, excessive bone loss around the component can head to a periprosthetic fracture in the remaining weakened bone. Revision THA surgery for symptomatic THA loosening may be required.

2.4.3.1 Outcomes of revision THA for loosening

Biring et al. (33) found that revision THA performed for aseptic loosening (compared to other indications such as infection, instability, periprosthetic fracture) was predictive of improved patient reported function and activity in their retrospective cohort analysis of 222 revision THA procedures. Phillipot et al. (34) reviewed 1176 revision THAs (minimum 10 year follow-up) and found no association between revision THA indication and patient reported outcomes (OHS), though patient satisfaction seemed to be greater in revision THA for loosening. They did however report that revision for THA loosening was predictive of improved survival at 10 years, when compared to other revision THA indications.

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[3] Crosslinked PE is manufactured by irradiation of ultrahigh molecular weight PE in an inert atmosphere (to avoid oxidation). Advantages include improved wear resistance, though fatigue fracture risks may increase with greater crosslinking

2.5 Acetabular component geometry

As outlined in section 2.3.2 (page 26), one of the implant related risk factors suggested to have an influence on the risk of dislocation (13) is acetabular component bearing geometry. As this is a factor that is controllable by the operating surgeon, it is potentially a modifiable factor that could influence the overall rates of dislocation, recurrent THA instability and volume of revision THA. In this section the different acetabular component bearing surface geometries will be described for both cemented and uncemented THAs.

2.5.1 Cemented cups

Figure 2-2 demonstrates the cross-sectional geometries of cemented acetabular components. These will be individually described to clarify the differences between them.

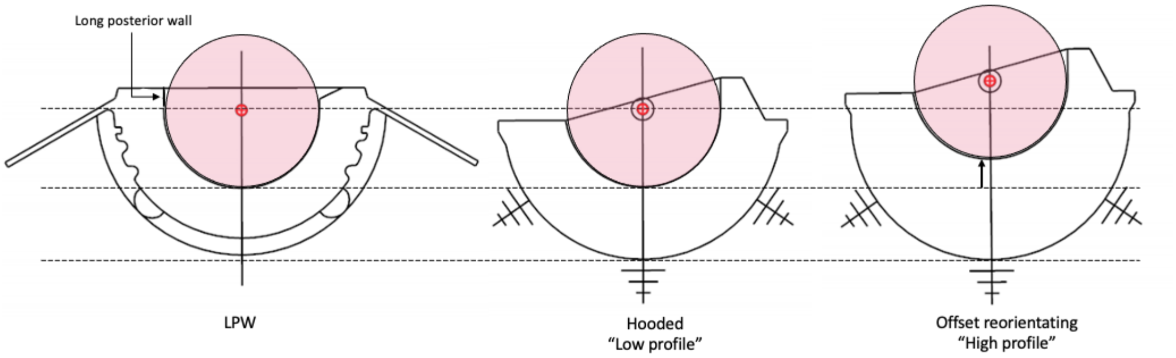

Figure 2-2 Cross-sectional geometry of cemented acetabular components[4]

2.5.1.1 LPW (long posterior wall) cup

The LPW cup is flat on its bearing surface (the surface that the femoral head sits against), with a vertical extension over part of the circumference that extends past the hemisphere. This extension is called the long posterior wall and it confers some extra stability to dislocation of the femoral head out of this area.

2.5.1.2 Hooded cups

Hooded cups (also called "Low profile" cups) have an elevated portion of the rim that extends the coverage of the femoral head further in the area of the hood. The cup can be inserted during cementation with the hood in the desired position to provide best stability

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[4] Redrawn from digital templating software – TraumaCad, BrainLab Inc.

to the THA, but once the cup is inserted this cannot be changed without fully removing the cup and cement mantle and starting again.

2.5.1.3 Offset reorientating cups

Offset reorientating cups (also called "High profile" cups) are similar to the hooded cups but have an increased PE thickness in the dome portion of the cup. This lateralises the centre of rotation of the hip.

2.5.2 Uncemented cups

Uncemented acetabular components have the benefit of being modular, consisting of a metal acetabular shell that is impacted into the patient's native acetabulum after preparation, and a liner that is impacted into the acetabular shell (see Figure 2-3).

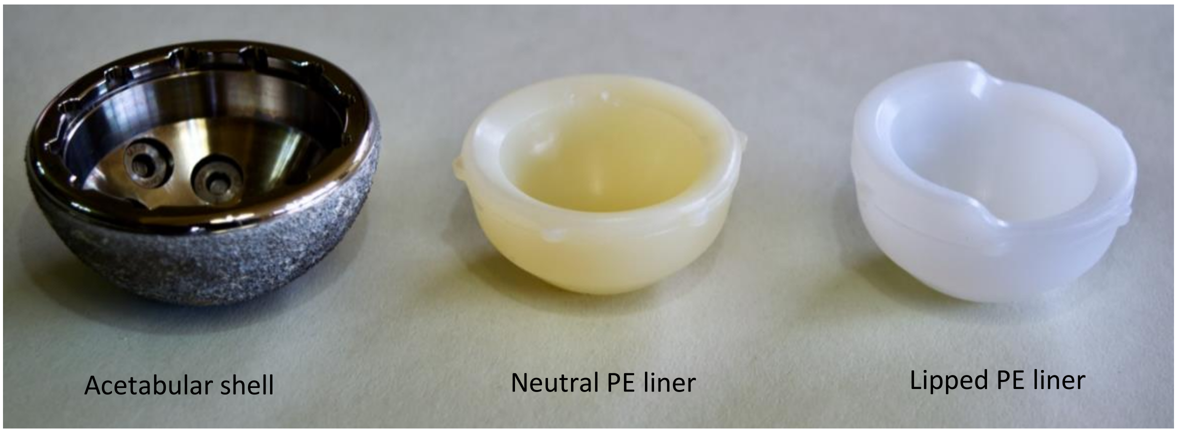


Figure 2-3 Uncemented acetabular shell with PE liners

These liners can be made of metal, ceramic or PE. The PE liners are available in neutral, lipped, offset neutral or offset reorientating geometries (see Figure 2-4), the other materials are only available in a neutral geometry. The surgeon can implant the acetabular shell in the desired orientation, and then "trial" the joint replacement with different liner geometries to assess the range of motion before impingement and dislocation. This gives the surgeon an idea of the overall stability of the joint replacement before committing to choosing a definitive acetabular liner that is then impacted into the acetabular shell.

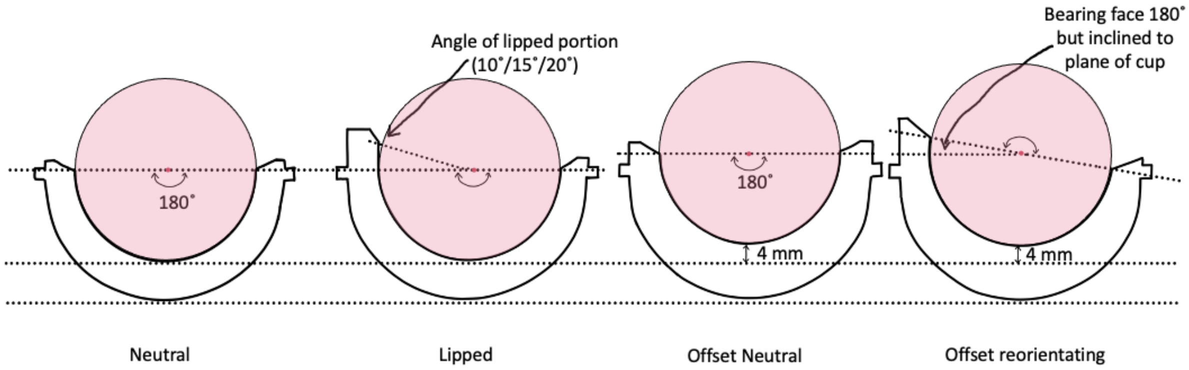


Figure 2-4 Cross-sectional geometry of uncemented acetabular PE liners[4]

2.5.2.1 Neutral

Neutral PE liners are flat on their bearing face and cover the femoral head by 180 degrees.

2.5.2.2 Lipped

Lipped liners have an elevated rim that extends vertically past the hemisphere of the cup (see Figure 2-5). The lipped portion of the liner covers half of the circumference of the bearing face, which includes the “ramp-up” portions from the non-lipped portion. The size of the lip (extending past the hemisphere) is often referred to by manufacturers as the angle subtended from the centre of rotation of the articulation to the highest point of the lip and is manufacturer specific, commonly 10-, 15-, or 20-degrees. The lip portion of the liner provides extra stability against dislocation.

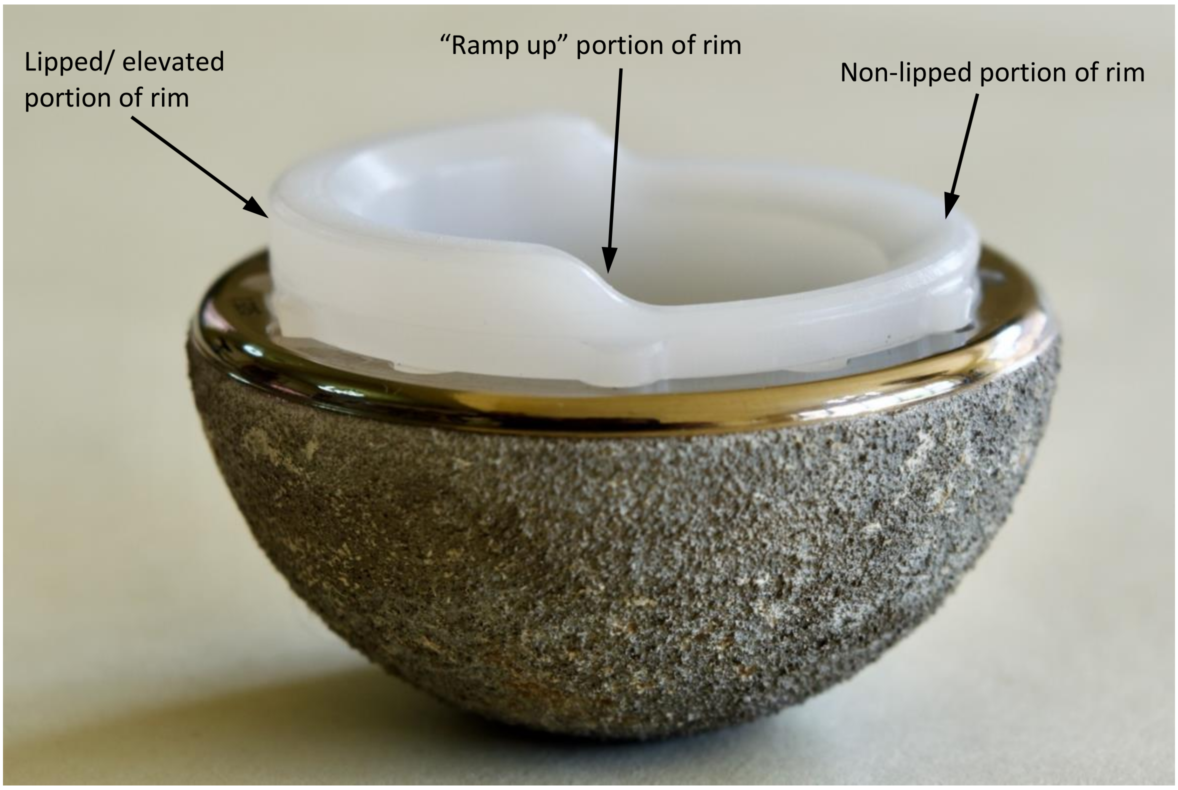
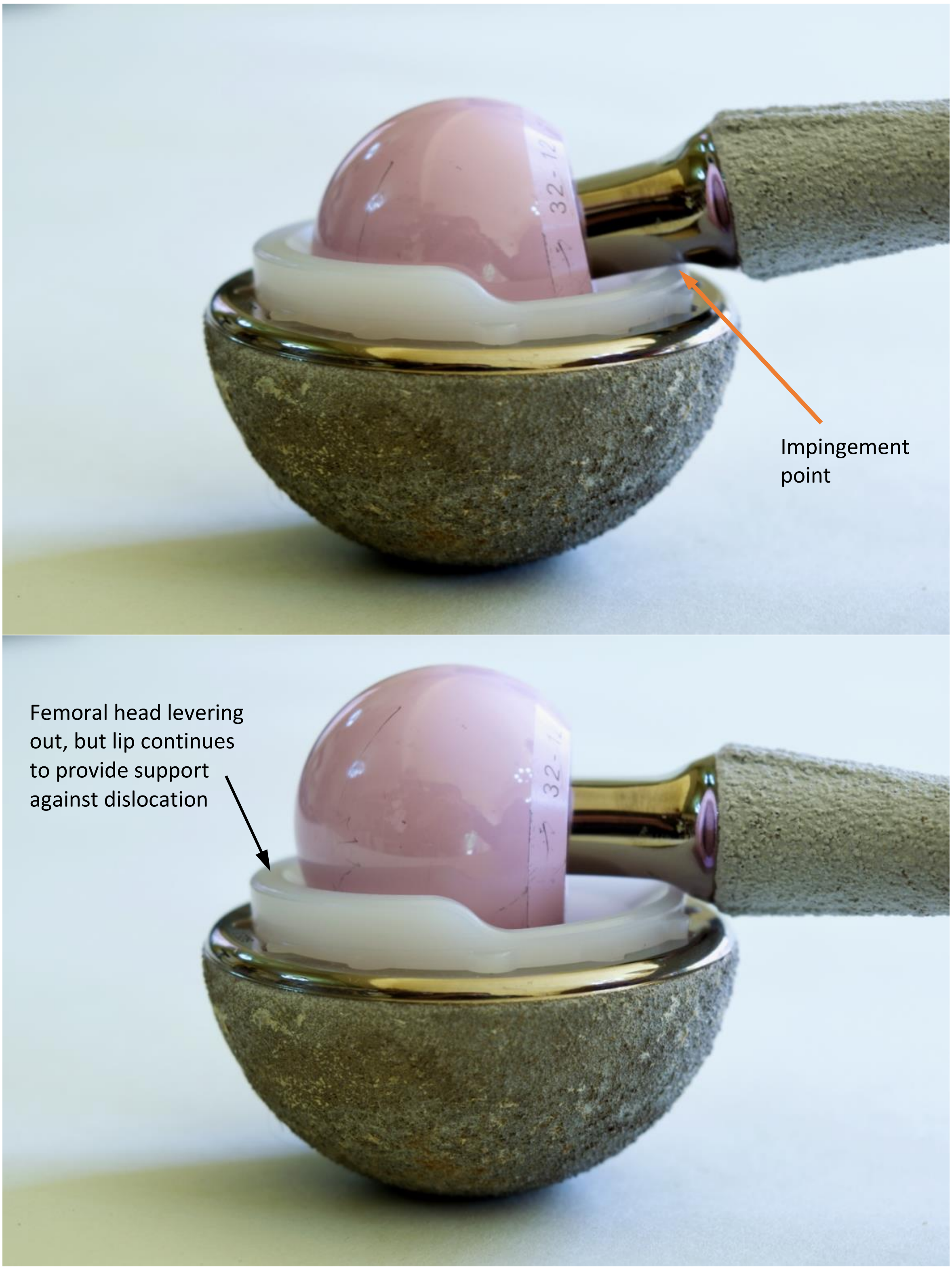


Figure 2-5 Uncemented acetabular cup with lipped PE liner

When impingement of the femoral neck on the acetabular rim opposite the lip occurs, the femoral head begins to lever out of the socket but remains contained by the lip. This is depicted in Figure 2-6, which shows how the lip continues to provide some cover of the femoral head even after femoral neck impingement has occurred and the femoral head is beginning to lever out, in comparison to a neutral liner (see Figure 2-7). The surgeon has the option of orientating the lip in the area where most stability is conferred during the trialling process, before inserting the definitive PE liner.



Impingement point

Femoral head levering out, but lip continues to provide support against dislocation

Figure 2-6 Protective effect of lipped liner

Figure 2-7 Comparison of neutral (left) and lipped (right) liners in impingement

A potential downside to the lipped geometry is that impingement may occur earlier on the lip itself, which reduces the primary arc of movement in the opposite direction and may lead to dislocation opposite the lip, as shown in Figure 2-8.

Figure 2-8 Impingement on lip of lipped liner

2.5.2.3 Offset neutral

Offset neutral liners are also flat on their bearing face, providing the same 180-degree coverage of the femoral head as neutral liners, but the PE is thicker in the dome area of the liner. This lateralises the centre of rotation of the hip joint articulation.

2.5.2.4 Offset reorientating

Like the offset neutral liners, the offset reorientating ones have an increased PE thickness in the dome portion of the liner that lateralises the centre of rotation. The bearing surface still only covers 180 degrees of the femoral head but is reorientated from the hemispherical plane of the cup. This reorientation of the bearing surface may improve the impingement free range of motion and reduce instability.

2.5.3 How do surgeons decide which acetabular component geometry to use?

There are no accepted guidelines concerning the use of particular geometries of acetabular components. Although there are no validated tools to predict instability, based on the presence of potential preoperative patient related risk factors (outlined earlier in section 2.3.2, page 26), a surgeon may consider the use of an elevated rim acetabular component to minimise the risk of dislocations. Few studies have addressed the rationale for use of a particular type of acetabular component geometry.

In Cobb et al.'s institutional retrospective cohort comparison (The Mayo Clinic, Rochester, Minnesota, USA) of over 5000 THAs and the effect of an elevated rim liner on postoperative dislocation (35), an informal opinion poll of surgeons at The Mayo Clinic was also performed. They report that most of their surgeons that used an elevated rim liner did so routinely because of personal preference, and not necessarily in response to the presence of preoperative risk factors for THA instability. Earll et al. (36) estimated that 80 – 90% of THAs in their region (Charlotte, North Carolina, USA) utilised an elevated rim liner, based on informal discussions with implant manufacturers. Shon et al. (37) report that elevated rim liners are used routinely in their institution (Hospital for Special Surgery, New York, USA) where the surgeon is concerned about the risk of instability. The senior surgeon on this report utilised an elevated rim liner in 40% of his primary THAs.

2.6 Effect of acetabular component geometry on THA stability, dislocation rates and revision for instability or loosening

The following section considers the effect of acetabular component geometry on THA stability (simulated and intraoperative), postoperative dislocation rates, prosthetic impingement and on the risk of revision surgery for instability or for loosening.

2.6.1 Effect of acetabular component geometry on THA stability

The effect of acetabular component geometry on THA stability cannot be directly observed *in vivo*, as the technology to view 3-dimensional THA motion dynamically during gait does not exist. The alternatives are to assess THA stability using model-based laboratory simulations, computer model-based simulations (finite element analysis) or observing THA stability intraoperatively. These methods have their limitations, and it is a big assumption that what is observed under these test conditions represents THA motion and stability *in vivo*.

2.6.1.1 Simulator studies

Biomechanical analyses of the effect of acetabular cup geometry have been performed in the laboratory setting using hip simulator testing apparatus designed to apply some compressive load across the prosthetic joint replacement whilst simulating hip joint range of movement until impingement and dislocation occur.

Nicholas et al. (38) compared the original cemented Charnley sockets that were neutral to those that had a long posterior wall (LPW). In their testing apparatus, the femoral head was dislocated out of the elevated rim sector. They found a reduced range of motion with the LPW components (95° vs 106°) before primary impingement occurred between the femoral neck and the acetabular component rim. Furthermore, the torque required to dislocate the femoral head from the LPW component (in the LPW portion of the cup) was higher than for the neutral component. In other words, once primary impingement has occurred, the elevated rim of the LPW socket continues to prevent dislocation and therefore a greater rotation is required to eventually dislocate the femoral head from it.

Krushell et al. (39) explored the influence in uncemented cups of both the use of an elevated rim acetabular liner, and of acetabular component positioning on the range of motion of the prosthetic joint and stability, using implants fixed into synthetic anatomical bone models. The range of motion in specific directions was measured till the point of impingement and subluxation and then at the point of dislocation. All tests were performed using standard and elevated rim liners, in both a standard acetabular component position and then repeated in a "mal-positioned" acetabular component position. In the standard acetabular component positioned implants, the elevated rim liner was found to increase resistance to dislocation (in the direction of the elevated rim) but not the point at which impingement/ subluxation occurs. In other words, impingement still occurs on the acetabular rim opposite to the elevated rim at the same point, but the elevated rim allows the femoral head to "ride up" the elevated portion increasing the range of motion in this direction before dislocation. It was noted, however, that the range of motion before dislocation was reduced in the opposite direction i.e.: impingement occurred earlier on the elevated rim. The authors also tested an offset reorientating liner. In the setting of the standard acetabular component positioning, this type of liner simply increases the range of motion in the direction of the reorientation, and decreases it in the opposite direction, which would give the same result as changing the orientation of the acetabular component and using a neutral liner. In the mal-positioned acetabular components, these offset reorientating liners had the ability of increasing dislocation free range of motion depending on where the apex of the reorientating face was placed. This simply compensated for the mal-positioning of the acetabular component position. The elevated rim liner was found to confer some increased range of motion before dislocation, but not as much as the offset reorientating liners. The authors concluded that the most important factor to prosthetic joint range of motion is correct acetabular component orientation.

2.6.1.2 Computer model-based studies

In his Doctoral Thesis, Daniel Huff (University of Denver) (40) utilised finite element analyses of THA constructs and included kinematic motion analysis data as well as representations of the PE liner behaviour and capsular restraint within subject specific THA models of patients performing activities that could generate impingement and posterior or anterior THA dislocation. He found that the use of a lipped PE liner, compared to a neutral liner, on average increased the THA flexion required to cause a posterior dislocation by 1.4° with a resulting increased resistive moment to dislocation of 5.2Nm (Newton metres) (tested across combinations of acetabular component orientations). There was however a corresponding reduction in resistance to anterior dislocation.

The effect of lip size was also modelled, a factor that has not been examined within the published literature. 10-, 15- and 20-degree lipped PE liners were modelled under the same finite element analysis models testing posterior dislocation. When compared to neutral liners the 10-, 15- and 20-degree lipped liners increased the jump distance (13.5%, 20.9% and 46.5% respectively), the resistive moment to dislocation (2Nm, 4Nm, 10Nm respectively) and the energy to dislocation (a measure of resistive moment compared to the flexion angle; 8%, 17% and 27% respectively). The effect on anterior dislocation was not examined in this these analyses.

From this finite element analysis, it seems that a lipped PE liner is protective of posterior dislocation but may increase the risk of anterior dislocation (due to earlier impingement of the femoral neck on the elevated lip) when compared to a neutral liner. Furthermore, it seems that the size of the lip has a dose-effect relationship in protecting against posterior dislocation, but importantly the reciprocal reduction in anterior stability was not considered or reported on. This may have significant clinical importance in deciding on the safest trade-off offered between increased posterior stability with bigger lips against decreasing anterior stability.

2.6.1.3 Intraoperative studies

One of the benefits of modular uncemented acetabular components, as mentioned previously, is the ability to implant the acetabular shell and then trial different acetabular liner geometries to assess joint stability before choosing and implanting a definitive acetabular liner. The biomechanical and mathematical models described in the previous section are a very crude representation of a joint replacement *in vivo* and do not account for the effects of surrounding capsular/ ligamentous/ tendinous and muscular structures. Two small cohort studies (20 and 50 THAs respectively) have been published reporting on the effects of liner geometry on intraoperative THA stability using trial acetabular liners (41,42). Both studies report that the range of motion before impingement and joint subluxation begins to occur is increased by 8.2° – 8.9° with the use of an elevated rim acetabular liner when assessing internal rotation at 90° hip. Furthermore, these studies also reported that the use of 32mm heads compared to 28mm heads also provided an increased range of internal rotation before impingement and subluxation of 7.3° – 8.1°. This effect of head size was independent of the use of an elevated rim liner. Both studies were unable to cause impingement of the femoral neck onto the elevated portion of the acetabular rim in hip external rotation with extension, or cause dislocation of the trial joint anteriorly, presumably due to the intact anterior joint capsule.

Whilst these *in vivo* intraoperative studies demonstrate the individual effects of acetabular component geometry and femoral head component size on joint stability, potential issues may have arisen in measurement. The method of measurement is crude and subjective with the use of a goniometer and visual confirmation of the angle between the tibia and the floor at the point of joint subluxation occurring. Measurement error may have arisen with slight differences in patient positioning on the operating table. Furthermore, it is a significant assumption that intraoperative THA stability equates to real-life THA stability. Tanino et al. (43) investigated this by performing a very similar intraoperative assessment of THA stability (utilising a sterile goniometer) to record how much internal rotation was possible of the THA in 90° flexion before subluxation began. They then followed up their cohort (185 THAs) and compared the intraoperative measured internal rotation between patients who suffered a postoperative posterior dislocation and those who did not. A cut-off of 51° intraoperative internal rotation was proposed. THAs with less than this were at higher risk of postoperative posterior dislocation. There are similar limitations in this study relating to measurement error from possible variability in patient positioning in theatre, no consideration of anterior THA instability and no consideration of the effects of active muscle tone, weightbearing or spino-pelvic mobility.

2.6.2 Effect of acetabular component geometry on postoperative dislocation

There have been few studies that investigate the effect of acetabular component geometry on the risk of postoperative dislocations. These have been limited to retrospective cohort comparisons. There are no prospective randomised controlled trials published assessing this issue in the current literature.

One of the earliest reports published on the effect of cemented acetabular component geometry on postoperative dislocations was by Etienne et al. (44) from the Centre for Hip Surgery at Wrightington Hospital. This study compared the number of dislocations occurring before and after the introduction of two changes – a change from the original Charnley cup (neutral face) to routine use of the Charnley LPW acetabular component, and routine restoration of hip centre of rotation instead of a higher position that was previously performed. Both changes were instituted at about the same time making the individual contributions difficult to quantify. The authors report a significant reduction in postoperative dislocations from 0.8% (in 3820 THAs, 1966 – 1969) to 0.4% (in 4706 hip replacements, 1972 – 1975). Though not directly investigated in this paper, the authors comment on the possibility of impingement between the femoral component neck and the elevated rim of the LPW socket and the importance of avoiding this, though there was no direct observation of this issue (e.g. in cases that underwent subsequent revision THA).

Cobb et al. (35) retrospectively compared the rates of dislocation following THA with standard or elevated rim uncemented acetabular components. Out of 5167 patients, 48% received an elevated rim liner (only 10° elevated rim liners included) and the rest received a neutral liner. Bigger elevated rims (15° or 20°) were excluded on the grounds that these might represent cases that the surgeon felt to be at inherently higher risk of postoperative dislocation. Excluding these cases from their analysis could have introduced selection bias and maybe the size of the elevated rim could have been used as a potential predictor variable in the authors' analyses to include all cases receiving an elevated liner. A significant difference in postoperative dislocations was noted within in the first 2 years after surgery, with 2.2% in the elevated-rim group and 3.9% in the neutral group. A similar, though non-significant difference was noted at 5 years postoperative in the remaining 1385 patients – 2.9% versus 4.5%. The authors attempted to control for some potential confounding factors such as surgical approach used, method of fixation of implants, primary or revision surgery. A significantly reduced dislocation risk in the elevated rim component group was still noted. Limitations of this study include the retrospective nature with lack of randomisation or matching, heterogeneity in the included patients (primary and revision THA) and the short-term follow-up. The authors concluded that the elevated rim acetabular component seems to reduce the risk of early dislocation following hip arthroplasty but cautioned that the long-term effects of an elevated rim acetabular component remained unknown and that increased torque at the implant-bone interface may be experienced due to the longer lever arm when the head is articulating on the elevated rim, that could lead to eventual implant loosening.

More recently, Partridge et al. (45) presented their findings of a retrospective cohort comparison at the British Hip Society Meeting in 2016 (Norwich, UK). Their dislocation rate with routine use of a hooded cemented acetabular component in their institution was 2.64%, which fell to 0.71% when they changed to routine use of a standard LPW cemented acetabular socket. The authors felt this reduction in dislocation rate was due to better cup positioning and avoidance of impingement that can occur with hooded acetabular components. As this is an abstract of presented findings, a more thorough critique of this unpublished study was not possible.

2.6.3 Effect of acetabular component geometry on prosthetic impingement

Prosthetic impingement, described in section 2.2 page 23, can lead to THA instability as well as PE wear that can drive PE induced prosthetic loosening. It is possible that impingement may occur earlier in the motion of a THA on an elevated rim acetabular component, which could possibly increase the risk of THA instability events and of component wear/ loosening through these mechanisms described previously. Murray (46) developed a mathematical model to compare the range of motion before impingement and dislocation occur between a standard Charnley socket (neutral) and a Charnley LPW socket. He concluded that impingement on the posterior acetabular rim occurred earlier in external rotation with the LPW than the standard socket (38° vs 53°). More importantly, he calculated that the peak torque applied to the acetabular component from posterior impingement with an LPW socket was nearly twice that calculated for the standard socket, due to a longer lever arm on the elevated rim from centre of rotation. This may have a mechanistic role in impingement related loosening of an acetabular component from repetitive transmission of torque to the prosthesis-host bone interface, as discussed in section 2.2.2 on page 25.

Prosthetic impingement cannot be viewed *in vivo*, but the effects can be studied from components that have been removed at the time of revision surgery (retrieval studies). Evidence of impingement wear/ erosion on the acetabular component seems to be relatively prevalent amongst acetabular components examined in retrieval studies (39 – 69%) (37,46-50). In cases where revision has been specifically for THA instability, retrieved components show a high incidence of impingement wear/ erosion (81 – 91%) (37,49), though one study did not find this association(47). Retrieved elevated rim components have been found to exhibit a higher incidence of impingement wear/ erosion (40 – 83%) (37,47,49,50), though one retrieval study did not support this finding (48). However, all the reviewed retrieval studies found that the location of the area of impingement wear/ erosion is usually on the elevated rim portion of the acetabular component (37,46-49).

As noted in the retrieval studies reviewed above, repetitive component impingement results in PE wear/ erosion at the site of impingement. Importantly, increased articular surface and backside wear (between the back of the PE liner and the acetabular shell) in retrieved components exhibiting significant impingement wear/ erosion has been reported as well (48). This association was attributed to eccentric wear of the articular surface opposite the site of impingement from point-loading as impingement and subluxation occur, as well as potential micromotion between the liner and acetabular shell (backside wear) that can be generated by femoral neck-acetabular liner impingement and transfer of torque to this interface. The PE wear debris generated from these potential sites (backside, impingement area, articular surface) can drive PE particle induced osteolysis as described previously (section 2.4, page 30). Together with the increased transfer of torque from impingement to the implant-host bone interface, this may result in loosening of the acetabular component. No clear association between revision for loosening and prosthetic impingement has been found however (36,51), though the theoretical risk has been proposed by some authors (35,46).

Whilst providing valuable tribological information, retrieval studies are inherently biased by selection to those THAs that have failed and undergone revision surgery.

2.6.4 Effect of acetabular component geometry on risk of revision THA surgery

The published evidence base for the effect of acetabular component geometry on revision for instability or for loosening will be considered separately.

2.6.4.1 Revision for instability

There have been two UK registry-based studies looking at the effect of acetabular component geometry on the risk of revision surgery. Both studies have been performed on single brand components.

In Jameson et al.'s (52) review of 34,721 cemented primary hip replacements performed with either an LPW or a hooded cemented acetabular component (Stryker), a higher risk of revision surgery (at medium term, 7 years) was found for any cause (hazard ratio (HR) 1.88) and specifically for instability (HR 2.34) in patients that received a hooded acetabular component. This increased risk of revision remained significant after controlling for potential confounding variables (age, sex, BMI, ASA grade, surgeon volume, surgical approach). The behaviour of offset reorientating components was not examined in this study, differences in revision for loosening were not specifically explored and competing failure risks/ non-proportional hazards were not considered.

In contrast, however, in a review of 35,386 primary uncemented THAs (53), an association between use of an elevated rim acetabular liner and risk of revision surgery for any cause at medium term follow-up (7.5 years) was not found. Again, attempts were made to control for similar potential confounding variables. This study was not designed to examine specifically the influence of PE liner geometry on revision for instability or for loosening and was heterogenous with multiple bearing combinations examined, including metal-on-metal articulations that are known to have a higher revision rate. This may in part explain why no apparent association between PE liner geometry and revision risk was found.

More recently published Registry-based analyses (54-56) have however shown a clear protective effect of lipped PE liners against revision for instability when compared to neutral liners, summarised in Table 2-1.

	Year	n	Mean follow-up (yrs)	Lipped liners (%)	Revision for instability (HR)
Insull (54)	2014	12,116	3	66	2.43
Bauze (55)	2019	192,659	5	65	1.31
Wyatt (56)	2020	31,247	5	65	1.84

Table 2-1 Comparison of published Registry based studies of risk of revision for instability (neutral vs. lipped liners)

Limitations in these studies include relatively small numbers (when compared to the annual volume of primary THAs recorded in the UK NJR) and minimal consideration of other potential confounding variables on the risk of revision surgery for instability (surgeon volume, BMI, femoral component geometry). The size of the lip (10-, 15- or 20-degree) is not examined for direct effects on the risk of revision for instability and the behaviours of other PE liners in clinical use such as the offset and offset reorientating liners, is not included. Furthermore, no mention is made of how competing risks were dealt with or whether proportionality was found in the risk of revision surgery over time. It would seem from other reports reviewed that the risk of THA dislocations is highest in the first year postoperatively (see section 2.3.1, page 26), and that therefore the risk of revision THA for instability would most likely be greatest within the first few years postoperative. It may be that a time-split proportional hazards model or alternative methods of assessing the risk of revision over time might be more appropriate. The authors do not mention the potential magnitude of unmeasured/ residual confounding that unfortunately can be an issue in analyses of Registry data where granularity of data can be lacking and specific potential predictor variables may not be recorded (e.g. implant orientations and biomechanics restoration on postoperative radiographs).

2.6.4.1.1 *Influence of surgical approach*

Surgical approach is an established risk factor for THA instability (13), with the posterior approach being associated with higher risk than lateral approaches. The published registry-based studies reviewed in the previous section consider surgical approach as a covariate in their analyses. However, the interaction between surgical approach and acetabular component geometry on risk of revision is not explored.

2.6.4.2 Revision for osteolysis/ loosening

The effect of acetabular component geometry on revision for loosening is unclear. It has been proposed from mathematical modelling that impingement can lead to increased torque transfer from the femoral neck to the acetabular component which may eventually lead to loosening of the acetabular component from the host bone (46). As mentioned in section 2.6.3 (page 43), retrieval studies have found a high prevalence of impingement damage in acetabular components revised for instability, but this association has not been found in those revised for loosening alone (37,49).

There have been no observational studies reporting specifically on the effect of cemented acetabular component geometry on the risk of osteolysis or revision THA for loosening.

Cobb et al. (57) retrospectively compared cumulative failure rates for revision for loosening in their cohort of 5167 THAs (mixed primary and revision THAs) with uncemented acetabular components and standard or 10-degree elevated rim (48% of cohort) PE liners. No difference in survival free of revision for loosening between the liner geometry groups was found at 5 years postoperative (elevated rim = 98.8%; neutral = 98.3%). No covariate adjustments were incorporated into the Kaplan-Meier survival analyses and competing risk failures were not accounted for either.

Bosco et al. (58) report on a single case of early femoral component loosening at 2 years after routine primary THA with uncemented prostheses and a 20° offset lip PE liner. At revision surgery, there was excessive acetabular PE wear noted with a trough being worn into the elevated rim portion of the acetabular liner. Histological tissue samples confirmed the presence of an inflammatory response with abundant PE wear particles present and some metal debris particles. The authors surmised that the cause for early loosening of the femoral component was likely due to impingement on the elevated rim of the acetabular liner leading to excessive PE wear that stimulated an inflammatory response leading to osteolysis. They also proposed that the impingement on the elevated rim could transfer increased torsional forces to the femoral stem that could contribute to stem loosening too.

Earll et al. (36) report on 4 cases where a lipped acetabular liner was used. All 4 cases had evidence of periacetabular osteolysis by 5 – 7 years after surgery and required revision surgery. At revision surgery, 3 out of 4 cases had grossly loose acetabular components. All 4 cases had evidence of significant erosion of the elevated acetabular rim from impingement with the femoral neck. The authors concluded that elevated rim acetabular liners should be avoided where possible and that proper positioning of the acetabular component to allow the use of a neutral acetabular liner is desirable to maximise impingement free range of motion.

Gerhardt et al. (51) report on 34 consecutive revisions performed of THAs with hooded acetabular liners at a mean of 10 years (range 1.3 – 20.4 years) postoperative. The indication for revision was acetabular osteolysis and at revision surgery, evidence of impingement wear/ erosion on the hooded portion of the PE liner was consistently found as well as evidence of osteolytic defects behind the removed acetabular shells.

Shin et al. (59) report a non-matched case-control comparison of wear rates between neutral and elevated rim cross-linked PE liners (78 and 34 THAs respectively) at a minimum 15 year follow-up. No significant difference was found between the liner groups in linear or volumetric wear, observed osteolysis or revision rates. The authors concluded that elevated rim cross-linked PE liners do not seem to have increased wear rates over neutral liners at long-term follow-up.

There have been three Registry-based studies reporting on the influence of acetabular liner geometry on the risk of revision for loosening (see Table 2-2). Bauze et al. report a higher risk in the Australian Registry (55) with the use of neutral liners compared to lipped liners, as do Davis et al. (60) from the NJR (though this study was aimed primarily at evaluating PE manufacturing characteristics on the risk of all cause revision). Wyatt et al. (56), however, report no difference from the New Zealand Registry.

	Year	**n**	**Mean follow-up (yrs)**	**Lipped liner (%)**	**Revision for loosening (HR)**
Bauze (55)	2019	192,659	5	65	1.19
Wyatt (56)	2020	31,247	5	65	No difference
Davis (60)	2020	292,920	4	53	1.14

Table 2-2 Comparison of published Registry based studies of risk of revision for loosening (neutral vs. lipped liners)

2.7 Summary

The reviewed literature presents contrasting evidence regarding the influence of acetabular component geometry on the risk of dislocation/ revision surgery for instability. Whilst finite element analysis, biomechanical and intraoperative studies suggest that a lipped acetabular component can enhance stability in the area of the lip, implant retrieval studies show quite consistent evidence of prosthetic impingement (particularly in cases that have been revised for instability) that could lead on to increased PE wear, osteolysis and possibly to component loosening. The effect of lip size has only been investigated in finite element analyses and seems to have a dose-effect response with greater protection against posterior dislocation for larger lip sizes. It is uncertain if this effect is seen *in vivo* and if this also translates to a reduction in revision THA for instability.

Several authors strongly suggest avoiding the use of lipped acetabular components, aiming instead to optimise the position of the acetabular component to allow the use of a neutral acetabular component that will maximise the impingement free range of motion.

A number of retrospective studies from institutional cohorts and worldwide Registry data suggest that the use of a lipped liner in uncemented acetabular components is associated with a lower risk of revision for instability. However, in cemented acetabular components the opposite has been reported with higher revision rates in hooded components. It is unclear if acetabular component geometry influences the risk of revision for loosening.

2.7.1 Identified knowledge gaps in the current literature

Amongst the reviewed literature regarding revision risk related to acetabular component geometry, the following points remain unaddressed:

1. the behaviour of offset neutral and offset reorientating acetabular geometries
2. the influence of lip size (in uncemented THA)
3. the influence of surgical approach
4. the influence of time after primary surgery
5. the effect of acetabular component geometry on the risk of revision surgery for loosening

Whilst a prospective, randomised controlled trial between neutral and elevated rim acetabular components might address some of the methodological flaws associated with the reports reviewed, such a trial in reality would not be pragmatic, would most likely have poor surgeon uptake/ equipoise in the matter of treatment randomisation and would need a long follow-up period to detect both early and late failure differences. An appropriate analysis of Registry data that has longer follow-up, with larger numbers, avoiding brand selection and including all acetabular components (cemented and uncemented) would give further insight into whether a difference in the risk of revision surgery exists between acetabular component geometries.

Chapter 3: Aim

3.1 Aims

The broad aim of this study was to investigate the effect of acetabular component geometry on the risk of revision for instability or loosening, following primary THA.

3.2 Specific objectives

1. does acetabular component geometry, including offset and offset reorientating designs, influence the risk of revision THA for either instability or for loosening
2. does uncemented lip size influence the risk of revision for instability or for loosening
3. how does surgical approach influence the risk of revision related to acetabular component geometry
4. does the risk of revision related to acetabular component geometry vary with time after primary THA

Chapter 4: Methodology

4.1 Summary

This chapter describes the methods used in this study including a description of the NJR and the dataset used in the analysis. Variables included in the analysis are summarised and how these were categorised for the purpose of the analysis. The statistical methods used to explore covariate associations with the exposure groups (acetabular component geometry), exposure associations with the outcome group (revision due to instability/ loosening) and competing risks survival analyses are described.

4.2 Study design

This study is an observational cohort analysis of nationally collected data from the NJR (www.njrcentre.org.uk), on primary THAs performed with PE acetabular components.

4.2.1 Background on the NJR

The NJR currently collects information on all hip, knee, ankle, elbow and shoulder replacement operations (primary and revision) performed in England, Wales, Northern Ireland, the Isle of Man and the states of Guernsey. It began collecting hip and knee replacement data in April 2003, and since 2011 data submission has been mandatory for NHS hospitals. The NJR is now the biggest orthopaedic device registry in the World, with over 3 million records and survival data for hip and knee replacement implants reaching 15 years follow-up.

The NJR's mission statement is as follows:

> *'The purpose of the National Joint Registry, which covers England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey, is to collect high quality and relevant data about joint replacement surgery in order to provide an early warning of issues relating to patient safety. In a continuous drive to improve the quality of outcomes and ensure the quality and cost-effectiveness of joint replacement surgery, the NJR will monitor and report on outcomes, and support and enable related research.'*
>
> *- www.njrcentre.org.uk/njrcentre/About-the-NJR*

4.3 Dataset

4.3.1 NJR application

An application for NJR primary THA data was made to the NJR Scientific Sub-committee (https://www.njrcentre.org.uk/njrcentre/Research) and approved in July 2017. Due to internal NJR data restructuring, the full dataset was not released. Data for the most common manufacturer brands for cemented (DePuy and Stryker) and uncemented (DePuy, Stryker, Zimmer) acetabular components were released for analysis.

The dataset provided by the NJR included 429,471 primary THAs, with PE acetabular components, performed between 2003 and March 2017 with a minimum 5-month follow-up period (data extracted August 2017). All surgical indications were included. The dataset was split for further preparation and analysis by acetabular component fixation – cemented or uncemented. There were 224,923 cemented and 2045,48 uncemented acetabular components.

4.3.2 Case exclusions

Of the 224,923 cemented acetabular components, 49 were excluded due to incomplete or inconsistent data records (age at surgery, implant details, follow-up time), leaving 224,874 for analysis.

Of the 204,548 uncemented acetabular components, 2037 were excluded leaving 202,511 for analysis. Missing acetabular liner information was found in 1163 records. Non-standard acetabular liners were excluded, including 450 constrained liners[5] and 355 dual mobility liners[6]. These were excluded as they function differently to standard acetabular liners and are designed to provide more stability by their design. Their inclusion in this study would therefore be inappropriate, given that one of the primary outcomes of interest was revision for instability. A further 69 records were excluded due to incomplete or inconsistent data (age at surgery, follow-up times, mixed or implausible implant combinations).

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[5] Constrained liners capture the prosthetic femoral head within the acetabular liner, usually with a locking ring mechanism, that prevents the femoral head from dislocating out of the liner

[6] Dual mobility liners consist of a regular prosthetic femoral head captured within a larger PE head that then articulates against a metal liner that is inserted into the acetabular cup. The resulting construct allows a greater range of motion, with 2 interfaces for rotation, before impingement and dislocation occurs

Records were not excluded on the basis of missing BMI data, accounting for approximately 40% of cases in both groups, as this would have significantly reduced the cohort size for analysis.

4.3.3 Acetabular component geometry

Acetabular component geometry was confirmed using recorded implant specific information (cup/ liner description, product catalogue numbers) and checked against manufacturer specifications (available in public domain online through manufacturer websites). Where implant specific information was not sufficient to determine the geometry of the component, manufacturers were contacted directly to ascertain this information.

The cemented acetabular cups were grouped into the following cup geometries (see Figure 2-2 page 32 for description of cross-sectional geometries):

1. LPW – 81.2%
2. Hooded – 18.7%
3. Offset reorientating – 0.1%

The uncemented acetabular liners were grouped into the following liner geometries (see Figure 2-4 page 34 for description of cross-sectional geometries):

1. Neutral – 39.4%
2. Offset neutral – 0.9%
3. Lipped – 10-degree – 34.5%
4. Lipped – 15-degree – 21.6%
5. Lipped – 20-degree – 0.8%
6. Offset reorientating – 2.8%

4.3.4 Revision THA surgery

The main outcome of interest was revision surgery for instability or for loosening – recorded in the database during the period of observation (2003 to December 2017). A revision operation refers to a procedure performed subsequent to the primary THA, where any prosthetic arthroplasty component is removed, or replaced with another component.

4.3.4.1 Overall outcome

The overall cohort outcomes were recorded as “unrevised”, “revised” (any reason) or “died” and the proportions are shown in Table 4-1. In this cohort, 1.5% (6527) underwent a revision procedure and 13.1% (56,058) died without having a revision procedure.

Outcome	Cemented		Uncemented		Total	
	n	%	n	%	n	%
Unrevised	184,533	82	180,267	89	364,800	85.4
Died	37,028	16.5	19,030	9.4	56,058	13.1
Revised	3313	1.5	3214	1.6	6527	1.5
Total	**224,874**		**202,511**		**427,385**	

Table 4-1 Outcomes after primary THA

4.3.4.2 Revision reason

The indication for revision surgery recorded in NJR data can be difficult to interpret, as surgeons can assign multiple reasons with no clear indication of the prevailing revision reason. Table 4-2 summarises the number of revision reasons recorded per case that underwent revision surgery.

Recorded revision reasons	Cemented		Uncemented		Total	
	n	%	n	%	n	%
1	2493	75.2	2528	78.7	5021	76.9
2	614	18.5	536	16.7	1150	17.6
3	154	4.6	106	3.3	260	4
≥4	52	1.6	44	1.4	96	1.5
Total	**3313**		**3214**		**6527**	

Table 4-2 Number of revision reasons recorded per revision case

Nearly 23% of revisions had 2 or more recorded revision reasons. Therefore, a hierarchical approach (outlined below and in order) was taken to assigning the most likely cause for revision surgery:

1. infection – significant prosthetic joint infections can cause damage to the soft tissues around a joint and loosening of THA components, which may lead to dislocation
2. periprosthetic fracture – a fracture of the bone around the components of a THA can lead to acute implant loosening and loss of alignment that can result in dislocation.

3. implant fracture – failure of a prosthesis, usually the femoral neck, though very rare can cause a dislocation
4. loosening – implants that become loose can lose their alignment and therefore dislocate
5. wear – eventually, PE acetabular components will wear out. As this happens, the femoral head is no longer centred within the acetabular component and can dislocate
6. adverse reaction to metal debris – occasionally, mechanical fretting and galvanic corrosion between modular metal components (usually the femoral head and the trunnion of the femoral stem) can lead to metal debris that causes a localised soft tissue reaction (61). The resulting soft tissue damage could lead to dislocation
7. liner dissociation – if the PE liner of an uncemented acetabular component is not accurately and fully seated at the time of surgery into the shell, it may later become dislodged leading to a dislocation
8. instability

After applying the hierarchical method for deciding the most likely "main" reason for revision surgery, the categories and proportions of revision THA reasons were as shown in Table 4-3. The most common revision reasons recorded were instability (23%), loosening (22%), infection (20%) and periprosthetic fracture (19%), together accounting for 84% of all revision THAs.

Revision reason	**Cemented**		**Uncemented**		**Total**	
	n	**%**	**n**	**%**	**n**	**%**
Instability	815	24.6	690	21.5	1505	23.1
Loosening	838	25.3	604	18.8	1442	22.1
Infection	734	22.2	596	18.5	1330	20.4
Periprosthetic fracture	507	15.3	715	22.2	1222	18.7
Other	84	2.5	119	3.7	203	3.1
Malalignment	88	2.7	114	3.5	202	3.1
Pain	82	2.5	116	3.6	198	3.0
Wear	70	2.1	86	2.7	156	2.4
Implant fracture	66	2.0	57	1.8	123	1.9
Liner dissociation	15	0.5	62	1.9	77	1.2
Adverse reaction to metal debris	10	0.3	42	1.3	52	0.8
Incorrect sizing	4	0.1	13	0.4	17	0.3

Table 4-3 Revision reasons

Smaller revision reason categories were then collapsed together under "other", and the final revision reason categories were – instability, loosening, infection, periprosthetic fracture and other, see Table 4-4.

Revision reason	Cemented		Uncemented		Total	
	n	%	n	%	n	%
Instability	815	24.6	690	21.5	1505	23.1
Loosening	838	25.3	604	18.8	1442	22.1
Infection	734	22.2	596	18.5	1330	20.4
Periprosthetic fracture	507	15.3	715	22.2	1222	18.7
Other	419	12.6	609	18.9	1028	15.7

Table 4-4 Revision reasons, collapsed categories

4.3.5 Covariate descriptions and preparation

The NJR records some data fields that may be potential confounders for revision risk (see Section 2.3.2 page 26), and these were used as covariates in the analyses. Some covariate data fields required preparation for analysis, most commonly collapsing of multiple categorical levels with very small observed frequencies, as described below.

4.3.5.1 Age

Age at the time of primary THA was recorded in years and treated as a continuous variable.

4.3.5.2 Gender

Gender was recorded as female or male and treated as a categorical variable.

4.3.5.3 BMI

BMI data was recorded as a continuous variable, but found to be missing or containing biologically unlikely values (<15 or >65). After removal of these values, there were 58% of cemented and 66% of uncemented records with BMI data.

4.3.5.4 ASA grade

ASA is graded from 1 (healthy person) to 5 (moribund, not expected to survive). Given the very small proportions of ASA grades 4 and 5, the ASA grades were collapsed into ASA 1, 2 and ≥3 as shown in Table 4-5.

ASA Grade	Cemented	Uncemented	Total

	n	%	n	%	n	%
1	25,843	11.5	27795	13.7	53,638	12.6
2	154,987	68.9	143,346	70.8	298,333	69.8
3	42,419	18.9	30,445	15.0	72,864	17.0
4	1586	0.7	903	0.4	2489	0.6
5	39	0.0	22	0.0	61	0.0
Collapsed ASA categories						
1	25843	11.5	27,795	13.7	53,638	12.6
2	154,987	68.9	143,346	70.8	298,333	69.8
≥3	44,044	19.6	31,370	15.5	75,414	17.6

Table 4-5 ASA grade, including collapsed categories

4.3.5.5 Indication for THA

Multiple indications for primary THA can be recorded by the operating surgeon, without the prevailing indication being clear. Table 4-6 summarises the number of indications recorded per case.

Recorded Indications	**Cemented**		**Uncemented**		**Total**	
	n	**%**	**n**	**%**	**n**	**%**
0	1239	0.55	1019	0.50	2258	0.53
1	217,868	96.88	196,330	96.95	414,198	96.91
2	5302	2.36	4790	2.37	10,092	2.36
3	433	0.19	349	0.17	782	0.18
4	28	0.01	20	0.01	48	0.01
5	1	0.00	2	0.00	3	0.00
6	2	0.00	0	0.00	2	0.00
7	1	0.00	1	0.00	2	0.00

Table 4-6 Number of Indications recorded per case

Whilst 97% in cemented and uncemented groups had a single surgical indication recorded, 0.5% had none and 2.5% had 2 or more indications recorded. Those with no indication recorded were recoded as “unknown”. In the cases with multiple indications recorded, the most likely indication for surgery was assigned based on clinical judgement. Where previous surgery was recorded, this was taken as the main indication regardless of the other recorded indications. Where OA and another underlying indication was recorded, the underlying indication was recorded as the main indication for surgery. For example, many disease processes will eventually lead to secondary OA – AVN, inflammatory arthropathies, childhood hip disorders (Perthes disease, dysplasia, slipped upper femoral epiphysis), septic arthritis. Table 4-7 summarises the final indications recorded.

Indication	**Cemented**		**Uncemented**		**Total**	
	n	**%**	**n**	**%**	**n**	**%**
osteoarthritis	203,250	90.38	184,227	90.97	387,477	90.66
acute trauma	8105	3.60	6353	3.14	14,458	3.38
AVN	4094	1.82	3511	1.73	7605	1.78
trauma – other	2441	1.09	1912	0.94	4353	1.02
inflammatory	2558	1.14	1824	0.90	4382	1.03
childhood hip disorder	1487	0.66	2506	1.24	3993	0.93
unknown	1241	0.55	1020	0.50	2261	0.53
previous surgery – trauma	806	0.36	586	0.29	1392	0.33
tumour	368	0.16	90	0.04	458	0.11
previous surgery – non-trauma	165	0.07	231	0.11	396	0.09
infection	221	0.10	148	0.07	369	0.09
previous surgery – arthrodesis	67	0.03	71	0.04	138	0.03
other	71	0.03	32	0.02	103	0.02

Table 4-7 Indication for primary THA

Less frequent indications (unknown, previous surgery – trauma, tumour, previous surgery – non-trauma, infection, previous surgery – arthrodesis, other) were collapsed together into a single category "other", and the final categories and are represented in Table 4-8.

Indication	**Cemented**		**Uncemented**		**Total**	
	n	%	n	%	n	%
osteoarthritis	203,250	90.4	184,227	91.0	387,477	90.7
acute trauma	8105	3.6	6353	3.1	14,458	3.4
AVN	4094	1.8	3511	1.7	7605	1.8
other	9425	4.2	8420	4.2	17,845	4.2

Table 4-8 Indication for primary THA, collapsed categories

4.3.5.6 Side

Side was treated as a categorical variable with values of left or right.

4.3.5.7 Treating organisation

The type of treating organisation was treated as a categorical variable, with values – NHS (National Health Service) hospital, independent hospital or independent treatment centre.

4.3.5.8 Operating surgeon grade

The lead or operating surgeon grade recorded refers to the grade of the surgeon performing the majority of that surgical procedure. Operating surgeon grade was treated as a categorical variable, with values – consultant, trainee, speciality & associate specialist (SAS) or other. The category "trainee" included all doctors in UK training programmes from Foundation Year to Specialist Training Registrars and Fellows who have completed their speciality training. The category "SAS" included all associate specialist, speciality doctor and staff grade doctors. Table 4-9 summarises the operating surgeon grades.

Operating surgeon grade	Cemented		Uncemented		Total	
	n	%	n	%	n	%
Consultant	176,994	78.7	169,422	83.7	346,416	81.1
Trainee	25,537	11.4	17,213	8.5	42,750	10.0
SAS	16,039	7.1	8638	4.3	24,677	5.8
Other	6304	2.8	7238	3.6	13,542	3.2

Table 4-9 Operating surgeon grade

4.3.5.9 Surgical approach

Table 4-10 summarises the surgical approaches used for THAs, as recorded in the extracted NJR dataset, the most common being the posterior approach (61%), followed by the lateral approach (31%).

Surgical Approach	Cemented		Uncemented		Total	
	n	%	n	%	n	%
Anterior	479	0.2	179	0.1	658	0.2
Antero-lateral	7491	3.3	3259	1.6	10,750	2.5
Lateral	81,127	36.1	52,283	25.8	133,410	31.2
Other	10,934	4.9	8203	4.1	19,137	4.5
Posterior	123,850	55.1	138,470	68.4	262,320	61.4
Trochanteric osteotomy	993	0.4	117	0.1	1110	0.3

Table 4-10 Surgical approach

The antero-lateral approach was grouped together in the lateral group, being a similar surgical variant, and the less frequent surgical approaches were grouped together into "Other" (other, trochanteric osteotomy, anterior); see Table 4-11.

Surgical Approach	Cemented		Uncemented		Total	
	n	%	n	%	n	%
Posterior	123,850	55.1	138,470	68.4	262,320	61.4
Lateral	88,618	39.4	55,542	27.4	144,160	33.7
Other	12,406	5.5	8499	4.2	20,905	4.9

Table 4-11 Surgical approach, collapsed categories

4.3.5.10 Prosthetic femoral head size

Prosthetic femoral head size (diameter) is an ordinal categorical variable and there are a number of possible head sizes used, see Table 4-12.

Head size (mm)	Cemented		Uncemented		Total	
	n	%	n	%	n	%
22.225	9518	4.23	264	0.13	9782	2.29
26	17,164	7.63	387	0.19	17,551	4.11
28	151,263	67.27	64,929	32.06	216,192	50.58
30	721	0.32	0		721	0.17
32	42,657	18.97	83,285	41.13	125,942	29.47
36	3523	1.57	49,539	24.46	53,062	12.42
40	28	0.01	3174	1.57	3202	0.75
44	0		933	0.46	933	0.22

Table 4-12 Prosthetic femoral head sizes

The smaller frequency levels were collapsed as follows – 22.225mm, 26mm, 28mm, 30/ 32mm, 36mm and >36mm (see Table 4-13).

Head size (mm)	Cemented		Uncemented		Total	
	n	%	n	%	n	%
22.225	9518	4.23	264	0.13	9782	2.29
26	17,164	7.63	387	0.19	17,551	4.11
28	151,263	67.27	64,929	32.06	216,192	50.58
30/ 32	43,378	19.29	83,285	41.13	126,663	29.64
36	3523	1.57	49,539	24.46	53,062	12.42
>36	28	0.01	4107	2.03	4135	0.97

Table 4-13 Prosthetic femoral head sizes, collapsed categories

4.3.5.11 PE crosslinking

Manufacturer information was checked to confirm if the PE used for the acetabular cup/ liner was crosslinked or not, recorded as a binomial variable.

4.3.5.12 Manufacturer brand

Acetabular component manufacturer brand was recorded as a categorical variable – DePuy or Stryker for cemented cups; and DePuy, Stryker or Zimmer for uncemented cups. Within the cemented components, all hooded or offset reorientating cups were manufactured by

Stryker and therefore manufacturer brand was not included in regression analyses of cemented components.

4.4 Analyses

The analyses and interpretation of results were performed separately on the cemented and uncemented acetabular groups. This was done because cemented and uncemented acetabular components have significant differences in surgical preparation and implantation that may translate to differences in THA stability. The geometries are different between the groups and not comparable – for example, the LPW in the cemented cups is different to a neutral liner in the uncemented cups. Uncemented cups benefit from modularity; once the acetabular shell is impacted into the prepared host bone, different liner geometries can be trialled to assess stability before implanting the definitive liner choice, or even repositioning the acetabular cup completely if during intraoperative trialling the surgeon feels stability is compromised by poor cup orientation. Once a cemented cup is inserted and the cement has set (usually within 5 – 10 minutes depending on the type of PMMA cement used), the only way of altering the cup position would be to fully remove it and start again.

Descriptive statistics were used to describe subject characteristics and regression methods used to determine the association between the various exposures (acetabular component bearing geometry) and the risk of revision surgery. Further details are outlined in the Chapter 5 and Chapter 6. All analyses were performed in STATA v15.1 (StataCorp, USA). Statistical significance was set at $p<0.05$.

4.4.1 Subject characteristics by acetabular component geometry group

Differences in subject characteristics between acetabular component geometry groups were examined using one-way ANOVA (analysis of variance) with Bonferroni correction for continuous variables and Chi-square tests for independence for categorical variables.

4.4.2 Trend in acetabular component geometry use

Relative proportions of acetabular component geometry types per year were plotted as stacked bar charts to examine for changes in usage over time for the dataset study period.

4.4.3 Acetabular component geometry and the risk of revision

Regression analyses were performed separately for risk of revision for instability and risk of revision for loosening.

4.4.3.1 Covariate association with revision

Univariable log-binomial regression analyses were performed on all covariates individually to examine potential associations with the risk of revision surgery for instability or for loosening. Results are presented as relative risk rations (RRR) with 95% confidence intervals (CIs).

4.4.3.2 Effect of acetabular component geometry on revision

In analysis of the risk of revision for cemented cups, the reference category was LPW, while in the analysis of the data on uncemented cups it was the neutral liner. All covariates, except BMI due to significant missing data, were included in adjusted multiple variable log-binomial regression models for the risk of revision for instability or for loosening. The results are expressed as RRRs with 95% CIs.

The multiple variable regression analyses were repeated including BMI, in the subset of subjects in whom BMI data present, to determine if BMI influenced the observed effect sizes of acetabular component geometry on revision risk. As BMI was not found to influence effect sizes, it was omitted as a covariate from further analyses.

4.4.3.3 Competing risks survival analyses

Follow-up time is recorded in the NJR dataset up to revision surgery, mortality or ongoing survival (free of revision or mortality) at the point of data extraction. As the overall incidence of competing risks (revision for other causes and mortality) were not small, competing risks survival analyses were performed (STATA module stcrreg; Fine & Gray (62)) for revision for instability or for loosening. Competing risks were revision for other causes or mortality, adjusting for the same covariates as the log-binomial regression models. Results are presented as subhazard ratios (SHR) with 95% CIs.

4.4.3.3.1 Sensitivity analyses

Sensitivity analyses was performed, on the competing risks regression outputs, to determine the potential strength of any unmeasured confounding (STATA E-value module (63,64)). The E-values generated represent the minimum strength of association that an unmeasured confounder would need to have (above the included covariates) with both acetabular component geometry and revision (for instability or for loosening), to negate the observed association between acetabular component geometry and risk of revision for instability or for loosening.

4.4.3.3.2 Non-proportional hazards and time varying SHR

A proportional hazards test (Schonfeld residuals) was performed on each adjusted Cox regression analysis, assuming that if the proportional hazards assumption was met in the Cox model it would also be met in the competing risks model. This was done because no post-estimation function in STATA exists to test the proportional hazards assumption after a competing risks analysis. If non-proportionality was encountered, the dataset was split by time intervals (deciles for revision events), each time interval was reassessed with the adjusted Cox model and proportional hazards test, and then the adjusted competing risk regression model was applied to each time interval to determine the time-specific SHRs of revision by acetabular component geometry. The time-specific SHRs of revision were then plotted against time, with 95% CIs.

4.4.3.3.3 Stratification by surgical approach

Surgeons will tend to use one surgical approach for all, or the vast majority of their primary THAs, usually determined by where and who the surgeon has trained with. As surgical approach is known to be independently associated with the risk of instability (13), it would probably affect the baseline hazard. Stratified competing risks analyses in the Fine & Gray method (STATA module stcrreg) are not possible, therefore adjusted competing risks analyses were performed on each surgical approach group one at a time to examine how acetabular component geometry (and other covariates) influenced revision risk within each surgical approach, for instability and for loosening. Postestimation pairwise comparisons of predicted margins (STATA module pwcompare) between all acetabular component geometries were then performed, with Bonferroni error control.

4.4.3.3.4 Manufacturer brand analysis

To determine if a difference in revision risk for instability exists within acetabular component bearing geometries, separate adjusted competing risk analysis was performed for cemented LPW and uncemented neutral liners. As strong associations between acetabular component geometry and manufacturer brand were found, these analyses were restricted to geometries that were not unique or heavily proportioned to a manufacturer (see Table 4-14). Cemented LPW and uncemented neutral liners, were therefore analysed. A similar analysis of revision for loosening by manufacturer brand was not included as most manufacturers have developed and altered their PEs over this study period with changing characteristics, particularly PE crosslinking and post-crosslinking treatments[7] (60), that can influence oxidative PE wear and therefore loosening.

	Styker	**DePuy**	**Zimmer**
Cemented			
LPW	96058 (52.6%)	86523 (47.4%)	0
Hooded	42124 (100%)	0	0
Offset reorientating	169 (100%)	0	0
Uncemented			
Neutral	26159 (32.8%)	38535 (48.3%)	15128 (19%)
Offset neutral	1 (0.1%)	1766 (99.9%)	0
10-degree	45732 (65.4%)	0	24162 (34.6%)
15-degree	0	43722 (100%)	0
20-degree	323 (20.2%)	0	1278 (79.8%)
Offset reorientating	28 (0.5%)	5677 (99.5%)	0

Table 4-14 Manufacturer brands, by acetabular component geometry

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[7] PE crosslinking is performed to improve the wear characteristics of the PE. The process can generate free radicals that remain within the PE structure, and can lead on to oxidative PE damage later. Post-crosslinking treatments aim to remove these free radicals, by encouraging their movement leading to saturation of crosslinking. 1) Annealing involves heating the PE to just below its melting temperature. 2) Remelting is performed at a higher temperature, but a potential downside to remelting is the reduction of the PE crystallinity and crystal grain size that reduces the ultimate tensile strength. 3) Vitamin E diffusion into PE before thermal stabilisation reduces oxidative free radical damage. The vitamin E molecules act as free radical scavengers.

Chapter 5: Paper 1 – The Effect of Cemented Acetabular Component Geometry on the Risk of Revision for Instability or Loosening: A Study of 224,874 Primary Hip Replacements from the National Joint Registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey

5.1 Introduction

This chapter is presented in journal style, and the represents the first of two anticipated publication outputs from this research thesis, looking specifically at the cemented acetabular components in the analysed dataset.

5.1.1 Publication authorship

Hiren Divecha, Terence W O'Neill, Mark Lunt, Timothy Board.

5.2 Abstract

5.2.1 Aim

To determine if primary cemented acetabular component geometry (LPW, hooded, offset reorientating) influences the risk of revision THA surgery for instability or loosening.

5.2.2 Methods

The NJR dataset was analysed for primary THAs performed between 2003 – 2017. A cohort of 224,874 cemented acetabular components were included. The effect of acetabular component geometry on the risk of revision for instability or for loosening was investigated using binomial regression adjusting for age, gender, ASA grade, indications, side, institution type, operating surgeon grade, surgical approach, PE crosslinking and head size. A competing risk survival analysis was performed with the competing risks being revision for other indications or death.

5.2.3 Results

Among the cohort of subjects included in the analysis the distribution of acetabular component geometries was: LPW – 81.2%, hooded – 18.7% and offset reorientating – 0.1%. There were 3,313 (1.47%) revision THAs performed, of which 815 (0.36%) were for instability and 838 (0.37%) were for loosening. Compared to the LPW group, the adjusted SHR of revision for instability in the hooded group was 2.31 ($p<0.001$) and 4.12 ($p=0.047$) in the offset reorientating group. Likewise, the SHR of revision for loosening was 2.65 ($p<0.001$) in the hooded group and 13.61 ($p<0.001$) in the offset reorientating group. A time-varying SHR of revision for instability (hooded vs LPW) was found, being greatest within the first 6 months.

5.2.4 Conclusion

This Registry based study confirms a significantly higher risk of revision THA for instability and for loosening when a cemented hooded or offset reorientating acetabular component is used, compared to an LPW component. Further research is required to clarify if certain patients benefit from the use of hooded or offset reorientating components, but we recommend caution when using such components in routine clinical practice.

5.3 Introduction

Instability following THA represents a common reason for revision THA in the NJR, although the absolute incidence is low. A total of 123,891 revision THA procedures have been recorded in the NJR (17th NJR Annual Report (6)) of which 18,085 (15%) were for instability. Revision surgery is associated with an increased exposure to further surgical risks, reduced patient reported satisfaction/ outcomes (14), higher healthcare costs (8) and most importantly, an even higher risk of further revision surgery (6), especially if the first revision occurs soon after the index primary THA. Therefore, minimising the risk of revision surgery following primary THA is paramount to ensuring good patient outcomes and avoiding the increased cost burden on healthcare systems from dislocations and revision THA surgery.

Stability of a THA is multifactorial and the interplay between patient, surgeon and implant factors is complex (12). Acetabular bearing geometry plays a role in determining the range of motion before impingement, subluxation and dislocation occurs. The most commonly used cemented acetabular design is the long posterior wall (LPW). This has a straight extension of the wall, running around the posterior socket rim, designed to reduce the risk of posterior dislocation. Some acetabular components have a more pronounced hood, designed to further reduce the risk of the dislocation. The surgeon has the option of locating this hood where needed to provide extra cover against dislocation. Another variant is the offset reorientating cup, where the bearing surface is lateralised and reorientated from the hemispherical plane of the cup (see Figure 2-2 page 32).

A downside to hooded and offset reorientating designs is the possibility of impingement of the femoral component neck on the hooded portion of the acetabular component. This may lead to subluxation and dislocation of the prosthetic femoral head in the direction opposite to the hood. It has been proposed from mathematical modelling that impingement can lead to increased torque transfer from the femoral neck to the acetabular component which may eventually lead to loosening of the acetabular component (46). Retrieval studies have found a high prevalence of impingement damage in acetabular components revised for instability, but this association has not been found in those revised for loosening alone (37,49). To our knowledge, there have been no studies reporting specifically on the effect of cemented acetabular component design on the risk of revision THA for loosening.

Jameson et al. (52) report the only known study, to our knowledge, evaluating the effect of cemented acetabular component geometry on the risk of revision THA for instability. They found an increased risk of revision THA for dislocation in hooded components compared to LPW. Their study was limited to a single brand analysis and did not consider the potential effects of competing risks for failure (revision for other causes and mortality) or whether the risk varied with time following surgery. It has been reported that the rate of dislocation after primary THA changes with time, being highest within the first 3 months to 1 year and then falling until after 10 years (65).

Using data from the NJR, and taking account of competing risks for failure, the aim of our study was to determine if cemented acetabular component geometry influences the risk of revision THA for either instability or for loosening. Furthermore, we sought to determine if the revision risk varied with time after primary THA.

5.4 Methods

We used data from the NJR to address our objectives. We included subjects from inception of the NJR (2003) to March 2017 (data extracted August 2017), who received a primary THA with a cemented acetabular component from one of the two most common manufacturer brands, Stryker and DePuy, representing 62% of all recorded primary cemented THAs.

5.4.1 Acetabular components

Acetabular component geometry was categorised as LPW, hooded or offset reorientating. Product specific information was reviewed to confirm component geometry, and if this was insufficient, manufacturing companies were contacted directly to confirm this.

5.4.2 Covariates

Using the NJR we obtained information about additional factors which may influence the risk of revision surgery including age at surgery, gender, BMI, ASA grade, indication (OA, acute trauma, AVN, other), treating organisation (NHS, independent treatment centre, independent hospital), operating surgeon grade (Consultant, trainee, SAS, other), side, surgical approach (posterior, lateral, other (including trochanteric osteotomy and anterior)) and prosthetic head size (22.225mm, 26mm, 28mm, 30/32mm, 36mm, >36mm). PE crosslinking was confirmed from manufacturer specific information.

5.4.3 Outcomes

The main outcomes were revision THA for instability or for loosening. Indications for revision THA recorded in NJR data can be difficult to interpret, as surgeons can assign multiple reasons with no clear indication of the prevailing revision reason. Where multiple revision reasons were recorded (two = 19%, three = 5%, four or more = 1.6%), a hierarchical approach was taken to assigning the most likely cause of revision (in order: infection, periprosthetic fracture, implant fracture, loosening, wear, adverse reaction to metal debris, instability). Revision reasons were then grouped into the following categories: instability, loosening, infection, periprosthetic fracture and other. Mortality was also recorded.

5.4.4 Analyses

Subject characteristics were described using summary statistics including means with SDs and percentages. Differences in covariates between acetabular component geometry groups were examined using one-way ANOVA with Bonferroni correction for continuous covariates, and Chi-square tests for independence for categorical covariates. Relative proportions of acetabular component geometry types per year were plotted as stacked bar charts to examine for changes in usage over time.

The association between the risk of revision THA for instability or for loosening and acetabular component geometry was examined using separate log-binomial regression models for each revision reason. Univariable analyses were performed, followed by a multiple variable model adjusted for covariates (age at surgery, gender, ASA grade, indication, treating organisation, operating surgeon, side, surgical approach, prosthetic head size and polyethylene crosslinking). The results are expressed as RRRs with 95% CIs. We repeated the analysis with further adjustment for BMI among the subset of patients in whom this data was available. Separate competing risks survival analyses were performed (Fine & Gray (62)) for revision THA for instability and for loosening, and results are expressed as subhazard ratios (SHRs) with 95% CIs. Competing risks were revision THA for other causes or mortality and these regression models were adjusted for the same covariates as the log-binomial regression models. Sensitivity analyses were performed, to determine the potential strength of any unmeasured confounding (STATA E-value module (63,64)). The E-values generated represent the minimum strength of association that an unmeasured confounder would need to have (above the included covariates) with both cup geometry and revision THA for instability (or loosening), to negate the observed association between cup geometry and risk of revision THA for instability (or loosening).

A stratified competing risks analysis by surgical approach was also performed, given most surgeons are likely to use one approach for the majority of their primary THAs and that surgical approach is known to be an independent predictor of THA instability (13). Within these stratified analyses, pairwise comparisons between all acetabular component geometries were performed with Bonferroni adjustment of the error rate.

Finally, in a fully adjusted model we examined whether the assumption of proportional hazards was met by performing a proportional hazards test (Schonfeld residuals) following Cox regression analysis. For non-proportionality, we planned to split the dataset by time intervals (deciles for revision events), reassess each time interval with the adjusted Cox model and proportional hazards test and then apply the competing risk regression models to each time interval to determine the time-specific SHRs ratios of revision by cup geometry. Analyses were performed using Stata for Mac (v15.1, StataCorp, USA). Statistical significance was taken at $p < 0.05$.

5.5 Results

5.5.1 Subject characteristics

224,874 primary THAs were included in the analysis. The mean age at time of surgery was 72.9 years (SD 9.2 years; range: 15 – 101 years) and 66% of patients were female. Subject characteristics are presented in Table 5-1 for the whole cohort and also stratified by acetabular geometry type. The most commonly used cemented acetabular component geometry was the "LPW" (81.2%) followed by "hooded" (18.7%) and "offset reorientating" (0.1%). There were no clear differences in baseline covariate patterns between the LPW and hooded groups, except for surgical approach and head size. The posterior approach was used in 56% of LPW patients compared to 51% of hooded patients. The 22.225mm head size was used in 5% of LPW patients compared to <0.1% in the hooded group. The small numbers in the offset reorientating group made comparisons of covariate patterns difficult. Lateral and "other" approaches were used more frequently in this group, as were 28mm heads, compared to the LPW or hooded groups.

	LPW 182,581 (81.2%)		Hooded 42,124 (18.7%)		Offset reorientating 169 (0.1%)		Total 224,874		P-value
Mean Age (SD)	72.8 (9.3)		74.1 (8.6)		71.8 (10.5)		73 (9.2)		
Age difference			1.35		-0.94				
p-value			**<0.001**		0.546				
Mean BMI (SD) [8]	28.4 (5.2)		28 (5)		27.4 (5.1)		28.4 (5.2)		
BMI difference			-0.44		-1.06				
p-value			**<0.001**		0.509				
Gender									
Female	119,179	65.3%	28,591	67.9%	84	49.7%	147,854	65.7%	
Male	63,402	34.7%	13,533	32.1%	85	50.3%	77,020	34.3%	**<0.001**
ASA									
1	20,725	11.4%	5087	12.1%	31	18.3%	25,843	11.5%	
2	126,099	69.1%	28,779	68.3%	109	64.5%	154,987	68.9%	
≥3	35,757	19.6%	8258	19.6%	29	17.2%	44,044	19.6%	**<0.001**
Indication									
OA	164,752	90.2%	38,346	91%	152	89.9%	203,250	90.4%	
Acute trauma	6729	3.7%	1372	3.3%	4	2.4%	8105	3.6%	
AVN	3366	1.8%	722	1.7%	6	3.6%	4094	1.8%	
Other	7734	4.2%	1684	4%	7	4.1%	9425	4.2%	**<0.001**
Side									
Left	80,937	44.3%	18,543	44%	81	47.9%	99,561	44.3%	
Right	101,644	55.7%	23,581	56%	88	52.1%	125,313	55.7%	0.326

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[8] BMI data only available for 130,511 procedures

	LPW 182,581 (81.2%)		Hooded 42,124 (18.7%)		Offset reorientating 169 (0.1%)		Total 224,874		P-value
Organisation									
NHS	131,008	71.8%	28,088	66.7%	119	70.4%	159,215	70.8%	
Ind. Hosp.	43,040	23.6%	11,736	27.9%	50	29.6%	54826	24.4%	
Ind. Tr Cntr	8533	4.7%	2300	5.5%	0		10,833	4.8%	**<0.001**
Surgeon grade									
Consultant	143,292	78.5%	33,566	79.7%	136	80.5%	176,994	78.7%	
Trainee	20,773	11.4%	4747	11.3%	17	10.1%	25,537	11.4%	
SAS	13,201	7.2%	2822	6.7%	16	9.5%	16,039	7.1%	
Other	5315	2.9%	989	2.3%	0		6304	2.8%	**<0.001**
Approach									
Posterior	102,386	56.1%	21,404	50.8%	60	35.5%	123,850	55.1%	
Lateral	70,937	38.9%	17,606	41.8%	75	44.4%	88,618	39.4%	
Other	9258	5.1%	3114	7.4%	34	20.1%	12,406	5.5%	**<0.001**
Head size (mm)									
22.225	9502	5.2%	16	<0.1%	0		9518	4.2%	
26	14,522	8%	2626	6.2%	16	9.5%	17,164	7.6%	
28	119,577	65.5%	31,536	74.9%	150	88.8%	151,263	67.3%	
30/ 32	35,429	19.4%	7946	18.9%	3	1.8%	43,378	19.3%	
36	3523	1.9%	0		0		3523	1.6%	
>36	28	<0.1%	0		0		28	<0.1%	**<0.001**
PE crosslinked									
No	132,610	72.6%	25,299	60.1%	0		157,909	70.2%	
Yes	49,971	27.4%	16,825	39.9%	169	100%	66,965	29.8%	**<0.001**

	LPW 182,581 (81.2%)		Hooded 42,124 (18.7%)		Offset reorientating 169 (0.1%)		Total 224,874		P-value
Cup Manufacturer									
DePuy	86,523	47.4%	0		0		86,523	38.5%	
Stryker	96,058	52.6%	42,124	100%	169	100%	138,351	61.5%	

Table 5-1 Subject characteristics, by cemented acetabular component geometry

5.5.2 Trend in component usage over time

Figure 5-1 demonstrates the changes in relative proportions of acetabular component geometry usage per year over the study dataset period. The proportion of hooded components used falls steadily from 29.8% in 2003 to 10% in 2017, with a reciprocal increase in LPW usage. The offset reorientating components also seemed to have a trend towards decreased usage starting at 0.5% in 2003 and falling to 0.1% in 2011, after which point there less than 6 implantations of this component geometry recorded per year.

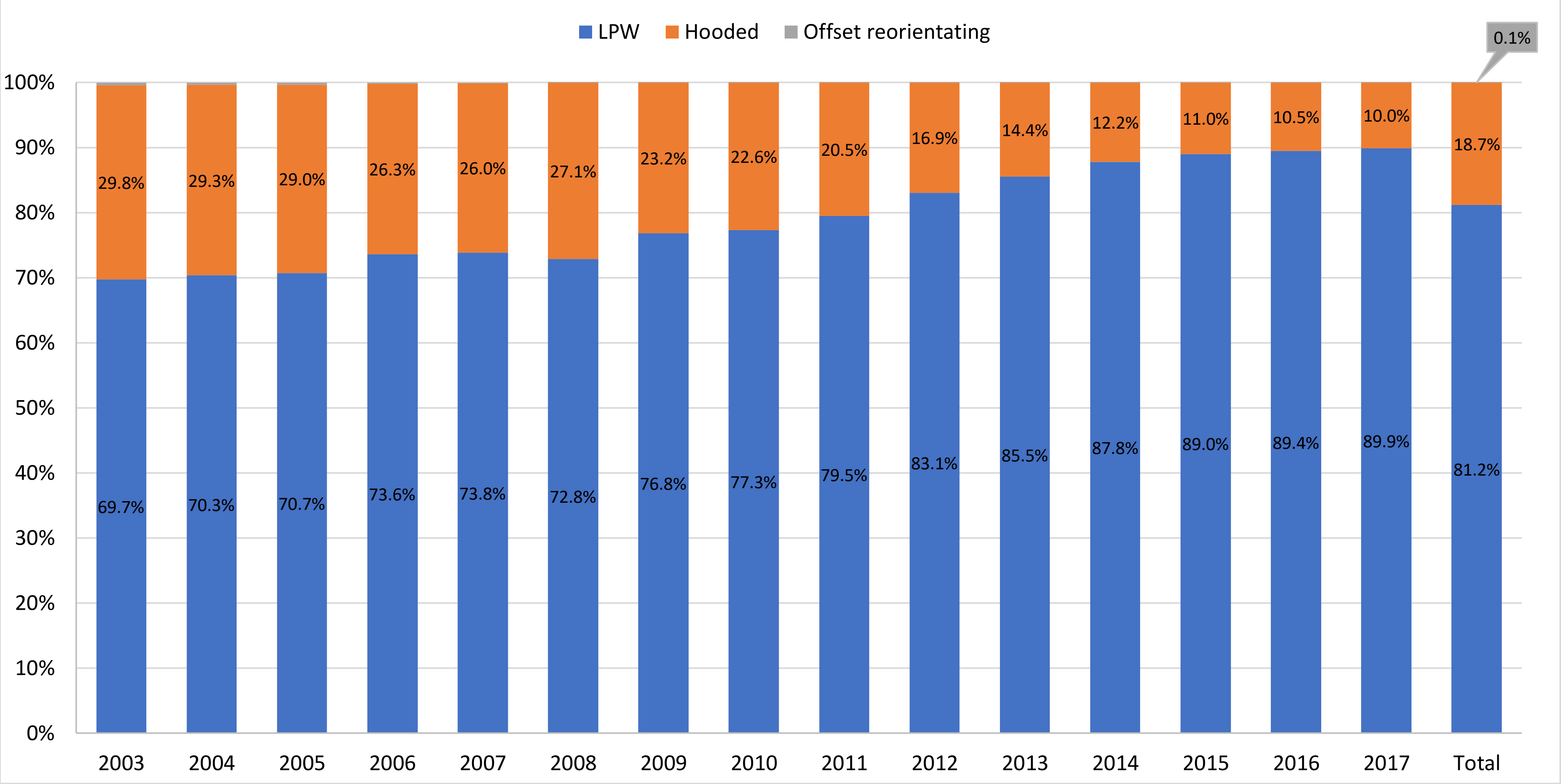

Figure 5-1 Trend in cemented acetabular component geometry usage

5.5.3 Outcome following THA

The median follow-up time cohort was 4.3 years (IQR = 2.1 – 7.3 years, max = 15.3 years). During follow up there were 3313 (1.5%) revisions and 37028 (16.5%) deaths. The most common reasons for revision were loosening (838; 0.37%), instability (815; 0.36%), infection (734; 0.33%), periprosthetic fracture (507; 0.23%) and “other” (419; 0.17%), see Table 5-2 (page 80). Compared to LPW, the hooded group had a higher revision rate (2.44% vs 1.24%), mainly due to instability and loosening. The offset reorientating group had small numbers, but an even higher revision rate (7.69%) was noted than the other groups, the excess of revisions being mainly due to loosening though all revision indications, other than infection, were over-represented.

5.5.4 Risk of revision

Compared to the LPW components, the use of hooded or offset reorientating components was associated with an increased risk of revision THA for instability in univariable, adjusted multiple variable and competing risk regression analyses (see Table 5-3, page 80). The full regression outputs are presented in Table 5-9 (page 95) for revision for instability. We repeated the analyses with BMI as a covariate, among the subset of patients with BMI data (58%), however the risk ratios for revision THA by acetabular geometry remained unchanged, therefore BMI was not included in our final regression models.

	LPW	Hooded	Offset reorientating	Total
Unrevised	152,524 (83.54%)	31,908 (75.75%)	101 (59.76%)	184,533 (82.06%)
Died	27,786 (15.22%)	9187 (21.81%)	55 (32.54%)	37,028 (16.47%)
Revised	2271 (1.24%)	1029 (2.44%)	13 (7.69%)	3313 (1.47%)
Instability	535 (0.29%)	278 (0.66%)	2 (1.18%)	815 (0.36%)
Loosening	498 (0.27%)	331 (0.79%)	9 (5.33%)	838 (0.37%)
Infection	568 (0.31%)	166 (0.39%)	0	734 (0.33%)
Periprosthetic fracture	384 (0.21%)	122 (0.29%)	1 (0.59%)	507 (0.23%)
Other	286 (0.16%)	132 (0.31%)	1 (0.59%)	419 (0.19%)

Table 5-2 Outcome following primary THA by cemented acetabular component geometry

	LPW	Hooded		Offset reorientating	
Revision for instability	0.29%	0.66%		1.18%	
unadjusted log-binomial	1	2.25 (1.95 – 2.6)	**<0.001**	4.04 (1.02 – 16.06)	**0.047**
adjusted log-binomial	1	2.66 (2.28 – 3.09)	**<0.001**	5.61 (1.4 – 22.43)	**0.015**
competing risk	1	2.31 (1.97 – 2.71)	**<0.001**	4.12 (1.02 – 16.69)	**0.047**
Revision for loosening	0.27%	0.79%		5.33%	
unadjusted log-binomial	1	2.88 (2.51 – 3.31)	**<0.001**	19.53 (10.28 – 37.1)	**<0.001**
adjusted log-binomial	1	3.53 (3.04 – 4.09)	**<0.001**	23.97 (12.61 – 45.56)	**<0.001**
competing risk	1	2.65 (2.28 – 3.08)	**<0.001**	13.61 (6.85 – 27.04)	**<0.001**

Table 5-3 Risk of revision THA for instability or for loosening, by cemented acetabular component geometry[9]

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[9] LPW group used as reference. Log-binomial regression outputs are RRRs with 95% CI, competing risk outputs are SHRs with 95% CI. Covariate adjustments – age at surgery, gender, ASA grade, indication, treating organisation, operating surgeon, side, surgical approach, prosthetic head size and PE crosslinking

In the analyses stratified by surgical approach (see Table 5-4, page 83), hooded cups remain at higher risk of revision for instability (compared to LPW cups) across all surgical approaches. Offset reorientating cups had a higher risk of revision for instability (compared to LPW cups) in “other” surgical approaches but numbers were too small to analyse in the posterior and lateral approach groups. Compared to 28mm head sizes, 22.225mm heads remained at higher risk of revision for instability across all surgical approaches, whereas 30/32mm heads only seemed to be protective of revision for instability in the posterior surgical approach group.

Following pairwise comparisons (see Table 5-5, page 83) of all cup geometries, the overall pattern of higher revision risk for instability in hooded compared to LPW cups remained across all surgical approaches. In the “other” surgical approaches, offset reorientating cups were at higher risk of revision for instability compared to LPW and compared to hooded cups.

		Posterior approach 123,850 (55%)		**Lateral approach 88,618 (39%)**		**Other approaches 12,406 (6%)**	
		SHR (95% CI)	**P**	**SHR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age		1.01 (0.99 – 1.02)	0.305	0.98 (0.97 – 0.99)	**0.045**	0.99 (0.96 – 1.02)	0.44
Gender	(Ref. Female)						
Male		1.04 (0.87 – 1.25)	0.673	0.73 (0.54 – 0.99)	**0.041**	1.17 (0.65 – 2.09)	0.604
ASA	(Ref. 1)						
	2	1.3 (0.95 – 1.77)	0.104	1.26 (0.8 – 1.97)	0.317	1.51 (0.72 – 3.16)	0.278
	≥3	1.43 (1 – 2.03)	**0.049**	1.53 (0.92 – 2.56)	0.102	0.96 (0.31 – 2.97)	0.945
Indication	(Ref. OA)						
	Acute Trauma	2.9 (2.05 – 4.09)	**<0.001**	2.61 (1.52 – 4.48)	**<0.001**	4.03 (0.9 – 18.19)	0.069
	AVN	2.59 (1.68 – 4)	**<0.001**	1.51 (0.66 – 3.43)	0.332	3.54 (1.28 – 9.82)	**0.015**
	Other	1.49 (1.02 – 2.18)	**0.038**	1.03 (0.52 – 2.02)	0.942	1.03 (0.28 – 3.75)	0.961
Side	(Ref. Left)						
	Right	1.08 (0.91 – 1.28)	0.399	0.91 (0.7 – 1.18)	0.472	1.64 (0.92 – 2.95)	0.097
Treating organisation	(Ref. NHS)						
	Ind. Hospital	1.2 (0.97 – 1.48)	0.099	1.06 (0.75 – 1.5)	0.742	1.1 (0.59 – 2.04)	0.771
	Ind. Tr. Cntr.	1.56 (1.11 – 2.21)	**0.011**	0.6 (0.27 – 1.32)	0.205	0.94 (0.11 – 7.77)	0.953
Surgeon grade	(Ref. Consultant)						
	Trainee	1.23 (0.96 – 1.59)	0.107	1.58 (1.08 – 2.3)	**0.018**	1.04 (0.4 – 2.7)	0.93
	SAS	0.96 (0.61 – 1.52)	0.861	0.83 (0.51 – 1.35)	0.459	0.91 (0.36 – 2.35)	0.849
	Other	1.41 (0.86 – 2.3)	0.178	1.31 (0.63 – 2.71)	0.466	1.27 (0.38 – 4.24)	0.701
Head size (mm)	(Ref. 28mm)						
	22.225	2.38 (1.3 – 4.35)	**0.005**	2.27 (1.5 – 3.44)	**<0.001**	8.03 (3.3 – 19.58)	**<0.001**
	26	0.94 (0.63 – 1.39)	0.737	1.29 (0.88 – 1.88)	0.187	2.93 (1.3 – 6.61)	**0.01**
	30/ 32	0.65 (0.52 – 0.83)	**<0.001**	0.6 (0.32 – 1.12)	0.108	3.05 (0.98 – 9.55)	0.055

	Posterior approach		**Lateral approach**		**Other approaches**	
	123,850 (55%)		**88,618 (39%)**		**12,406 (6%)**	
	SHR (95% CI)	**P**	**SHR (95% CI)**	**P**	**SHR (95% CI)**	**P**
36	0.67 (0.29 – 1.53)	0.34	*too few*		*too few*	
>36	*too few*		*too few*		*too few*	
Cup geometry (Ref. LPW)						
Hooded	2.23 (1.84 – 2.69)	**<0.001**	2.69 (1.95 – 3.71)	**<0.001**	2.83 (1.23 – 6.5)	**0.014**
Offset reorientating	*too few*		*too few*		31.68 (5.75 – 174.56	**<0.001**
PE crosslinked (Ref. No)						
Yes	0.85 (0.69 – 1.03)	0.102	0.69 (0.46 – 1.04)	0.074	1.14 (0.57 – 2.25)	0.716

Table 5-4 Revision for instability. Adjusted competing risks analyses, stratified by surgical approach in cemented cups

	Posterior approach		**Lateral approach**		**Other approaches**	
	SHR (95% CI)	**P-value**	**SHR (95% CI)**	**P-value**	**SHR (95% CI)**	**P-value**
Hooded vs LPW	2.23 (1.76 – 2.81)	**<0.001**	2.69 (1.81 – 3.98)	**<0.001**	2.83 (1.02 – 7.82)	**0.043**
Offset reorientating vs LPW	*too few*		*too few*		31.68 (3.94 – 254.71)	**<0.001**
Offset reorientating vs Hooded	*too few*		*too few*		11.2 (1.56 – 80.38)	**<0.001**

Table 5-5 Revision for instability. Adjusted competing risks analyses, stratified by surgical approach – pairwise comparisons of cemented cup geometries

In revision for loosening, compared to the LPW components, the use of hooded or offset reorientating components was associated with an increased risk in univariable, adjusted multiple variable and competing risk regression analyses (see Table 5-3, page 80). The full regression outputs are presented in Table 5-10, page 97.

In the stratified analyses by surgical approach (see Table 5-6, page 86), hooded and offset reorientating cups remain at higher risk of revision for loosening (compared to LPW cups) across all surgical approaches. PE crosslinking was protective against revision for loosening in posterior and lateral approaches, but not in “other” approaches. Compared to 28mm head sizes, 36mm heads had an increased risk of revision for loosening in posterior and lateral approaches and 22.225mm heads had an increased risk of revision for loosening in lateral approaches.

Following pairwise comparisons of all cup geometries (see Table 5-7, page 86), hooded and offset reorientating cups remained at higher risk or revision for loosening compared to LPW cups across all surgical approaches. Additionally, in the posterior and lateral surgical approach groups, offset reorientating cups were at higher risk of revision for loosening than hooded cups.

		Posterior approach 123,850 (55%)		**Lateral approach 88,618 (39%)**		**Other approaches 12,406 (6%)**	
		SHR (95% CI)	**P**	**SHR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age		0.95 (0.94 – 0.96)	**<0.001**	0.94 (0.93 – 0.95)	**<0.001**	0.95 (0.93 – 0.96)	**<0.001**
Gender	(Ref. Female)						
	Male	0.99 (0.78 – 1.25)	0.935	0.88 (0.71 – 1.08)	0.221	1.11 (0.73 – 1.7)	0.619
ASA	(Ref. 1)						
	2	0.84 (0.62 – 1.13)	0.245	1.03 (0.79 – 1.35)	0.81	0.9 (0.56 – 1.45)	0.663
	≥3	0.98 (0.66 – 1.44)	0.907	0.87 (0.61 – 1.25)	0.458	0.88 (0.41 – 1.91)	0.746
Indication	(Ref. OA)						
	Acute Trauma	0.36 (0.12 – 1.12)	0.078	0.82 (0.42 – 1.61)	0.565	*too few*	
	AVN	1.42 (0.77 – 2.63)	0.258	0.99 (0.51 – 1.95)	0.981	1.08 (0.33 – 3.56)	0.896
	Other	0.79 (0.47 – 1.33)	0.378	0.49 (0.26 – 0.91)	**0.023**	0.38 (0.12 – 1.25)	0.111
Side	(Ref. Left)						
	Right	1.03 (0.83 – 1.28)	0.801	1.02 (0.84 – 1.24)	0.833	0.97 (0.65 – 1.45)	0.878
Treating organisation	(Ref. NHS)						
	Ind. Hospital	0.9 (0.68 – 1.19)	0.448	1.02 (0.81 – 1.29)	0.866	1.76 (1.01 – 2.83)	**0.021**
	Ind. Tr. Cntr.	1.45 (0.95 – 2.23)	0.089	1.07 (0.74 – 1.57)	0.716	1.62 (0.56 – 4.74)	0.377
Surgeon grade	(Ref. Consultant)						
	Trainee	1.09 (0.78 – 1.52)	0.616	0.99 (0.7 – 1.38)	0.93	0.87 (0.34 – 2.26)	0.777
	SAS	1.4 (0.83 – 2.34)	0.205	0.75 (0.52 – 1.08)	0.12	0.71 (0.28 – 1.79)	0.467
	Other	1.68 (0.94 – 3.02)	0.082	0.44 (0.18 – 1.08)	0.073	2.04 (0.9 – 4.67)	0.09
Head size (mm)	Ref. 28mm						
	22.225	1 (0.37 – 2.73)	0.996	1.46 (1.04 – 2.06)	**0.029**	1.53 (0.86 – 2.73)	0.15
	26	1.37 (0.95 – 1.98)	0.092	0.84 (0.61 – 1.14)	0.266	0.99 (0.59 – 1.66)	0.959
	30/ 32	0.91 (0.66 – 1.25)	0.558	1.28 (0.86 – 1.89)	0.228	0.4 (0.05 – 2.99)	0.368

	Posterior approach 123,850 (55%)		Lateral approach 88,618 (39%)		Other approaches 12,406 (6%)	
	SHR (95% CI)	**P**	**SHR (95% CI)**	**P**	**SHR (95% CI)**	**P**
36	2.84 (1.35 – 5.99)	**0.006**	3.43 (1.05 – 11.18)	**0.041**	*too few*	
>36	*too few*		*too few*		*too few*	
Cup geometry (Ref. LPW)						
Hooded	2.26 (1.79 – 2.86)	**<0.001**	3.09 (2.45 – 3.88)	**<0.001**	2.46 (1.44 – 4.19)	**0.001**
Offset reorientating	15.47 (5.65 – 42.4)	**<0.001**	13.72 (4.13 – 45.6)	**<0.001**	8.31 (1.8 – 8.46)	**0.007**
PE crosslinked (Ref. No)						
Yes	0.73 (0.56 – 0.94)	**0.017**	0.65 (0.49 – 0.86)	**0.003**	0.97 (0.59 – 1.58)	0.895

Table 5-6 Revision for loosening. Adjusted competing risks analyses, stratified by surgical approach in cemented cups

	Posterior approach		Lateral approach		Other approaches	
	SHR (95% CI)	**P-value**	**SHR (95% CI)**	**P-value**	**SHR (95% CI)**	**P-value**
Hooded vs LPW	2.26 (1.7 – 3.01)	**<0.001**	3.09 (2.33 – 4.09)	**<0.001**	2.46 (1.28 – 4.71)	**0.003**
Offset reorientating vs LPW	15.47 (4.52 – 53.02)	**<0.001**	13.72 (3.16 – 59.5)	**<0.001**	8.31 (1.28 – 53.99)	**0.02**
Offset reorientating vs Hooded	6.84 (1.99 – 23.49)	**<0.001**	4.44 (1.05 – 18.89)	**0.041**	3.38 (0.54 – 21.28)	0.338

Table 5-7 Revision for loosening. Adjusted competing risks analyses, stratified by surgical approach – pairwise comparisons of cemented cup geometries

Based on the adjusted competing risk survival analyses, the cumulative incidence of revision THA by acetabular component geometry is presented in Figure 5-2 for instability and in Figure 5-3 for loosening. The 10-year cumulative incidence of revision THA for instability from this analysis was 0.36% for LPW, 0.83% for hooded and 1.48% for offset reorientating components. For revision THA for loosening, the 10-year cumulative incidences were 0.43% for LPW, 1.13% for hooded and 5.66% for offset reorientating components.

The sensitivity analyses estimated that an unmeasured confounder would need to have a 4.05-fold (minimum 3.35) association with both the use of a hooded component (over LPW) and revision THA for instability to explain away the observed SHR of 2.31. For revision THA for loosening, this was estimated at 4.74-fold (minimum 3.99), to explain away the observed SHR of 2.65.

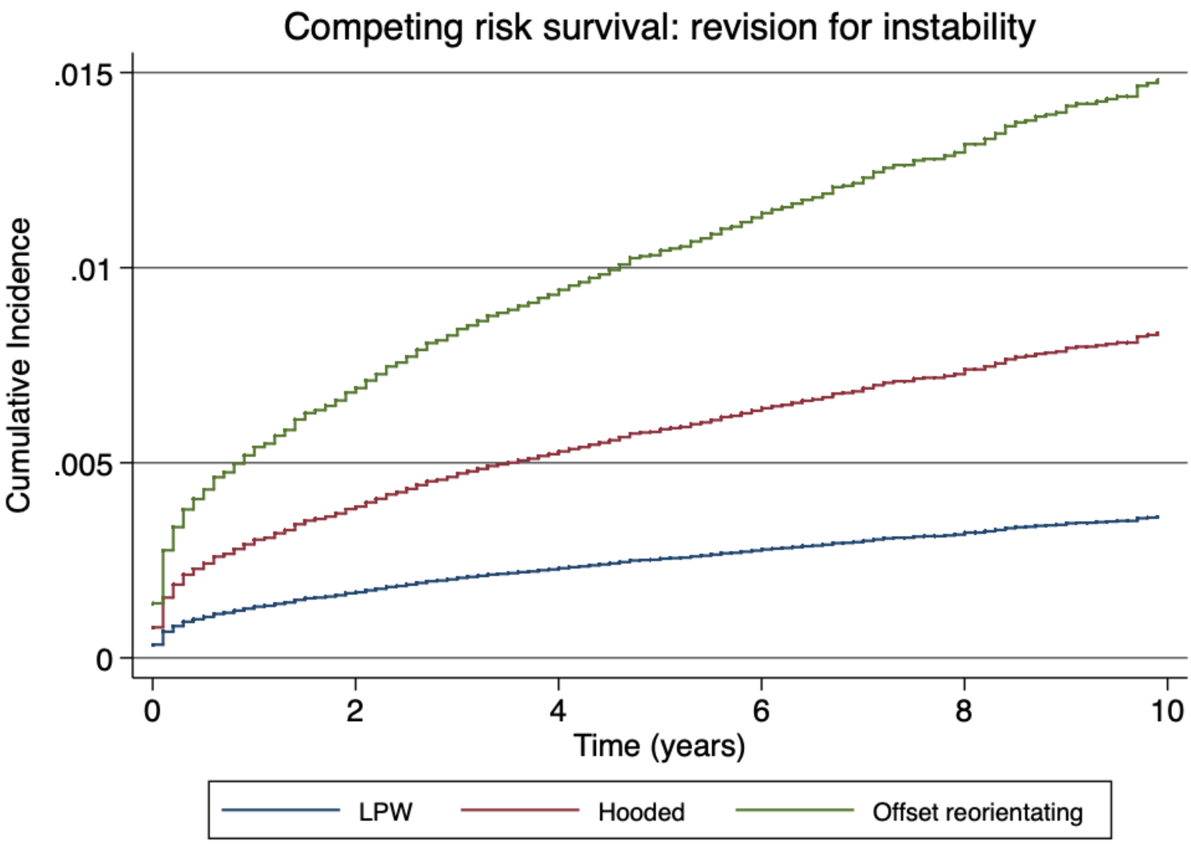

Figure 5-2 Cumulative incidence of revision THA for instability by cemented acetabular component geometry. An adjusted competing risks analysis

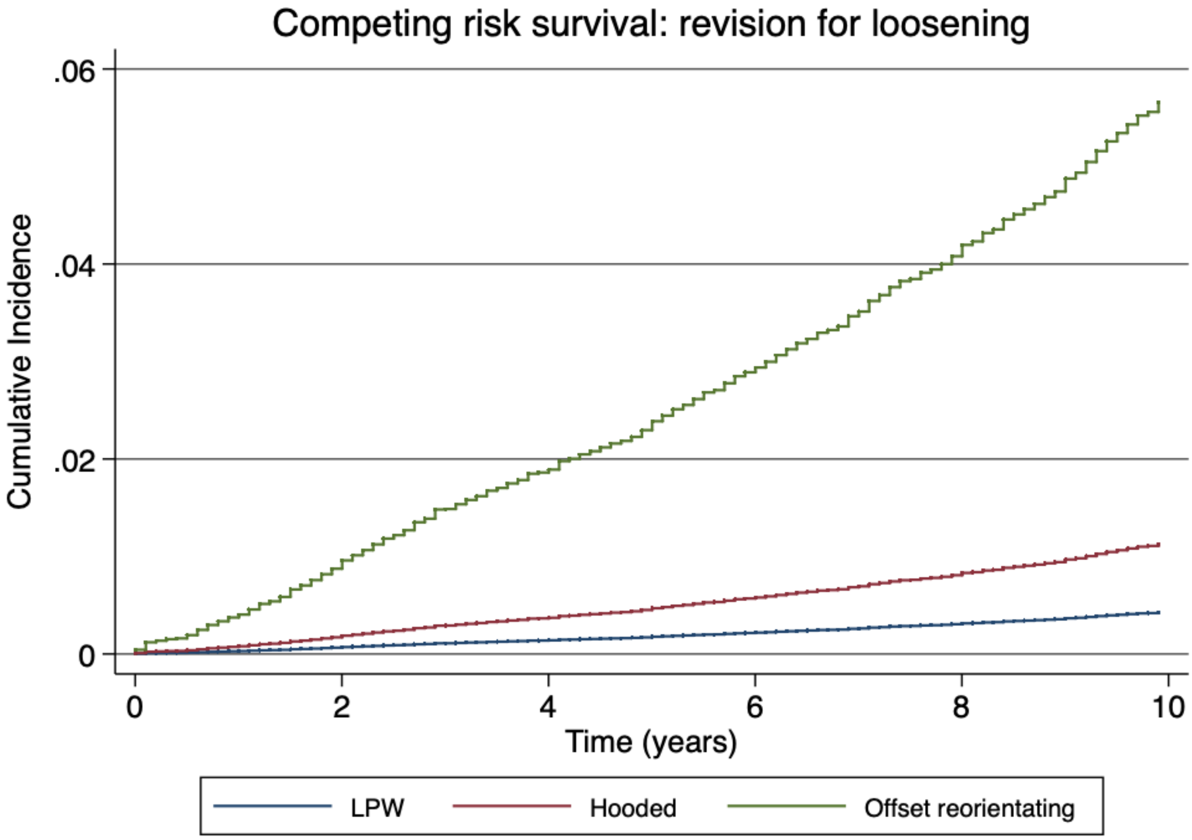

Figure 5-3 Cumulative incidence of revision THA for loosening by cemented acetabular component geometry. An adjusted competing risks analysis

5.5.5 Risk of revision: Influence of time from primary THA

In the adjusted Cox proportional hazards model (same covariates used as the competing risks model), we found that the proportional hazards assumption was not met for revision for instability but was for revision for loosening. Consequently, for revision for instability, we split the dataset by time intervals and reassessed each time interval with the adjusted Cox model and proportional hazards test. Deciles for revision THA for instability events were used to generate the time intervals – 0.1, 0.2, 0.5, 1.1, 1.9, 2.7, 4.2, 6.4 and 8 years. The competing risk regression model was then applied to these time intervals to determine the time-specific SHRs of revision for instability by acetabular component geometry. Analysis of the offset reorientating cup group was not included due to small numbers. The time-varying SHRs were plotted against time with 95% CIs (see Figure 5-4). The increased SHR of revision THA for instability in hooded vs LPW cups was greatest immediately postoperative (4.8), falling rapidly over the first 3 months to 2.31 and then more gradually to 1.66 at 1 year. There was a further rise in the SHR to 2.4 at 2.5 years after which it decreased till 4 years at which point the lower bound 95% CI remained below 1 for the rest of the analysis period.

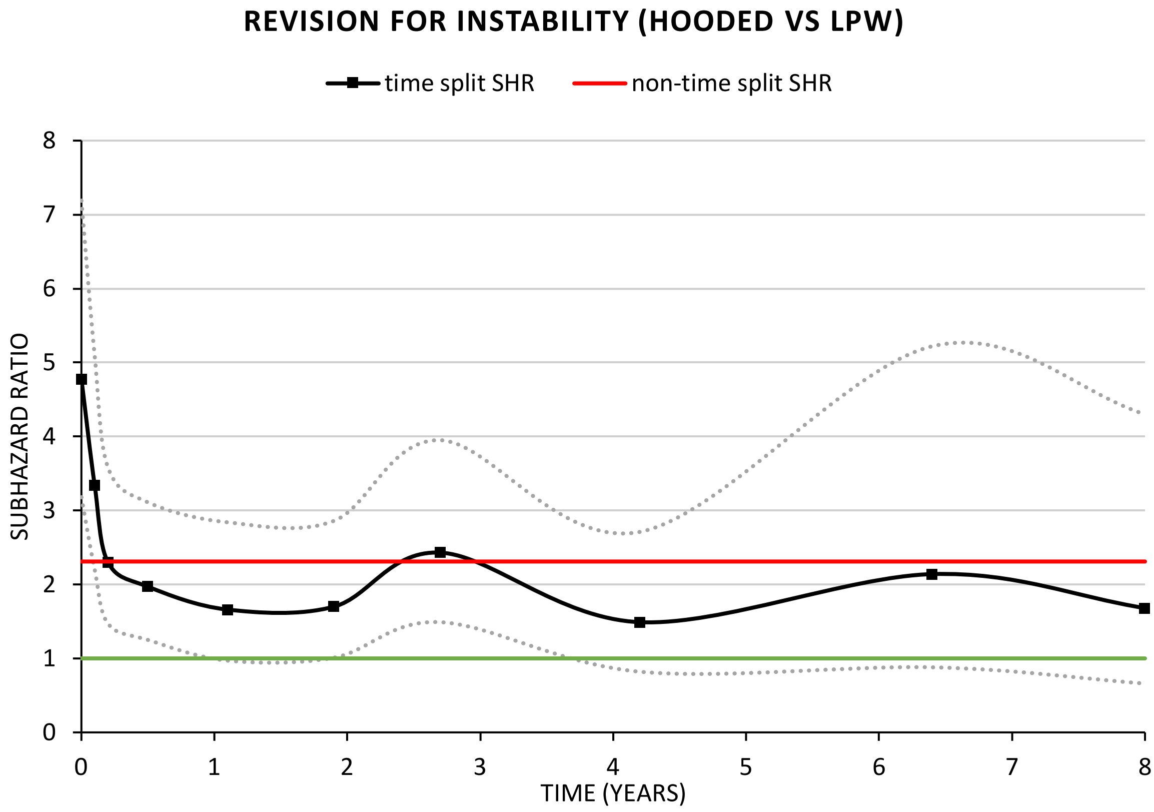

Figure 5-4 Subhazard ratio of revision THA for instability (hooded vs. LPW) by time from primary THA. A competing risks analysis

5.6 Discussion

In this analysis of primary THA data from the NJR we have shown that, compared to those with an LPW acetabular component, there is a significantly higher risk of revision THA for instability and for loosening when a cemented hooded or offset reorientating acetabular component is used, irrespective of the surgical approach used. Furthermore, the revision risk for instability is most marked immediately postoperative, decreases rapidly over the first 3 months but remains increased for several years. A decreasing trend in usage of hooded and offset reorientating components was noted over the dataset period.

There have been some retrospective cohort-based studies reporting on the association between risk of dislocation and cemented acetabular component geometry. In an early report from our Unit, a reduction in dislocation rate (0.8% to 0.4%) was found with a switch from the original neutral faced Charnley cup to the Charnley LPW design (44) (now the most common cemented acetabular component geometry design), though the authors mention the possibility of impingement on the LPW and subsequent dislocation. Partridge et al. (45) reported a reduction in dislocation rates when their unit changed from routine use of hooded components (2.64%) to LPW components (0.71%). The authors felt this reduction in dislocation rate was due to better cup positioning and avoidance of impingement that can occur with hooded components.

We are aware of one other study that investigated the association between cemented acetabular component geometry and the risk of revision THA (see Table 5-8 for comparison to current study's results).

	Registry	Year	n	Mean follow-up (yrs)	Geometry (%)	Revision for instability (HR)	Revision for loosening (HR)
Jameson et al. (52)	UK	2012	34,721	7	hooded (30.3%)	2.34	Not reported
current study	UK	2021	202,511	4	hooded (35%)	2.31	2.65
					offset reorientating (22%)	4.12	13.61

Table 5-8 Comparison of current study with published Registry based studies – revision risk in cemented hooded vs. LPW cups

Jameson et al.'s (52) NJR based analysis was restricted to a single manufacturer, did not include the offset reorientating cup geometries, did not take account of potential competing risks (revision THA for other causes and mortality) and did not consider the effect of time on revision risk (i.e.: non-proportional hazards). Our data extends these findings to other manufacturers' implants, describes the risk with offset reorientating components (though a very small group), and highlights that the risk of revision for instability between LPW and hooded geometries changes with time, being highest within the first 6 months postoperative. We speculate this is likely to be due to component orientation issues at implantation leading to increased occurrence of impingement sufficient to generate early dislocation events. The secondary peak in revision risk at 2.5 years is difficult to explain, but may represent those patients that go on to delayed revision surgery after multiple dislocation events. Additionally, our analyses also describe for the first time, an increased risk of revision specifically for loosening with the use of hooded and offset reorientating cemented acetabular components, compared to LPW, though a time-varying effect on revision risk was not found.

Our study was large and the data collected in a standardised fashion, but there are a number of limitations which need to be considered in interpreting these results. Revision THA for instability has been used as the main endpoint in our analyses as dislocation events are not recorded in the NJR. The total number of patients who experience dislocations will likely be higher than those who are revised, some patients with dislocations will not undergo revision or were pending surgery at the time of data extraction. We felt the use of revision THA as an endpoint was appropriate, and probably more important, as the implications of further surgery are significant both for patients involved and for healthcare systems providing these services.

Data within the NJR is dependent on surgeon self-reporting and subject therefore to errors of reporting. Any misclassification however is unlikely to be associated with the type of acetabular component used, nor the outcomes of interest (revision for instability or loosening) and if anything would tend to result in an attenuation of effect. It is possible that other procedure related factors may have influenced the outcomes such as femoral component details, component orientation, biomechanics restoration and patient specific factors. Such data are not currently available within Registry based data sources such as the NJR. It seems unlikely, however, that such factors would have any association with the type of acetabular component used and therefore unlikely to have had a significant impact on our results. This is supported by the sensitivity analyses we performed, which suggests that any unmeasured confounder(s) would need to have a fairly large association (4.05) with both the choice of acetabular component geometry and the risk of revision THA for instability to negate the observed SHR of revision THA for instability between LPW and hooded acetabular components (2.31). Finally, our data are based on a predominantly Caucasian population and should be extrapolated beyond this group only with caution.

The mechanism by which hooded and offset reorientating cemented acetabular components are associated with an increased risk of revision is unclear. We hypothesise that it may relate to component malorientation during implantation, possibly due to impaired visualisation, leading to increased femoral component neck – hood impingement that then generates a dislocation opposite to the hooded area. This would align with our findings of a higher revision risk for instability in the immediate postoperative period as malalignment/ impingement generated dislocations are more likely to be an early occurrence. Furthermore, retrieval studies consistently report the location of impingement wear/ erosion is usually on the elevated rim of such acetabular components (37,46-49,51), and that components revised specifically for instability have a very high incidence of impingement wear/ erosion (81 – 91%) (37,49). A similar mechanical explanation for the increased revision risk for loosening, due to impingement on the hood and increased torque transfer to the cement-bone interface, has been proposed based on mathematical modelling (46), but further research in this area is needed.

In summary our study confirms previous findings suggesting an increased risk of revision for instability when a cemented hooded cup is used, and highlights an increased risk with offset reorientating acetabular components. An increased risk of revision is also found for loosening with the use of cemented hooded components. Furthermore, the risk of revision for instability appears most marked in the early postoperative period though continues for several years. Further studies are needed to determine whether there are particular clinical circumstances where hooded cups may be beneficial, however, until then caution is needed when using these components in clinical practice.

5.7 Supplementary Tables

		Unadjusted log-binomial Regression		**Adjusted log-binomial Regression**		**Competing Risk Regression**	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age		1 (0.99 - 1.01)	0.539	1 (0.99 - 1.01)	0.771	1 (0.99 – 1.01)	0.668
BMI[8 (page 74)]		1.01 (0.99 – 1.02)	0.63				
Gender	**(Ref. Female)**						
	Male	0.87 (0.75 - 1.01)	0.074	0.98 (0.84 - 1.13)	0.745	0.96 (0.82 – 1.11)	0.559
ASA Grade	**(Ref. 1)**						
	2	1.22 (0.96 – 1.55)	0.102	1.24 (0.97 – 1.58)	0.08	1.31 (1.03 – 1.67)	**0.029**
	≥3	1.33 (1.02 – 1.74)	**0.035**	1.35 (1.02 – 1.78)	**0.036**	1.44 (1.09 – 1.9)	**0.011**
Indication	**(Ref. OA)**						
	Acute Trauma	2.01 (1.53 - 2.64)	**<0.001**	2.49 (1.88 - 3.29)	**<0.001**	2.84 (2.13 – 3.77)	**<0.001**
	AVN	2.32 (1.63 - 3.3)	**<0.001**	2.36 (1.65 - 3.36)	**<0.001**	2.33 (1.63 – 3.33)	**<0.001**
	Other	1.32 (0.97 - 1.8)	0.08	1.35 (0.98 - 1.85)	0.064	1.33 (0.97 – 1.83)	0.08
Side	**(Ref. Left)**						
	Right	1.04 (0.91 - 1.19)	0.55	1.05 (0.92 - 1.21)	0.469	1.05 (0.91 – 1.21)	0.489
Treating Organisation	**(Ref. NHS)**						
	Ind. Hosp	1.03 (0.88 - 1.21)	0.739	1.15 (0.96 - 1.37)	0.127	1.15 (0.96 – 1.37)	0.12
	Ind. Trt. Cntr.	1.19 (0.88 - 1.61)	0.255	1.39 (1.02 - 1.9)	**0.038**	1.26 (0.93 – 1.73)	0.142
Surgeon grade	**(Ref. Consultant)**						
	Trainee	1.34 (1.1 - 1.62)	**0.004**	1.36 (1.11 - 1.67)	**0.003**	1.32 (1.07 – 1.62)	**0.009**
	SAS	0.78 (0.57 - 1.06)	0.11	0.91 (0.67 - 1.24)	0.55	0.9 (0.66 – 1.24)	0.523
	Other	1.26 (0.87 - 1.84)	0.228	1.43 (0.98 - 2.11)	0.066	1.35 (0.92 – 1.98)	0.13
Approach	**(Ref. Posterior)**						
	Lateral	0.58 (0.49 - 0.67)	**<0.001**	0.45 (0.38 - 0.53)	**<0.001**	0.42 (0.36 – 0.5)	**<0.001**

		Unadjusted log-binomial Regression		**Adjusted log-binomial Regression**		**Competing Risk Regression**	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
	Other	0.96 (0.72 - 1.28)	0.785	0.61 (0.45 - 0.83)	**0.001**	0.54 (0.4 – 0.72)	**<0.001**
Head size (mm)	**(Ref. 28mm)**						
	22.225	1.76 (1.36 - 2.28)	**<0.001**	3.21 (2.42 - 4.25)	**<0.001**	2.7 (2.05 – 3.56)	**<0.001**
	26	1.15 (0.9 - 1.46)	0.269	1.45 (1.13 - 1.85)	**0.003**	1.19 (0.93 – 1.52)	0.157
	30/32	0.63 (0.51 - 0.78)	**<0.001**	0.55 (0.45 - 0.69)	**<0.001**	0.69 (0.56 – 0.86)	**0.001**
	36	0.45 (0.2 – 1.01)	0.053	0.59 (0.26 - 1.33)	0.203	0.66 (0.29 – 1.51)	0.325
	>36	too few		too few		too few	
Cup geometry	**(Ref. LPW)**						
	Hooded	2.25 (1.95 - 2.6)	**<0.001**	2.66 (2.28 - 3.09)	**<0.001**	2.31 (1.97 – 2.71)	**<0.001**
	Offset reorientating	4.04 (1.02 - 16.06)	**0.047**	5.61 (1.4 - 22.43)	**0.015**	4.12 (1.02 – 16.69)	**0.047**
PE crosslinked	**(Ref. No)**						
	Yes	0.85 (0.73 – 0.99)	**0.041**	0.76 (0.64 - 0.89)	**0.001**	0.82 (0.69 – 0.98)	**0.028**

Table 5-9 Revision for instability. Univariable (unadjusted), multiple variable (adjusted) log-binomial regression and competing risks regressions in cemented cups

		Unadjusted log-binomial Regression		**Adjusted log-binomial Regression**		**Competing Risk Regression**	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age (years)		0.96 (0.95 - 0.96)	**<0.001**	0.95 (0.94 - 0.95)	**<0.001**	0.95 (0.94 - 0.95)	**<0.001**
BMI [8 (**page** Error! Bookmark not defined.)]		1.02 (0.99 - 1.04)	0.052				
Gender	(Ref. Female)						
	Male	1.02 (0.89 - 1.18)	0.771	0.98 (0.85 - 1.13)	0.763	0.95 (0.82 - 1.1)	0.486
ASA	(Ref. 1)						
	2	0.61 (0.51 - 0.73)	**<0.001**	0.84 (0.7 - 1.01)	0.062	0.94 (0.79 - 1.13)	0.535
	≥3	0.49 (0.39 - 0.62)	**<0.001**	0.81 (0.64 - 1.04)	0.098	0.93 (0.73 - 1.19)	0.562
Indication	(Ref. OA)						
	Acute trauma	0.39 (0.22 - 0.69)	**0.001**	0.47 (0.27 - 0.84)	**0.01**	0.62 (0.35 - 1.09)	0.097
	AVN	1.55 (1.03 - 2.32)	**0.035**	1.22 (0.81 - 1.83)	0.351	1.18 (0.78 - 1.79)	0.437
	Other	0.9 (0.63 - 1.28)	0.543	0.62 (0.43 - 0.89)	**0.01**	0.6 (0.42 - 0.87)	**0.007**
Side	(Ref. Left)						
	Right	1 (0.87 - 1.15)	0.999	1.02 (0.89 – 1.17)	0.754	1.02 (0.89 – 1.17)	0.767
Treating Organisation	(Ref. NHS)						
	Ind. Hospital	1.17 (1 - 1.37)	**0.045**	1.03 (0.88 – 1.22)	0.699	1.04 (0.88 - 1.23)	0.629
	Ind. Trt. Cntr.	1.76 (1.37 - 2.28)	**<0.001**	1.48 (1.14 – 1.94)	**0.004**	1.27 (0.97 - 1.67)	0.082
Surgeon grade	(Ref. Consultant)						
	Trainee	0.92 (0.74 - 1.15)	0.463	1.08 (0.86 - 1.37)	0.487	1.03 (0.82 - 1.3)	0.793
	SAS	0.91 (0.69 - 1.19)	0.48	0.92 (0.69 - 1.22)	0.546	0.87 (0.65 - 1.16)	0.332
	Other	1.01 (0.67 - 1.51)	0.978	1.13 (0.75 - 1.71)	0.55	1.08 (0.71 - 1.63)	0.726
Approach	(Ref. Posterior)						
	Lateral	1.78 (1.54 - 2.06)	**<0.001**	1.4 (1.21 - 1.63)	**<0.001**	1.24 (1.06 - 1.44)	**0.007**
	Other	2.87 (2.28 - 3.61)	**<0.001**	1.76 (1.38 - 2.24)	**<0.001**	1.23 (0.97 - 1.57)	0.094
Head size (mm)	(Ref. 28mm)						

	Unadjusted log-binomial Regression		Adjusted log-binomial Regression		Competing Risk Regression	
	RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
22.225	1.82 (1.42 - 2.35)	**<0.001**	2.09 (1.59 - 2.73)	**<0.001**	1.41 (1.07 - 1.85)	**0.013**
26	1.57 (1.28 - 1.93)	**<0.001**	1.47 (1.18 - 1.81)	**<0.001**	0.99 (0.8 - 1.23)	0.911
30/ 32	0.43 (0.34 - 0.55)	**<0.001**	0.57 (0.44 - 0.73)	**<0.001**	1 (0.78 - 1.28)	0.979
36	0.81 (0.45 - 1.47)	0.485	2.03 (1.09 – 3.76)	**0.025**	3 (1.61 - 5.58)	**0.001**
>36	too few	0.987	too few		too few	
Cup geometry (Ref. LPW)						
Hooded	2.88 (2.51 - 3.31)	**<0.001**	3.53 (3.04 - 4.09)	**<0.001**	2.65 (2.28 - 3.08)	**<0.001**
Offset reorientating	19.53 (10.28 - 37.09)	**<0.001**	23.97 (12.61 – 45.56)	**<0.001**	13.61 (6.85 - 27.04)	**<0.001**
PE crosslinked (Ref. No)						
Yes	0.78 (0.67 – 0.92)	**0.002**	0.59 (0.49 – 0.7)	**<0.001**	0.71 (0.59 – 0.84)	**<0.001**

Table 5-10 Revision for loosening. Univariable (unadjusted), multiple variable (adjusted) log-binomial regression and competing risks regressios in cemented cups

5.8 Analyses not included in journal paper

5.8.1 Manufacturer brand analysis

The adjusted competing risk model for cemented LPW components revealed an increased SHR for revision for instability with the use of Stryker compared to DePuy components (SHR 1.33; 1.09 – 1.62, p=0.005) (see Table 5-11). The other covariates maintained a similar pattern to the main regression model (all component geometries) – higher SHRs with increasing ASA grade, non-OA surgical indications and 22.225mm head sizes; lower SHRs with lateral/ other approaches and with increasing head sizes. The sensitivity analysis performed suggested any unmeasured confounding would need to have a moderate association with both the choice of manufacturer brand and with the risk of revision for instability to negate the observed association effect size (E-value = 1.99; minimum 1.4).

This represents a novel finding, but must be interpreted cautiously as there are potentially several unmeasured confounding variables not considered in this analysis that might influence this observed association (component orientation, femoral stem specifics, biomechanics restoration, other patient specific risk factors). It is unlikely, however, that these unmeasured confounders would result in bias within manufacturer brands and this is supported by the moderate E-value from the sensitivity analysis performed. Finally, "within" brand differences may exist where manufacturers have more than one LPW component (e.g.: older variants still in clinical use). Design differences with implant evolution have not been accounted for here.

A potential explanation could be due to subtle geometric differences in acetabular component bearing surfaces of LPW components between manufacturers. This finding warrants further investigation with careful consideration and measurement of the geometry of bearing surfaces of similar sized cups to inform comparisons.

	SHR (95% CI)	P
Age	1 (0.99 – 1.01)	0.514

		SHR (95% CI)	P
Gender	(Ref. Female)		
	Male	0.87 (0.72 – 1.06)	0.162
ASA	(Ref. 1)		
	2	1.45 (1.06 – 1.99)	**0.022**
	≥3	1.61 (1.13 – 2.29)	**0.009**
Indication	(Ref. OA)		
	Acute Trauma	3.41 (2.48 – 4.69)	**<0.001**
	AVN	2.56 (1.67 – 3.92)	**<0.001**
	Other	1.4 (0.95 – 2.07)	0.087
Side	(Ref. Left)		
	Right	1.02 (0.86 – 1.21)	0.796
Treating organisation	(Ref. NHS)		
	Ind. Hospital	1.05 (0.83 – 1.31)	0.706
	Ind. Tr. Cntr.	1.84 (1.3 – 2.6)	**0.001**
Surgeon grade	(Ref. Consultant)		
	Trainee	1.11 (0.86 – 1.45)	0.423
	SAS	0.9 (0.62 – 1.32)	0.6
	Other	1.26 (0.79 – 2.02)	0.326
Approach	(Ref. Posterior)		
	Lateral	0.43 (0.35 – 0.53)	**<0.001**
	Other	0.57 (0.39 – 0.82)	**0.003**
Head size (mm)	(Ref. 28mm)		
	22.225	3.01 (2.22 – 4.08)	**<0.001**
	26	1.12 (0.82 – 1.53)	0.475
	30/ 32	0.74 (0.55 – 0.98)	**0.036**
	36	0.52 (0.22 – 1.21)	0.129
	>36	*too few*	
Manufacturer brand	(Ref. Stryker)		
	DePuy	1.33 (1.09 – 1.62)	**0.005**
PE crosslinked	(Ref. No)		
	Yes	1.07 (0.83 – 1.37)	0.624

Table 5-11 Revision for instability. Adjusted competing risks analysis of cemented LPW components, by manufacturer brand

Chapter 6: Paper 2 – The Effect of Uncemented Acetabular Liner Geometry And Lip Size On The Risk Of Revision For Instability or Loosening: A Study On 202,511 Primary Hip Replacements From The UK National Joint Registry For England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey

6.1 Introduction

This chapter is presented in journal style, and the represents the second of two anticipated publication outputs from this research thesis, looking specifically at the uncemented acetabular components in the analysed dataset.

6.1.1 Publication authorship

Hiren Divecha, Terence W O'Neill, Mark Lunt, Timothy Board.

6.2 Abstract

6.2.1 Aim

To determine if uncemented PE acetabular liner geometry, and lip size, influences the risk of revision for instability or loosening.

6.2.2 Methods

202,511 primary THAs with uncemented acetabular components were identified from the NJR dataset (2003 – 2017). The effect of liner geometry on the risk of revision for instability or loosening was investigated using competing risk regression analyses adjusting for age, gender, ASA grade, indication, side, institution type, surgeon grade, surgical approach, head size and PE crosslinking. Stratified analyses by surgical approach were performed, including pairwise comparisons of liner geometries.

6.2.3 Results

The distribution of liner geometries were: neutral – 39.4%, offset neutral – 0.9%, 10-degree – 34.5%, 15-degree – 21.6%, 20-degree – 0.8% and offset reorientating – 2.8%. There were 690 (0.34%) revisions for instability. Compared to neutral liners, the adjusted SHR of revision for instability was 10-degree: 0.64 ($p<0.001$), 15-degree: 0.48 ($p<0.001$) and offset reorientating: 1.6 ($p=0.01$). No association was found with other geometries. 10- and 15-degree liners had a time-dependent lower risk of revision for instability within the first 1.2 years. In posterior approaches, 10- and 15-degree liners had a lower risk of revision for instability, with no significant difference between them. The protective effect of lipped over neutral liners was not observed in lateral approach THAs. There were 604 (0.3%) revisions for loosening, but no association between liner geometry and revision for loosening was found.

6.2.4 Conclusion

This Registry based study confirms a lower risk of revision for instability in posterior approach THAs with 10- or 15-degree lipped liners compared to neutral liners, but no significant difference between these lip sizes. A higher revision risk is seen with offset reorientating liners. The benefit of lipped geometries against revision for instability was not seen in lateral approach THAs. Liner geometry does not seem to influence the risk of revision for loosening.

6.3 Introduction

There are many factors that influence stability of a primary THA (13). Uncemented acetabular components benefit from modularity, allowing the surgeon to implant the cup in the planned orientation and then trial a variety of liners to determine which provides the best stability through a functional range of motion, before the definitive liner is inserted. PE liner geometries vary amongst manufacturers, but most produce neutral, offset neutral, lipped and offset reorientating options (see Figure 2-4 page 34). Lipped liners have an elevated rim (past the equator of the liner) over half of the circumference of the bearing face, which includes the "ramp-up" portions from the non-lipped portion. Lipped and offset reorientating liners can be implanted with the elevated rim in the position that most enhances THA stability, as tested intraoperatively during trialling. A downside to lipped and offset reorientating designs is the potential for generating impingement of the prosthetic femoral neck on the elevated rim, which could lead to subluxation or frank dislocation in the opposite direction. It has also been suggested that repetitive impingement may transfer excess torque to the bone-implant interface and result in loosening of the acetabular component over time (35,46).

There have been a few studies published examining the effect of the lipped PE liner on THA stability. Intraoperative visual estimation studies, though limited by study design (41,42) demonstrate improved stability with lipped liners. A cohort study by Cobb et al. (35) found a reduced risk of dislocation after THA with a 10-degree lipped PE liner, but raised concern regarding the potential risk of impingement and loosening with these components. The same authors found no difference in revision for loosening between elevated rim and neutral liners in a later analysis of the same patient cohort (57).

More recently, there have been a number of arthroplasty Registry based studies examining the effect on risk of revision for instability with the use of lipped PE liners (54-56), and report compelling evidence of a reduced risk. The effect of lipped PE liners on revision for loosening is less clear with Bauze et al. (55) and Davis et al. (60) finding a lower risk in the Australian Registry and in the NJR respectively, with the use of lipped PE liners. Conversely however, Wyatt et al. (56) report no association from the New Zealand Registry.

None of the published studies have considered whether the size of the lip has an independent effect on the risk of revision for instability or loosening, nor the effects of offset/ offset reorientating liner designs. Using data from the National Joint Registry for England, Wales, Northern Ireland & the Isle of Man (NJR), and taking account of competing risks for failure, the aim of our study was to determine if uncemented acetabular PE liner geometry, including lip size, influences the risk of revision for instability or for loosening. Furthermore, we sought to determine if the revision risk varied with time after primary THA.

6.4 Methods

We used data from the NJR to address our objectives. We included subjects from inception of the NJR (2003) to March 2017 (data extracted August 2017), who received a primary THA with an uncemented acetabular component from one of the three most common manufacturer brands (DePuy, Stryker and Zimmer), implanted with a PE liner. The dataset we analysed had 202,511 THAs.

6.4.1 Acetabular components

Acetabular liner geometry was categorised as neutral, offset neutral, lipped, offset reorientating (see Figure 2-4). The lipped liners were further divided according to the size of the lip (10-degree, 15-degree, 20-degree). For each component the product specific information was reviewed to confirm liner geometry, and if insufficient, the manufacturing companies were contacted directly to confirm this.

6.4.2 Covariates

Using the NJR dataset we obtained information about additional factors which may influence the risk of revision surgery including age at surgery, gender, BMI, ASA grade, indication (OA, acute trauma, AVN, other), treating organisation (NHS, independent treatment centre, independent hospital), operating surgeon grade (Consultant, trainee, SAS, other), side, surgical approach (posterior, lateral, other (including trochanteric osteotomy and anterior)) and prosthetic head size (22.225mm, 26mm, 28mm, 32mm, 36mm, >36mm). PE crosslinking was confirmed from manufacturer specific information.

6.4.3 Outcomes

The main outcomes were revision for instability or for loosening. Indications for revision recorded in NJR data can be difficult to interpret, as surgeons can assign multiple reasons with no clear indication of the prevailing revision reason. Where multiple revision reasons were recorded (two = 16.7%, three = 3.3%, four or more = 1.4%), a hierarchical approach was taken to assign the most likely cause of revision (in order: infection, periprosthetic fracture, implant fracture, loosening, wear, adverse reaction to metal debris, liner dissociation, incorrect sizing, instability). Revision reasons were then grouped into the following categories: instability, loosening, infection, periprosthetic fracture and other. Mortality was also recorded.

6.4.4 Analyses

Subject characteristics were described using summary statistics including means with SDs and percentages. Differences in covariates between acetabular liner geometry groups were examined using one-way ANOVA with Bonferroni correction for continuous covariates, and Chi-square tests for independence for categorical covariates. Relative proportions of acetabular liner geometry types per year were plotted as stacked bar charts to examine for changes in usage over time.

Univariable and then multiple variable log-binomial regression analyses were performed (adjusted for age at surgery, gender, ASA grade, indication, treating organisation, operating surgeon grade, side, surgical approach, prosthetic head size and PE crosslinking). The results are expressed as RRRs with 95% CIs. We repeated the analysis with further adjustment for BMI among the subset of patients in whom this data was available. Separate competing risks survival analyses were performed (Fine & Gray (62)) for revision for instability and for loosening, and results are expressed as SHRs with 95% CIs. Competing risks were revision for other causes or mortality, adjusting for the same covariates as the binomial regression models. A stratified competing risks analysis by surgical approach was also performed, given most surgeons are likely to use one approach for the majority of their primary THAs and that surgical approach is known to be an independent predictor of THA instability (13). Within these stratified analyses, pairwise comparisons between all liner geometries were performed along with Bonferroni adjustment of the error rate.

A sensitivity analysis was performed, on the full regression outputs, to determine the potential strength of any unmeasured confounding (STATA E-value module (63,64)). The E-values generated represent the minimum strength of association that an unmeasured confounder would need to have (above the included covariates) with both liner geometry and revision for instability (or loosening), to negate the observed association between liner geometry and risk of revision for instability (or loosening).

Finally, we examined whether the assumption of proportional hazards was met by performing a proportional hazards test (Schonfeld residuals) following adjusted Cox regression analysis. For non-proportionality, we planned to split the dataset by time intervals (deciles for revision events), reassess each time interval with the adjusted Cox model and proportional hazards test and then apply the competing risk regression models to each time interval to determine the time-specific SHRs ratios of revision by liner geometry. Analyses were performed using Stata for Mac (v15.1, StataCorp, USA). Statistical significance was taken at $p < 0.05$.

6.5 Results

6.5.1 Subject characteristics

202,511 primary THAs with uncemented acetabular components and PE liners were included in the analysis. The mean age at time of surgery was 69.7 years (SD 9.9 years; range: 13 – 101 years) and 60% were female. Subject characteristics are presented in Table 6-1 for the whole cohort and also stratified by acetabular liner geometry type. The most commonly used PE liner geometry was neutral (39.4%) followed by 10-degree (34.5%), 15-degree (21.6%), offset reorientating (2.8%), offset neutral (0.9%) and 20-degree (0.8%).

There were small but statistically significant differences between liner groups in most of the covariates considered (see Table 6-1). For head size, the neutral group tended to 32 and 36mm heads, whilst the offset neutral/ reorientating groups had a clear preponderance to 36mm sizes (77% and 63% respectively). The 10- and 20-degree groups had higher proportions of 32mm sizes, whilst the 15-degree group tended towards 28mm.

	Neutral	**Offset neutral**	**10-degree**	**15-degree**	**20-degree**	**Offset reorientating**	**Total**	**P-value**
	79,822 (39.4%)	**1767 (0.9%)**	**69,894 (34.5%)**	**43,722 (21.6%)**	**1601 (0.8%)**	**5705 (2.8%)**	**202,511**	
Mean Age (SD)	70.1 (10.1)	68.6 (10.6)	69.5 (10)	69.3 (9.4)	68.1 (11.1)	68.9 (10.4)	69.7 (10)	
Age difference		-1.5	-0.5	-0.8	-2	-1.1		
p-value		**<0.001**	**<0.001**	**<0.001**	**<0.001**	**<0.001**		
Mean BMI (SD) [10]	28.6 (5.2)	28.8 (5.3)	28.5 (5.3)	29 (5.2)	28.4 (5.2)	29 (5.2)	28.7 (5.3)	
BMI difference		0.2	-0.1	0.4	-0.2	0.3		
p-value		1	**0.006**	**<0.001**	1	**0.001**		
Gender								
Female	49,154 (61.58%)	923 (52.24%)	41,357 (59.17%)	26,769 (61.23%)	1032 (64.46%)	2691 (47.17%)	121,926 (60.21%)	
Male	30,668 (38.42%)	844 (47.76%)	28,537 (40.83%)	16,953 (38.77%)	569 (35.54%)	3014 (52.83%)	80,585 (39.79%)	**<0.001**
ASA								
1	10,578 (13.25%)	263 (14.88%)	10,433 (14.93%)	5575 (12.75%)	243 (15.18%)	703 (12.32%)	27,795 (13.73%)	
2	56,446 (70.71%)	1254 (70.97%)	48,719 (69.7%)	32,016 (73.23%)	983 (61.4%)	3928 (68.85%)	143,346 (70.78%)	
≥3	12,798 (16.03%)	250 (14.15%)	10,742 (15.37%)	6131 (14.02%)	375 (23.42%)	1074 (18.83%)	31,370 (15.49%)	**<0.001**
Indication								
OA	71,915 (90.09%)	1592 (90.1%)	63,256 (90.5%)	40,984 (93.74%)	1389 (86.76%)	5091 (89.24%)	184,227 (90.97%)	
Acute trauma	3084 (3.86%)	58 (3.28%)	2116 (3.03%)	827 (1.89%)	24 (1.5%)	244 (4.28%)	6353 (3.14%)	
AVN	1390 (1.74%)	35 (1.98%)	1389 (1.99%)	564 (1.29%)	35 (2.19%)	98 (1.72%)	3511 (1.73%)	
Other	3433 (4.3%)	82 (4.64%)	3133 (4.48%)	1347 (3.08%)	153 (9.56%)	272 (4.77%)	8420 (4.16%)	**<0.001**
Side								
Left	35,927 (45.01%)	837 (47.37%)	31,612 (45.23%)	19,524 (44.65%)	712 (44.47%)	2603 (45.63%)	91,215 (45.04%)	
Right	43,895 (54.99%)	930 (52.63%)	38,282 (54.77%)	24,198 (55.35%)	889 (55.53%)	3102 (54.37%)	111,296 (54.96%)	0.13

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[10] BMI data only available for 132,576 procedures

	Neutral	Offset neutral	10-degree	15-degree	20-degree	Offset reorientating	Total	P-value
	79,822 (39.4%)	**1767 (0.9%)**	**69,894 (34.5%)**	**43,722 (21.6%)**	**1601 (0.8%)**	**5705 (2.8%)**	**202,511**	
Organisation[11]								
NHS	51,806 (41.95%)	1220 (0.96%)	43,175 (34.13%)	25,460 (20.13%)	1017 (0.8%)	3826 (3.02%)	126,504 (62.47%)	
Ind. Hospital	24,398 (39.63%)	414 (0.67%)	25,908 (42.08%)	8975 (14.58%)	578 (0.94%)	1297 (2.11%)	61,570 (30.4%)	
Ind. Trt. Cntr.	3618 (25.06%)	133 (0.92%)	811 (5.62%)	9287 (64.33%)	6 (0.04%)	582 (4.03%)	14,437 (7.13%)	**<0.001**
Surgeon grade								
Consultant	65,794 (82.43%)	1448 (81.95%)	57,463 (82.21%)	38,611 (88.31%)	1348 (84.2%)	4758 (83.4%)	169,422 (83.66%)	
Trainee	6549 (8.2%)	106 (6%)	7441 (10.65%)	2411 (5.51%)	184 (11.49%)	522 (9.15%)	17,213 (8.5%)	
SAS	3779 (4.73%)	30 (1.7%)	2685 (3.84%)	1959 (4.48%)	52 (3.25%)	133 (2.33%)	8638 (4.27%)	
Other	3700 (4.64%)	183 (10.36%)	2305 (3.3%)	741 (1.69%)	17 (1.06%)	292 (5.12%)	7238 (3.57%)	**<0.001**
Approach								
Posterior	49,162 (61.59%)	1328 (75.16%)	50,887 (72.81%)	31,308 (71.61%)	1280 (79.95%)	4505 (78.97%)	138,470 (68.38%)	
Lateral	26,576 (33.29%)	353 (19.98%)	15,984 (22.87%)	11,294 (25.83%)	267 (16.68%)	1068 (18.72%)	55,542 (27.43%)	
Other	4084 (5.12%)	86 (4.87%)	3023 (4.33%)	1120 (2.56%)	54 (3.37%)	132 (2.31%)	8499 (4.2%)	**<0.001**
Head size (mm)								
22.225	154 (0.19%)	0	80 (0.11%)	0	6 (0.37%)	24 (0.42%)	264 (0.13%)	
26	200 (0.25%)	0	182 (0.26%)	0	4 (0.25%)	1 (0.02%)	387 (0.19%)	
28	17,488 (21.91%)	200 (11.32%)	20,586 (29.45%)	24,830 (56.79%)	476 (29.73%)	1349 (23.65%)	64,929 (32.06%)	
32	27,594 (34.57%)	192 (10.87%)	35,032 (50.12%)	18,883 (43.19%)	854 (53.34%)	730 (12.8%)	83,285 (41.13%)	
36	30,314 (37.98%)	1368 (77.42%)	14,002 (20.03%)	9 (0.02%)	261 (16.3%)	3585 (62.84%)	49,539 (24.46%)	
>36	4072 (5.1%)	7 (0.4%)	12 (0.02%)	0	0	16 (0.28%)	4107 (2.03%)	**<0.001**

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[11] Organisation percentages are row, not column

	Neutral **79,822 (39.4%)**	**Offset neutral** **1767 (0.9%)**	**10-degree** **69,894 (34.5%)**	**15-degree** **43,722 (21.6%)**	**20-degree** **1601 (0.8%)**	**Offset reorientating** **5705 (2.8%)**	**Total** **202,511**	**P-value**
PE crosslinked								
No	10,939 (13.7%)	59 (3.34%)	18,301 (26.18%)	7573 (17.32%)	614 (38.35%)	188 (3.3%)	37,674 (18.6%)	
Yes	68,883 (86.3%)	1708 (96.66%)	51,593 (73.82%)	36,149 (82.68%)	987 (61.65%)	5517 (96.7%)	164,837 (81.4%)	**<0.001**
Cup manufacturer								
DePuy	38,535 (48.28%)	1766 (99.94%)	0	43,722 (100%)	0	5677 (99.51%)	89,700 (44.29%)	
Stryker	26,159 (32.77%)	1 (0.06%)	45,732 (65.43%)	0	323 (20.17%)	28 (0.49%)	72,243 (35.67%)	
Zimmer	15,128 (18.95%)	0	24,162 (34.57%)	0	1278 (79.83%)	0	40,568 (20.03%)	**<0.001**

Table 6-1 Subject characteristics by uncemented acetabular liner geometry

6.5.2 Trend in component usage over time

Figure 6-1 (page 112) demonstrates the relative proportions of acetabular liner geometries used per year over the dataset period. There is a steady decrease in the use of lipped liners (all lip sizes grouped together) over the study period from 75% in 2003 to 51% in 2017, with a reciprocal increase in the use of neutral liners from 24% in 2003 to 46% in 2017.10-degree liner usage falls most notably from 69% in 2003 to 31% in 2017. 15-degree liners initially increase from 1.3% in 2003 to 26% in 2011, before falling to 20% in 2017. 20-degree liner usage falls from 5% in 2003 to 0.8% in 2017. Offset neutral and offset reorientating liner usage seem to reach a peak of usage in 2010 (2.8% and 5% respectively) before steadily falling over the remaining period to 0.9% and 2.8% respectively in 2017.

6.5.3 Outcome following THA

The median follow-up time for this cohort was 3.6 years (IQR = 1.6 – 6.3 years, max = 15.1 years). There were 3214 (1.6%) revisions and 19030 (9.4%) deaths. The most common reasons for revision were periprosthetic fracture (715; 22.2%), instability (690; 21.5%), “other” (609; 19%), loosening (604; 18.8%) and infection (596; 18.5%) (see Table 6-2, page 113).

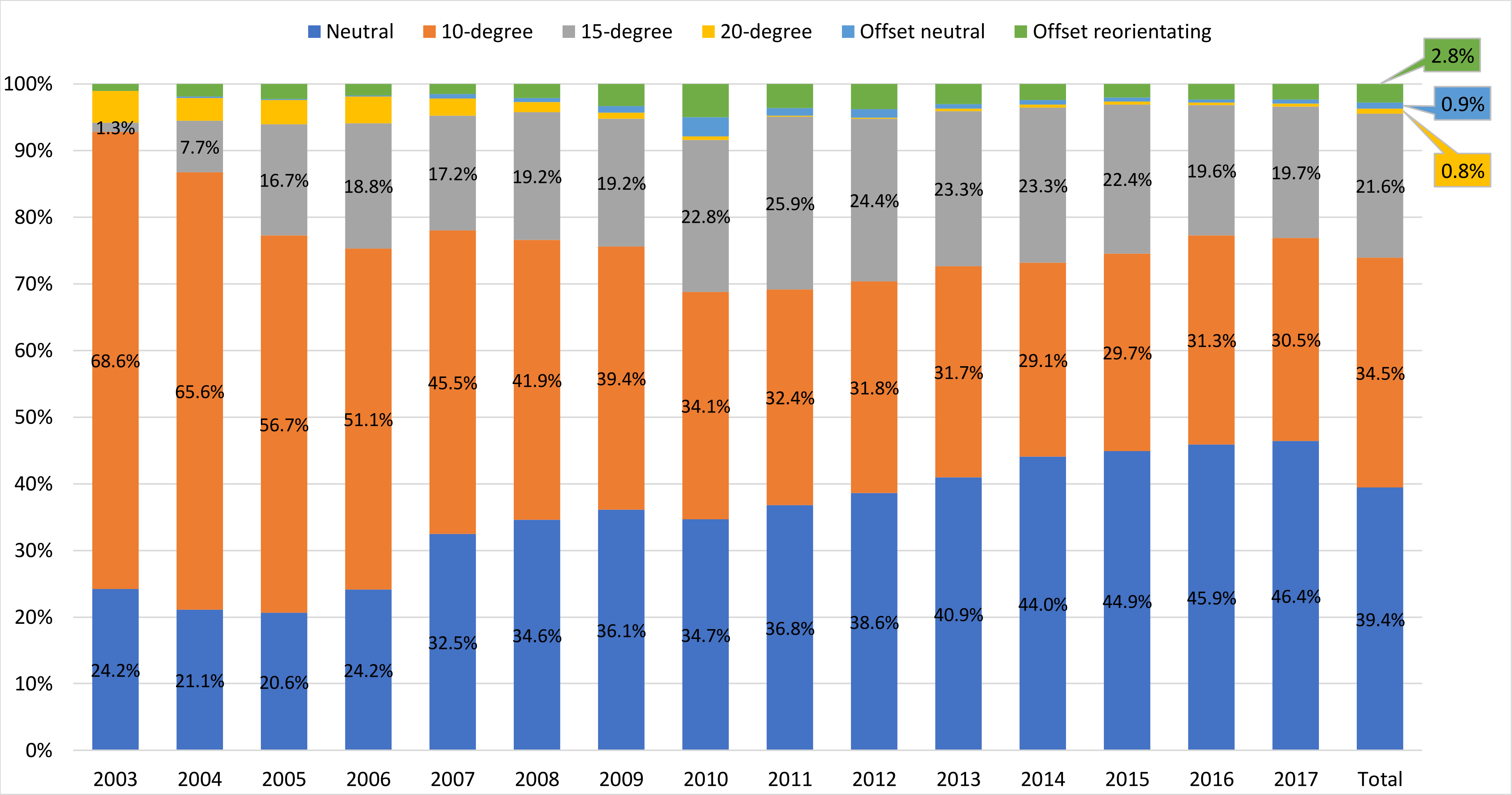

Figure 6-1 Trend in uncemented acetabular liner geometry usage over time

	Neutral	**Offset neutral**	**10-degree**	**15-degree**	**20-degree**	**Offset reorientating**	**Total**
Unrevised	71,693 (89.8%)	1549 (87.7%)	61,148 (87.5%)	39,669 (90.7%)	1237 (77.3%)	4971 (87.1%)	180,267 (89%)
Died	6818 (8.6%)	180 (10.2%)	7601 (10.9%)	3491 (8%)	328 (20.5%)	612 (10.7%)	19,030 (9.4%)
Revised	1311 (1.6%)	38 (2.1%)	1145 (1.6%)	562 (1.3%)	36 (2.2%)	122 (2.2%)	3214 (1.6%)
Instability	288 (22%)	5 (13.2%)	226 (19.7%)	125 (22.2%)	7 (19.4%)	39 (32%)	690 (21.5%)
Loosening	229 (17.5%)	7 (18.4%)	217 (19%)	124 (22.1%)	10 (27.8%)	17 (13.9%)	604 (18.8%)
Infection	226 (17.2%)	9 (23.7%)	237 (20.7%)	103 (18.3%)	4 (11.1%)	17 (13.9%)	596 (18.5%)
Periprosthetic fracture	311 (23.7%)	11 (28.9%)	251 (21.9%)	109 (19.4%)	9 (25%)	24 (19.7%)	715 (22.3%)
Other	257 (19.6%)	6 (15.8%)	214 (18.7%)	101 (18%)	6 (16.7%)	25 (20.5%)	609 (18.9%)

Table 6-2 Outcome following primary THA by uncemented acetabular liner geometry

6.5.4 Risk of revision

In univariable, adjusted multiple variable and competing risk regression analyses (see Table 6-3, page 115), a significant association between liner geometry and revision for instability was found. Compared to neutral liners, the SHR for revision for instability was lower with 10-degree (0.64; 95% CI: 0.51 – 0.79) and 15-degree liners (0.48; 0.37 – 0.62). The offset reorientating liners had a higher SHR for revision for instability (1.61; 1.12 – 2.2), whilst the offset neutral (0.87; 0.35 – 2.14) and 20-degree liners (0.63; 0.29 – 1.35) showed no significant difference. Other variables associated with lower revision for instability risk included lateral and “other” surgical approaches (compared to posterior) and 32mm/ 36mm/ >36mm head sizes (compared to 28mm). Higher revision risk was found in acute trauma and “other” indications (compared to OA) (see supplementary Table 6-9, page 128). We repeated the analysis with BMI as a covariate, among the subset of patients with BMI data (66%), however the risk ratios for revision by liner geometry remained unchanged, therefore BMI was not included in our final regression model.

In the analyses stratified by surgical approach (see Table 6-4), the posterior approach THAs had a similar pattern with 10- and 15-degree lipped liners remaining protective of revision for instability compared to neutral liners (SHR 10-degree = 0.59 (0.39 – 0.88); SHR 15-degree = 0.36 (0.23 – 0.56)).

	Neutral	Offset neutral		10-degree		15-degree		20-degree		Offset reorientating	
Revision for instability	0.36%	0.28%		0.32%		0.29%		0.44%		0.68%	
unadjusted log-binomial	1	0.78 (0.32 – 1.9)	0.59	0.9 (0.75 – 1.07)	0.217	0.79 (0.64 – 0.98)	**0.03**	1.21 (0.57 – 2.56)	0.615	1.9 (1.36 – 2.64)	**<0.001**
adjusted log-binomial	1	1 (0.41 – 2.43)	0.991	0.67 (0.53 – 0.83)	**<0.001**	0.5 (0.39 – 0.64)	**<0.001**	0.7 (0.32 – 1.5)	0.357	1.8 (1.26 – 2.59)	**0.001**
competing risk	1	0.87 (0.35 – 2.14)	0.758	0.64 (0.51 – 0.79)	**<0.001**	0.48 (0.37 – 0.62)	**<0.001**	0.63 (0.29 – 1.35)	0.236	1.61 (1.12 – 2.32)	**0.01**
Revision for loosening	0.29%	0.4%		0.31%		0.28%		0.62%		0.3%	
unadjusted log-binomial	1	1.38 (0.65 – 2.92)	0.399	1.08 (0.9 – 1.3)	0.404	0.99 (0.8 – 1.23)	0.918	2.18 (1.16 – 4.09)	**0.016**	1.04 (0.64 – 1.7)	0.88
adjusted log-binomial	1	1.62 (0.75 – 3.52)	0.223	1.15 (0.91 – 1.47)	0.251	1.37 (1.03 – 1.82)	**0.033**	2.22 (1.16 – 4.27)	**0.017**	1.34 (0.79 – 2.28)	0.273
competing risk	1	1.23 (0.56 – 2.68)	0.611	1.05 (0.82 – 1.33)	0.71	1.19 (0.89 – 1.6)	0.241	1.6 (0.83 – 3.09)	0.165	1.05 (0.63 – 1.77)	0.847

Table 6-3 Risk of revision for instability or for loosening, by uncemented acetabular liner geometry[12]

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[12] Neutral liner group used as reference. Log-binomial regression outputs are RRRs with 95% CI, competing risk outputs are SHRs with 95% CI. Covariate adjustments – age at surgery, gender, ASA grade, indication, treating organisation, operating surgeon, side, surgical approach, prosthetic head size and PE crosslinking)

		Posterior		Lateral	
		138,467 (68%)		55,540 (27%)	
		SHR (95% CI)	P	SHR (95% CI)	P
Age		1 (0.99 – 1.01)	0.392	0.98 (0.97 - 0.99)	**0.025**
Gender	(Ref. Female)				
	Male	1.06 (0.88 – 1.27)	0.538	0.81 (0.58 – 1.12)	0.203
ASA	(Ref. 1)				
	2	1.08 (0.82 – 1.42)	0.589	1.09 (0.69 – 1.73)	0.699
	≥3	1.4 (0.99 – 1.96)	0.055	0.86 (0.47 – 1.58)	0.633
Indication	(Ref. OA)				
	Acute Trauma	2.08 (1.33 - 3.26)	**0.001**	1.86 (0.92 – 3.74)	0.084
	AVN	1.48 (0.84 – 2.61)	0.181	1.2 (0.43 – 3.33)	0.726
	Other	1.88 (1.33 - 2.66)	**<0.001**	1.47 (0.78 – 2.75)	0.23
Side	(Ref. Left)				
	Right	1.01 (0.84 – 1.2)	0.944	0.95 (0.7 – 1.29)	0.732
Treating organisation	(Ref. NHS)				
	Ind. Hospital	1.01 (0.81 – 1.26)	0.914	0.88 (0.6 – 1.29)	0.503
	Ind. Trt. Cntr.	1.34 (0.97 – 1.83)	0.073	0.49 (0.18 – 1.36)	0.17
Surgeon grade	(Ref. Consultant)				
	Trainee	0.76 (0.54 – 1.06)	0.105	1.09 (0.65 – 1.83)	0.739
	SAS	0.79 (0.42 – 1.5)	0.474	0.66 (0.34 – 1.28)	0.22
	Other	1.1 (0.7 – 1.72)	0.678	1.28 (0.55 – 2.98)	0.575
Head size (mm)	Ref. 28mm				
	22.225	1.77 (0.55 – 5.75)	0.341	1.25 (0.17 – 8.99)	0.827
	26	*too few*		0.98 (0.13 – 7.54)	0.983
	32	0.42 (0.33 - 0.52)	**<0.001**	0.55 (0.35 - 0.84)	**0.006**
	36	0.31 (0.23 - 0.41)	**<0.001**	0.23 (0.11 - 0.51)	**<0.001**
	>36	0.07 (0.02 - 0.29)	**<0.001**	0.61 (0.23 – 1.67)	0.338
Liner geometry	(Ref. Neutral)				
	Offset neutral	0.53 (0.17 – 1.7)	0.287	3.56 (0.85 – 14.9)	0.082
	10-degree	0.59 (0.45 - 0.77)	**<0.001**	0.82 (0.54 – 1.24)	0.347
	15-degree	0.36 (0.27 - 0.48)	**<0.001**	0.89 (0.52 – 1.52)	0.672
	20-degree	0.51 (0.2 – 1.26)	0.142	0.92 (0.13 – 6.71)	0.936
	Offset reorientating	1.24 (0.83 – 1.84)	0.297	4 (1.68 - 9.53)	**0.002**
PE crosslinked	(Ref. No)				
	Yes	0.86 (0.68 – 1.08)	0.182	0.82 (0.56 – 1.21)	0.318
Cup manufacturer	(Ref. DePuy)				
	Stryker	0.82 (0.61 – 1.12)	0.21	1.53 (0.89 – 2.61)	0.122
	Zimmer	0.94 (0.68 – 1.3)	0.727	1.5 (0.86 – 2.63)	0.151

Table 6-4 Revision for instability. Adjusted competing risks analyses, stratified by surgical approach[13] in uncemented cups

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[13] "Other" surgical approaches excluded due to small numbers (4.2% of cohort)

Following pairwise comparisons (see Table 6-5) of all liner geometries, no significant differences were found between 10-, 15- and 20- degree liners. Offset reorientating liners had a higher risk of revision for instability than 10- and 15-degree liners. In the lateral approach THAs, no significant effect of liner geometry was found apart from offset reorientating liners remaining higher risk compared to neutral, 10- and 15-degree liners.

	Posterior approach		Lateral approach	
	SHR (95% CI)	**P-value**	**SHR (95% CI)**	**P-value**
Offset neutral vs Neutral	0.53 (0.09 – 3.04)	1	3.56 (0.42 – 30.37)	1
10 degree vs Neutral	0.59 (0.39 – 0.88)	**0.002**	0.82 (0.44 – 1.53)	1
15 degree vs Neutral	0.36 (0.23 – 0.56)	**<0.001**	0.89 (0.4 – 1.98)	1
20 degree vs Neutral	0.51 (0.13 – 1.97)	1	0.92 (0.05 – 18.04)	1
Offset reorientating vs Neutral	1.24 (0.68 – 2.25)	1	4 (1.09 – 14.68)	**0.026**
10 degree vs Offset neutral	1.11 (0.18 – 6.83)	1	0.23 (0.02 – 2.17)	0.818
15 degree vs Offset neutral	0.68 (0.12 – 4)	1	0.25 (0.03 – 2.15)	0.877
20 degree vs Offset neutral	0.95 (0.1 – 8.9)	1	0.26 (0.01 – 10.1)	1
Offset reorientating vs Offset neutral	2.33 (0.39 – 13.92)	1	1.13 (0.11 – 11.89)	1
15 degree vs 10 degree	0.62 (0.35 – 1.1)	0.213	1.09 (0.4 – 2.96)	1
20 degree vs 10 degree	0.86 (0.23 – 3.3)	1	1.13 (0.06 – 21.93)	1
20 degree vs 15 degree	1.4 (0.34 – 5.83)	1	1.03 (0.05 – 22.58)	1
Offset reorientating vs 10 degree	2.11 (1.01 – 4.41)	**0.046**	4.9 (1.14 – 21.02)	**0.02**
Offset reorientating vs 15 degree	3.42 (1.83 – 6.37)	**<0.001**	4.49 (1.2 – 16.76)	**0.012**
Offset reorientating vs 20 degree	2.44 (0.55 – 10.84)	1	4.34 (0.17 – 110.67)	1

Table 6-5 Revision for instability. Adjusted competing risks analyses, stratified by surgical approach – pairwise comparisons of uncemented liner geometries[13]

No significant association between liner geometry and revision for loosening was found in the adjusted competing risks analysis (see Table 6-3). Other factors associated with increased revision for loosening risk included male gender, independent hospitals, lateral approaches and 36/ >36mm head sizes; lower risk was found with increasing age at surgery and crosslinked PE (see supplementary Table 6-10, page 130). In the stratified analyses by surgical approach (see Table 6-6), the posterior approach THAs had a lower revision risk for loosening with 10-degree liners, compared to neutral liners. In lateral approach THAs, 10- and 20-degree liners had a higher revision risk than neutral liners.

		Posterior approach		**Lateral approach**	
		138,467 (68%)		**55,540 (27%)**	
		SHR (95% CI)	**P**	**SHR (95% CI)**	**P**
Age		0.97 (0.96 – 0.98)	**<0.001**	0.96 (0.94 – 0.97)	**<0.001**
Gender	(Ref. Female)				
	Male	1.42 (1.13 – 1.79)	**0.003**	1.09 (0.85 – 1.4)	0.489
ASA	(Ref. 1)				
	2	0.94 (0.7 – 1.26)	0.665	1.06 (0.75 – 1.49)	0.734
	≥3	0.89 (0.58 – 1.35)	0.579	1.27 (0.8 – 2.02)	0.307
Indication	(Ref. OA)				
	Acute Trauma	0.81 (0.33 – 1.95)	0.631	0.29 (1.76)	0.463
	AVN	1.47 (0.76 – 2.82)	0.252	0.44 (0.14 – 1.4)	0.164
	Other	1.24 (0.79 – 1.95)	0.352	0.69 (0.35 – 1.34)	0.271
Side	(Ref. Left)				
	Right	0.92 (0.74 – 1.14)	0.445	1.16 (0.91 – 1.49)	0.238
Treating organisation	(Ref. NHS)				
	Ind. Hospital	1.25 (0.96 – 1.62)	0.101	1.47 (1.1 – 2)	**0.01**
	Ind. Trt. Cntr.	0.92 (0.58 – 1.45)	0.707	0.9 (0.45 – 1.79)	0.754
Surgeon grade	(Ref. Consultant)				
	Trainee	1.22 (0.83 – 1.78)	0.309	1.14 (0.71 – 1.81)	0.588
	SAS	0.42 (0.13 – 1.31)	0.135	0.99 (0.6 – 1.63)	0.962
	Other	0.97 (0.53 – 1.78)	0.916	0.77 (0.31 – 1.9)	0.57
Head size (mm)	Ref. 28mm				
	22.225	2.22 (0.54 – 9.14)	0.268	*too few*	
	26	*too few*		0.95 (0.12 – 7.56)	0.962
	32	0.87 (0.64 – 1.18)	0.359	1.17 (0.83 – 1.65)	0.386
	36	1.18 (0.8 – 1.75)	0.408	1.94 (1.21 – 3.11)	**0.006**
	>36	1.68 (0.85 – 3.29)	0.134	4.91 (2.69 – 8.97)	**<0.001**
Liner geometry	(Ref. Neutral)				
	Offset neutral	1 (0.35 – 2.83)	0.998	1.93 (0.59 – 6.29)	0.275
	10-degree	0.67 (0.47 – 0.95)	**0.024**	1.6 (1.09 – 2.35)	**0.017**
	15-degree	1.14 (0.76 – 1.72)	0.518	0.94 (0.6 – 1.49)	0.795
	20-degree	0.56 (0.17 – 1.85)	0.339	3.45 (1.48 – 8.04)	**0.004**
	Offset reorientating	1.25 (0.71 – 2.21)	0.444	0.24 (0.03 – 1.77)	0.16
PE crosslinked	(Ref. No)				
	Yes	0.61 (0.44 – 0.83)	**0.002**	0.47 (0.34 – 0.66)	**<0.001**
Cup manufacturer	(Ref. DePuy)				
	Stryker	1.07 (0.7 – 1.61)	0.765	1.11 (0.69 – 1.76)	0.673
	Zimmer	1.02 (0.64 – 1.62)	0.933	0.46 (0.27 – 0.78)	**0.004**

Table 6-6 Revision for loosening. Adjusted competing risks analyses, stratified by surgical approach in uncemented cups

Following pairwise comparisons of all liner geometries (see Table 6-7), no significant differences in revision for loosening were found between liner geometries in posterior or lateral approaches.

	Posterior approach		Lateral approach	
	SHR (95% CI)	**P-value**	**SHR (95% CI)**	**P-value**
Offset neutral vs Neutral	1 (0.21 – 4.76)	1	1.93 (0.33 – 11.31)	1
10 degree vs Neutral	0.67 (0.4 – 1.13)	0.360	1.60 (0.9 – 2.84)	0.260
15 degree vs Neutral	1.14 (0.62 – 2.11)	1	0.94 (0.47 – 1.87)	1
20 degree vs Neutral	0.56 (0.09 – 3.36)	1	3.45 (0.97 – 12.25)	0.061
Offset reorientating vs Neutral	1.25 (0.53 – 2.94)	1	0.24 (0.01 – 4.81)	1
10 degree vs Offset neutral	0.67 (0.13 – 3.6)	1	0.83 (0.13 – 5.36)	1
15 degree vs Offset neutral	1.15 (0.24 – 5.55)	1	0.49 (0.08 – 2.94)	1
20 degree vs Offset neutral	0.56 (0.05 – 6.2)	1	1.79 (0.21 – 15.14)	1
Offset reorientating vs Offset neutral	1.25 (0.24 – 6.55)	1	0.12 (0 – 3.65)	1
15 degree vs 10 degree	1.71 (0.79 – 3.67)	0.603	0.59 (0.24 – 1.43)	1
20 degree vs 10 degree	0.83 (0.15 – 4.75)	1	2.16 (0.65 – 7.23)	0.904
20 degree vs 15 degree	0.49 (0.08 – 3.15)	1	3.67 (0.85 – 15.78)	0.133
Offset reorientating vs 10 degree	1.87 (0.68 – 5.15)	1	0.15 (0.01 – 3.21)	1
Offset reorientating vs 15 degree	1.09 (0.48 – 2.51)	1	0.25 (0.01 – 5.18)	1
Offset reorientating vs 20 degree	2.25 (0.31 – 16.58)	1	0.07 (0 – 1.72)	0.220

Table 6-7 Revision for loosening. Adjusted competing risk analysis, stratified by surgical approach – pairwise comparisons of uncemented liner geometries

Based on the competing risk adjusted survival analyses, the cumulative incidence of revision by liner geometry is presented in Figure 6-2 for instability and in Figure 6-3 for loosening. The 10-year cumulative incidences of revision for instability from this analysis were neutral = 0.55%; offset neutral = 0.48%; 10-degree = 0.35%; 15-degree = 0.27%; 20-degree = 0.35% and offset reorientating = 0.89%. For revision for loosening, the 10-year cumulative incidences were neutral = 0.44%; offset neutral = 0.54%; 10-degree= 0.47%; 15-degree = 0.53%; 20-degree = 0.7% and offset reorientating =0.47%.

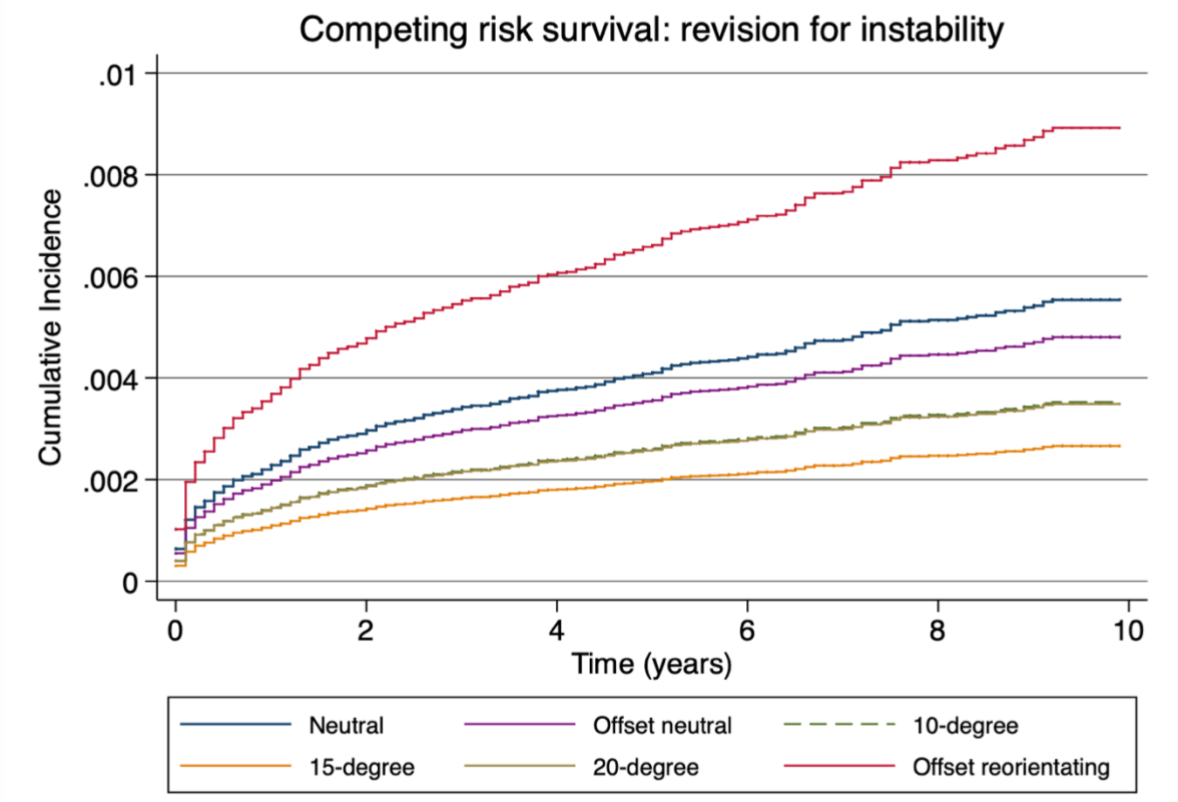

Figure 6-2 Cumulative incidence of revision for instability by uncemented acetabular liner geometry. An adjusted competing risks analysis (10- and 20-degree plots overlapping)

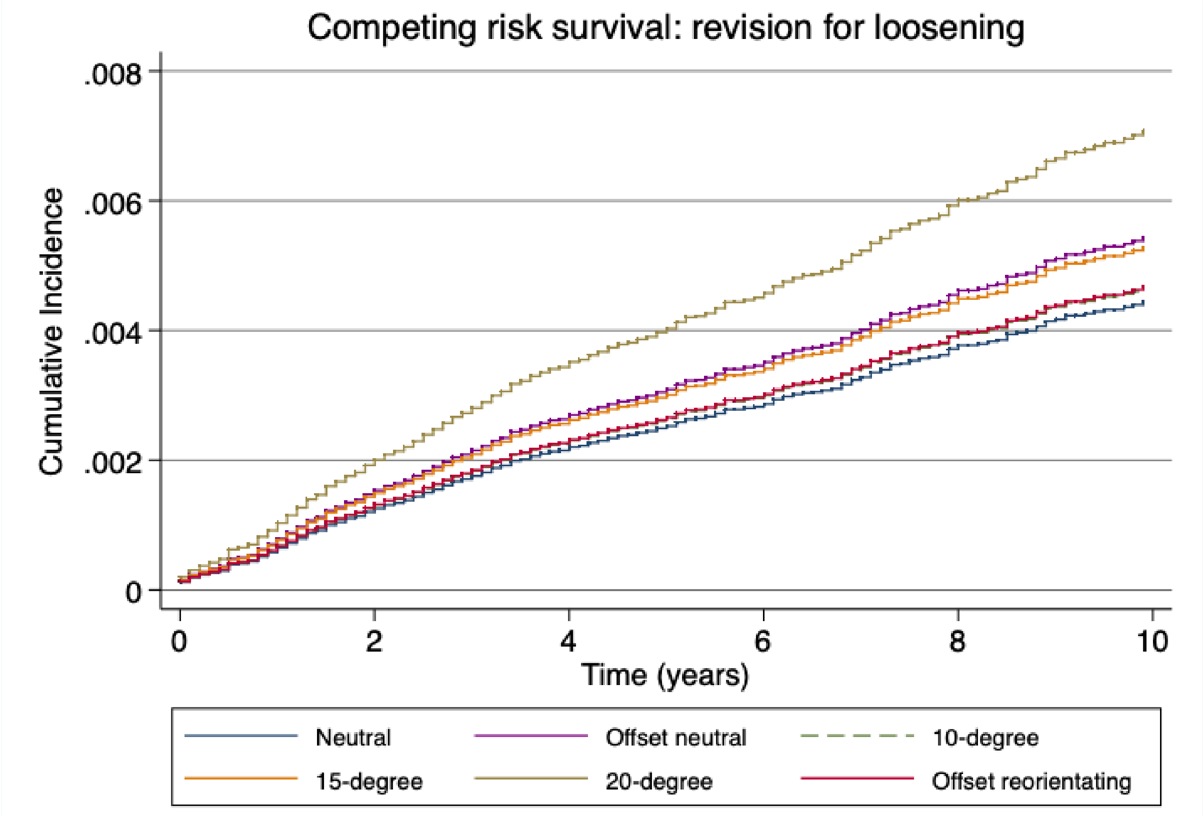

Figure 6-3 Cumulative incidence of revision for loosening by uncemented acetabular liner geometry. An adjusted competing risks analysis

The sensitivity analyses estimated the size of association an unmeasured confounder would need to have with both the use of a specific liner geometry (over the neutral liners) and revision for instability to explain away the observed significant SHRs, reported as point estimates with a lower limit: 10-degree = 2.5 (minimum 1.85), 15-degree = 3.59 (minimum 2.61) and offset reorientating = 2.6 (minimum 1.49). Sensitivity analyses were not performed on non-significant SHRs.

6.5.5 Risk of revision: Influence of time from primary THA

The proportional hazards assumption was not met for revision for instability. The time split deciles for revision for instability events were – 0.1, 0.2, 0.3, 0.65, 1.2, 2, 3.3, 5.2 and 8 years. Analysis of the offset neutral, 20-degree and offset reorientating groups were not included due to small numbers and non-significance in the competing risk regression models. The time-varying SHRs ratios were plotted against time with 95% confidence intervals. For 10-degree liners vs. neutral (see Figure 6-4), there was no difference in the SHR immediately postoperative, but there was a rapid downward trend from 5 weeks with a reduced SHR of revision for instability with 10-degree liners, apart from a small upward trend at 14 weeks. This reduced SHR remained significant (upper limit below 1) until just after 1.2 years. From this point onwards, the SHR remains below 1, though the upper confidence band crosses 1. A very similar but slightly more pronounced pattern was seen with the 15-degree liners up to 1.2 years, compared to neutral (Figure 6-5). As liner geometry was not associated with revision for loosening, a time split analysis was not performed.

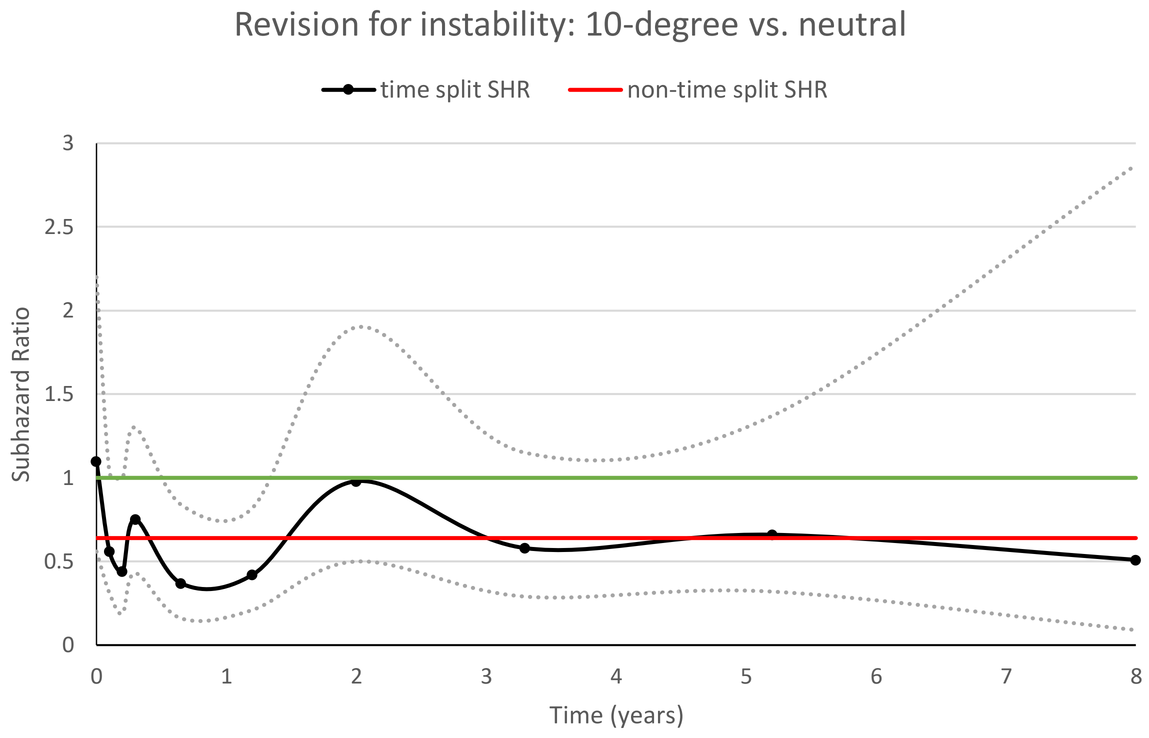

Figure 6-4 Subhazard ratio of revision for instability by time from primary THA, 10-degree vs. neutral. A competing risks analysis

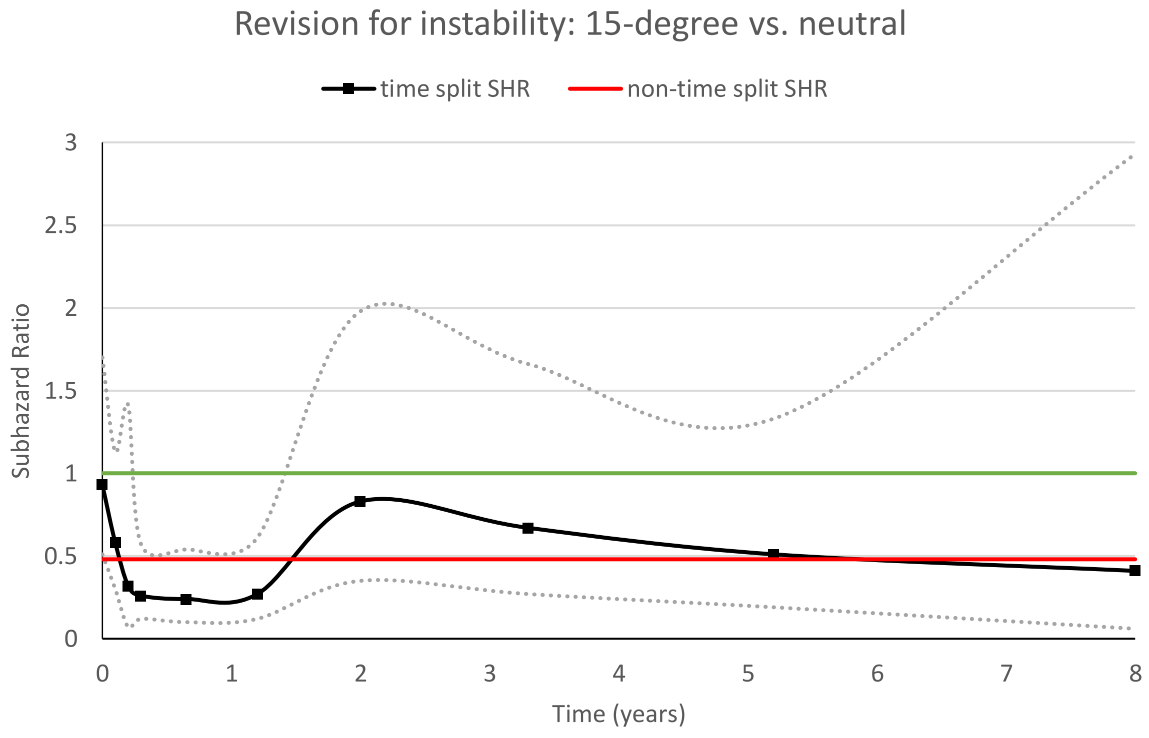

Figure 6-5 Subhazard ratio of revision for instability by time from primary THA, 15-degree vs. neutral. A competing risks analysis

6.6 Discussion

In this analysis of primary uncemented THA data from the NJR, we have shown that 10- and 15-degree lipped PE acetabular liners are associated with a lower risk of revision for instability, compared to neutral liners, whilst offset reorientating liners have a higher risk (despite being used frequently with 36mm or larger head sizes). The offset neutral and 20-degree lipped liners showed no difference. The revision risk seems lowest in the early postoperative period up to 1.2 years for 10- and 15-degree liners. We find that in posterior approaches, 10- and 15-degree liners have a lower risk of revision for instability than neutral liners, but there was no significant difference between these lipped liners. The additional benefit of lipped liners seems to be lost in lateral approach THAs, which may be because the lateral approaches are inherently associated with a lower baseline risk of dislocation/ instability (13). Offset reorientating liners seem to have a higher risk of revision for instability compared to 10- and 15-degree liners regardless of the surgical approach used. We found no association between PE liner geometry and the risk of revision for loosening, even after stratifying by surgical approach and performing pairwise comparisons of all liner geometries. The overall trend in liner usage over the dataset period seems to be a decrease in the use of lipped liners compared to neutral liners, but a steady increase in the use of 15-degree liners within the lipped liner groups. The remaining liner geometries (20-degree, offset neutral and offset reorientating) represented low frequency usage with a decreasing trend in usage over time.

Retrieval studies, though inherently biased by selection bias, have consistently found an almost ubiquitous association between revision for instability and evidence of liner impingement (37,49), and a greater incidence of liner impingement damage in lipped liners with damage usually being located on the elevated rim portion (48-50). Published case series of revision THAs have cautioned on the possible association between lipped liner use and impingement leading to wear and osteolysis (36,51). No clear association between revision for loosening and liner impingement has been found however (37,49), though the theoretical risk has been proposed by many authors (35,46).

Cobb et al. (35) found a lower risk of dislocation with the use of a 10-degree lipped liner (1.43%) compared to neutral liners (2.35%) at a minimum 2 years follow-up in 4117 primary THA patients. Whilst this study is limited to single centre data and not modelling potential confounding variables into the survival analyses, it represents the first study published examining the effect of uncemented acetabular PE liner geometry on the risk of THA for instability. The authors' reported no increased risk of revision for loosening in a further paper (57) on the same cohort. Jameson et al.'s single brand NJR analysis of all cause revision THA (53) found no significant differences between standard and lipped PE liners. Surgical indications were limited to primary OA only and the authors did not examine the effect of lipped liners specifically on revision for instability. More recently published Registry based analyses have however shown a clear protective effect of a lipped PE liner from revision for instability (54-56) and possibly also against revision for loosening (55,60). Table 6-8 (page 125) summarises these publications, including the results of our study for comparison. Our results seem consistent with those already published and extend the knowledge base further by reporting on the effect of the lip size and by including offset/ offset reorientating liners. Additionally, our study utilises competing risks survival methodologies (62), providing a more realistic estimate of failure rates considering the risks of revision from other revision causes and particularly from mortality (66), which was 9% in our series. We find the protective effect of 10- and 15-degree liners against revision for instability seems to be highest within the first 1.2 years after primary THA, a finding not investigated nor reported in previous studies.

	Registry	Year	n	Mean follow-up (yrs)	Liner geometry (%)	Revision for instability (HR)	Revision for loosening (HR)
Insull (54)	New Zealand	2014	12,116	3	Lipped (66%)	0.41 [14]	Not reported
Bauze (55)	Australia	2019	192,659	5	Lipped (65%)	0.76 [14]	0.84 [14]
Wyatt (54)	New Zealand	2020	31,247	5	Lipped (65%)	0.54 [14]	No difference
Davis (60)	UK	2020	292,920	4	Lipped (53%)	Not reported	0.84
current study	UK	2021	202,511	4	10-degree (35%)	0.64	No difference
					15-degree (22%)	0.48	
					20-degree (0.8%)	No difference	
					Offset neutral (0.9%)	No difference	
					Offset reorientating (2.8%)	1.61	

Table 6-8 Comparison of current study with published Registry based studies – revision risk in uncemented lipped vs. neutral liners

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[14] Published studies HRs are neutral versus lipped. These were inverted to obtain lipped versus neutral HRs to allow comparison with current study's SHRs

Although this study using standardised nationally collected Registry data is large, there are several limitations which should be considered in interpreting the results. As dislocation events aren't captured in NJR data, it is probable that the number of dislocations will be higher than revisions for instability as some patients may not undergo revision or were pending surgery at the time of data extraction. We felt the use of revision THA as an endpoint was appropriate, and probably more important, as the implications of further surgery are significant both for patients involved and for healthcare systems providing these services.

Data within the NJR is dependent on surgeon self-reporting and subject to errors of reporting. Potential misclassification however is unlikely to be associated with the choice of acetabular liner used, nor the outcomes of interest (revision for instability or loosening) and if anything would tend to result in an attenuation of effect. It is possible that other procedure related factors may have influenced the outcomes such as soft tissue/ capsular repair (particularly with posterior approaches), femoral component details, component orientation, orientation of the lipped liner when used (67,68), biomechanics restoration and patient specific factors. Such data are not currently available within the NJR, but it seems unlikely that such factors would have an association with a surgeon's choice of acetabular liner and therefore unlikely to have had a significant impact on these results. This is supported by the sensitivity analyses we performed, which suggests that any unmeasured confounder(s) would need to have a fairly large association with both the choice of acetabular liner and the risk of revision for instability to negate the observed SHRs of revision for instability. Finally, our data are based on a predominantly Caucasian population and should be extrapolated beyond this group cautiously.

Though not a substitute for meticulous surgical planning, technique and THA component orientation, the routine use of a 10- or 15-degree PE liner in posterior approach THAs may reduce the mid-term risk of revisions for instability without increasing the risk of revision for loosening. Lateral approach THAs do not seem to benefit from lipped PE liner geometries. Further studies are needed to determine if a true difference exists between 10- and 15-degree liners, and whether the benefits of lipped liners persist into longer term follow up. The routine use of offset reorientating liners should be avoided, with their higher risk of revision for instability, but further study is required to determine if certain indications benefit from its use.

6.7 Supplementary Tables

		Unadjusted log-binomial Regression		**Adjusted log-binomial Regression**		**Competing Risk Regression**	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age (years)		0.99 (0.99 – 1)	0.089	1 (0.99 – 1.01)	0.671	1 (0.99 – 1.01)	0.492
BMI [10 (page 108)]		1 (0.98 – 1.02)	0.96	1 (0.98 – 1.02)	0.759		
Gender	(Ref. Female)						
	Male	0.84 (0.72 – 0.99)	**0.032**	1.01 (0.86 – 1.19)	0.901	1.01 (0.86 – 1.18)	0.920
ASA	(Ref. 1)						
	2	1.04 (0.83 – 1.3)	0.756	1.09 (0.87 – 1.37)	0.455	1.12 (0.89 – 1.42)	0.333
	≥3	1.17 (0.89 – 1.54)	0.256	1.24 (0.93 – 1.65)	0.149	1.29 (0.97 – 1.73)	0.084
Indication	(Ref. OA)						
	acute trauma	1.48 (1.02 – 2.13)	0.037	1.84 (1.27 – 2.68)	**0.001**	2 (1.37 – 2.91)	**<0.001**
	AVN	1.43 (0.87 – 2.34)	0.161	1.35 (0.82 – 2.22)	0.242	1.33 (0.81 – 2.18)	0.262
	other	2.04 (1.55 – 2.69)	**<0.001**	1.82 (1.37 – 2.43)	**<0.001**	1.8 (1.33 – 2.41)	**<0.001**
Side	(Ref. Left)						
	Right	0.96 (0.83 – 1.12)	0.634	0.98 (0.84 – 1.13)	0.756	0.98 (0.84 – 1.14)	0.774
Treating Organisation	(Ref. NHS)						
	Ind. Hosp.	0.83 (0.7 – 0.99)	**0.037**	0.95 (0.79 – 1.14)	0.569	1 (0.83 -1.2)	0.961
	Ind. Trt. Cntr.	1.15 (0.88 – 1.51)	0.308	1.2 (0.89 – 1.6)	0.235	1.16 (0.87 – 1.55)	0.323
Surgeon grade	(Ref. Consultant)						
	Trainee	1 (0.76 – 1.3)	0.977	0.86 (0.65 – 1.14)	0.288	0.85 (0.64 – 1.12)	0.252
	SAS	0.71 (0.46 – 1.09)	0.117	0.72 (0.46 – 1.13)	0.152	0.74 (0.47 – 1.16)	0.187
	Other	1.08 (0.74 – 1.59)	0.681	1.09 (0.73 – 1.63)	0.658	1.1 (0.74 – 1.63)	0.638
Approach	(Ref. Posterior)						
	Lateral	0.82 (0.69 – 0.97)	**0.023**	0.58 (0.48 – 0.69)	**<0.001**	0.56 (0.47 – 0.68)	**<0.001**

		Unadjusted log-binomial Regression		Adjusted log-binomial Regression		Competing Risk Regression	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
	Other	0.68 (0.44 – 1.05)	0.082	0.49 (0.32 – 0.76)	**0.002**	0.47 (0.3 – 0.73)	**0.001**
Head size (mm)	(Ref. 28mm)						
	22.225	3.21 (1.34 – 7.69)	**0.009**	2.02 (0.83 – 4.93)	0.123	1.85 (0.75 – 4.58)	0.183
	26	0.44 (0.06 – 3.11)	0.409	0.35 (0.05 – 2.47)	0.291	0.35 (0.05 – 2.49)	0.293
	32	0.38 (0.32 – 0.45)	**<0.001**	0.4 (0.33 – 0.48)	**<0.001**	0.45 (0.37 – 0.55)	**<0.001**
	36	0.37 (0.3 – 0.45)	**<0.001**	0.3 (0.23 – 0.39)	**<0.001**	0.31 (0.24 – 0.41)	**<0.001**
	>36	0.29 (0.14 – 0.61)	**0.001**	0.25 (0.11 – 0.54)	**<0.001**	0.19 (0.09 – 0.43)	**<0.001**
Liner geometry	(Ref. Neutral)						
	Offset neutral	0.78 (0.32 – 1.9)	0.59	1 (0.41 – 2.44)	0.991	0.87 (0.35 – 2.14)	0.758
	10-degree	0.9 (0.75 – 1.07)	0.217	0.67 (0.53 – 0.83)	**<0.001**	0.64 (0.51 – 0.79)	**<0.001**
	15-degree	0.79 (0.64 – 0.98)	**0.03**	0.5 (0.39 – 0.64)	**<0.001**	0.48 (0.37 – 0.62)	**<0.001**
	20-degree	1.21 (0.57 – 2.56)	0.615	0.7 (0.32 – 1.5)	0.357	0.63 (0.29 – 1.35)	0.236
	offset reorientating	1.9 (1.34 – 2.64)	**<0.001**	1.8 (1.26 – 2.59)	**0.001**	1.61 (1.12 – 2.32)	**0.010**
PE crosslinked	(Ref. No)						
	Yes	0.43 (0.37 – 0.5)	**<0.001**	0.64 (0.53 – 0.78)	**<0.001**	0.84 (0.7 – 1.02)	0.086
Cup manufacturer	(Ref. DePuy)						
	Stryker	0.78 (0.65 – 0.93)	**0.006**	1 (0.76 – 1.29)	0.945	0.99 (0.76 – 1.28)	0.907
	Zimmer	1.29 (1.08 – 1.55)	**0.006**	1.19 (0.91 – 1.57)	0.204	1.09 (0.83 – 1.43)	0.522

Table 6-9 Revision for instability. Univariable (unadjusted), multiple variable (adjusted) log-binomial and competing risks regression in uncemented cups

		Unadjusted log-binomial Regression		Adjusted log-binomial Regression		Competing Risk Regression	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Age (years)		0.97 (0.96 - 0.98)	**<0.001**	0.97 (0.96 - 0.97)	**<0.001**	0.97 (0.96 - 0.97)	**<0.001**
BMI [10 (page 108)]		1.03 (1.01 - 1.05)	**0.006**	1.02 (1 – 1.04)	0.057		
Gender	(Ref. Female)						
	Male	1.27 (1.08 - 1.48)	**0.004**	1.17 (1 – 1.38)	0.058	1.2 (1.02 - 1.42)	**0.028**
ASA	(Ref. 1)						
	2	0.73 (0.59 - 0.89)	**0.003**	0.92 (0.74 – 1.14)	0.437	0.96 (0.78 – 1.2)	0.73
	≥3	0.67 (0.5 - 0.89)	**0.006**	0.92 (0.68 – 1.24)	0.575	0.99 (0.73 – 1.34)	0.953
Indication	(Ref. OA)						
	acute trauma	0.58 (0.32 – 1.06)	0.077	0.69 (0.38 – 1.26)	0.229	0.79 (0.43 – 1.43)	0.43
	AVN	1.35 (0.79 – 2.29)	0.272	1.02 (0.6 – 1.74)	0.938	0.98 (0.57 – 1.69)	0.944
	other	1.32 (0.93 – 1.88)	0.118	0.99 (0.69 – 1.43)	0.973	0.96 (0.67 – 1.38)	0.824
Side	(Ref. Left)						
	Right	0.97 (0.83 – 1.14)	0.685	0.99 (0.85 – 1.17)	0.94	1 (0.85 – 1.17)	0.955
Treating Organisation	(Ref. NHS)						
	Ind. Hosp.	1.08 (0.91 – 1.29)	0.368	1.22 (1.01 – 1.48)	**0.038**	1.32 (1.09 – 1.6)	**0.004**
	Ind. Trt. Cntr.	0.85 (0.6 – 1.19)	0.344	1.02 (0.71 – 1.46)	0.935	0.98 (0.68 – 1.42)	0.909
Surgeon grade	(Ref. Consultant)						
	Trainee	1.11 (0.85 – 1.46)	0.451	1.17 (0.88 – 1.56)	0.275	1.15 (0.86 – 1.54)	0.345
	SAS	0.93 (0.62 – 1.4)	0.736	0.83 (0.55 – 1.27)	0.386	0.85 (0.56 – 1.3)	0.46
	Other	0.83 (0.52 – 1.33)	0.45	0.98 (0.6 – 1.58)	0.919	0.96 (0.59 – 1.56)	0.865
Approach	(Ref. Posterior)						
	Lateral	1.98 (1.68 - 2.33)	**<0.001**	1.68 (1.41 - 2)	**<0.001**	1.57 (1.31 - 1.87)	**<0.001**
	Other	1.42 (0.97 – 2.09)	0.074	1.24 (0.84 – 1.82)	0.288	1.1 (0.75 – 1.63)	0.617

		Unadjusted log-binomial Regression		**Adjusted log-binomial Regression**		**Competing Risk Regression**	
		RRR (95%CI)	**P**	**RRR (95% CI)**	**P**	**SHR (95% CI)**	**P**
Head size (mm)	(Ref. 28mm)						
	22.225	1.89 (0.47 – 7.57)	0.367	1.23 (0.3 – 4.96)	0.774	1.05 (0.26 – 4.21)	0.946
	26	1.94 (0.62 – 6.01)	0.253	1.66 (0.53 – 5.19)	0.383	1.56 (0.5 – 4.89)	0.449
	32	0.49 (0.4 - 0.59)	**<0.001**	0.85 (0.67 – 1.06)	0.143	1.04 (0.83 – 1.31)	0.72
	36	0.68 (0.55 - 0.83)	**<0.001**	1.57 (1.17 - 2.1)	**0.002**	1.64 (1.22 - 2.19)	**0.001**
	>36	2.55 (1.85 - 3.53)	**<0.001**	5.17 (3.37 - 7.93)	**<0.001**	3.26 (2.14 - 4.98)	**<0.001**
Liner geometry	(Ref. Neutral)						
	Offset neutral	1.38 (0.65 – 2.92)	0.399	1.62 (0.75 – 3.52)	0.223	1.23 (0.56 – 2.68)	0.611
	10-degree	1.08 (0.9 – 1.3)	0.404	1.15 (0.9 – 1.47)	0.251	1.05 (0.82 – 1.33)	0.71
	15-degree	0.99 (0.8 – 1.23)	0.918	1.37 (1.03 - 1.82)	**0.033**	1.19 (0.89 – 1.6)	0.241
	20-degree	2.18 (1.16 - 4.09)	**0.016**	2.22 (1.16 - 4.27)	**0.017**	1.6 (0.83 – 3.09)	0.165
	offset reorientating	1.04 (0.64 – 1.7)	0.88	1.34 (0.79 – 2.28)	0.273	1.05 (0.63 – 1.77)	0.847
PE crosslinked	(Ref. No)						
	Yes	0.37 (0.31 - 0.43)	**<0.001**	0.3 (0.24 - 0.38)	**<0.001**	0.52 (0.42 - 0.66)	**<0.001**
Cup manufacturer	(Ref. DePuy)						
	Stryker	1.31 (1.1 - 1.57)	**0.003**	1.21 (0.89 -1.65)	0.218	1.12 (0.83 – 1.5)	0.468
	Zimmer	1.19 (0.96 – 1.47)	0.123	0.85 (0.61 – 1.18)	0.322	0.71 (0.5 - 0.99)	**0.041**

Table 6-10 Revision for loosening. Univariable (unadjusted), multiple variable (adjusted) log-binomial and competing risks regression in uncemented cups

6.8 Analyses not included in journal paper

6.8.1 Manufacturer brand analysis

The adjusted competing risks model for uncemented neutral liners revealed no association between manufacturer brand and risk of revision for instability (see Table 6-11). The other covariates maintained a similar pattern to the main regression model (all component geometries) – higher SHRs with increasing ASA grade and non-OA surgical indications; lower SHRs with lateral/ other approaches and with increasing head sizes.

This finding would suggest that, all other confounding variables being equal, neutral liner geometries seem to behave similarly between these manufacturer brands when considering revision risk for instability.

		SHR (95% CI)	P
Age		1 (0.99 – 1.02)	0.616
Gender	(Ref. Female)		
	Male	0.98 (0.76 – 1.25)	0.842
ASA	(Ref. 1)		
	2	1.24 (0.84 – 1.83)	0.277
	≥3	1.61 (1.01 – 2.56)	**0.046**
Indication	(Ref. OA)		
	Acute Trauma	1.96 (1.13 – 3.38)	**0.017**
	AVN	1.4 (0.66 – 2.98)	0.387
	Other	1.64 (1.02 – 2.63)	**0.041**
Side	(Ref. Left)		
	Right	0.98 (0.77 – 1.23)	0.844
Treating organisation	(Ref. NHS)		
	Ind. Hospital	1.01 (0.76 – 1.34)	0.958
	Ind. Trt. Cntr.	1.17 (0.72 – 1.88)	0.529
Surgeon grade	(Ref. Consultant)		
	Trainee	0.68 (0.43 – 1.1)	0.116
Approach	(Ref. Posterior)		
	Lateral	0.4 (0.3 – 0.53)	**<0.001**
	Other	0.38 (0.2 – 0.71)	**0.003**
	SAS	0.74 (0.37 – 1.48)	0.396
	Other	1.22 (0.71 – 2.09)	0.47
Head size (mm)	(Ref. 28mm)		
	22.225	0.71 (0.1 – 5.27)	0.735
	26	0.67 (0.09 – 5.17)	0.699
	32	0.4 (0.29 – 0.54)	**<0.001**
	36	0.26 (0.18 – 0.37)	**<0.001**
	>36	0.19 (0.08 – 0.45)	**<0.001**
Manufacturer brand	(Ref. DePuy)		
	Stryker	0.87 (0.63 – 1.21)	0.413
	Zimmer	1.32 (0.97 – 1.8)	0.082
PE crosslinked	(Ref. No)		
	Yes	0.95 (0.69 – 1.3)	0.74

Table 6-11 Revision for instability. Adjusted competing risks analysis of uncemented neutral liners, by manufacturer brand

Chapter 7: Discussion

7.1 Summary

Discussions within each paper (see section 5.6 page 90 for Paper 1 on cemented acetabular components and section 6.6 page 123 for Paper 2 on uncemented acetabular components) will not be repeated in this chapter. This discussion chapter will provide a broad review of the key findings of this study along with their clinical relevance. These will be contextualised within the existing published literature on this topic. Strengths and limitations will be broadly reviewed, along with potential future research directions in this area.

7.2 Key findings

This study represents the largest Registry based analysis of risk of revision for instability or for loosening related to acetabular component geometry for cemented and uncemented acetabular components.

The key findings are summarised below for cemented and uncemented acetabular components separately, highlighting findings that are concordant with the published literature in this topic area followed by novel findings.

7.2.1 Cemented acetabular components

A decreasing trend in usage of hooded and offset reorientating components was found over the dataset period.

7.2.1.1 Concordant findings

1. Hooded acetabular cups have a higher risk of revision for instability than LPW cups.

7.2.1.2 Novel findings

1. Offset reorientating cups (vs. LPW) have a higher risk of revision for instability
2. Hooded cups (vs. LPW) remained at higher risk of revision for instability across all surgical approaches, with too few to analyse in the offset reorientating group.

3. The time dependent risk of revision for instability with hooded cups (vs. LPW) was highest immediately postoperatively, declines rapidly in the first 3 months, but remains elevated till 1 year postoperative.
4. Stryker LPW components seem to have an increased risk of revision for instability when compared to DePuy LPW cups.
5. Hooded and offset reorientating cups (vs. LPW) remained at higher risk of revision for loosening across all surgical approaches.

7.2.2 Uncemented acetabular liners

A trend to decreasing lipped liner usage was noted over the dataset period, but with an increasing trend in use of 15-degree liners within the lipped groups. Twenty-degree, offset neutral and offset reorientating liner usage was relatively low frequency but also showed a trend in declining usage over time.

7.2.2.1 Concordant findings

1. Lipped liners (vs. neutral) have a lower risk of revision for instability than neutral liners.
2. Uncemented liner geometry does not seem to influence risk of revision for loosening.

7.2.2.2 Novel findings

1. Compared to neutral liners, the risk of revision for instability was lower with 10- and 15-degree liners, no different with 20-degree and offset neutral liners, and higher with offset reorientating liners.
   a. In posterior approach THAs, 10- and 15-degree liners remain protective against revision for instability and offset reorientating liners remain at higher risk (vs. neutral).
   b. In lateral approach THAs, no difference was seen with lipped liners and offset reorientating liners remained at higher risk (vs. neutral).
2. No differences in revision risk for instability was found between the lip sizes (i.e.: no apparent dose-effect response)
3. The time dependent risk of revision for instability with 10- and 15-degree liners (vs. neutral liners) reaches its lowest by 4 months postoperative and remains protective for the first year.

4. No association between manufacturer brand and revision risk for instability in neutral liners was found.
5. No association between liner geometry and risk of revision for loosening was found.

7.3 Comparison with current literature

Apart from the novel findings, the results of this study regarding the influence of acetabular component geometry on the risk of revision for instability seem consistent with those of previously published large Registry based studies, as summarised in Table 5-8 (page 91) for cemented and Table 6-8 (page 125) for uncemented acetabular components. Similar HRs of revision for instability with hooded versus LPW and lipped versus neutral liners are found when comparing this study's result to published results from Registries around the World.

Furthermore, the analyses in this study show consistencies with published data about how other covariates influence the risk of revision for instability. Factors such as higher ASA grades, non-OA indications for THA (acute trauma, AVN), posterior surgical approach were all associated with increased risks, whilst the use of larger head sizes (32mm or larger) were associated with lower risks.

The trend for decreasing use of lipped liners in favour of neutral liners seen over the dataset period is interesting given the presence of contemporaneous published literature suggesting a benefit with lipped liners in reducing the risk of dislocation (35) and of revision for THA instability (54), though this later publication in 2014 was towards the end of the dataset period (2017). The reasons behind this observed trend are unclear. It may simply represent a lag-time in published evidence influencing clinical practice, or may be due to clinician concerns regarding the longer term behaviour of lipped PE liners particularly with regards to the risks of impingement and loosening.

Lip size was not found to have an independent effect on the risk of revision for instability, a novel finding previously not investigated in the current literature. This seems to be at odds with a published finite element analysis study by Daniel Huff (40) that suggested a greater resistance to dislocation should be experienced with increasing lip sizes. This current study does not support a translation of Huff's basic science modelling work to real-world reduction of revision risk. There may be a number of reasons for this. The NJR dataset used for analysis in this current study does not include specific details of component orientation, which is known (for acetabular and femoral component orientation) to influence THA stability (69-71). Additionally, details of where the lip of a lipped liner is positioned in the acetabular component, are not included in the NJR dataset and this is also known to influence the changes to THA stability (67,68) – a lip positioned in the postero-inferior quadrant of an acetabular cup will provide greater resistance to posterior dislocation when the hip is flexed up and internally rotated (position of risk in posterior approach THAs). A lip positioned directly posteriorly in the acetabular component is more likely to generate impingement with the femoral neck in extension and external rotation that could lead to a dislocation in the opposite direction (i.e.: anteriorly), and this risk is potentially increased with increasing lip sizes (40). This may in part explain why the expected reduction in THA instability with increasing lip size is not observed.

The influence of cemented acetabular component geometry on the risk of revision for loosening has not been described or reported in the published literature. The results regarding uncemented acetabular liner geometry on the risk of revision for loosening (see Table 6-8, page 125) seem to support Wyatt et al.'s New Zealand Registry based results (56) suggesting no difference in risk, which is also in line with longer term case-control results from Shin et al. (59) showing no difference in wear rates or observed osteolysis between lipped and neutral liners. Bauze et al.'s Australian Registry based results (55), however, suggest a higher revision risk with neutral compared to lipped liners, as do results from Davis et al. (60) who utilised the same NJR dataset as this current study (though with larger numbers including all uncemented acetabular components with a PE liner; 292,920). The reason for this disparity is unclear, but may be due to competing risks not being considered in their study, which was primarily aimed to determining all cause revision risk. Additionally, differentiation of non-neutral liner geometries was not made and surgical approach was not used as a covariate. A novel association was found in this current study with a higher risk of revision for loosening in lateral approach THAs (cemented and uncemented acetabular components), though the reason for this finding is unclear and not reported elsewhere in the literature.

Other covariates associated with an increased risk of revision for loosening were found to be consistent with other published data; lower age at surgery, male gender, larger head sizes (36mm or larger), and the use of non-crosslinked PE were all associated with increased risks.

7.4 Strengths and limitations

This NJR Registry dataset-based study involves 427,385 primary THAs and represents the largest study to date on this topic area. The NJR is currently the largest joint replacement Registry Worldwide and since 2014, has had a robust strategy in place to improve data quality and completeness of data capture ("Supporting Data Quality Strategy", https://www.njrcentre.org.uk/njrcentre/Data-quality). Additionally, also implemented since 2014, NJR data submission compliance by local NHS Trusts has become linked to a Best Practice Tariff (BPT) and is one of a number of mandatory indicators (with a minimum 85% data completeness stipulation) for Trusts to receive BPT renumeration on THA procedures.

Unlike some earlier published studies in this topic area (52,53), this study was not limited to single brand/ manufacturer analyses which removes the potential for selection bias and improves the generalisability of the observed results.

The analytical methods used are appropriate and improve on similar published Registry based studies in this topic area that have not considered the effects of competing risks (revision THA for other causes, mortality) when performing survival analyses. There is growing appreciation and support for the use of competing risks methodologies when presenting implant related survival analyses (72-74); not accounting for competing risks such as revision for other causes and mortality will lead to non-informative censoring and an over-estimation of failure risk. Additionally, the influence of time on revision risk related to acetabular component geometry has been analysed (i.e.: non-proportional hazards) and provides a novel finding of time-dependent risk changes that are most notable in the early postoperative period and up to 1 year after primary THA surgery. This finding is line with published observational data reporting that the highest risk of THA dislocation is within the first 3 months, and less so up to 12 months after primary THA (9-11).

There are a number of potential limitations with this study to be considered. As dislocation events are not recorded in the NJR, an alternative endpoint (revision for THA instability) was used. It is probable that the observed frequency of revision THA is lower than the frequency of THA dislocation as not all THA dislocations will go on to require revision THA surgery. Some patients may not be physiologically fit enough to undergo revision surgery, and others may choose not to have revision surgery. Arguably though, revision THA surgery is probably a more important endpoint for patients, surgeons and healthcare systems as it reflects increased patient risk exposure (through further surgery that is often more complex), reduced patient reported outcomes and increased healthcare resource utilisation that could potentially be avoided (or at least minimised) by optimising surgical and implant related factors that are modifiable unlike some patient risk factors (age, comorbidities). The NJR dataset reflects a predominantly Caucasian population (though ethnicity is not recorded in the dataset), and this may make the outputs less generalisable to other ethnic groups particularly given that ethnicity does seem to influence the risk of THA instability (13) (Caucasian ethnicity associated with greater risk of THA instability compared to Asian ethnicity).

Information on prosthetic head material (metal or ceramic) was not included in the NJR dataset provided and this may alter the observed effect sizes for revision for loosening. Ceramic heads, compared to metal, are known to reduce wear rates (and therefore potential revision for loosening) when used with non-crosslinked PE (29,30), but not when used with crosslinked PE (31). Additionally, details regarding the femoral component were not included (fixation type, offset) in the NJR dataset provided and therefore adjustments could not be made for these potential covariates, known to influence the risk of THA instability (13). It seems unlikely however that differences in femoral stem and head component specifics would result in bias with the choice of acetabular component geometry.

Misclassification of submitted Registry data is a potential source of error, either in the accuracy of recording of component details (very unlikely as this is performed off implant barcodes) or in the classification of a revision THA event (explained in section 4.3.4.2, page 55). Under-reporting of revision THA events is also a potential source of error, and although there are robust mechanisms in place to ensure and encourage NJR data submission completeness, previous NJR Data Quality audits have identified that overall compliance with data submission is lower for revision THA compared to primary THAs procedures. It should be noted that a BPT for revision THA does not currently exist, probably due to the complexity in defining what “Best Practice” for revision THA involves. It seems unlikely, however, that these potential sources of error from under-reporting of revision THA events or from misclassification would bias one or other acetabular component geometry groups in these analyses and therefore, are probably less likely to influence the observed revision risks.

Registry datasets are limited by the lack of granular data, and the lack of ability to access granular data to link in at an individual patient/ THA level. Details such as comorbidities, differences in spinopelvic mobility, postoperative restoration of joint biomechanics, preservation of soft tissue integrity/ function, THA component orientation, positioning of a lip (if used) would most likely add significant covariate information to analyses on revision for THA instability. The sensitivity analyses performed, however, would suggest that unmeasured confounders/ covariates would need to have a reasonably large association with both the exposure (acetabular component geometry choice) and with the outcome (revision for THA instability) to completely negate the adjusted SHRs in this study. This can potentially be explained by the assumption that missing or unmeasured confounders are unlikely to be biased in one or other acetabular component geometry groups and therefore, are probably less likely to influence the observed revision risks.

7.5 Future research

The declining trend in usage of cemented hooded and particularly cemented offset reorientating acetabular cups may preclude any meaningful further analyses of outcomes with these component geometries to determine if certain situations benefit from their use. The novel finding of an association between manufacturer brand and revision risk for instability in LPW components may be due to subtle differences in internal bearing surface geometry and would be of interest to investigate further. Precise description and measurement of internal bearing surface geometry would be required to allow comparisons, and other unmeasured confounding variables would need to be considered as far as possible (femoral component specifics), with a broader inclusion of other manufacturer brands with LPW components recorded in the NJR.

It would be of interest to monitor the trend in uncemented acetabular liner geometry usage, given the more recent larger Registry based publications (55,56), along with this current study, showing reduced revision risks for instability with lipped PE liners over neutral liners with no obvious mid-term influence on revision for loosening.

It remains unclear if a true difference between lip sizes and the risk of revision for instability exists, i.e.: a dose-effect relationship. Additionally, it is unclear if the observed effects on revision risk (for instability or for loosening) related to acetabular component geometry persist into the longer-term follow-up, or whether later effects of lipped liner geometries alter the risk profile particularly for revision for loosening as postulated (but not substantiated) by some earlier publications (35,46,57). Future research to further investigate these areas will most likely be in the form of Registry based studies as joint registries continue to mature in follow-up length. International joint Registry collaborations are an attractive possibility for further investigation, benefitting from very large combined numbers. Difficulties in this approach may lie however with ensuring important covariates are included from all sources, accounting for variability of unmeasured population specific influences, data quality and outcome follow-up between individual Registries.

Some issues with depth of granular data inclusion in Registry based studies may be overcome as mechanisms to link together National datasets improve, for example obtaining comorbidity data from CPRD (Clinical Practice Research Datalink) or coded dislocation events from HES (Hospital Episodes Statistics). These data linkage processes currently are possible, but are difficult to gain approval from all data controlling bodies as well as having prohibitive access costs.

Consideration could be made for expanding the depth of data collected by the NJR, though this may come at the price of reduced submission compliance/ data quality. Information on the orientation of a lipped liner, when used, would be a small but useful inclusion in NJR captured data. Improving the classification of revision THA indications may be useful in better understanding the prevailing reasons for revision amongst multiple options that can be recorded for each procedure. Many THA related outcomes can be linked to measurable factors on postoperative radiographs, a mechanism of including such radiographic measurements linked to a primary THA procedure would add a powerful level of data granularity to future Registry based THA outcome studies. There are already exciting developments in artificial intelligence and deep learning tools that can automate the analysis of postoperative radiographic acetabular component on plain radiographs with very high accuracy (75). The validity of measurements of 3-dimensional orientation based off 2-dimensional radiographs needs further investigation, and a method of measuring femoral component orientation would also need developing similarly, but this could conceivably culminate in an automated system that adds significantly useful data to an NJR data record with the simple upload of a digital image file containing plain radiographs.

7.6 Conclusions

In primary THA surgery with a cemented acetabular component, the use of a hooded or offset reorientating component is associated with a higher risk of revision for instability or for loosening, regardless of the surgical approach used, compared to LPW components.

In primary THA surgery performed through a posterior approach with an uncemented acetabular component, the use of a 10- or 15-degree lipped liner is associated with lower risks of revision for instability compared to neutral liners. This protective effect is not seen in lateral approach THAs. Offset reorientating liners are associated with higher revision risks for instability regardless of surgical approach used. No association between revision risk for loosening and acetabular liner geometry was found.

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Appendices

World Arthroplasty Congress e-poster

The Effect Of Uncemented Acetabular Liner Geometry And Lip Size On The Risk Of Revision For Instability or Loosening. A Study On 202,511 Primary Hip Replacements From The National Joint Registry For England, Wales, Northern Ireland & the Isle of Man

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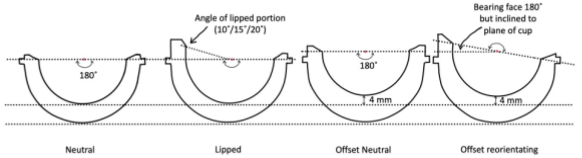
Introduction

Acetabular liner geometry can influence THA stability, but it is unknown if the lip size of lipped PE liners has an independent effect on revision for instability, or if liner geometry influences revision for loosening.



Aim

To determine if liner geometry and lip size influence the risk of revision THA for instability or for loosening.

Methods

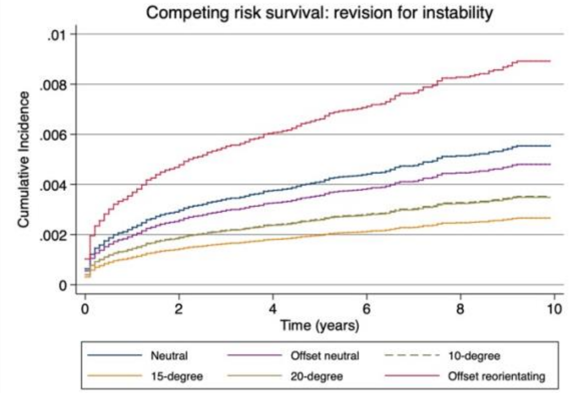
- 202,511 primary THAs with uncemented acetabular components were identified from the NJR dataset (2003 – 2017)
- The effect of liner geometry on the risk of revision for instability or loosening was investigated using competing risk regression analyses
    - Adjusted for age, gender, ASA grade, indication, side, institution type, surgeon grade, surgical approach, head size and PE crosslinking
    - Competing risks were revision for other causes or death
    - Results expressed as subhazard ratios (SHRs) with 95% CIs
    - Non-proportional hazards explored by time-split analyses
- Stratified analyses by surgical approach were also performed, including pairwise comparisons of liner geometries

Results

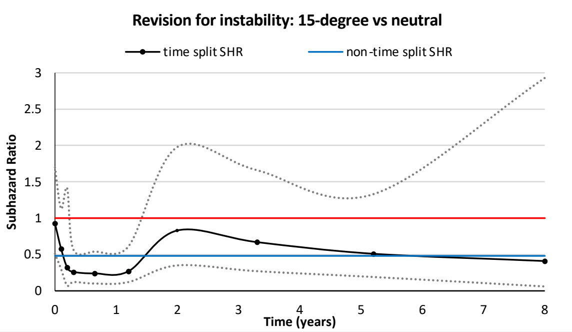
- The distribution of liner geometries were: neutral – 39.4%, offset neutral – 0.9%, 10-degree – 34.5%, 15-degree – 21.6%, 20-degree – 0.8% and offset reorientating – 2.8%
- Revisions: instability = 690 (0.34%); loosening = 604 (0.3%)
- Median follow-up = 4 years (IQR: 2 – 6yrs; max = 15yrs)

Revision for instability

1. Compared to neutral liners, the adjusted SHR was:
    a) 10-degree: 0.64 (0.51–0.79; p<0.001)
    b) 15-degree: 0.48 (0.37–0.62, p<0.001)
    c) offset reorientating: 1.6 (1.12–2.2, p=0.01)
    d) no association found in other liner geometries


Competing risk survival: revision for instability

2. A time-dependent lower risk of revision for instability within the first 1.2 years, was found with 10- and 15-degree liners
3. In posterior approach THAs, 10- and 15-degree liners had a lower risk of revision for instability, but no significant difference between them
4. In lateral approach THAs, the protective effect of lipped over neutral liners was not observed


Revision for instability: 15-degree vs neutral

Results

Revision for loosening

No association between liner geometry and revision for loosening was found.

Conclusions

1. Though not a substitute for meticulous surgical planning, technique and THA component orientation, the routine use of a 10- or 15-degree PE liner in posterior approach THAs may reduce the mid-term risk of revisions for instability without increasing the risk of revision for loosening.
2. Lateral approach THAs do not seem to benefit from lipped PE liner geometries.
3. Lip size does not seem to exert an independent effect on revision risk.
4. The routine use of offset reorientating liners should be avoided, with their higher risk of revision for instability