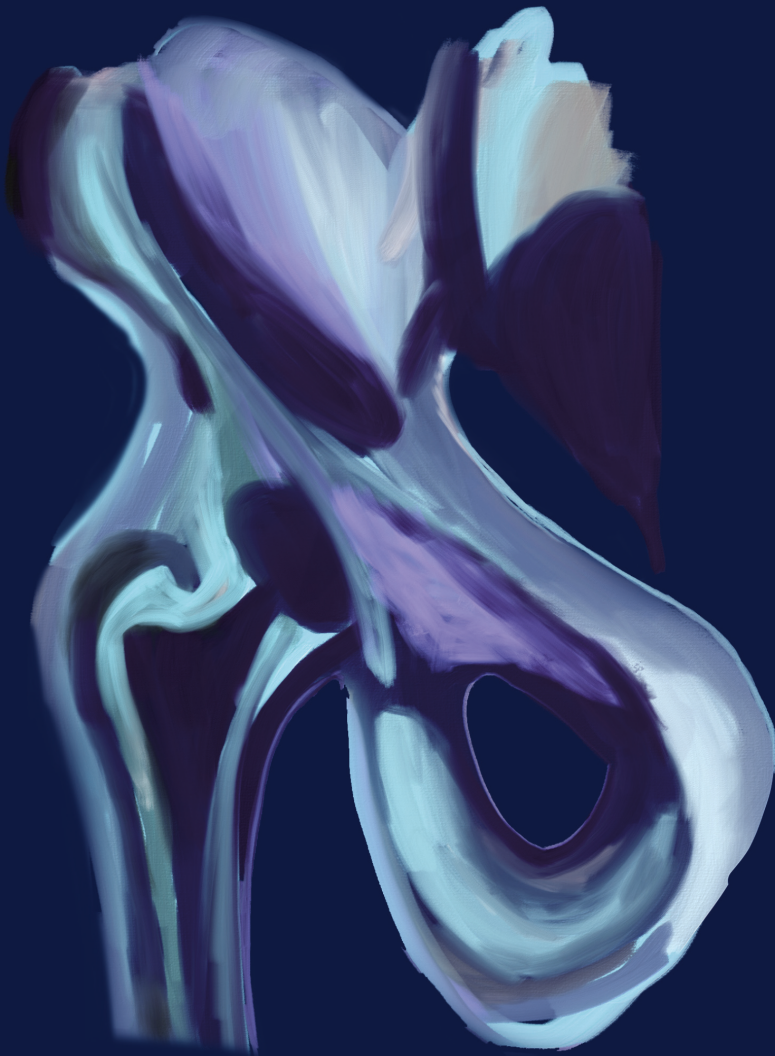


Hip Arthroplasty in the Fragile Patient

Recommendations based on the Dutch Arthroplasty Register



ESTHER MARGOT BLOEMHEUVEL

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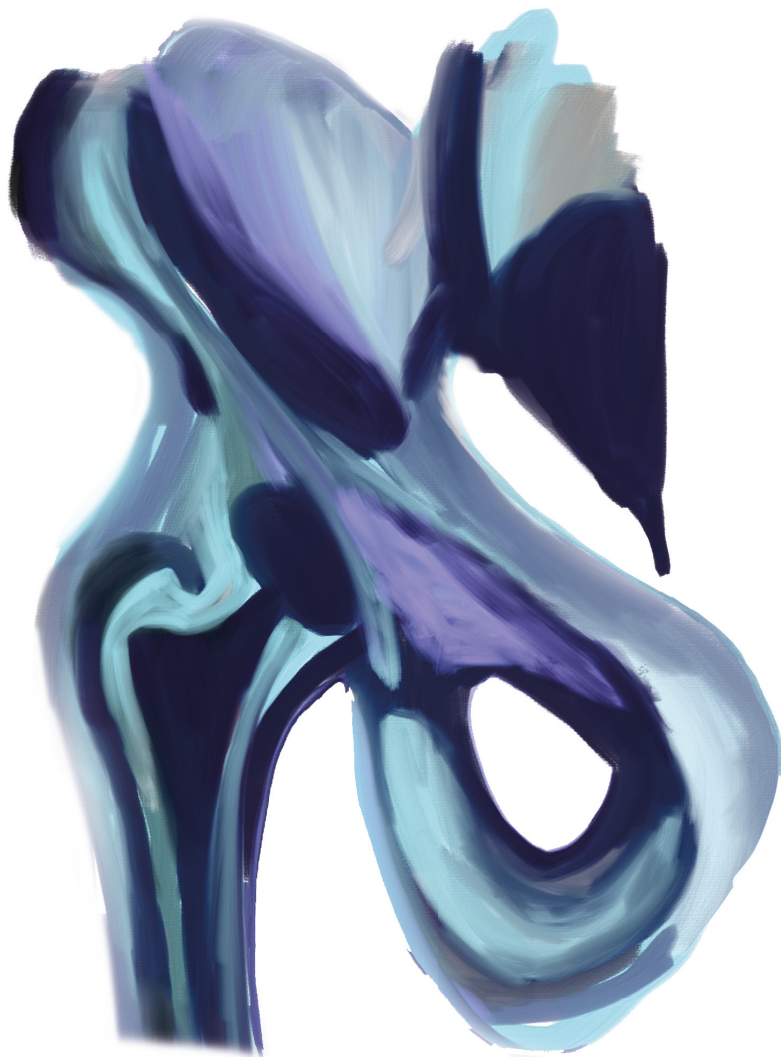
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Chapter 1



General introduction and thesis outline

General introduction

This thesis starts with a general introduction containing a brief history of total hip arthroplasty (THA) and arthroplasty registries. After an introduction, this thesis is divided into two parts: Part 1 is about THA in octogenarians and part 2 is about possible implant solutions for dislocations.

Background of total hip arthroplasty

THA for osteoarthritis of the hip is one of the most successful surgical procedures worldwide and has even been called the operation of the century (1). More than 150 years ago, the first attempt to treat osteoarthritis of the hip was done by Léopold Ollier. He resected the arthritic head and used interpositional tissue like skin or fascia between the pelvis (acetabulum) and the upper femoral bone (thigh). A few decades later, it was Professor Themistocles Glück who performed the first documented hip replacements in 1891 in joints destroyed by tuberculosis with an ivory ball and socket. The next generation THA was developed in 1938 by Philip Wiles (2). He replaced the femoral head with a metal ball that was fixed with a plate on the femoral bone and inserted a metal cup in the pelvis (Figure 1).



Figure 1. Radiograph of the left hip with Philips Wiles metal on metal total hip arthroplasty

Source: picture courtesy of JISRF archives



Figure 2. Radiograph of the left hip with first generation Charnley low friction arthroplasty

Source: Caton J, Prudhon JL. Over 25 years survival after Charnley's total hip arthroplasty. Int Orthop. 2011 Feb;35(2):185-8

After this revolutionary concept, the development of THA continued. A big step forward was made by Sir John Charnley. He introduced the low friction arthroplasty that was based on a small 22 mm metal head articulating in a high-molecular polyethylene cup. Both this polyethylene cup and the metal stem were fixed to the bone using acrylic cement. He wrote about this 'new operation' in the Lancet in 1961 (3) (Figure 2).

With many iterations to improve the concept, THA has been further developed. However, there were still short- and long-term complications that hampered the spread of the technique. Early infections and dislocations were the most seen short-term complications. The high infection rate was reduced by better aseptic conditions during surgery and the use of antibiotics around the surgery. Dislocation rates were reduced over time, but still are a persisting problem in THA nowadays. Long-term complications were both implant fractures of the metal stem as well as periprosthetic fractures of the surrounding femoral bone, loosening of the implant and wear of the polyethylene cup. To reduce the failure rates of the implant itself, the mechanisms behind loosening, implant fracture and wear were analyzed. This resulted in better, stronger and more wear resisted implants.

Nowadays, more than 60 years later, a THA exists of a metal stem with a ball on top (femoral head) that articulates in a socket (cup). The ball is exchangeable on the proximal taper of the stem. The stem is fixed in the femur and the cup is fixed in the acetabulum. Cemented or uncemented fixation techniques are both performed, which are feasible both for the cup and the stem. Most common articulation bearings are Metal-on-Polyethylene, Ceramic-on-Polyethylene and Ceramic-on-Ceramic (Figure 3).

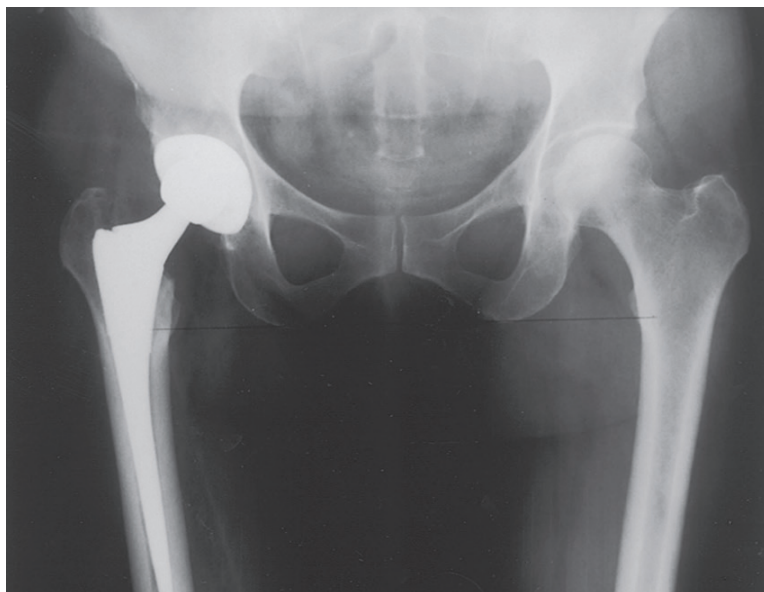


Figure 3. Radiograph of the right hip with total hip arthroplasty used nowadays

Source: Campbell's Operative Orthopaedics , twelfth edition. Ch 3: Arthroplasty of the hip. Figure 3-36

Background of arthroplasty registries

It was Göran Bauer, professor of orthopedic surgery in Lund, Sweden, who realized that there was a need for large data-bases to study the survivorship of different types of joint implants (4). This led to the first national register in 1975 in Sweden for knee arthroplasty. The aim of this register was to collect, analyze and render information to organize a continuously follow-up of the quality of the arthroplasty. In addition, data from this register could also be used to guide further improvements and to deliver results for research. This could lead to get more knowledge of a surgical procedure and to provide the best possible care for patients (5). After the success of this first nationwide register for total knee arthroplasty in Sweden, the Swedish register for THA was founded in 1979. Since 1979, also other (Scandinavian) countries started with national arthroplasty registries.

International Society of Arthroplasty Registries

In 2004, the International Society of Arthroplasty Registries (ISAR) was established. The aim of this society is to utilize the strength of cooperation and sharing of information to further enhance the capacity of individual registries to

meet their own aims and objectives. The society is involved in the development of frameworks to encourage collaborative activities and provides a support network for established and developing registries. The Dutch Arthroplasty Register (LROI) is one of the 31 full members of the ISAR (6).

The Nordic Arthroplasty Register Association (NARA)

The NARA was established in 2007 by arthroplasty register representatives from Sweden, Norway and Denmark with the overall aim to improve the quality of research and thereby enhance the possibility for quality improvement with arthroplasty surgery (7). Finland joined the NARA in 2010. Recently, a first comparison was performed for THA between the Netherlands and NARA countries (8).

Dutch Arthroplasty Register (LROI)

In the Netherlands, the LROI (Landelijke Registratie Orthopedische Interventies) started in 2007 to collect data about hips and knee arthroplasties. In 2022 the completeness of the primary total hip data in the LROI was 99% (9). Over the years, the LROI has been extended to shoulder, elbow, wrist, finger and ankle arthroplasties. In 2022, the total number of registered arthroplasties in the LROI exceeded 1 million cases. Most of the registered arthroplasties are hips (about 550.000 arthroplasties) and knees (about 400.000 arthroplasties) (10). The LROI collects data including patient details like age, sex, diagnosis, BMI and ASA class. In addition, surgical factors like approach or surgical technique are included as well as prosthesis characteristics (9).

The LROI contains all primary joint arthroplasties for hip, knee, shoulder, ankle, elbow, wrist and finger joints, as well as all revision procedures for these joints. A revision is defined as a procedure where one of the prosthesis components is being revised, added or removed (9). In 2014, Patient Reported Outcome Measures (PROMs) were added to the LROI for primary total hip and knee arthroplasties for osteoarthritis (10). This was extended in 2020 to all hip and knee arthroplasty procedures for all diagnosis (9).

Registration in the LROI is performed using a registration form specific for each joint, like hip, knee or shoulder. These forms are nowadays often integrated in the hospital electronic medical record system. The requested information is filled in by the surgeon after the operation at the OR theatre and entered in a central database.

The encrypted social security number (BSN) is registered to link several procedures to a patient. The social security number is encrypted for privacy reasons. Details of the prosthesis are being registered in the LROI using barcodes provided by the company that produced the prosthesis components. These can be scanned and entered into the database. The sticker of each prosthesis component contains a product number (REF-number) and a batch number (LOT-number) (Figure 4). The product number is used to identify the characteristics of the implant, while the batch number can be used to identify the production details. The LROI collects details of all used prostheses in the Netherlands in their implant library. Nowadays, there are more than 36,000 different prosthesis components within the implant library of the LROI (11, 12). These prosthesis characteristics include among others the name of the prosthesis, the manufacturer, the component, the type, the material, the coating, and the method of sterilization.

Date of death of deceased patients are retrieved from Vektis, which contains information based on health insurance data in the Netherlands (13). This combination of data registries adds date of death of deceased patients.

Arthroplasty registers with analysis of their 'real world data' have already influenced the orthopedic practice in many aspects like used fixation method, per-operative management and patient selection. One of the most important registry findings was in 2011, when the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) registry reported problems with the 'ASR XL prostheses' (a large metal head articulating with a metal cup) and showed increased revision rates. This alertness of the registry ultimately led to the withdrawal of this type of prosthesis worldwide. (14).

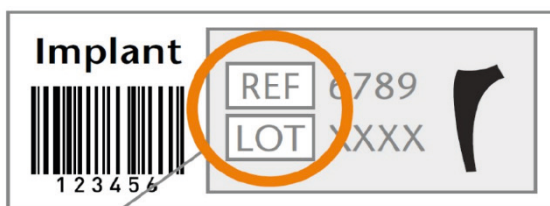


Figure 4. An example of a sticker attached to the used components
The sticker contains a product number (REF-number) and a batch number (LOT-number).

Source: www.lroi.nl/media/jzpet12v/methodologie-voor-verzameling-van-lroi-data.pdf

About the Thesis

Part one: Total Hip Arthroplasty in octogenarians

Many patients benefit from a THA since it reduces pain, restores impaired function and improves the reduced quality of life due to primary or secondary osteoarthritis. The procedure is also very cost-effective (15). Initially, THA was mainly performed in patients between 65 and 80 years who were in a good medical condition. However, recently more patients aged over 80 years old were also treated with THA. Despite age related health issues in this patient group, they might benefit from hip- or knee replacement (16). The question arises whether (national) registers could provide us more information about operation risks and survival of implants in this specific patient group.

Unfortunately, there are only a few registry studies in patient- and implant-survival in this age group (17). One of them is from the New Zealand Joint Register. Nugent et al. showed an overall 10-year implant survival rate of 93.6% and even a 10-year survival rate of 97.5% in the oldest group (90-95 years old). Higher ASA classes were associated with an increased lifetime risk of revision across all ages (18). The Australian registry (AOANJRR) included a whole chapter about patients 80 years and older, also called 'octogenarians', in their annual report of 2018. Apart from implant survival, they also calculated patient survival rate. The report showed that the risk of both early and late mortality increased with increasing age. Patients aged ≥ 90 years showed a 2.5 times increased risk of mortality after 10 years compared to those aged 80-89 years (19). Male sex and an increased ASA class were associated with higher mortality rates. Despite the higher mortality rate in older individuals, the cumulative incidence of revision for < 80 years, 80-89 years and ≥ 90 years was not largely changing with age. A likely reason that older patients have a lower revision rate is because these patients do not survive long enough to be revised (19). In addition, their activity level is often low, so prothesis are not at high stresses for wear out. Furthermore, the AOANJRR showed that the most important prosthesis factor that affected the revision rate in these patients is the use of uncemented femoral stems (19). Also, in the national register of Finland a higher early failure rate after uncemented THA has been shown in patients 80 years or older (average follow-up was 4 years) (20). Thomsen et al. have found that patients with poor bone quality could have a higher risk for periprosthetic fractures by examining fracture loads in cemented and uncemented hip stems implanted in fresh frozen femora (donor medial

age 78 years) (21). This is probably the reason for more periprosthetic fractures in the octogenarian group.

In view of the scarce existing data for older patients, we studied the implant- and patient-survival after primary THA for osteoarthritis in octogenarians using Dutch register data for the **first** part of this thesis. (see Chapter 2).

Part two: Possible implant solutions for dislocation

In the **second part** of this thesis we focused on one of the most common (early) reasons for revision: dislocation. A dislocation occurs when the head of the prosthesis jumps out of the socket. Generally, the risk of dislocation after a primary THA varies in reports from 0.4-8.7% (22). A dislocation of the hip is a real disaster for the patient and dramatically reduces quality of life, particularly if it becomes recurrent. Based on previous research, different patient and surgical risk factors for dislocation have been found. Patient factors could be muscle weakness like neuromuscular disorders, obesity or a stiff spine. Surgical risk factors are suboptimal placement of the cup in the acetabulum or inappropriate version of the stem (23). Finally, the femoral head size is also an important factor. Larger femoral head size decreases the dislocation risk (24). For patients with recurrent dislocations of their hip, revision is the final solution. In 2017, the annual report of the LROI showed the results of the first years of national registration. Dislocation was the main reason (36.3%) for a 'substantial revision' (a revision including exchange of the acetabular or femoral component) within one year after the primary THA (n = 1,443 from 2011-2015) (25).

Research has led to the development of several adaptations in the design of prosthesis and surgical technique of THA to reduce the risk for dislocation. One of the technical solutions to prevent recurrent dislocation is the use of a dual mobility cup (DMC). According to the LROI annual report of 2017, DMCs were the most frequently registered acetabular components in hip revision arthroplasties in the Netherlands in 2016 (25). A possible explanation for this is that dislocation rates after revision surgery are higher than in primary THA. For the **second part** of this thesis we have focused on these different implant solutions for dislocation in hip arthroplasty: dual mobility cups and bipolar heads.

Dual mobility cups

In the mid-1970's, Bousquet in France developed the DMC; a polyethylene liner is added to the femoral head to create two articulations; one between femoral head and polyethylene liner and one between mobile polyethylene liner and cup (Figure 5). The dual articulation is based on two principles. First, a larger head creates a larger jumping distance and thereby reduces the risk for dislocation (Figure 6). Second, the dual articulation creates a greater range of motion before impingement (Figure 7).

Since its introduction, this DMC has been used in revision procedures for THA with recurrent instability (26). Its anatomic design offers joint stability and a large range of motion.

For this thesis, we focus on LROI register data about DMC implants. There were only a few register studies published on this subject. In 2012, Hailer et al. published a study of 228 patients from the Swedish Hip Arthroplasty Register with a DMC after revision due to instability; only 4 (2%) had been re-revised due to dislocation during the follow-up period (median 2 years (0-6 years)) (27). In 2017, Tarasevicius et al. found in a study of 12,657 primary THAs (620 with DMC) in the Lithuanian Arthroplasty Register an overall unadjusted cumulative revision rate for any reason of 3.9% after 5 years in the DMC group, which was lower than in the group with the normal head (5.2%) (28). In 2017, Kreipke et al. did a matched population-based study using the NARA database including 2,277 patients comparing DMC and Metal-on-Polyethylene or Ceramic-on-Polyethylene bearings. There was no difference in overall risk of revision between the two groups (29).

Internationally, the use of these DMC implants is very different. In some countries DMCs are frequently used, in other only in specific cases. Since the last 10 years, we have noticed an increased use of DMC in the Netherlands for primary and revision THA. So, for the **third chapter** of this thesis we have determined the use of DMC in primary THA in the Netherlands and calculated mid-term cup revision rates of DMC compared to standard unipolar cup (UC) THAs (see Chapter 3).

DMC in revision total hip arthroplasty

As a logical consequence we were also interested in the results of DMC used in revision cases. For the **fourth chapter** of this thesis we investigated re-revision rates of DMC compared with UC after revision THA and analyzed risk factors for re-revision. (See Chapter 4).



Figure 5. Image of a dual mobility cup

The head consists of two articulations; one between femoral head and polyethylene liner and one between polyethylene liner and cup.

Source: https://www.researchgate.net/figure/A-dual-mobility-cup-articulating-with-a-ceramic-head-inserted-on-a-cementless-stem_fig2_342585538

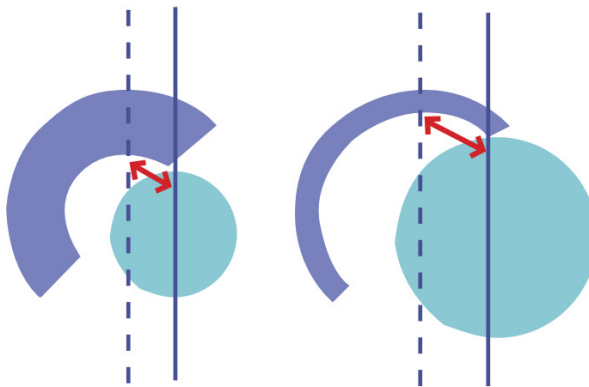


Figure 6. Image showing two different articulations in total hip arthroplasty

The cup is drawn by a pink half circle. The head is drawn by a blue circle. A large head creates a larger jumping distance (the distance for the head to jump out of the cup is indicated by the red arrow).

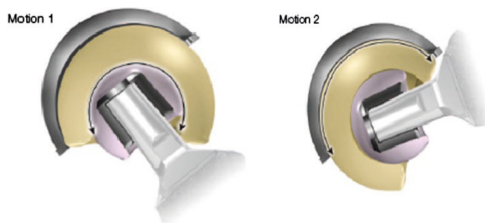


Figure 7. Image showing the two articulations of a dual mobility cup

Together they create a large range of motion.

Source: van Heumen M, Heesterbeek PJ, Swierstra BA, et al. Dual mobility acetabular component in revision total hip arthroplasty for persistent dislocation: no dislocations in 50 hips after 1-5 years. *J Orthop Traumatol.* 2015 Mar;16(1):15-20.

THA with DMC in acute hip fractures

THAs with a DMC are also frequently used in patients with an acute hip fracture. Hip fractures in older patients are unfortunately frequently seen and have a major impact on our health care system. When the fractured hip joint (femoral neck) could not be saved by osteosynthesis, an arthroplasty is often performed. There are two options: THA or hemiarthroplasty (HA). In case of THA after a fracture of the femoral neck, one of the most frequent reasons for cup revisions is dislocation (30,31). This is partly caused by the patient characteristics as the patients are often old, difficult to instruct, have weak muscles and no pre-existing joint stiffness like in osteoarthritis. A DMC might reduce this dislocation risk. Therefore, for the **fifth chapter** of this thesis we have investigated the cup revision rate after THA for an acute fracture according to type of cup (DMC or UC) in the Netherlands (See Chapter 5).

Hemiarthroplasty in acute hip fractures

Only a minority of all hip fractures is treated with a THA (7% in 2019). An hemiarthroplasty (HA) is more frequently used (33% in 2019) (32). In HA, the head of the hip joint is replaced by a large metal head that is fitted on a femoral stem. The large head articulates in the original acetabulum of the patient (Figure 8). The use of HA in case of hip fractures was introduced by Moore and Thompson in 1952 for salvage after failure of internal fixation (33,34).

Unipolar head hemiarthroplasty

The head of the HA can be fixed directly on the taper of the prosthesis, this is called an unipolar head. All movements made by the joint are then between the artificial head and the cartilage of the socket (Figure 8).

Bipolar head hemiarthroplasty

In bipolar HA the head is made of two components to create an additional articulation: the bipolar head consists of a smaller spheric head articulating within an outer shell which articulates directly within the acetabulum (Figure 9). This concept was designed by James Bateman in 1974 to limit friction with wear of the acetabular surface (35). Besides, the reduction of cartilage wear it could theoretically decrease dislocation rate.

In 2021, Farey et al. analyzed the revision rates of 62,875 primary HAs from the Australian AOANJR and found the risk for revision for unipolar HA being comparable with a bipolar HA for the first 2.5 years but higher after 2.5 years (HR 1.9 (CI 1.5-2.4)) (36).

For the **sixth chapter** of this thesis we studied the revision rates of bipolar and unipolar HA of the hip after an acute fracture of the hip in the Netherlands, focusing on revision for dislocation using data from the LROI (see Chapter 6).

In the final chapters the preceding papers are summarized and discussed (see Chapter 7 and 8).



Figure 8. Illustration of hemiarthroplasty showing a large head articulation in the acetabulum of the patient and a stem in the femur of the patient



Figure 9. Illustration of hemiarthroplasty with a bipolar head showing a small head articulating in an outer shell which articulates in the acetabulum of the patient

In summary, the research questions of this thesis were:

Part 1 Arthroplasties in octogenarians

1. What is the mortality and prosthesis revision rate of primary total hip arthroplasty for osteoarthritis in patients 80 years and older and which patient and implant related factors are associated with the outcome in the Netherlands?

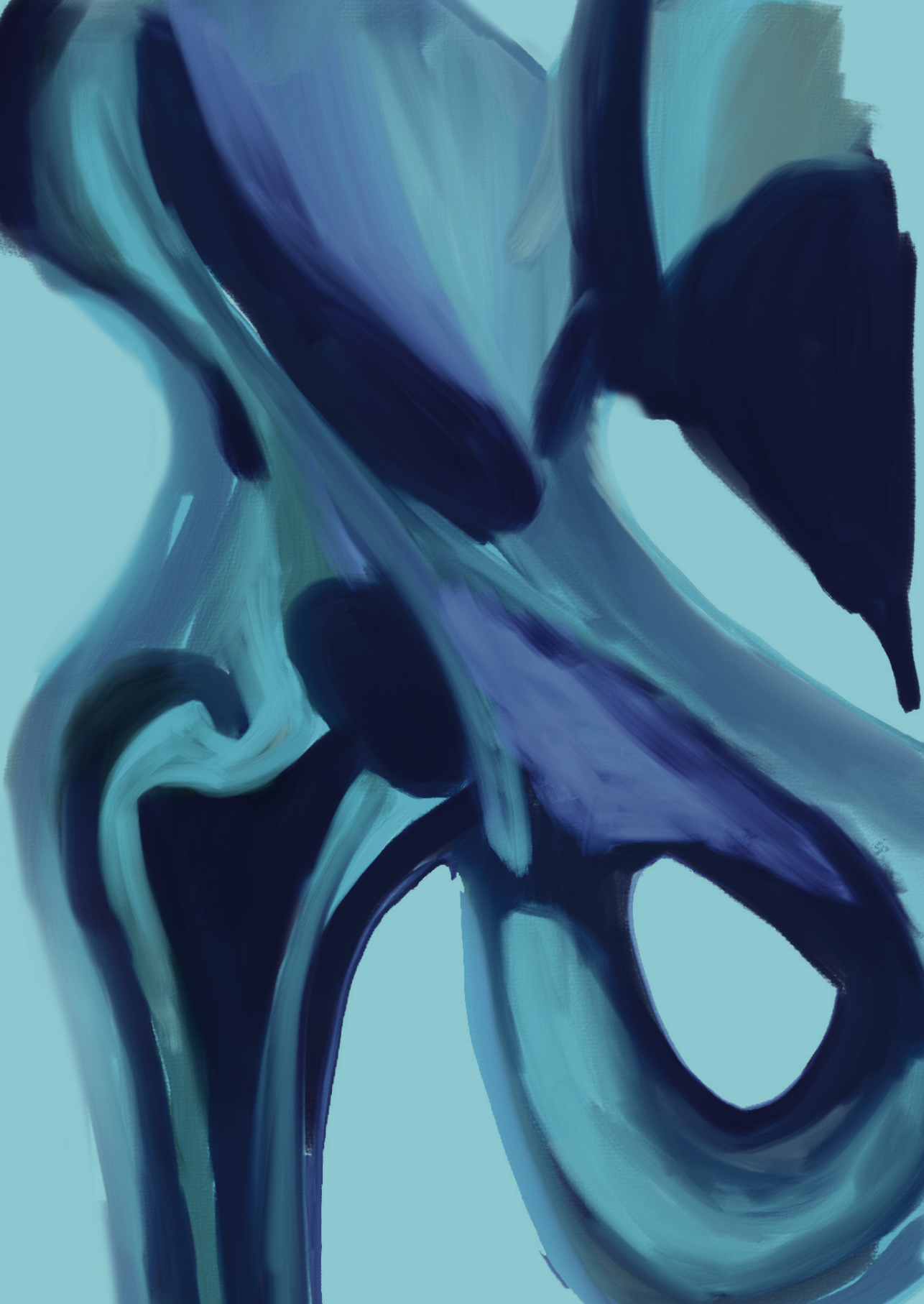
Part 2 Possible implant solutions for dislocation

2. What is the use of dual mobility cups for primary total hip arthroplasty in case of osteoarthritis and what are the patient characteristics in the Netherlands? Are the survival rates comparable with unipolar cups?
3. What is the use of dual mobility cups for revision total hip arthroplasty and what are the patient characteristics in the Netherlands? Are the survival rates comparable with unipolar cups, especially for dislocations?
4. What is the survival rate of total hip arthroplasty with dual mobility cup after an acute fracture of the hip in the Netherlands? What are the reasons for revision? Are the revision rates different between dual mobility cups and unipolar cups?
5. What is the use of bipolar hemiarthroplasty after an acute fracture of the hip in the Netherlands? Are the revision rates different between bipolar and unipolar hemiarthroplasty and does this depend on other patient or surgery related factors?

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Part 1

Chapter 2



Comparable mortality but higher revision rate after uncemented compared with cemented total hip arthroplasties in patients 80 years and older

Report of 43,053 cases of the Dutch Arthroplasty Register

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Abstract

Background and purpose

Mortality and revision risks are important issues during shared decision-making for total hip arthroplasty (THA) especially in elderly patients. We examined mortality and revision rates as well as associated patient and prosthesis factors in primary THA for osteoarthritis (OA) in patients ≥ 80 years in the Netherlands.

Patients and methods

We included all primary THAs for OA in patients ≥ 80 years in the period 2007–2019. Patient mortality and prosthesis revision rates were calculated using Kaplan-Meier survival analyses. Risk factors for patient mortality and prosthesis revision were analyzed using multivariable Cox regression analysis adjusted for age, sex, ASA class, fixation method, head size, and approach.

Results

Mortality was 0.2% at 7 days, 0.4% at 30 days, 2.7% at 1 year, and 20% at 5 years. Mortality was higher in males and higher ASA class, but did not differ between fixation methods. The 1-year revision rate was 1.6% (95% CI 1.5–1.7) and 2.6% (CI 2.5–2.7) after 5 years. Multivariable Cox regression analysis showed a higher risk of revision for uncemented (hazard ratio (HR) 1.6; CI 1.4–1.8) and reverse hybrid THAs (HR 2.9; CI 2.1–3.8) compared with cemented THAs. Periprosthetic fracture was the most frequently registered reason for revision in uncemented THAs.

Interpretation

Mortality is comparable but revision rate is higher after uncemented compared with cemented THA in patients 80 years and older, indicating that cemented THA might be a safer option in this patient group.

Background

Mortality and revision risks are important issues during shared decision-making for total hip arthroplasty (THA) especially in elderly patients. Associations have been found between higher mortality and some patient factors like sex, Body Mass Index (BMI), and comorbidity (1,2). Concerns have been raised about early mortality due to bone cement implantation syndrome (3), but an unambiguous association between early or late mortality and prosthesis fixation type has not been found in several register studies (1,4-7).

Beside mortality, revision rates are also influenced by patient and prosthesis factors (such as femur head size and type of fixation). Although the revision rate in the elderly could be influenced by the fact that not all patients are willing to undergo revision surgery due to comorbidity, the most important prosthesis factor that affects the rate of revision in elderly patients is the type of fixation. Higher revision rates, especially due to a periprosthetic fracture after uncemented hip replacement, have been found in several register studies (1,2,8-11).

Patient and surgical procedure characteristics as well as revision rates differ between countries (12), which justifies looking for confirmation of these international results in the Netherlands (17.5 million inhabitants).

We examined mortality and revision rates as well as associated patient and prosthesis factors in primary THA for OA in patients 80 years and older in the Netherlands.

Patients and methods

The Dutch Arthroplasty Register (LROI) was started in 2007 and has a completeness of 99% for primary and 97% for hip revision arthroplasty (www.lroi-report.nl). The LROI database contains patient, procedure, and prosthesis characteristics. For each component a product number is registered to identify the characteristics of the prosthesis.

The vital status of all patients is obtained actively on a regular basis from Vektis, the national insurance database on healthcare in the Netherlands, which records all deaths of Dutch citizens (13). The LROI uses the opt-out system to

require informed consent of patients. Revision is defined as a procedure where 1 or more components of the prosthesis were exchanged, added, or removed.

For this study we included all primary THAs for primary OA in patients 80 years and older in the period 2007–2019 and estimated mortality and revision rates. For mortality, all patients were included with their first primary THA only in the case of bilaterality. 39,984 patients were included. For revision, all procedures (also patients with bilateral THA) were included (n = 43,053) (Figure 1). Second, we examined associated patient and prosthesis factors.

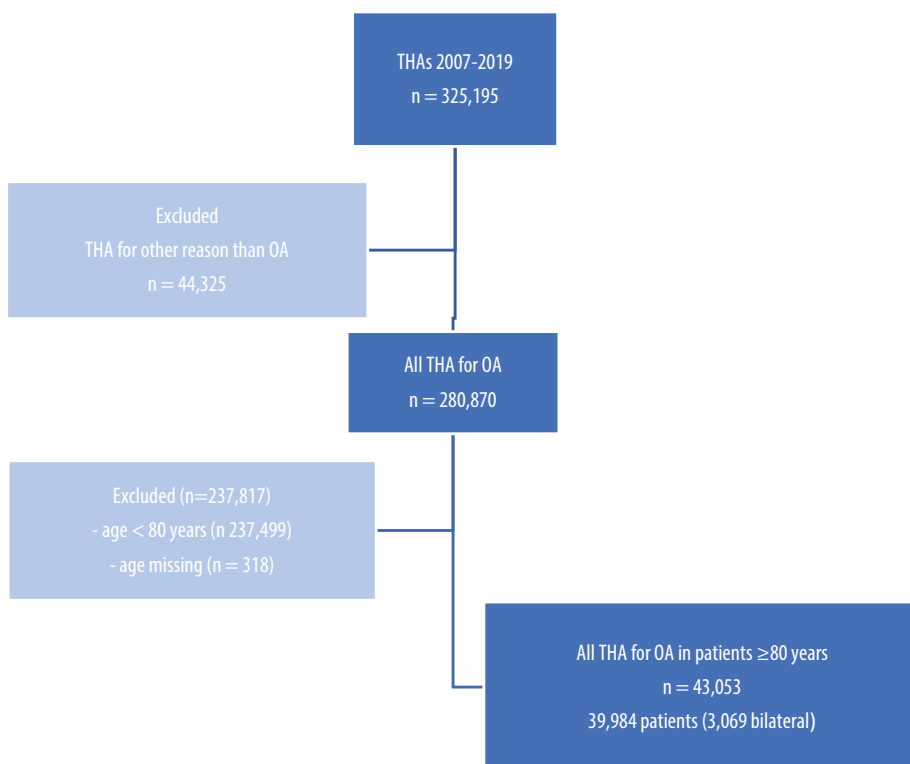


Figure 1. Patient flow

Statistics

The trend over time in primary THA for OA in elderly patients was described, as well as patient and procedure characteristics using numbers and percentages. Patient factors like age and ASA class were categorized to analyze according to the LROI report.

Mortality

Survival time of the patient was calculated as the time from first primary THA to death of the patient or end of follow-up (January 1st 2020). Postoperative mortality at 7, 30, and 90 days, and 1, 3, and 5 years was calculated using Kaplan-Meier survival analyses and stratified by age, sex, ASA class, and fixation method because of their suspected influence on mortality. We considered non-overlapping 95% confidence intervals (CI) as statistically significant.

Independent risk factors for mortality were analyzed using Cox regression analysis. The comparisons were performed without adjustment (univariate analysis) and with adjustments for age, sex, ASA class, and type of fixation. For CIs, we assumed that the number of observed cases followed a Poisson distribution. The results of the Cox regression analyses are presented as hazard ratio (HR) with CI.

Revision

Revision was defined as an intervention where 1 or more components of the prosthesis are exchanged, added, or removed.

We calculated incidence of revision after 1, 3, and 5 years using Kaplan-Meier survival analyses. In addition, competing risk analyses were performed as additional analysis to examine crude incidence of revision where death was considered to be a competing risk. Revision-free time of the prosthesis was calculated as the time from primary THA to revision procedure for any reason, death of the patient, or end of follow-up (January 1st, 2020).

Independent risk factors for revision were analyzed using Cox regression analysis. The comparisons were performed without adjustment (univariate analysis) and with adjustments for age, sex, ASA class, type of fixation, head size, and approach because of their suspected influence on revision.

For all covariates added to the model, the proportional hazards assumption was checked by inspecting log-minus-log curves and met. Reasons for revision according to fixation method were described. This study was reported in accordance with the STROBE guidelines.

Ethics, data sharing plan, funding, and potential conflicts of interests

The dataset was processed in compliance with the regulations of the LROI governing research on registry data. Data is available from the LROI but restrictions apply to the availability of this data, which was used under license for the current study. No external funding was received. No competing interests were declared.

Results

43,053 THA procedures in 39,984 patients were included and a rising trend in the annual number of THAs of patients ≥ 80 years was observed (2,792 in 2010 and 4,335 in 2019). The proportion of patients ≥ 80 years was stable (15% in 2010 and 2019) (14). 75% of patients were female, and 90% of them had ASA class II-IV and about half of THAs were performed with cemented fixation (Table 1).

Mortality

Of the 39,984 patients 5,867 died (7.7%) within 5 years after their primary THA (median follow-up 4.2 years (0-13)). Mortality rate was 0.2% (CI 0.2-0.2) within 7 days, 0.4% (CI 0.4-0.4) within 30 days, 0.8% (CI 0.8-0.8) within 90 days, 2.7% (CI 2.6-2.8) within 1 year, 9.6% (CI 9.4-9.8) within 3 years, and 20% (CI 20-20) within 5 years. Mortality was higher in males compared with females. Patients with a higher age and ASA class had higher mortality rates. Mortality was similar between fixation methods (Table 2).

Adjusted survival analyses using Cox regression models adjusted for age, sex, ASA class, and fixation showed that higher age (≥ 85 years), male sex, and higher ASA class were associated with a higher risk of death < 5 years after THA (age 85-89 HR 1.5 (CI 1.5-1.6), age ≥ 90 HR 2.4 (CI 2.2-2.6), male sex HR 1.5 (1.4-1.5), ASA class III-IV HR 1.6 (CI 1.6- 1.7)). Type of fixation was not associated with a higher mortality risk (Table 3).

Table 1. Patient and prosthesis characteristics of 43,053 total hip arthroplasty (THA) procedures in patients aged ≥ 80 years

	Total n = 43,053 (number (%))
Sex	
Male	10,931 (25)
Female	32,073 (75)
Missing	49 (0)
Age (years median(range))	
	83 (80-108)
ASA class	
I	3,034 (7)
II	26,978 (63)
III-IV	11,929 (28)
Missing	1,112 (2)
Approach	
Anterior	6,082 (14)
Anterolateral	3,024 (7)
Direct lateral	7,958 (19)
Posterolateral	25,467 (59)
Other	178 (0)
Missing	344 (1)
Fixation	
Cemented	22,025 (51)
Hybrid	3,243 (8)
Reverse hybrid	987 (2)
Uncemented	16,376 (38)
Missing	422 (1)
Diameter femoral head	
22-28 mm	14,177 (33)
32 mm	21,741 (50)
36 mm	5,717 (13)
≥ 38 mm	337 (1)
Missing	1,081 (3)

Table 2. Mortality rates (%) with 95% CI in primary total hip arthroplasty (THA) in patients aged ≥ 80 years

	n	Mortality					
		7 day	30 day	90 day	1-year	3-year	5-year
Total	39,984	0.2 (0.2-0.2)	0.4 (0.4-0.4)	0.8 (0.8-0.8)	2.7 (2.6-2.8)	9.6 (9.4-9.8)	20 (20-20)
Sex							
Male	10,255	0.2 (0.2-0.2)	0.6 (0.5-0.7)	1.3 (1.2-1.4)	4.0 (3.8-4.2)	13 (13-13)	26 (26-27)
Female	29,683	0.1 (0.1-0.1)	0.3 (0.3-0.3)	0.7 (0.7-0.7)	2.2 (2.1-2.3)	8.5 (8.3-8.7)	18 (18-18)
Missing	46						
Age (years)							
80-84	28,839	0.1 (0.1-0.1)	0.3 (0.3-0.3)	0.6 (0.6-0.6)	2.1 (2.0-2.2)	7.9 (7.7-8.1)	17 (17-17)
85-89	9,526	0.2 (0.2-0.2)	0.6 (0.5-0.7)	1.3 (1.2-1.4)	3.7 (3.5-3.9)	13 (12-13)	26 (25-26)
≥ 90	1,619	0.4 (0.2-0.6)	1.2 (0.9-0.1.5)	2.6 (2.2-3.0)	6.4 (5.8-7.0)	23 (21-24)	42 (41-44)
Missing	0						
ASA class							
I	2,841	0.0 (0.0-0.0)	0.1 (0.1-0.1)	0.4 (0.3-0.5)	1.5 (1.3-1.7)	5.9 (5.4-6.3)	12 (11-13)
II	25,045	0.1 (0.1-0.1)	0.3 (0.3-0.3)	0.6 (0.6-0.6)	1.9 (1.8-2.0)	7.8 (7.6-8.0)	18 (17-18)
III-IV	11,017	0.4 (0.3-0.5)	0.8 (0.7-0.9)	1.6 (1.5-1.7)	4.7 (4.5-4.9)	16 (15-16)	31 (30-31)
Missing	1,081						
Fixation							
Cemented	20,425	0.2 (0.2-0.2)	0.4 (0.4-0.4)	0.9 (0.8-1.0)	2.8 (2.7-2.9)	10 (10-10)	21 (20-21.0)
Uncemented	15,215	0.1 (0.1-0.1)	0.4 (0.3-0.5)	0.8 (0.7-0.9)	2.6 (2.5-2.7)	8.8 (8.5-9.1)	19 (19-20)
Reverse hybrid	908	0.0 (0.0-0.0)	0.1 (0.0-0.2)	0.6 (0.4-0.8)	2.5 (2.0-3.0)	10 (9.2 (11)	21 (19-22)
Hybrid	3,036	0.1 (0.0-0.2)	0.4 (0.3-0.5)	0.7 (0.5-0.9)	2.3 (2.0-2.6)	9.9 (9.3-11)	20 (19-21)
Missing	400						

Table 3. Risk factors for mortality adjusted for sex, age, ASA class and fixation. N = 39,984 patients

	Total number THA	Mortality HR adjusted
Sex		
Male	10,255	1.5 (1.4-1.5)
Female	29,683	1.0
Missing	46	
Age (years)		
80-84	28,839	1.0
85-89	9,526	1.5 (1.5-1.6)
≥ 90	1,619	2.4 (2.2-2.6)
ASA class		
I	2,841	0.7 (0.7-0.8)
II	25,045	1.0
III-IV	11,017	1.6 (1.6-1.7)
Missing	1,081	
Fixation		
Cemented	20,425	1.0
Hybrid	3,036	1.0 (0.9-1.0)
Reverse hybrid	908	0.9 (0.8-1.1)
Uncemented	15,215	1.0 (0.9-1.0)
Missing	400	

THA: total hip arthroplasty

Revision

In 43,053 primary THA procedures 1,064 revisions were seen. 983 (94%) revisions were registered within 5 years after the primary THA. The median follow-up was 4.1 years (0-13) with the majority of revisions being a partial revision (cup or stem n = 580, femoral head and/or inlay n = 260), or total revision (including Girdlestone procedure) (n = 126).

The revision rate was 1.6% (CI 1.5-1.7) at 1-year follow-up and 2.6% (CI 2.5-2.7) at 5-year follow-up (Table 4). Male patients had a higher revision rate within 1, 3, and 5 years compared with females. Patients with an ASA class III-IV had a higher revision rate within 1 and 3 years, although not after 5 years. Uncemented THAs had a higher revision rate compared with cemented THAs (1-year revision rate uncemented THAs 2.0% (CI 1.9-2.1) versus 1.3% (CI 1.2-1.4) for cemented THAs; 5-year revision rate uncemented THAs 3.2% (CI 3.0-3.5) vs. 2.2% (CI 2.1-2.3)). Reverse hybrid THAs (uncemented stem) also showed high revision rates at 1, 3, and 5-year follow-up, but numbers were small (n = 987). No statistically significant differences were seen in the case

of larger femoral head size and different approaches; only head size ≥ 38 mm showed higher revision rates, but the amounts were low ($n = 337$) (Table 4).

Competing risk analyses showed comparable crude revision rates (Table X, see Supplementary data). Multivariable Cox regression analysis adjusted for age, sex, ASA class, fixation, approach, and head size showed a higher risk of revision for males (HR 1.2 (CI 1.1–1.4)) and no statistically significant difference in risk of revision by age group and ASA class. Uncemented and reverse hybrid THAs (uncemented stem) were associated with a higher risk of revision (HR 1.6 (CI 1.4–1.8)) and HR 3.0 (CI 2.3–4.0)) compared with cemented and hybrid THAs (cemented stem) (Table 5).

Table 4. Kaplan-Meier net revision rate (%) with 95% CI in primary total hip arthroplasty (THA) in patients aged ≥ 80 years

	n	Revision rate		
		1-year	3-year	5-year
Total	n = 43,053	1.6 (1.5-1.7)	2.3 (2.2-2.4)	2.6 (2.5-2.7)
Sex				
Male	10,931	2.1 (2.0-2.2)	2.5 (2.2-2.7)	3.3 (3.1-3.5)
Female	32,073	1.5 (1.4-1.6)	2.1 (2.0-2.2)	2.4 (2.3-2.5)
Missing	49			
Age (years)				
80-84	30,643	1.6 (1.5-1.7)	2.0 (1.9-2.1)	2.6 (2.5-2.7)
85-89	10,624	1.8 (1.7-1.9)	2.4 (2.2-2.6)	2.8 (2.6-3.0)
≥ 90	1,786	1.8 (1.5-2.1)	2.2 (1.8-2.6)	2.2 (1.8-2.6)
Missing	0			
ASA class				
I	3,034	1.3 (1.1-1.5)	2.1 (1.8-2.4)	2.8 (2.5-3.1)
II	26,978	1.6 (1.5-1.7)	2.2 (2.1-2.3)	2.6 (2.5-2.7)
III-IV	11,929	1.9 (1.8-2.0)	2.4 (2.2-2.6)	2.7 (2.5-2.9)
Missing	1,112			
Fixation				
Cemented	22,025	1.3 (1.2-1.4)	1.8 (1.7-1.9)	2.2 (2.1-2.3)
Hybrid	3,243	1.4 (1.2-1.6)	1.8 (1.6-2.0)	2.0 (1.7-2.3)
Reverse hybrid	987	4.0 (3.4-4.6)	5.6 (4.8-6.2)	6.2 (5.4-7.0)
Uncemented	16,376	2.0 (1.9-2.1)	2.8 (2.7-2.9)	3.2 (3.0-3.5)
Missing	422			
Head size				
22-28 mm	14,177	1.4 (1.3-1.5)	2.1 (2.0-2.2)	2.6 (2.5-2.7)
32 mm	21,741	1.7 (1.6-1.8)	2.2 (2.1-2.3)	2.4 (2.3-2.5)
36 mm	5,717	2.1 (1.9-2.3)	2.8 (2.6-3.0)	3.2 (1.9-3.5)
≥ 38 mm	337	2.5 (1.6-3.4)	5.0 (3.7-6.3)	7.5 (5.9-9.1)
Missing	1,081			

Table 4. Continued

	n	Revision rate		
		1-year	3-year	5-year
Approach				
Anterior	6,082	1.6 (1.4-1.8)	2.1 (1.9-2.3)	2.6 (2.3-2.9)
Anterolateral	3,024	1.3 (1.1-1.5)	1.6 (1.4-1.8)	2.1 (1.8-2.4)
Direct lateral	7,958	1.4 (1.3=1.5)	2.0 (1.8-2.2)	2.3 (2.1-2.5)
Posterolateral	25,467	1.8 (1.7-1.9)	2.4 (2.3-2.5)	2.8 (2.7-2.9)
Other	178	3.0 (1.7-4.3)	4.4 (2.5-6.3)	4.4 (2.5-6.3)
Missing	344			

Table 5. Risk factors for revision adjusted for age, sex, ASA class, fixation, head size and approach (N = 43,053)

	n	Revision HR adjusted (CI)
Sex		
Male	10,931	1.2 (1.1-1.4)
Female	32,073	1.0
Missing	49	
Age (years)		
80-84	30,643	1.0
85-89	10,624	1.1 (1.0-1.3)
≥ 90	1,786	0.9 (0.6-1.3)
ASA class		
I	3,034	1.0 (0.8-1.3)
II	26,978	1.0
III-IV	11,929	1.1 (0.9-1.2)
Missing	1,112	
Fixation		
Cemented	22,025	1.0
Hybrid	3,243	1.0 (0.8-1.3)
Reverse hybrid	987	2.9 (2.1-3.8)
Uncemented	16,376	1.6 (1.4-1.8)
Missing	422	
Head size		
22-28mm	14,177	1.1 (0.9-1.3)
32 mm	21,741	1.0
36 mm	5,717	1.1 (0.9-1.3)
≥38 mm	337	2.3 (1.5-3.5)
Missing	1,081	
Approach		
Anterior	6,082	0.8 (0.7-1.0)
Anterolateral	3,024	0.7 (0.5-0.9)
Direct lateral	7,958	0.8 (0.7-0.9)
Posterolateral	25,467	1.0
Other	178	1.6 (0.7-3.7)
Missing	344	

The most frequently registered reasons for revision were dislocation and periprosthetic fracture. Reasons for revision differed between types of fixation, with periprosthetic fracture being the most frequently registered reason for revision in uncemented THAs (185/492 = 38%) and reverse hybrid THAs (25/57 = 44%) compared with cemented THAs (26/427 = 6%) and hybrid THAs (2/61 = 3%). Dislocation was the most often registered reason for revision in cemented THAs (108/427 = 42%) and hybrid THAs (24/61 = 39%) (Figure 2).

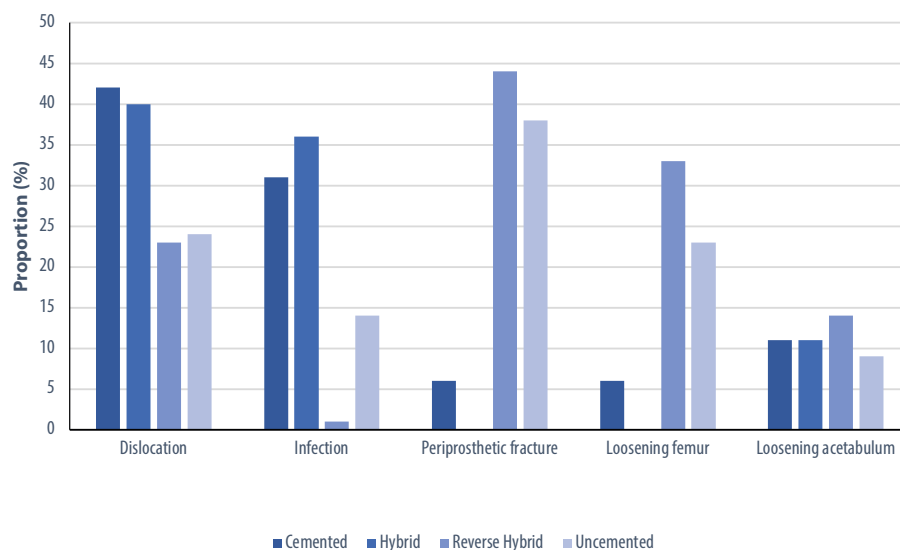


Figure 2. Reasons for revision (%) after total hip arthroplasty in patients aged ≥ 80 years according to fixation method

Discussion

Mortality

We found higher mortality rates in male patients, higher ASA class, and higher age. The Australian register reported comparable percentages of mortality of patients aged 80–89 years ($n = 48,737$); respectively 0.5% after 30 days, 0.9% after 90 days, 2.7% after 1 year, and 22% after 5 years (1).

Mortality was similar between patients with cemented, uncemented, hybrid, and reverse hybrid THAs at 7 days, 30 days, 90 days, 1, 3, and 5 years. This is comparable to other register studies. Jämsen et al. (8) found no differences

in mortality between fixation methods at 90 days and 1 year of 4,777 primary THAs in 4,509 octogenarian patients with primary OA based on the Finnish Arthroplasty Register. Also, Pedersen et al. (7) showed similar early (within 90 days) mortality rates in the Nordic Arthroplasty Register Association (NARA) database in 108,572 cemented and 80,034 uncemented THAs for OA after adjustment for comorbidity (HR 0.97 (CI 0.79–1.2)).

Ekman et al. (5) examined early postoperative mortality of patients (1–2 days and 3–10 days) in relation to bone cement implantation syndrome and early cardiovascular mortality based on Finnish registry data. They showed no differences between cemented and uncemented groups. Also, Dale et al. (2) found comparable 3-day mortality risks after cemented, uncemented, reverse hybrid, and hybrid THAs. We considered deaths within 7 days postoperatively as potentially associated with the cementation. Some differences were seen in < 7-day mortality between the cemented, uncemented, reverse hybrid, and hybrid fixation but the small numbers do not justify conclusions.

Revision

We showed higher revision rates in males, patients with higher ASA class, and uncemented THAs, especially uncemented stems (uncemented and reverse hybrid THA). Differences in revision rates according to fixation method were largely related to periprosthetic fractures in uncemented stems.

When we compare these results with other register studies, the Australian register also reported higher revision rates in patients aged > 75 years with uncemented THA after 1 year (2.3% (CI 2.2–2.4)), 3 years (3.2% (CI 3.0–3.3)), and 5 years (3.8% (CI 3.6–4.0)) compared with cemented and hybrid fixation (1). Even when only analyzing the 3 prostheses with the lowest revision rate in > 1,000 procedures Tanzer et al. (11) found higher early revision rates in uncemented THA in patients 75 years and older using Australian registry data.

Jämsen et al. (8) presented results from the Finnish register where uncemented femoral stems had a 1.7-fold (CI 1.3–2.2) risk of early revision compared with their cemented counterparts. Periprosthetic fracture was the leading mode of failure after uncemented hip replacement (8).

In a benchmark study using data from the National Joint Registry of England, Wales, Northern Ireland, and the Isle of Man, the Exeter cemented THA scored the best in the male and female group aged 75 years and older (15).

All these results are still in accordance with the conclusion from Troelsen et al. (16) in a review of current fixation use and registry outcomes after data extraction from the annual reports of 7 national hip arthroplasty registries in THA from 2006 to 2010, suggesting that cemented fixation has the lowest risk for revision in patients older than 75 years.

Revision is defined in the LROI as an intervention where 1 or more of the prostheses are exchanged, removed, or added. Therefore, closed reduction as well as wound drainage and periprosthetic fractures without component exchange are not included in this study. Furthermore, as in any register study there might be selection bias as it is possible that a revision (for example because of wear) is no longer performed because of (increasing) comorbidity. Therefore, we focused on the revision rate in the relative short term (within 5 years after the primary operation).

In conclusion, this clinical-question-driven register report of 43,053 procedures of the Dutch Arthroplasty Register (LROI) shows that mortality is comparable but revision rate is higher after uncemented compared with cemented THA in patients 80 years and older, indicating that cemented THA might be a safer option in this patient group.

Author contributions

All authors contributed to the conception of the study, data analysis, and preparation of the manuscript.

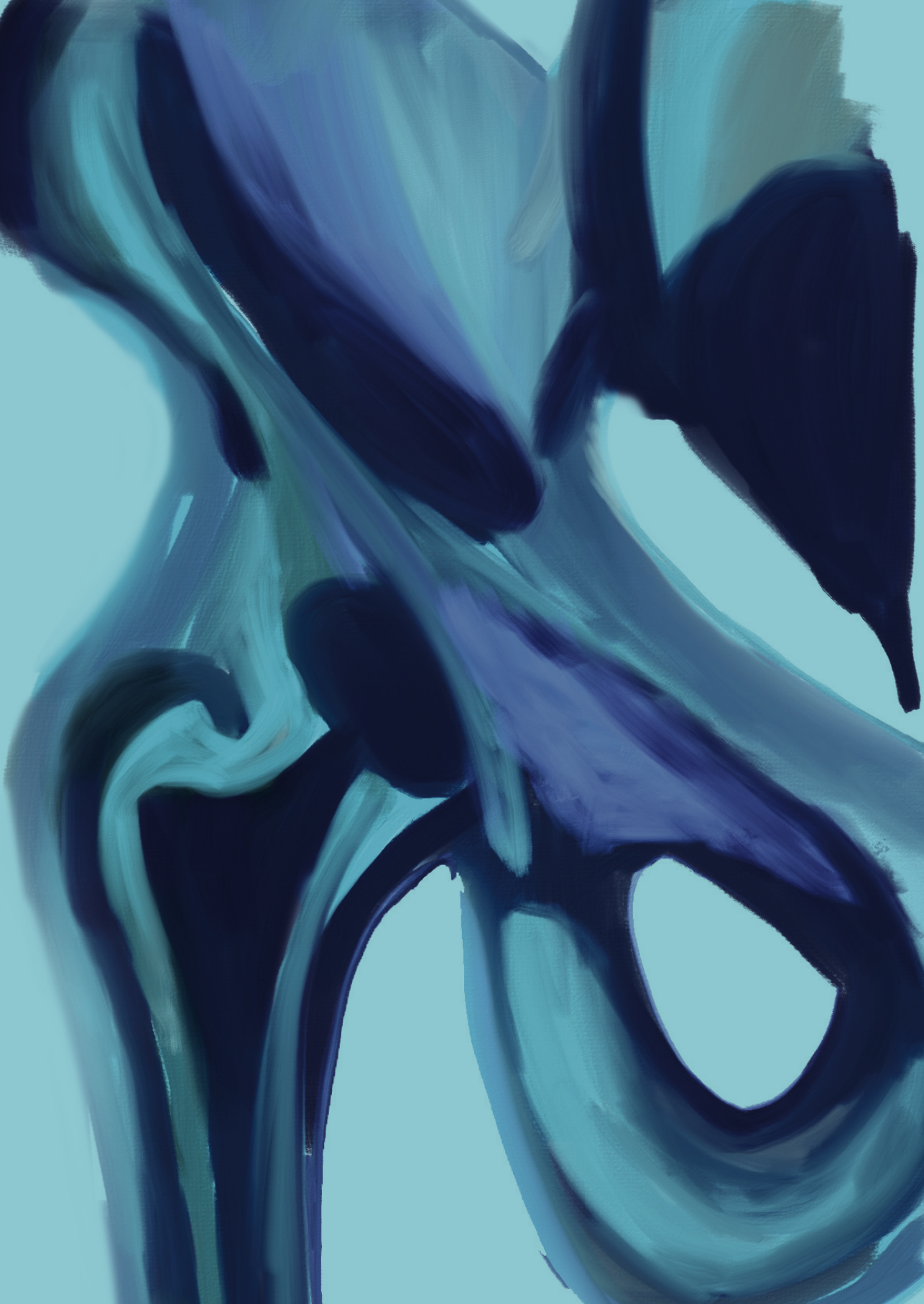
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Supplementary data

Table X. Crude cumulative incidence of revision (%) with 95% CI in primary total hip arthroplasty (THA) in patients aged ≥ 80 years

Factor	n	Revision rate		
		1-year	3-year	5-year
Total	43,053	1.6 (1.5-1.7)	2.2 (2.0-2.3)	2.5 (2.4-2.7)
Sex				
Male	10,931	2.0 (1.7-2.3)	2.7 (2.4-3.1)	3.1 (2.7-3.4)
Female	32,073	1.5 (1.3-1.6)	2.0 (1.8-2.2)	2.3 (2.2-2.5)
Missings	49			
Age (years)				
80-84	30,643	1.5 (1.4-1.7)	2.1 (2.0-2.1)	2.6 (2.3-3.0)
85-89	10,624	1.8 (1.6-2.1)	2.3 (2.0-2.6)	2.8 (2.6-3.0)
≥ 90	1,786	1.8 (1.2-2.5)	2.1 (1.5-2.9)	2.1 (1.5-2.9)
ASA class				
I	3,034	1.2 (0.9-1.7)	2.1 (1.6-2.6)	2.7 (2.1-3.3)
II	26,978	1.2 (1.4-1.7)	2.1 (2.0-2.3)	2.5 (2.3-2.7)
III-IV	11,929	1.8 (1.6-2.1)	2.3 (2.1-2.6)	2.5 (2.2-2.8)
Missings	1,112			
Fixation				
Cemented	22,025	1.3 (1.1-1.4)	1.7 (1.6-1.9)	2.0 (1.8-2.3)
Hybrid	3,243	1.2 (0.9-1.7)	1.7 (1.3-2.2)	1.9 (1.4-2.5)
Reverse hybrid	987	3.8 (2.8-5.3)	5.3 (4.1-7.0)	5.8 (4.5-7.6)
Uncemented	16,376	2.0 (1.8-2.2)	2.7 (2.4-3.0)	3.0 (2.8-3.3)
Missings	422			
Head size				
22-28mm	14,177	1.4 (1.2-1.6)	2.0 (1.8-2.3)	2.4 (2.2-2.7)
32mm	21,741	1.6 (1.5-1.8)	2.1 (1.9-2.3)	2.3 (2.1-2.6)
36mm	5,717	2.0 (1.7-2.4)	2.7 (2.3-3.2)	3.0 (2.6-3.5)
≥ 38 mm	337	2.1 (1.0-4.4)	4.4 (2.6-7.3)	6.5 (4.2-9.9)
Missings	1,081			
Approach				
Anterior	6,082	1.6 (1.3-1.9)	2.0 (1.7-2.5)	2.5 (2.0-3.0)
Anterolateral	3,024	1.2 (0.9-1.7)	1.6 (1.2-2.1)	2.0 (1.5-2.6)
Direct lateral	7,958	1.4 (1.2-1.7)	2.0 (1.7-2.3)	2.2 (1.9-2.6)
Posterolateral	25,467	1.7 (1.5-1.8)	2.3 (2.1-2.5)	2.5 (2.3-2.7)
Other	178	2.9 (1.2-7.0)	4.3 (1.8-9.9)	4.3 (1.8-9.9)
Missings	344			



Part 2

Chapter 3



Dual mobility cups in primary total hip arthroplasties

Trend over time in use, patient characteristics, and mid-term revision in 3,038 cases in the Dutch Arthroplasty Register (2007-2016)

EM Bloemheugel
LN van Steenbergem
BA Swierstra

Abstract

Background and purpose

We noticed an increased use of dual mobility cups (DMCs) in primary total hip arthroplasty (THA) despite limited knowledge of implant longevity. Therefore, we determined the trend over time and mid-term cup revision rates of DMC compared with unipolar cups (UCs) in primary THA.

Patients and methods

All primary THAs registered in the Dutch Arthroplasty Register (LROI) during 2007-2016 were included (n = 215,953) and divided into 2 groups: DMC THAs (n = 3,038) and UC THAs (n = 212,915). Crude competing risk and Multivariable Cox regression analyses were performed with cup revision for any reason as primary endpoint. Adjustments were made for sex, age, diagnosis at primary THA, previous surgery on the affected hip, ASA class, type of fixation, surgical approach, and femoral head size.

Results

The proportion of primary DMC THA increased from 0.8% (n = 184) in 2010 to 2.6% (n = 740) in 2016. Patients who underwent DMC THA more often had a previous surgery on the affected hip, a higher ASA class, and the diagnosis acute fracture or late posttraumatic status compared with the UC THA group. Overall 5-year cup revision rate was 1.5% (95% CI 1.0-2.3) for DMC THA and 1.4% (CI 1.3-1.4) for UC THA. Stratified analyses for patient characteristics showed no differences in cup revision rates between the 2 groups. Multivariable Cox regression analyses showed no statistically significantly increased risk for revision for DMC THA (HR 0.9 (CI 0.6-1.2)).

Interpretation

The use of primary DMC THA increased with differences in patient characteristics. The 5-year cup revision rates for DMC THA and UC THA were comparable.

Background

The most frequent reason for revision in the 1st year after total hip arthroplasty (THA) is dislocation (1). Dislocation of a hip prosthesis is multifactorial including femoral head diameter. Mechanical studies have shown that instability could be decreased by increasing the diameter of the femoral head. With a larger head diameter, the head-neck ratio is higher and therefore there is a lower potential for instability (2).

Dual articulation implants were designed to increase implant stability but also to decrease polyethylene rim damage from contact between femoral neck and acetabular liner and to restore near-normal range of motion. The dual mobility cup (DMC) is a 'cup in a cup' and was developed in the 1970s to combine the low-friction arthroplasty principle of Charnley with the advantage of a big femoral head principle of McKee (3).

Despite concerns about increased polyethylene wear due to the large femoral head, the DMC is not only used for revisions but also in primary THA to reduce dislocations. This was shown by De Martino et al. (4) who counted, in a review of English articles between 1974 and 2016, 12,844 primary DMC THAs and 5,064 revision DMC THAs. Many of these articles focused more on dislocation rates than on longevity of the implant. Also in our daily practice we noticed an increase in the use of DMC in primary THA. Therefore, we determined the trend over time and mid-term cup revision rates of DMC compared with unipolar cup (UC) in primary THA with data from the Dutch Arthroplasty Register.

Patients and methods

The Dutch Arthroplasty Register (LROI) is a nationwide population-based register that includes information on arthroplasties in the Netherlands since 2007. The LROI was initiated by the Netherlands Orthopaedic Association and is well supported by its members. This results in coverage of 100% of Dutch hospitals and a completeness of reporting of over 95% for primary THAs and 88% for hip revision arthroplasty (5).

The LROI database contains information on patient, procedure, and prosthesis characteristics registered by registrars from each hospital. For each component a product number is registered to identify the characteristics of the prosthesis.

The vital status of all patients is obtained actively on a regular basis from Vektis, the national insurance database on health care in the Netherlands, which records all deaths of Dutch citizens. The LROI uses the opt-out system to require informed consent of patients.

For the present study we included all patients that underwent a primary THA in the period 2007–2016. Metal-on-metal (MoM) THAs ($n = 6,626$) and records with a missing product number ($n = 7,017$) were excluded. The remaining 215,953 hips comprised 3,038 DMC THAs and 212,915 UC THAs. Diagnosis was categorized as osteoarthritis (OA), acute fracture, late posttraumatic, and other. Other diagnoses registered in the LROI are hip dysplasia, inflammatory arthritis, osteonecrosis, post-Perthes, and tumor (unspecified). Cup revision was defined as a revision procedure where at least the cup was exchanged or removed. Closed reduction after a dislocation or incision and drainage for infection were not included in the LROI. The median follow-up was 3 years (0–9).

Statistics

Survival time was calculated as the time from primary THA to 1st revision arthroplasty for any reason, death of the patient, or the end of the study follow-up (January 1, 2017). Cumulative crude incidence of revision was calculated using competing risk analysis, where death was considered to be a competing risk (6, 7). In addition Kaplan–Meier survival analyses were performed.

Multivariable Cox proportional hazard ratios were performed to compare adjusted revision rates between DMC and UC THA. Adjustments were made for sex, age at surgery, diagnosis at primary THA, previous surgery on the affected hip, ASA class, type of fixation, surgical approach, and diameter of the femoral head to discriminate independent risk factors for cup revision arthroplasty. Body Mass Index (BMI), Charnley score, and smoking status were not included as covariates, since these were only available in the LROI database since 2014. For all covariates added to the model, the proportional hazards assumption was met after inspecting log-minus-log curves.

Reasons for revision were described according to type of hip arthroplasty and compared using a chi-square test to test differences between types of THA (SPSS 22.0; IBM Corp, Armonk, NY, USA).

More than 1 reason could be chosen. P-values below 0.05 were considered statistically significant. For the 95% confidence intervals (CI), we assumed that the number of observed cases followed a Poisson distribution.

Ethics, funding, and potential conflicts of interests

The dataset was processed in compliance with the regulations of the LROl governing research on registry data. No external funding was received. No competing interests were declared.

Results

The use of DMC THA increased from 184 (0.8% of all THAs) in 2010 to 740 (2.6% of all THAs) in 2016 (Figure 1) with 8 different types of DMC used (Table 1).

In the DMC THA group more patients had undergone previous surgery on the affected hip and had a higher ASA class. Furthermore the distribution of diagnoses at primary surgery was different compared with the UC THA group (Table 2).

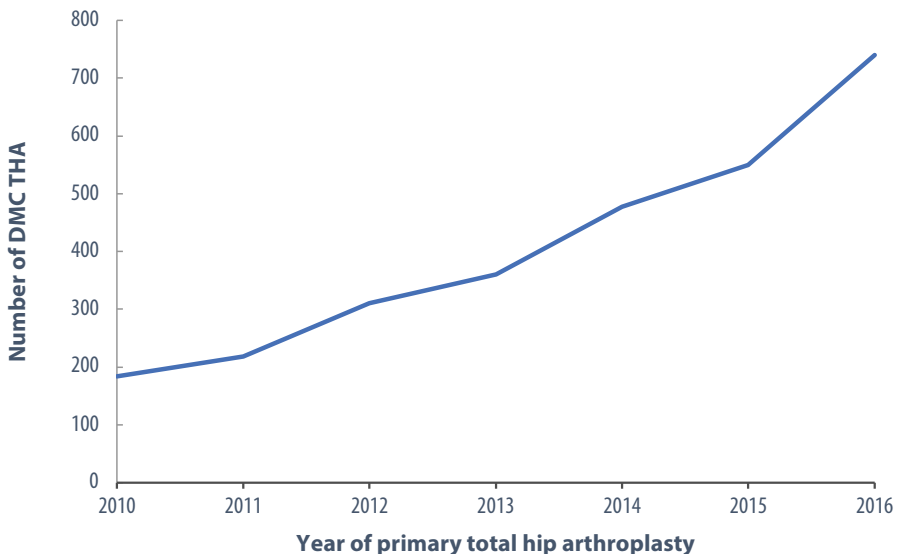


Figure 1. Trend in the use of dual mobility cup (DMC) in total hip arthroplasty (THA) in the period 2010 - 2016 in the Netherlands (n=3,308)

Table 1. Types of dual mobility cups total hip arthroplasty used in the period 2007-2016 the Netherlands (n=3,038)

Type	Cemented	Uncemented
Biomet Avantage	1,904	84
Biomet Avantage Reload	-	339
Biomet Avantage Rev HA	-	5
Smit & Nephew Polarcup	79	-
Amplitude Saturne	164	85
Mathys SeleXys DS Cup	27	54
Groupe Lepine Cupule Quattro	17	-
Groupe Lepine Cupule HAP Press-F	-	7

Table 2. Patient characteristics in total hip arthroplasty (THA) according to type of acetabular cup (n =212,915)

	DMC THA N = 3,038	UC THA N = 212,915
Gender (male)	1,104 (36%)	70,144 (33%)
Age (mean (SD) years)	70 (13)	69 (11)
Operations before (yes)	632 (21%)	10,048 (5%)
ASA class		
I	308 (10%)	47,409 (22%)
II	1,724 (57%)	129,460 (61%)
III-IV	951 (31%)	27,748 (13%)
Fixation		
Cemented	1,710 (56%)	60,955 (29%)
Reverse Hybrid	495 (16%)	9,033 (4%)
Hybrid	126 (4%)	9,932 (5%)
Uncemented	674 (22%)	130,911 (62%)
Diagnosis		
Osteoarthritis	1,688 (56%)	185,062 (87%)
Fracture (acute)	424 (14%)	7,065 (3%)
Late posttraumatic	406 (13%)	4,415 (2%)
Other*	476 (16%)	14,163 (7%)
Approach		
Anterior	96 (3%)	21,102 (10%)
Anterolateral	41 (1%)	15,801 (7%)
Direct lateral	254 (8%)	44,249 (21%)
Posterolateral	2,607 (86%)	128,275 (60%)
Trochanter osteotomy	1 (0%)	71 (0%)
Other	8 (0%)	635 (0%)
Diameter femoral head		
22-28 mm	2,784 (92%)	66,703 (31%)
32 mm		93,619 (44%)
36 mm		4,002 (19%)
≥ 38 mm		1,452 (1%)

Numbers do not add up to total due to missing data

* Other: dysplasia, inflammatory arthritis, osteonecrosis, post-Perthes, tumor (unspecified)

DMC: Dual mobility cup, UC: Unipolar cup

The 5-year crude cup revision rate for DMC THA was 1.5% (CI 1.0–2.3) and 1.4% (CI 1.3–1.4) for UC THA (Figure 2). Stratified analyses according to diagnosis at primary THA, previous surgery on the affected hip, and fixation of the cup showed similar 5-year crude cumulative incidence of cup revisions between the DMC and UC THA groups (Table 3). Kaplan-Meier survival analyses showed comparable revision rates (Table X, see Supplementary data).

The unadjusted hazard ratio for cup revision of DMC THA compared to UC THA was 1.2 (CI 0.8–1.6). Moreover, multivariable survival analyses showed a comparable risk for cup revision for DMC THA (HR 0.8 (CI 0.6–1.2)).

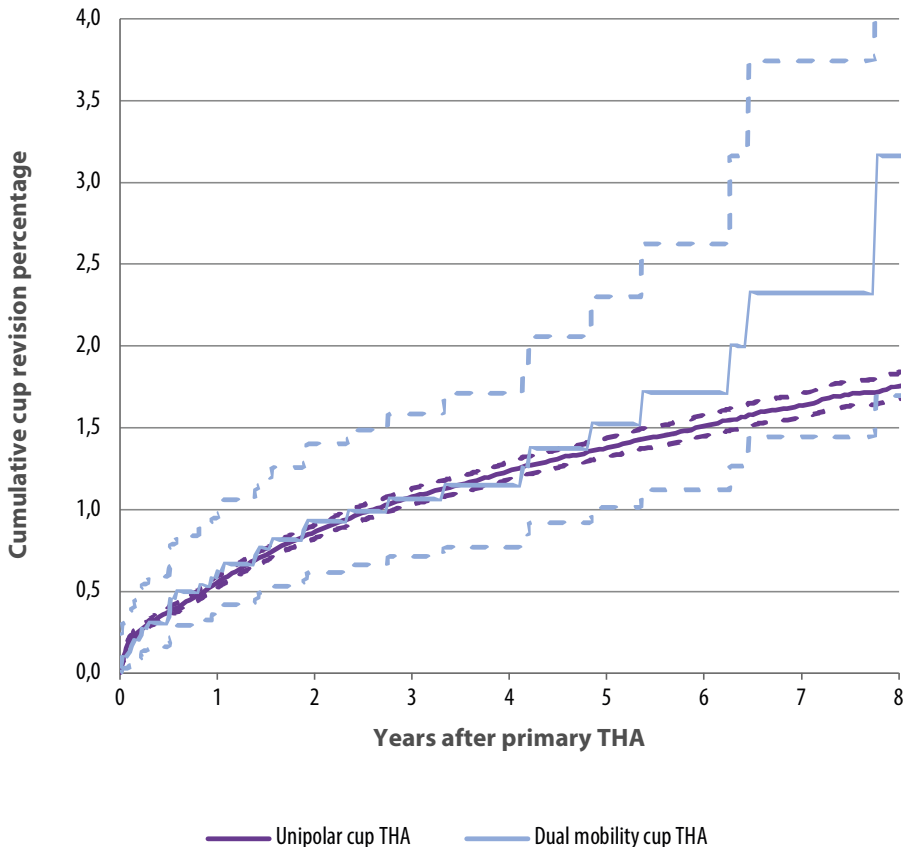


Figure 2. Cumulative incidence of cup revision according to type of cup (all diagnosis) in the period 2007-2016 in the Netherlands (n= 215,953). THA: total hip arthroplasty

Dislocation was the most frequently registered reason for revision in UC THA patients (0.5%), while in the DMC THA group 0.2% were revised due to dislocation. In the DMC THA group loosening of the cup, dislocation, and infection were mostly registered as reason for revision (Table 4). From the 18 DMCs that loosened 8 were cemented.

Table 3. Crude 5-year cumulative incidence of cup revision according to type of cup

	DMC THA		UC THA	
	n	5-year cumulative incidence of revision (CI)	n	5-year cumulative incidence of revision (CI)
Overall (all records)	3,038*	1.5 (1.0-2.3)	212,915	1.4 (1.3-1.4)
Diagnosis				
osteoarthritis	1,688	1.6 (0.9-2.9)	185,062	1.3 (1.2-1.4)
non-osteoarthritis	1,306	1.4 (0.8-2.4)	25,643	2.0 (1.9-2.2)
Previous surgery				
No	2,406	1.7 (1.1-2.7)	202,867	1.3 (1.3-1.4)
Yes	632	1.3 (0.5-3.2)	10,048	2.2 (1.9-2.5)
Cemented cup				
Yes	2,197	1.5 (0.9-2.6)	69,988	1.6 (1.5-1.7)
No	795	1.6 (0.8-3.1)	140,843	1.3 (1.2-1.3)

*Numbers do not add up to total due to missing data

DMC: Dual mobility cup, UC: Unipolar cup, THA: total hip arthroplasty

Table 4. Reason for cup revision according to type of cup

	DMC THA n = 3,308	UC THA n = 212,915
Reason for revision		
Dislocation	8 (0.2%)	1,017 (0.5%)
Infection	10 (0.3%)	451 (0.2%)
Periprosthetic fracture	3 (0.0%)	98 (0.0%)
Cup/liner wear	1 (0.0%)	85 (0.0%)
Girdlestone/spacer*	3 (0.0%)	173 (0.1%)
Loosening acetabular component	18 (0.5%)	648 (0.3%)
Loosening femoral component	2 (0.0%)	227 (0.1%)
Peri-articular ossification	1 (0.0%)	40 (0.0%)
Other	4 (0.3%)	435 (0.2%)

More than 1 reason could be filled in as reason for revision

* This reason for revision might be a result of registration error

DMC: Dual mobility cup, UC: Unipolar cup, THA: total hip arthroplasty

Discussion

We showed that the use of primary DMC THA increased in the Netherlands, with differences in patient characteristics between DMC and UC THA patients. The 5-year revision rates were comparable, with no differences in specific subgroups.

Our study is the first register study focusing on cup survival in primary use of DMC. Our 5-year cumulative incidences of cup revision of 1.5% in DMC THA and 1.4% in UC THA are lower than the overall revision rates from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) (8), which reported 4.6% revision in 2,640 primary DMC THA and 3.3% in 327,847 primary UC THA. They did not specify the type of revision (insert, femoral head, cup, stem, or all). They also performed subgroup analysis and did not find a higher revision rate in any subgroup (8).

Our results differ from the Swedish Hip Arthroplasty Register (SHAR) (9) where a hazard ratio of 2.4 for revision of Avantage DMC THA compared with UC THA after correction for case mix factors and after exclusion of infections was found. However, their result is also based on the overall revision rates, while our HR of 0.8 is based on cup revisions only.

Risk for cup revision due to dislocations was low with primary use of a DMC. In our study 8/3,038 (0.2%) DMC THA patients had a cup revision because of a dislocation versus 1,017/215,953 (0.5%) in UC THA. Tarasevicius et al. (10) found in the Lithuanian Arthroplasty register at 5 years a revision rate for dislocation of 4/620 (0.7%) for primary DMC THA in comparison with 52/2,170 (2.4%) in a cemented Exeter cup. Revisions of UC THA are often preceded by 1 or more closed reductions (which are not reported in arthroplasty registers), while dislocations of DMC THA, being intraprosthetic or not, are difficult to treat by closed reduction and will more often need surgery with exchange of components (which are reported in arthroplasty registers). So revision rates for dislocation in UC and DMC do not reflect instability in the same way.

(Suspicion of) infection was the second commonest reason for cup revision in the DMC THA group (10/36). In the LROI only (suspected) prosthetic joint infections as reason for revision were registered. As shown earlier, implant registries largely underscore prosthetic joint infections (11) since incisions and drainages without component exchange are not included. In this respect Mukka et al. (12) published a study of 34 hips with DMC THA with soft-tissue debridement of 3 hips due to

superficial infection. Chughtai et al. (13) reported 453 primary DMC THA with 2 septic revisions after 2 years. Differences in patient characteristics and particularly comorbidities are probably the explanation for our high amount (0.3%) of revisions due to suspected infection (14). Furthermore, differences in hospital guidelines (early debridement in the case of wound problems), diagnosis, and treatment of implant infections could be a reason for more reported infections (15).

Comparable risk for revision rates was seen between cemented and uncemented cups. Batailler et al. (16) reviewed 21 studies with different uncemented DMCs in primary THA with 0–8% aseptic loosening after 2–22 years. They argued that the fixation of uncemented DMC can be affected by poor bone quality. This could have been the case in patients with (post)traumatic diagnosis or other comorbidities.

Strengths of our study are, first, that the LROI contains a large population-based nationwide database of primary THAs, with a completeness of nearly 100% (1,5) and an 8-year follow-up. Second, we focused our analyses on cup revisions, since type of revision (cup, stem, insert, and/or femoral head exchange) is specified in the LROI.

A limitation of this study is that in registries only limited variables are collected, correctness of data cannot be proven, and causality cannot be proven due to its observational nature. This might lead to residual confounding. Furthermore, closed dislocations are missed, since this procedure is not registered in the LROI, when no prosthesis component is added, exchanged, or removed. Dislocations for a DMC THA are almost always registered in the LROI since closed dislocation for DMC THA is most often impossible. Conversely, closed dislocation for UC THA can often be performed without surgery. This could lead to a lower revision rate in the UC THA group. The limited reliability of a diagnosis of infection has been discussed above.

In summary, the use of primary DMC THA in the Netherlands increased with differences in patient characteristics in comparison with UC THA. The 5-year revision rates for DMC THA were comparable to UC THA, even after adjustment for casemix factors. However, we need to be aware of residual confounding. To determine the exact role of DMC in primary THA compared with UC, randomized controlled trials or more subgroup analyses are needed.

Author contributions

All authors contributed to the conception of the study, data analysis, and preparation of the manuscript.

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Supplementary data

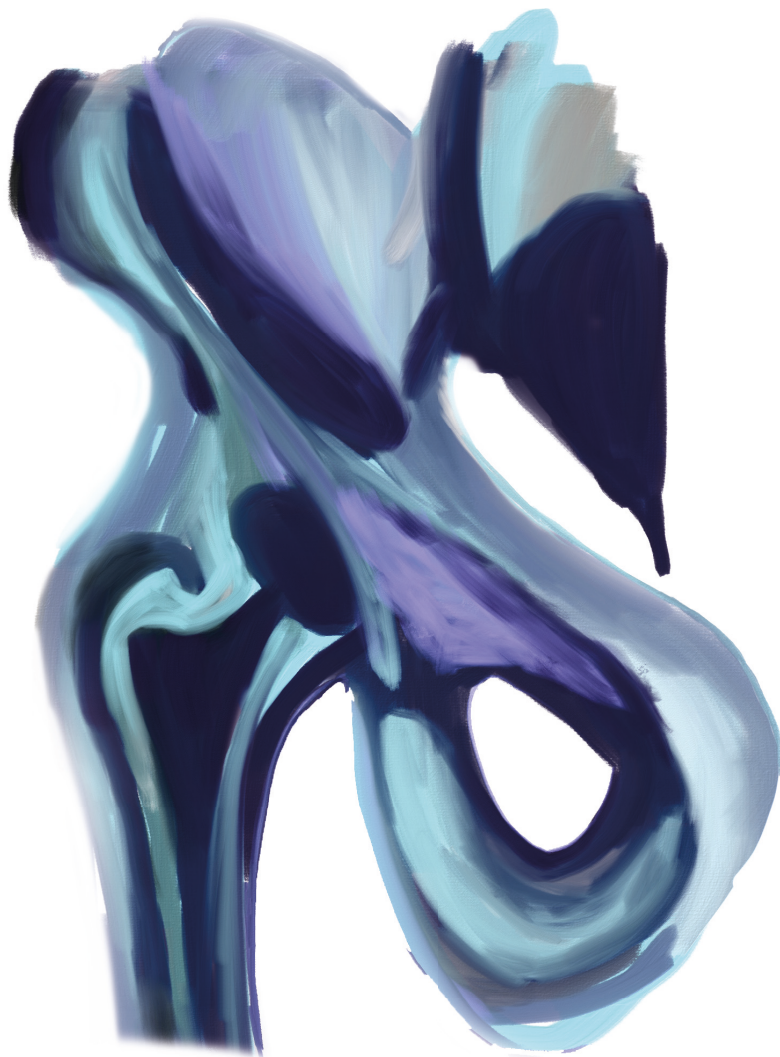
Table X. Kaplan-Meier survival rates of dual mobility cup and unipolar cup THA

	DMC THA		UC THA	
	n	5-year revision rate (CI)	n	5-year revision rate (CI)
Overall	3,038*	1.7% [1.0-2.5]	212,915	1.4% [1.4-1,4]
Diagnosis				
osteoarthritis	1,688	1.7% [0.7-2.8]	185,062	1.2% [1.3-1.3]
non-osteoarthritis	1,306	1.6% [0.8-2.4]	25,643	2.1% [1.9-3.0]
Previous surgery				
No	2,406	1.9% [0.9-2.9]	202,867	1.4% [1.4-1,4]
Yes	632	1.5% [0.1-1.6]	10,048	2.3% [2.0-2.7]
Cemented				
Yes	2,205	1.8% [0.6-3.0]	,988	1.7 [1.5-2,7]
No	800	1.7% [0.7-2,7]	140,843	1.3 [1.3-1,3]

*Numbers do not add up to total due to missing data

DMC: Dual mobility cup, UC: Unipolar cup, THA: Total hip arthroplasty

Chapter 4



Lower 5-year cup re-revision rate for dual mobility cups compared with unipolar cups

Report of 15,922 cup revision cases in the Dutch Arthroplasty Register (2007–2016)

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BA Swierstra

Abstract

Background and purpose

During revision hip arthroplasty the dual mobility cup (DMC) is widely used to prevent dislocation despite limited knowledge of implant longevity. We determined the 5-year cup re-revision rates of DMC compared with unipolar cups (UC) following cup revisions in the Netherlands.

Patients and methods

17,870 cup revisions (index cup revision) were registered in the Dutch Arthroplasty Register during 2007–2016. Due to missing data 1,948 revisions were excluded and the remaining 15,922 were divided into 2 groups: DMC (n = 4,637) and UC (n = 11,285). Crude competing risk and Multivariable Cox regression analysis were performed with cup re-revision for any reason as endpoint. Adjustments were made for known patient characteristics.

Results

The use of DMC (in index cup revisions) increased from 23% (373/1,606) in 2010 to 47% (791/1,685) in 2016. Patients in the index DMC cup revision group generally had a higher ASA class and the cups were mainly cemented (89%). The main indication for index cup revision was loosening. In the DMC group dislocation was the second main indication for revision. Overall 5-year cup re-revision rate was 3.5% (95% CI 3.0–4.2) for DMC and 6.7% (CI 6.3–7.2) for UC. Cup re-revision for dislocation was more frequent in the UC group compared with the DMC group (32% (261/814) versus 18% (28/152)). Stratified analyses for cup fixation showed a higher cup re-revision rate for UC in both the cemented and uncemented group. Multivariable regression analyses showed a lower risk for cup re-revision for DMC compared with UC (HR 0.5 (CI 0.4–0.6)).

Interpretation

The use of DMC in cup revisions increased over time with differences in patient characteristics. The 5-year cup re-revision rates for DMC were statistically significantly lower than for UC.

Background

Instability and dislocation after total hip arthroplasty (THA) is a common reason for revision surgery according to the implant registers of the Netherlands (22%) and Australia (23%) (1,2).

The dual mobility cup (DMC) is a “cup in a cup” and was developed in the 1970s to combine the low-friction arthroplasty principle of Charnley with the advantage of a big femoral head principle of McKee to increase implant stability (3). Second, the aim of this product was to decrease polyethylene rim damage from contact between femoral neck and acetabular liner and to restore near-normal range of motion.

Nowadays, the DMC is a well-accepted treatment option for patients with an increased risk for instability in primary and secondary THA (4). However, most literature has focused on dislocation rates rather than on longevity of the implant.

In the Dutch Arthroplasty Register (LROI) we found a 5-year cup revision rate for DMC of 1.5% (95% CI 1.0–2.3) after primary THA (5). In the Swedish arthroplasty register Hailer et al. (6) found a 2-year overall survival percentage of 93% (CI 90–97) for DMC after revision THA.

We studied the cup re-revision rates of DMC using data from the Dutch Arthroplasty Register and compared these results with unipolar cup (UC).

Patients and methods

The Dutch Arthroplasty Register (LROI) started in 2007 and has a completeness of 98% for hip revision arthroplasty (1). The LROI database contains patient, procedure, and prosthesis characteristics. For each component a product number is registered to identify the characteristics of the prosthesis, such as dual mobility or conventional cup.

The vital status of all patients is obtained on a regular basis from Vektis, the national insurance database on health care in the Netherlands, which records all deaths of Dutch citizens. For this study we included all index cup revisions in the period 2007–2016. An index cup revision was defined as the first registered

cup revision, isolated or as part of a total hip revision. A cup re-revision was defined as a procedure where at least the cup was exchanged or removed. Closed reduction after a dislocation or incision and drainage for infection without component exchange were not included in the LROI. Information from the primary (index) procedure is only known when the procedure was performed after 2007 and registered in the LROI. Records with a missing cup product number ($n = 1,948$) were excluded from the 17,870 index cup revisions registered. Thus, 15,922 index cup revisions were analyzed and divided into DMC ($n = 4,637$) or UC ($n = 11,285$) (Figure 1). The median follow-up was 6 (2-11) years.

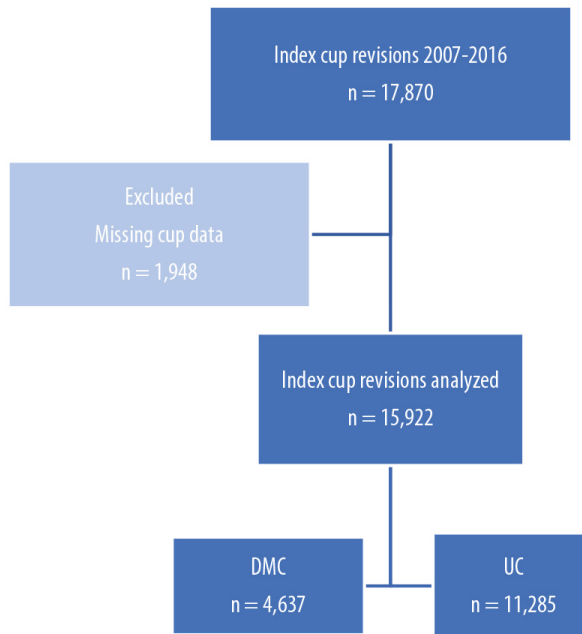


Figure 1. Patient flow

Statistics

The index UC and DMC revisions were described separately concerning patient and procedure characteristics. Survival time was calculated as the time from index cup revision to cup re-revision for any reason, death of the patient, or end of the follow-up (January 1, 2018). Cumulative crude incidence of cup re-revision was calculated using competing risk analysis, where death was

considered to be a competing risk (7). In addition, Kaplan–Meier survival analyses were performed.

Multivariable Cox proportional hazard analyses were performed to compare DMC and UC. Adjustments were made for sex, age at surgery, ASA class, and type of fixation to discriminate independent risk factors. BMI, Charnley score, and smoking status were not included as covariates, as these were only available in the LROI database since 2014.

For all covariates added to the model, the proportional hazards assumption was checked by inspecting log-minus-log curves and met.

Reasons for cup re-revision were described and compared using a chi-square test. P-values below 0.05 were considered statistically significant. For the 95% confidence intervals (CI), we assumed that the number of observed cases followed a Poisson distribution.

Ethics, funding, and potential conflicts of interests

The dataset was processed in compliance with the regulations of the LROI governing research on registry data. No external funding was received. No competing interests were declared.

Results

The use of DMC (in index cup revisions) increased from 23% (373/1,606) in 2010 to 47% (791/1,685) in 2016 (Figure 2) with 8 different types of DMC used (Table 1).

Patients who received a DMC had a higher ASA class and 89% of the DMC group was cemented versus 59% of the UC group. The most frequent indication for index cup revision was loosening of the acetabular component (37–47%) in both groups. Dislocation was more frequently registered as reason for revision in DMC (35% vs. 12%), while (suspicion of) infection was more frequently registered in the UC group (15% vs. 4%) (Table 2).



Figure 2. Trend in the use of dual mobility cup (DMC) in revision hip arthroplasty in the period 2010–2016 in the Netherlands (n=4,637)

Table 1. Types of dual mobility cups used in index cup revision in the period 2007–2016 the Netherlands

Type	Cemented	Uncemented
Biomet Advantage	3,492	86
Biomet Advantage Reload		167
Biomet Advantage Rev HA		19
Smith & Nephew Polarcup	211	194
Amplitude Saturne	250	43
Mathys SeleXys DS Cup	106	35
Groupe LEpine Cupule Quattro	32	
Groupe Lepine Cupule HAP Press-F		2

Over half of the cup re-revisions were performed for loosening of the acetabular component. Dislocation was the second most frequent reason for cup re-revision (32%) in the UC group, while this was 18% in the DMC group. Suspicion for infection was the 2nd most frequently registered reason (32%) for cup re-revision in the DMC group, compared with 16% in the UC group (Table 3). From the 79 DMC cup re-revisions that loosened, 67 were cemented.

Table 2. Patient characteristics in index cup revisions according to type of cup (n = 15,922)

	DMC N = 4,637	UC N = 11,285
Male sex, n (%)	1,445 (31%)	3,692 (33%)
Mean age in years (SD)	74 (10)	71 (12)
ASA class		
I	478 (11%)	1,824 (18%)
II	2,642 (60%)	6,307 (60%)
III-IV	1,287 (29%)	2,308 (22%)
Fixation cup		
Cemented	4,057 (89%)	6,468 (59%)
Uncemented	487 (11%)	4,554 (41%)
Type of revision		
Partially (only cup)	3,203 (69%)	6,411 (57%)
Total revision	1,434 (31%)	4,874 (43%)
Reason for index revision¹		
Loosening acetabular component	1,728 (37%)	5,320 (47%)
Dislocation	1,619 (35%)	1,301 (12%)
Infection	185 (4%)	634 (5%)
Loosening femoral component	673 (15%)	2,120 (19%)
Girdlestone/spacer	167 (4%)	534 (5%)
Periprosthetic fracture	223 (5%)	445 (4%)
Cup/liner wear	665 (14%)	1,278 (11%)
Peri-articular ossification	157 (3%)	387 (3%)
Symptomatic metal-on-metal bearing	234 (5%)	818 (7%)
Other	707 (15%)	2,592 (23%)

Numbers do not add up to total due to missings

¹ The total proportion is over 100% since more than 1 reason for revision can be registered

DMC: dual mobility cup, UC: unipolar cup

Table 3. Reason for cup re-revision according to type of acetabular cup

	DMC n = 152	UC n = 814
Reason for re-revision¹		
Loosening acetabular component	79 (52%)	423 (52%)
Dislocation	28 (18%)	261 (32%)
Infection	48 (32%)	127 (16%)
Loosening femoral component	12 (8%)	61 (8%)
Girdlestone/spacer	20 (12%)	44 (5%)
Periprosthetic fracture	8 (5%)	43 (5%)
Cup/liner wear	7 (5%)	27 (3%)
Peri-articular ossification	2 (1%)	17 (2%)
Symptomatic metal-on-metal bearing	2 (1%)	11 (1%)
Other	15 (10%)	88 (11%)

¹ The total proportion is over 100% since more than 1 reason for revision can be registered

DMC: dual mobility cup, UC: unipolar cup

The 5-year crude re-revision rate of DMC was 3.5% (CI 3.0-4.2) and 6.7% (CI 6.3-7.2) for UC (Figure 3). Stratified analyses according to type of cup fixation (cemented versus uncemented) showed comparable differences in 5-year crude cumulative incidence of re-revision in favor of the DMC group, both using competing risk analysis (Table 4) and Kaplan-Meier survival analysis (Table 5).

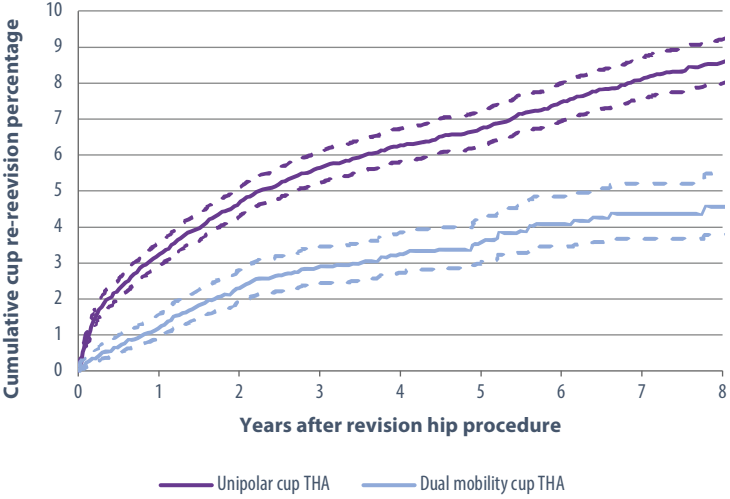


Figure 3. Cumulative incidence of cup re-revision according to type of cup in the period 2007-2016 in the Netherlands (n=15,923). THA: total hip arthroplasty

Table 4. Crude 5-year cumulative incidence of cup re-revision according to type of acetabular cup. Competing risk analysis was used

	DMC revision hip arthroplasty		UC revision hip arthroplasty	
	n	5-year cumulative incidence of cup-re-revision	n	5-year cumulative incidence of cup re-revision
Overall	4,637	3.5% (CI 3.0-4.2)	11,285	6.7% (CI 6.3-7.2)
Cup fixation				
Cemented	4,057	3.6% (CI 3.0-4.4)	6,466	7.4% (CI 6.7-8.1)
Uncemented	487	3.7% (CI 2.3-6.0)	4,554	5.7% (CI 5.1-6.5)

DMC: dual mobility cup, UC: unipolar cup

Table 5. 5-year cumulative incidence of cup re-revision according to type of acetabular cup using Kaplan-Meier survival analyses

	DMC revision hip arthroplasty		UC revision hip arthroplasty	
	n	5-year revision rate	n	5-year revision rate
Overall	4,637	3.8% (CI 3.2-4.4)	11,285	6.9% (CI 6.3-7.5)
Cup fixation				
Cemented	4,057	3.9% (CI 3.1-4.6)	6,466	7.7% (CI 6.9-8.5)
Uncemented	487	3.8% (CI 3.6-4.0)	4,554	5.9% (CI 5.1-6.7)

DMC: dual mobility cup, UC: unipolar cup

Multivariable survival analyses showed an adjusted hazard ratio of 0.5 (CI 0.4–0.6) for re-revision of DMC compared with UC. Adjustments were made for sex, age at surgery, ASA class, and type of fixation to discriminate independent risk factors.

Discussion

This large register study in the Netherlands showed lower cup re-revision rates of DMC compared with UC.

Currently, DMC is increasingly used in both primary and revision hip arthroplasty (5,8). A recent systematic review from Darrith et al. (8) containing all English-language articles dealing with dual mobility (primary and revision) arthroplasty between 2007 and 2016 showed low rates of dislocation (primary 0.5% and revision 2%). The overall survival of the DMC in revision THA was 97% at a mean of 5 years. A limitation of this study is that it could not distinguish between total and partial revisions.

The number of register studies of revision DMC is scarce. Gonzalez et al. (9) compared DMC and UC THA for prevention of dislocation after revision THA. In this prospective hospital registry-based cohort including all total and cup-only revision THAs (n = 316) they found a lower incidence of dislocation in the case of a DMC (2.7% versus 7.8%) but did not study the longevity of the implant.

In 2012 a register study based on 228 patients from the Swedish Hip Arthroplasty Register (SHAR) showed 7% overall re-revision rates for any reason after a DMC at 2 years follow-up (6). Until our study, this was the only register study focusing

on re-revision rates according to type of cup. We cannot compare their outcome with our results, as our endpoint was cup re-revision and not overall re-revision.

A limitation of register studies is the risk for selection bias. It is possible that different cup designs were used for different types of revisions or different types of patients. Therefore, we examined the patient characteristics in detail. We found higher ASA class in the DMC group, but after correction for casemix factors DMC still showed lower 5-year revision rates compared with UC. Recent annual reports from the Swedish and Australian hip registers found higher ASA class in case of revision surgery. (10, 11). However, they did not distinguish between types of cup.

Besides differences between patient characteristics we also examined differences in fixation method. In our study 89% of DMC were cemented, compared with 59% in UC. The amount of cup re-revision because of loosening was the same in the DMC and UC group (52%). We performed stratified analyses to correct for difference in fixation method between DMC and UC and still found a lower cup re-revision rate for DMC compared with UC. The annual report from Sweden showed a trend towards an increased use of cemented DMC in cup revisions (34% of the revision cases received a cemented Avantage cup) (11). However, these revision data were not analyzed in subgroups, for example type of fixation.

It is also interesting to analyze differences between various DMC designs as the choice of implant might depend on doctor or hospital preferences. Hopefully, after a few more years the numbers will increase and we shall be able to do further analyses. Nevertheless, register studies have a limited possibility to analyze differences in patient characteristics as this depends strongly on the number of registered variables. Therefore, registries should be taken along with prospective cohort studies, in order to collect a more extensive set of patient variables.

Our database on revision hip arthroplasties does not contain information on the procedures performed before the start of the LROI in 2007. Therefore, we do not know the type and follow-up of the primary procedure as well as the primary diagnosis of the patient. We do not know whether the first revision procedure (defined as index revision) included in our revision hip arthroplasty database was really the first revision of a hip or a consecutive revision procedure. On the other hand, including all revision hip arthroplasties available in the LROI

resulted in the largest population-based study to date of almost 18,000 cup revisions with a median follow-up of 6 years.

In summary, the use of DMC in cup revisions increased over time with differences in patient characteristics and indications. The 5-year cup re-revision rates for DMC were statistically significantly lower than for UC. This promising mid-term result justifies continued use of DMC in revision hip arthroplasty in anticipation of longer term results.

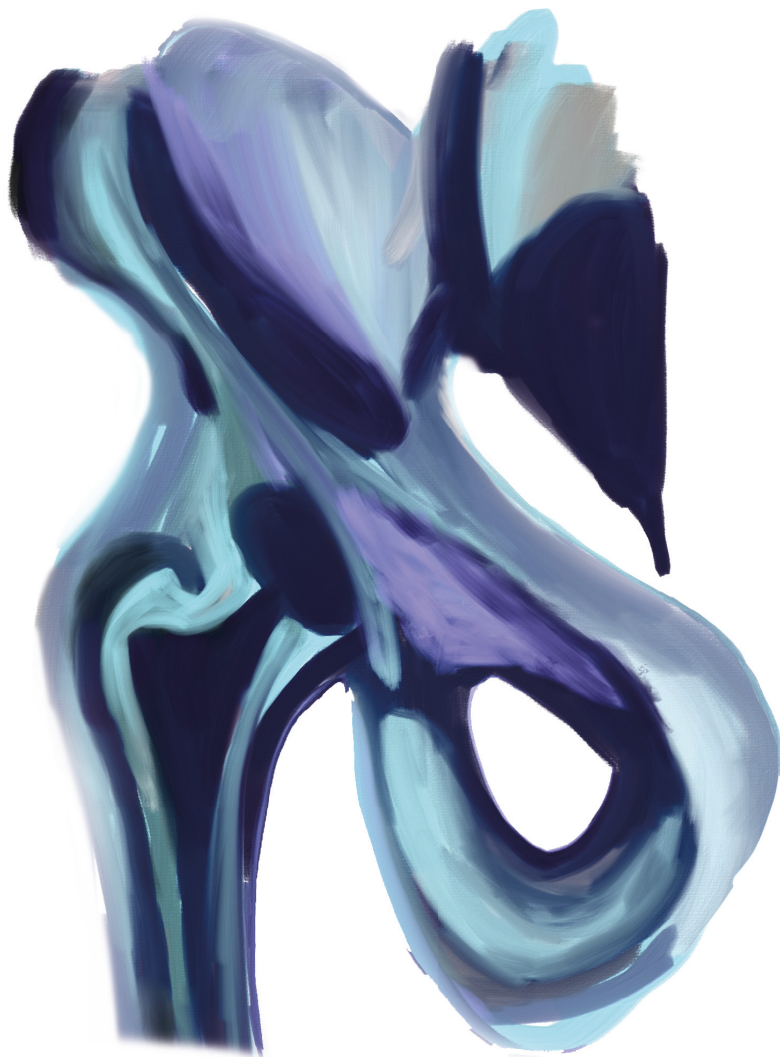
Author contributions

All authors contributed to the conception of the study, data analysis, and preparation of the manuscript.

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Chapter 5



Low revision rate of dual mobility cups after arthroplasty for acute hip fractures

Report of 11,857 hip fractures in the Dutch Arthroplasty Register (2007–2019)

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Abstract

Background and purpose

Dislocation is one of the most frequent reasons for cup revision after total hip arthroplasty (THA) for an acute fracture. A dual mobility cup (DMC) might reduce this risk. We determined the cup revision rate after THA for an acute fracture according to type of cup.

Patients and methods

All THAs for an acute fracture registered in the Dutch Arthroplasty Register (LROI) during 2007–2019 were included ($n = 11,857$). Type of cup was divided into DMC and unipolar cup (UC). Competing risk analyses were performed with cup revision for any reason as endpoint. Multivariable Cox regression analyses with outcome cup revision were performed adjusted for sex, age, ASA class, and surgical approach, stratified for UC THA with femoral head size of 32 mm and 22–28 mm.

Results

A DMC was used in 1,122 (9%) hips. The overall 5-year cup revision rate for any reason after THA for acute fracture was 1.9% (95% CI 1.6–2.2). Cup revision for dislocation within 5 years was performed in 1 of 6 DMC THAs versus 108 of 185 (58%) UC THAs. Univariable Cox regression analyses showed no statistically significant difference in cup revision rate between DMC and UC (HR 0.8 (CI 0.4–1.5)). Multivariable Cox regression analyses showed lower risk of cup revision in DMC THA ($n = 1,122$) compared with UC THA with 22–28 mm femoral head size ($n = 2,727$) (HR 0.4 (CI 0.2–0.8)).

Interpretation

The 5-year cup cumulative incidence of revision after THA for acute fracture was comparable for DMC and UC THA. However, DMC THA had a lower risk of cup revision than UC THA with 22–28 mm femoral head.

Background

The risk for revision in case of total hip arthroplasty (THA) after an acute fracture is higher than after hemiarthroplasty (1). Dislocation is one of the most frequent reasons for cup revision after an acute fracture (2). We have shown low cup revision rates for dislocation using dual mobility cup (DMC) THA in patients with osteoarthritis (3). The use of DMC in THA after an acute fracture might therefore be beneficial to prevent this complication. At the same time also femoral head size (in unipolar cups (UC)) and surgical approach influence the risk of revision for dislocation (4-7). We hypothesized that the cup revision rate for dislocation in THA for acute fracture is lower with DMC than UC but that this can be affected by femoral head size (in UC) and surgical approach. We therefore determined the cup revision rate because of dislocation after THA for an acute fracture according to type of cup and head size.

Patients and methods

The Dutch Arthroplasty Register (LROI) started in 2007 and has a completeness of 98% for primary and revision hip arthroplasty (8). The LROI database contains patient, procedure, and prosthesis characteristics. For each component a product number is registered to identify the characteristics of the prosthesis, such as dual mobility or unipolar cup.

The vital status of all patients is obtained actively on a regular basis from Vektis, the national insurance database on health care in the Netherlands, which records all deaths of Dutch citizens (9).

For this study we included all primary THAs in the period 2007–2019 with a diagnosis of acute fracture. A cup revision was defined as a procedure where at least the cup or the cup and liner were exchanged or removed. Closed reduction after a dislocation or incision and drainage for infection without component exchange are not included in the LROI.

Records with a missing cup product number ($n = 1,061$) and metal-on-metal hip arthroplasties were excluded ($n = 189$). 11,857 primary THAs were included and divided into 2 groups: DMC THA and UC THA (Figure 1).

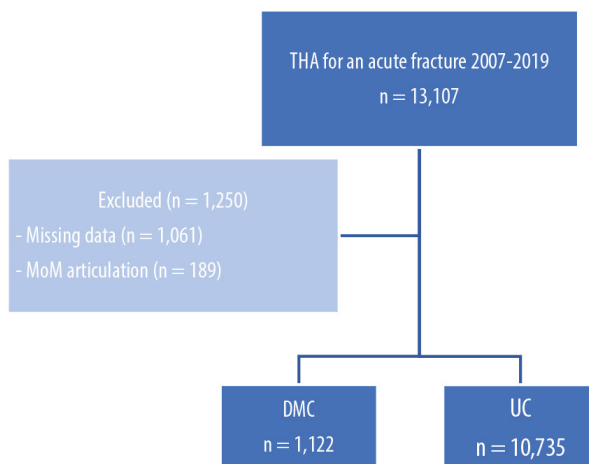


Figure 1. Patient flow

Statistics

UC THAs and DMC THAs were described separately concerning patient and procedure characteristics. Survival time was calculated as the time from primary THA to cup revision for any reason, death of the patient, or end of follow-up (December 31, 2019). Cumulative crude incidence of cup revision was calculated using competing risk analysis, where death was considered to be a competing risk (10, 11).

Multivariable Cox regression analyses were performed to compare DMC and UC THA. Adjustments were made for sex, age, ASA class, and surgical approach and stratified by UC femoral head size (22–28 mm and 32 mm). BMI and smoking status were not included as covariates, since these have only been available in the LROI database since 2014.

For all covariates added to the model, the proportional hazards assumption was checked by inspecting log-minus-log curves and met.

Reasons for cup revision were described and compared using a chi-square test. P-values below 0.05 were considered statistically significant. For the 95% confidence intervals (CI), we assumed that the number of observed cases followed a Poisson distribution.

Ethics, funding, and potential conflicts of interests

The LROI uses the opt-out system to require the informed consent of patients. The dataset was processed in compliance with the regulations of the LROI governing research on registry data. Data are available from the LROI but restrictions apply to the availability of these data, which were used under license for the current study. No external funding was received. No competing interests were declared.

Results

11,857 THAs for acute fracture were included. In 9% a DMC THA and in 91% a UC THA was used. The median follow-up was 3.4 years (0–13), with 35% of records having a follow-up period of 5 years or longer.

Of all included acute fracture THA patients, 26% (CI 22–31) in the DMC THA group died and 16% (CI 15–17) in the UC THA group died within 5 years of the primary procedure.

The use of a DMC THA in acute fracture patients increased from 15 in 2009 (3% of all THAs) to 299 (18% of all THAs) in 2019 (Figure 2). The mean age was 70 years in both groups. The proportion ASA class III–IV was higher in the DMC THA group (40%) compared with the UC DMC group (24%). In 70% the DMC THA was cemented compared with 32% in the UC THA group. The most frequent approach was posterolateral in both groups (Table 1). In the UC THA group, most often a 32 mm head was used (51%). There were 2,727 (26%) small-sized heads used (22–28 mm) and 23% had a 36 mm head size.

The overall 5-year cumulative incidence of cup revision rate for any reason after THA for acute fracture was 1.9% (CI 1.6–2.2) with 6 of 1,122 cup revisions for DMC THA and 185 of 10,735 cup revisions for UC THA. The 5-year cumulative incidence of cup revision rate for DMC THA was 1.0% (CI 0.4–3.0) and 2.0% (CI 1.7–2.3) for UC (Figure 3). In UC THA with 36 mm heads the 5-year cumulative incidence of cup revision rate was 1.4% (CI 0.9–2.0) and for UC THA with 32 mm heads this was 1.7% (CI 1.3–2.1), while for UC THA with 22–28 mm heads this was 2.7% (CI 2.2–3.4).

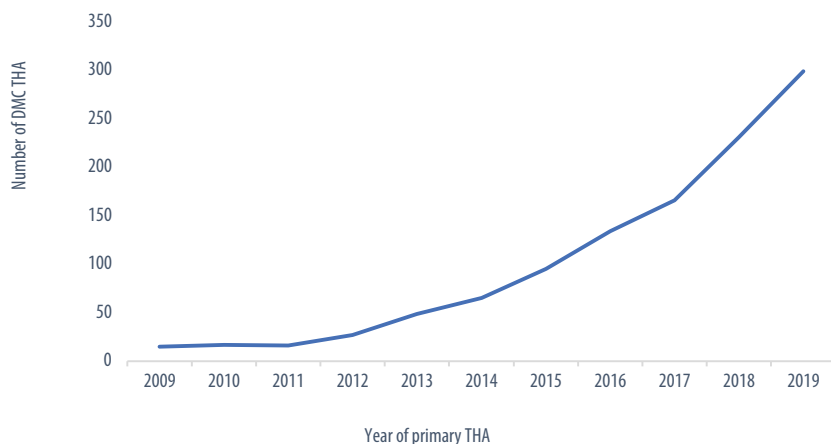


Figure 2. Use of DMC THA in case of an acute fracture in the period 2009–2019 in the Netherlands. DMC: dual mobility cup, THA: total hip arthroplasty

Table 1. Patient characteristics of THAs for acute fracture according to type of cup (n = 11,857). Values are count (%) unless otherwise specified

	DMC THA n = 1,122^b	UC THA n = 10,735^b
Sex (n (%))		
Male	382 (34)	3,324 (31)
Female	738 (66)	7,395 (69)
Age (median (p5-p95))^a		
	70(52-86)	70(54-84)
Previous surgery on affected hip (n (%))		
Yes	108 (10)	650 (6)
No	1,002 (90)	9,749 (94)
ASA class (n (%))		
I	75 (7)	1,702 (16)
II	595 (53)	6,153 (59)
III-IV	448 (40)	2,531 (25)
Fixation (n (%))		
Cemented	776 (70)	3,344 (32)
Reverse hybrid	135 (12)	327 (3)
Hybrid	58 (5)	997 (9)
Uncemented	137 (13)	5,923 (56)
Approach (n (%))		
Anterior	61 (5)	1,142 (11)
Anterolateral	10 (1)	874 (8)
Direct lateral	84 (8)	2,345 (22)
Posterolateral	955 (85)	6,240 (59)
Other	8 (1)	34 (0)
Diameter femoral head (n (%))		
22-28 mm	1094 (100)	2,727 (26)
32 mm	3 (0)	5,380 (51)
36 mm		2,382 (23)
≥ 38 mm		60 (0)

^a 5th percentile to 95th percentile, ^b Numbers do not add up to total due to missing data
DMC: dual mobility cup, UC: unipolar cup; THA: total hip arthroplasty

Univariable as well as Multivariable Cox regression analyses showed a statistically significant lower risk for cup revision in the DMC THA group compared with UC THA group with a 22–28 mm femoral head (HR adjusted 0.4 (CI 0.2–0.8)), but no statistically significant difference in cup revision rate between DMC and UC THAs with a 32 mm femoral head (HR adjusted 0.6 (CI 0.3–1.2)) (table 2).

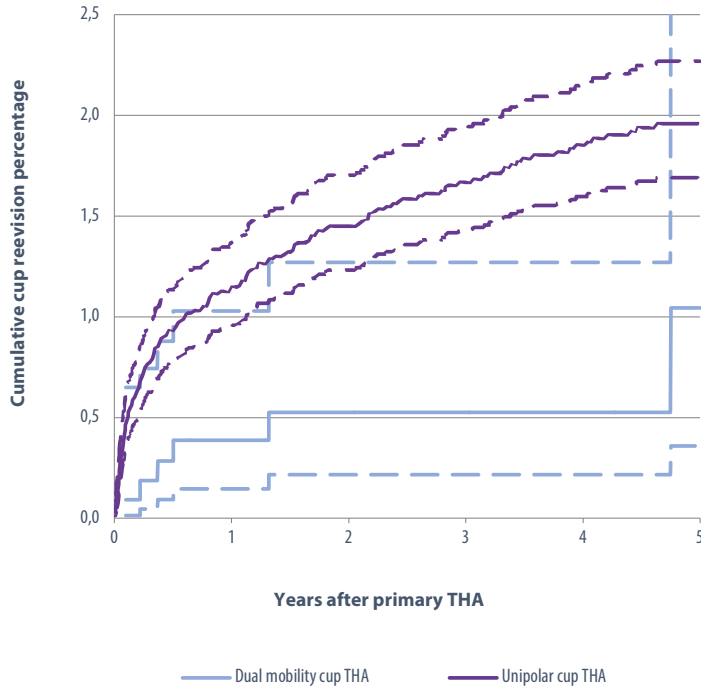


Figure 3. Crude cumulative overall cup revision rate of THAs for acute fracture according to type of cup

THA: total hip arthroplasty

Table 2. Multivariable Cox regression analysis for DMC THA and UC THA compared with UC THA 32 mm femoral head and 22–28 mm femoral head in acute fracture patients

	n	HR crude	HR adjusted ^a
Type of hip prosthesis			
DMC THA	1,122	0.7 (0.4-1.4)	0.6 (0.3-1.2)
UC THA 32 mm head	5,380	1.0	1.0
Type of hip prosthesis			
DMC THA	1,122	0.5 (0.2-0.9)	0.4 (0.2-0.8)
UC THA 22-28 mm head	2,727	1.0	1.0

^a Adjusted for age, sex, ASA classification, and surgical approach.

DMC: dual mobility cup, UC: unipolar cup, THA: total hip arthroplasty

1 of 6 DMC THAs were revised for dislocation versus 108 of 185 (58%) UC THAs. (Suspicion of) infection (3/6) and cup loosening (4/6) were other registered reasons for cup revision in the DMC group, compared with 23/185 (12%) and 29/185 (16%) in the UC group (table 3).

Table 3. Reason for cup revision within 5 years according to type of cup

	DMC THA n = 1,122	UC THA n = 10,735
All cup revisions within 5 years	6	185
Reason for revision^a		
Dislocation	1	108
Infection	3	23
Wear	0	5
Periprosthetic fracture	0	13
Loosening femoral component	1	18
Loosening acetabular component	4	29
Peri-articular ossification	1	2
Other	2	32

^aThe sum is higher than the total amount since more than 1 reason for revision can be registered
DMC: dual mobility cup, UC: unipolar cup, THA: total hip arthroplasty

Discussion

We found that DMC is increasingly used in THA for acute fractures. The clinicians' expectation to reduce the risk for dislocation is the most probable reason to use this more expensive cup. We found 6 cup revisions within 5 years when a DMC THA was used, and only 1 of these 6 was revised for dislocation. Our focus on short-term revision rates is justified as the majority of dislocations occur early after the index operation (12).

In the Nordic Arthroplasty Register Association (NARA) a reduced revision risk for DMC in THA for acute femoral neck fracture has been shown by Jobory et al. (13). They matched 4,520 hip fractures treated with a DMC THAs to 4,520 hip fractures with UC THAs and found a lower risk for cup revision for dislocation for DMC, with a hazard ratio of 0.32 adjusted for approach. However, they only included head size 32 and 36 mm in contrast to our study in which head sizes 22–28 mm were included as well. Tabori-Jensen et al. (14) found low dislocation rates of DMC THA after acute femoral neck fracture in a cohort study of 966 hips. After mean 5.4 years follow-up, 8 cups were revised, 3 due to repeated dislocations. Their findings are comparable to our results.

We found a statistically significant lower risk for cup revision in the DMC THA group compared with UC THA group with a 22–28 mm femoral head. This is in accordance with our hypothesis and with the findings of Kostensalo et al. (6), based on data from the Finnish Arthroplasty Register, who found a reduced dislocation revision rate in head sizes > 28 mm. Comparable results were found in register studies from Norway (4), Sweden (5) and the Netherlands (7).

Our hypothesis that surgical approach might influence the (cup) revision rate could not be confirmed. This influence has been shown in another recent LROI study by Moerman et al. (15), who found that posterolateral approach was a risk factor compared with other approaches (HR 1.0 versus 0.7) for revision in case of THA or hemiarthroplasty for hip fracture (74% of their study population underwent a hemiarthroplasty). Also based on LROI data, Zijlstra et al. (7) showed that the posterolateral approach resulted in higher revision rates due to dislocation compared with all other surgical approaches (HR = 1.0 vs. 0.5–0.6) in the case of THA for primary osteoarthritis.

A strength of our study is the focus on cup revisions only, since type of revision (cup, stem, insert, and/or femoral head exchange) is specified in the LROI.

A limitation of register studies is the risk for selection bias. First, there is a possibility that DMC was used exclusively in a few clinics and/or by single surgeons because of preference. Second, it is possible that different cup designs were used for different types of patients for other reasons such as patient comorbidity. We tried to make an estimation of frailty and comorbidity using patient characteristics available in the LROI and found no statistically significant differences between the 2 groups based on age and ASA classification. We plan further analyses with a more extensive set of patient variables including smoking status, Charnley score and BMI.

Another limitation of this study is the fact that an acute hip fracture was not further specified in the LROI database. Most often an acute femoral neck fracture will have been the indication for a THA, but some trochanteric fractures cannot be ruled out.

Closed reductions for dislocations are not registered in the LROI. Reductions for UC THA can often be performed without surgery, but closed reductions are often impossible in DMC THA needing surgery with component exchange and hence registration in the LROI. This means that the dislocation revisions in DMC

reflect the number of postoperative dislocations better than the dislocation revisions in UC.

In conclusion, the 5-year cumulative incidence of cup revision rate after THA for acute fractures was 1.9% (CI 1.6–2.2) being comparable for DMC and UC THA with a 32 mm femoral head. However, DMC THA had a lower risk of cup revision than UC THA with a 22–28 mm femoral head.

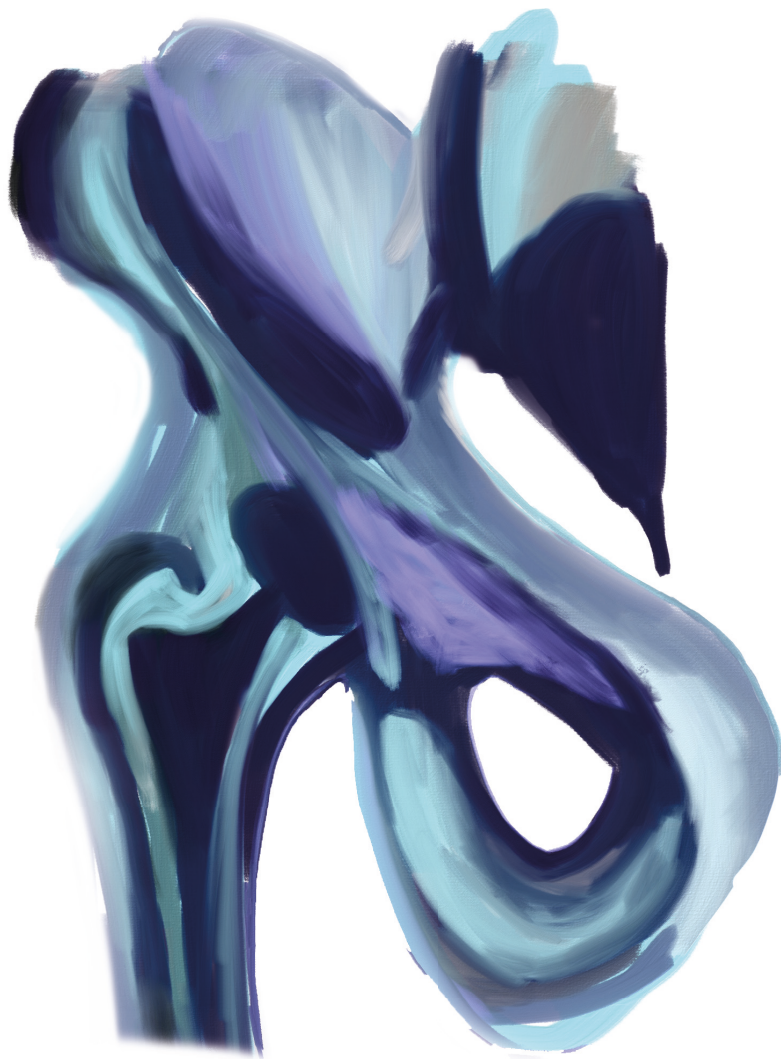
Author contributions

All authors contributed to the conception of the study, data analysis, and preparation of the manuscript.

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Chapter 6



Revision Risk of Unipolar and Bipolar Hemiarthroplasties in the Dutch Arthroplasty Register

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Abstract

Background

Hemiarthroplasty (HA) for hip fractures can be performed with a unipolar or bipolar head. We describe the use of unipolar and bipolar HA after a hip fracture in the Netherlands and determined revision rates and risk factors.

Methods

All HAs for an acute hip fracture registered in the Dutch Arthroplasty Register (LROI) during 2007 to 2021 were included; 44,127(88%) unipolar and 6,013(12%) bipolar HAs. Competing risk survival analyses were performed with revision for any reason as the endpoint. Multivariable Cox regression analyses were performed adjusting for patient and surgery-related factors.

Results

The 1-year, 5-year, and 10-year revision rates were comparable for unipolar and bipolar HA. Cox regression analysis showed a hazard ratio of 1.2 (95% confidence interval (CI) 1.0 to 1.4) after adjustment for confounders for bipolar heads. In cases of a cemented stem, the 1-year cumulative incidence of revision was lower (1.5% (CI 1.4-1.7) compared to uncemented stems (2.4% (CI 2.1-2.7); uncemented stems showed higher risks for revision after adjustment compared to cemented stems (hazard ratio 1.4 (CI 1.2-1.5)). The anterior, anterolateral, and straight-lateral approach showed lower risk for revision compared to the posterolateral approach.

Conclusion

The revision rate for bipolar HA and unipolar HA was comparable. However, after adjustment for potential confounders the risk for revision showed an estimated 20% increased revision risk for bipolar heads, although not statistically significant. For both head types, the risk for revision was significantly higher when an uncemented stem was chosen or the posterolateral approach was used.

Background

Hemiarthroplasty (HA) in case of hip fractures was introduced by Moore and Thompson for salvage after failure of internal fixation with a large metal head articulating in the acetabulum (1,2). Early complications like periprosthetic fracture, dislocation, and infection have been described. Also, late complications, including cartilage wear of the acetabulum, protrusion of the metal head through the acetabulum, and femoral component loosening, were common. The ongoing development of HA resulted in different head types (unipolar and bipolar) and also different surgical techniques (type of approach and type of fixation). The bipolar head prosthesis consists of a smaller spheric head articulating within an outer shell which articulates directly with the acetabulum, and could theoretically reduce cartilage wear, decrease protrusion, and decrease dislocation rates compared to unipolar heads (3). However, the evidence for reduced revision risk in registry data is not unequivocal.

In 2014, Gjertsen et al. presented survival rates of bipolar HA in 2 Nordic registries and showed 96.3% survival after 1 year and 95.5% after 5 years (4). In 2018, Moerman et al. published revision rates and risk factors of total hip arthroplasty and HA after an acute hip fracture with data from the Dutch Arthroplasty Register (LROI) and did not show a statistically significant difference in revision hazards between unipolar and bipolar heads (hazard ratio (HR) 0.9 (95% confidence interval (CI) 0.7 to 1.1)) (5). More recently, in 2021, Farey et al. analyzed the revision rates of 62,875 primary HAs from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJR). The risk for revision for a unipolar HA was comparable to a bipolar HA for the first 2.5 years, but higher after 2.5 years (HR 1.9 (CI 1.5 to 2.4)) (6). However, patient and surgical procedure characteristics differ between countries, which justifies looking for confirmation of these international results in the Netherlands (7). The aim of our study was to describe the use of unipolar and bipolar HA after a hip fracture in the Netherlands and determine risk factors for revision. We hypothesized that the revision rates are lower in case of bipolar HA.

Materials and methods

The LROI started in 2007 and has a completeness of 96% for HA performed by orthopaedic surgeons and 74% for HA performed by trauma surgeons (8). The LROI database contains patient, procedure, and prosthesis characteristics.

We included sex, age, American Society of Anesthesiologists (ASA) physical status classification, body mass index (BMI), smoking, surgical approach, and stem fixation. The BMI data were only available in the LROI database since 2014 and was categorized as (underweight (<18.5), normal weight (>18.5 to 25), overweight (>25 to 30), obesity (>30 to 40), and morbid obesity (>40)). For each component, a product number was registered to identify characteristics of the prosthesis, including unipolar or bipolar head, based on the implant library. Vital status of all patients was obtained actively on a regular basis from Vektis, Zeist, the national insurance database on health care in the Netherlands, which records all deaths of Dutch citizens (9). The LROI uses the opt-out system to obtain informed consent of patients. Revision is defined by the LROI as a procedure where one or more components of the prosthesis were exchanged, added, or removed.

For this study, we included all registered primary HAs inserted for an acute fracture of the hip in the period 2007 to 2021. There were 923 cases excluded because the data about type of head (bipolar or unipolar) were missing. The remaining 50,140 cases existed of 44,127 (88%) unipolar and 6,013 (12%) bipolar HAs (Figure 1). Survival time was calculated as the time from the primary operation to the first revision for any reason, death of the patient or end of the follow-up (December 31st, 2021). Only revisions with component exchange are registered in the LROI database. The LROI does not record reoperations in which no component is exchanged, hence debridement for early infection or reoperations for femoral periprosthetic fractures with osteosynthesis were not included. Also, we had no information about conservatively treated dislocations.

Data analyses

Unipolar and bipolar HA were described separately concerning patient and procedure characteristics. Implant survival after 1-, 5-, and 10-years was calculated using competing risk (CR), where death was considered to be a competing risk because of the suspected high mortality rate in this elderly patient group (10). Multivariable Cox regression analyses were performed to compare risk for revision between unipolar and bipolar HA. Unadjusted and adjusted Cox models were performed to examine the association between head type and risk for revision with and without adjustment for potential confounders. Examined confounders were age (<50, 50 to 59, 60 to 69, 70 to 79, 80 to 84, 85 to 90 and >90 years), surgical approach (anterior, anterolateral, posterolateral, direct lateral, and other), and type of stem fixation (cemented or uncemented). As BMI as confounder was only available since 2014, a sensitivity analysis was

performed with and without adjustment for BMI. No change in HR occurred, and afterward we decided to exclude BMI as confounder and include also patients before 2014 in the Cox model. For all covariates added to the model, the proportional hazards assumption was checked by inspecting log-minus-log curves and met. More than one reason for revision can be chosen in the LROI. Reasons for revision were described and compared using Chi-square tests. P values below .05 were considered statistically significant. For the 95% CIs, we assumed that the number of observed cases followed the Poisson distribution. This study was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

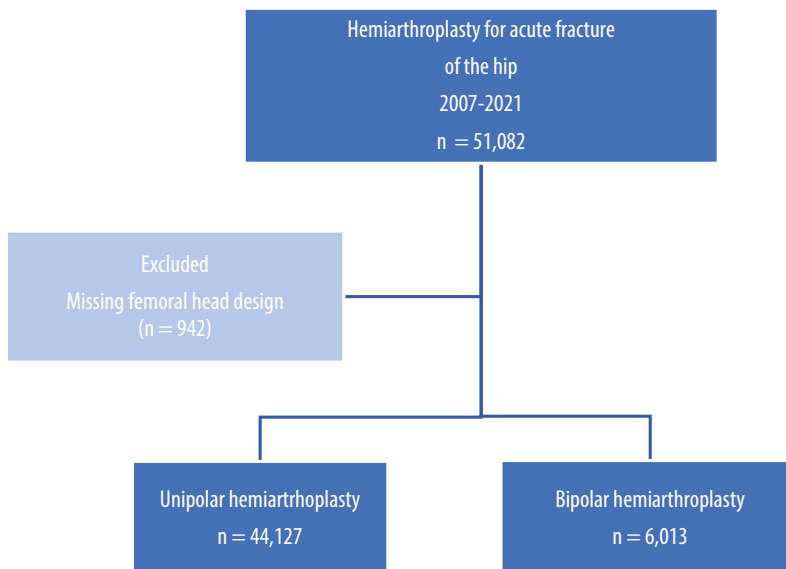


Figure 1. Patient Flow

Patient Characteristics

The median age was 84 years (p5-p95 range 69 to 94 years) in the unipolar and 82 years (p5-p95 range 67 to 93 years) in the bipolar group. The ratio of sex, ASA class, smoking, and BMI classification was comparable between the groups. The most frequently used surgical approach for either bipolar and unipolar HA was posterolateral and the majority of the stems were cemented (Table 1). The absolute use of bipolar heads in HA was stable over the last 10 years, although the proportion of bipolar heads decreased over time from 18% in 2015 to 8% in

2020 (Figure 2). The overall median follow-up was 2.1 years (range, 0 to 15), with 21% of records having a follow-up period of over 5 years. 46% (n = 20,422) of patients treated with a unipolar HA and 41% (n = 2,459) of patients treated with a bipolar HA died within 5 years after the procedure. There were 2.7% (n = 1,190) patients treated with a unipolar HA revised and 2.7% (n = 162) of patients treated with a bipolar HA revised.

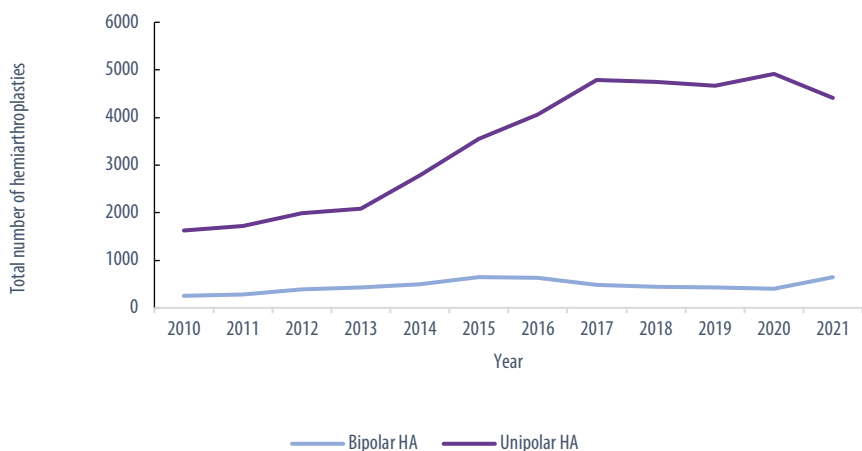


Figure 2. Use of unipolar and bipolar hemiarthroplasty over time in the Netherlands
HA: Hemiarthroplasty

Table 1. Patient characteristics of hemiarthroplasty for hip fracture according to type of head (n = 50,140)

	Bipolar HA n = 6,013	Unipolar HA n = 44,127
Sex (n (%))		
Men	1,944 (32)	14,148 (32)
Women	4,059 (68)	29,932 (68)
Missings	10 (0)	47 (0)
Age (median (p5-p95 range)) (years)		
Missing	2 (0)	51 (0)
ASA class (n (%))		
I	125 (2)	827 (2)
II	2,123 (35)	13,979 (32)
III-IV	3,645 (61)	28,695 (65)
Missing	120 (2)	626 (1)
BMI* (kg/m²) (n (%))		
Underweight (<18.5)	416 (7)	1,705 (4)
Normal weight (>18.5-25)	2,118 (35)	17,283 (39)
Overweight (>25-30)	1,195 (20)	9,297 (21)
Obesity (>30-40)	373 (6)	2,488 (6)
Morbid obesity (>40)	12 (0)	101 (0)
Missing	1,899 (32)	13,253 (30)

Table 1. Continued

	Bipolar HA n = 6,013	Unipolar HA n = 44,127
Smoking* (n (%)) Yes	361 (6)	2,383 (5)
No	3,563 (59)	29,890 (68)
Missing	2,089 (35)	11,854 (27)
Surgical approach (n (%)) Anterior	394 (6)	2,236 (5)
Anterolateral	558 (9)	5,523 (12)
Posterolateral	2,634 (44)	21,493 (49)
Direct lateral	2,346 (39)	14,274 (32)
Other	41 (1)	313 (1)
Missing	40 (1)	288 (1)
Stem fixation (n (%)) Cemented	4,198 (70)	33,332 (76)
Uncemented	1,773 (29)	10,430 (24)
Missing	42 (1)	365 (0)

* BMI and smoking registered since 2014

HA: Hemiarthroplasty

Results

Cumulative Incidence of Revision

Competing risk analyses showed an overall 1-year cumulative incidence of revision for unipolar HA of 1.7% (CI 1.6 to 1.8%) and for bipolar HA 2.0% (CI 1.6 to 2.4). Also, the 5-year incidence of revision was comparable for the 2 head types (2.9% (CI 2.7 to 3.0) for unipolar and 2.7% (CI 2.3 to 3.2) for bipolar HA). The 10-year incidence of revision was 3.2% (CI 3.1 to 3.4) for unipolar and 3.0% (CI 2.5 to 3.5) for bipolar HA. No statistically significant differences were seen (Figure 3 and Table 2). In cemented femoral stem HAs the 1-year cumulative incidence of revision was lower (1.5% (CI 1.4 to 1.7)) compared with uncemented stems (2.4% (CI 2.1 to 2.7)) (Figure 4 and Table 3). Furthermore, in sub analyses considering only HA with the posterolateral approach and/or only cemented femoral stems again no differences in survival rates between bipolar and unipolar HA were found.

Risk for Revision

Unadjusted Cox regression analyses showed statistically comparable risk for revision for bipolar and unipolar HA (HR 1.1 (CI 0.9 to 1.1)). Multivariable Cox regression analyses adjusted for age, surgical approach, and stem fixation showed an estimated 20% increased risk in revision for bipolar heads compared to unipolar heads (HR 1.2 (1.0-1.4)) (Table 4). Multivariable Cox regression analyses adjusted for confounders showed higher risk for revision in case of uncemented compared to cemented fixation (HR 1.4 (CI 1.2-1.5)). The anterior,

anterolateral, and direct lateral approach all showed lower unadjusted and adjusted risk for revision compared to the postero-lateral approach (Table 4).

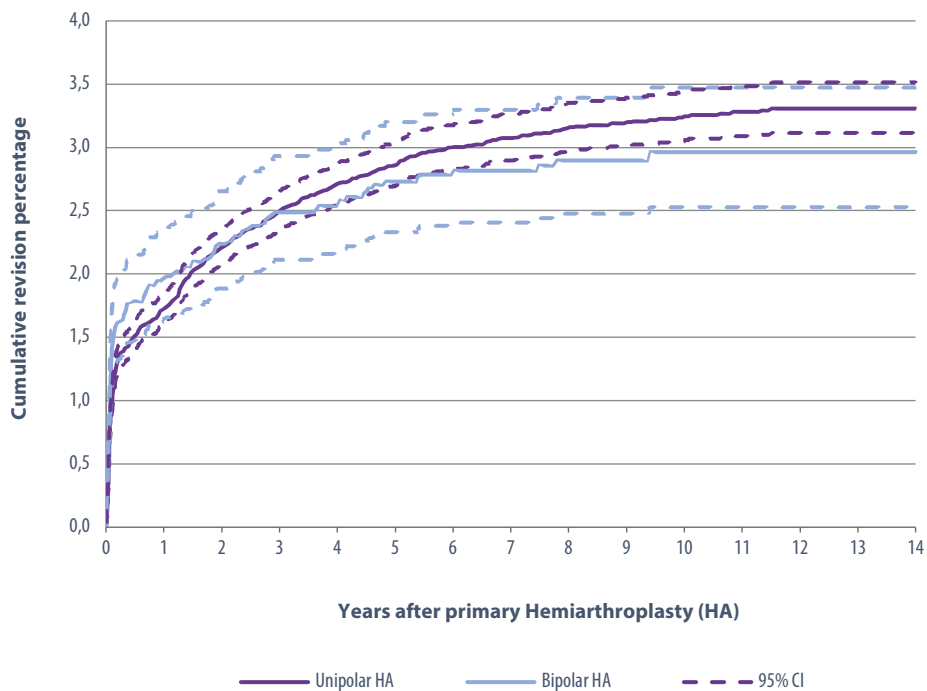


Figure 3. Cumulative incidence of revision based on competing risk analyses for hemiarthroplasty (HA) after acute fractures of the hip according to type of head

Table 2. Cumulative incidence of revision based on competing risk analyses for hemiarthroplasty (HA) after an acute fracture according to type of head (n = 50,140)

	Cumulative incidence of revision (% (95% CI))		
	1-year	5-years	10-years
Unipolar HA	1.7 (1.6-1.8)	2.9 (2.7-3.0)	3.2 (3.1-3.4)
Bipolar HA	2.0 (1.6-2.4)	2.7 (2.3-3.2)	3.0 (2.5-3.5)

HA: Hemiarthroplasty

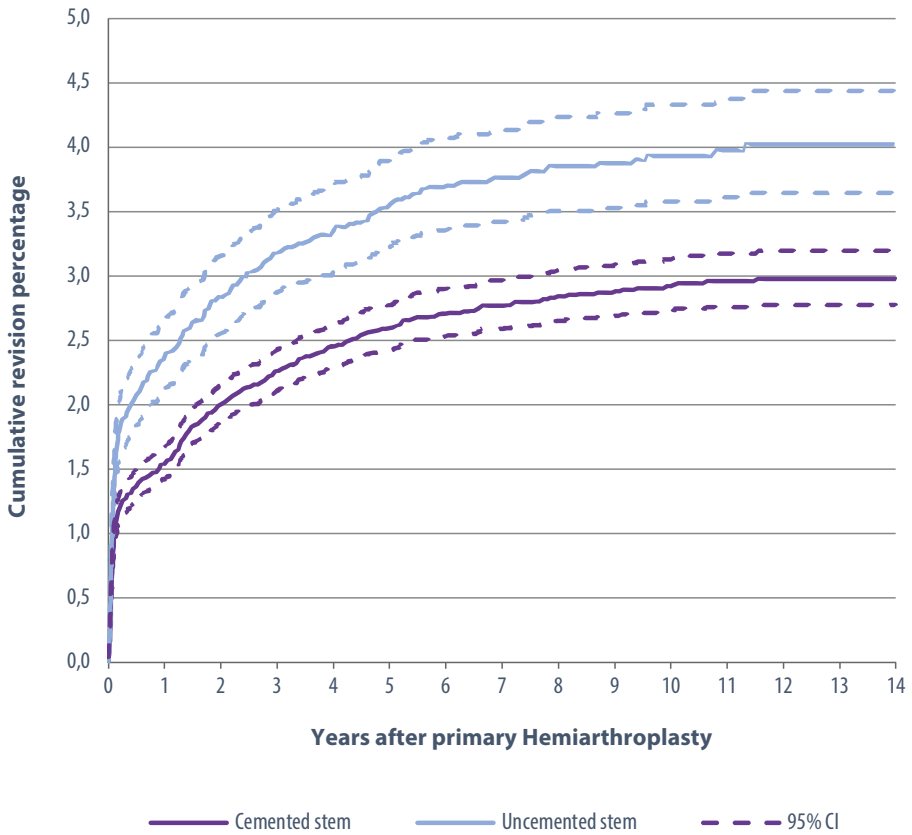


Figure 4. Cumulative incidence of revision based on competing risk analyses for hemiarthroplasty (HA) after acute fractures of the hip according to type of stem fixation

Table 3. Cumulative incidence of revision based on competing risk analyses for hemiarthroplasty after an acute fracture according to stem fixation (n = 50,140)

	Cumulative incidence of revision (% (95% CI))		
	1-year	5-years	10-years
Cemented stem HA	1.5 (1.4-1.7)	2.6 (2.4-2.8)	2.9 (2.7-3.1)
Uncemented stem HA	2.4 (2.1-2.7)	3.5 (3.2-3.9)	3.9 (3.6-4.3)

HA: hemiarthroplasty

Table 4. Multivariable Cox regression analysis for bipolar versus unipolar head hemiarthroplasty (HA) after an acute hip fracture

	n*	HR Unadjusted (95% CI)	HR Adjusted** (95% CI)
Type of head			
Bipolar	6,013	1.1 (0.9-1.3)	1.2 (1.0-1.4)
Unipolar	44,127	1.0	1.0
Age (years)			
<50	98	3.1 (1.5-6.6)	3.2 (1.5-6.8)
50-59	507	1.7 (1.1-2.8)	1.7 (1.1-2.8)
60-69	2,314	2.5 (2.0-3.1)	2.6 (2.1-3.2)
70-79	12,342	2.0 (1.7-2.3)	2.0 (1.8-2.4)
80-84	12,836	1.3 (1.1-1.5)	1.3 (1.1-1.5)
85-90	15,081	1.0	1.0
>90	6,909	0.8 (0.6-1.0)	0.8 (0.6-1.0)
Surgical approach			
Anterior	2,630	0.5 (0.4-1.7)	0.6 (0.4-0.8)
Anterolateral	6,081	0.7 (0.6-0.8)	0.7 (0.6-0.8)
Direct lateral	16,620	0.7 (0.6-0.8)	0.7 (0.6-0.8)
Other	354	1.6 (0.9-2.7)	2.1 (1.2-3.6)
Posterolateral	24,127	1.0	1.0
Stem fixation			
Cemented	37,530	1.0	1.0
Uncemented	12,203	1.4 (1.2-1.5)	1.4 (1.2-1.5)

* Missings (see table 1) are not included in this analysis (n = 788)

**Adjusted for age, approach and fixation

Reason for Revision

Dislocation and infection were the most frequently registered reasons for revision in both unipolar and bipolar HA. In bipolar HA, 66 (1.1%) of patients were revised for dislocation versus 299 (0.7%) in unipolar HA (Table 5). The total amount of revisions for dislocation was too low to differentiate between type of head.

Table 5. Reason for revision within 5 years according to type of head in hemiarthroplasty (HA)

Reason for revision	Bipolar HA n = 6,013		Unipolar HA n = 44,127	
	Revisions (n)	Proportion (%) HA n = 6,013	Revisions (n)	Proportion (%) HA n = 44,127
Dislocation	66	1.1%	299	0.7%
Infection	29	0.5%	266	0.6%
Cup/liner wear	4	0.1%	24	0.0%
Periprosthetic fracture	17	0.3%	187	0.4%
Loosening femoral component	17	0.3%	120	0.3%
Peri-articular ossification	1	0.0%	18	0.0%
Other	76	1.3%	418	1.0%
		n = 162		n = 1,190

The sum is higher than the total amount since more than 1 reason for revision can be registered

HA: hemiarthroplasty

Discussion

Our expectation that revision rates would be lower in case of bipolar compared to unipolar HA was not realized. The revision incidence rates of unipolar and bipolar HA from the competing risk analyses (not adjusted for other confounders) were similar. The Multivariable Cox regression analyses indicated a small increase of revision risk for bipolar, controlling for age, approach and fixation, though the lower 95% confidence bound could not exclude 1.0 (adjusted HR 1.2 (CI 1.0-1.4)). Despite these data, this finding could be relevant both for personal (patient, surgeon) decisions and for planning health care resources in view of the incidence of hip fractures. Additionally, this should be outweighed against implant costs. In December 2022, the price of a bipolar HA in the Netherlands was 1.5 to 2 times as much as a unipolar HA. In comparison with the literature, Farey et al. showed a significantly higher risk for revision for unipolar in comparison with bipolar HAs after 2.5 years follow-up (HR 1.9 (CI 1.5-2.4)) in a register study based on 62,875 procedures from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). However, they used Kaplan–Meier survival analysis (6). We think that, given the high mortality rate in this elderly patient group, competing risk analyses to calculate revision rates should be used, with death as a competing risk (11).

Use of Unipolar and Bipolar HA

Bipolar heads for HA were used in only 12% of the total number of HAs between 2007 and 2021 in the Netherlands. During this period, the percentage of bipolar HAs decreased from 18% in 2015 to 8% in 2020. This trend is in contrast with some Scandinavian countries, especially Sweden and Norway, where respectively in 51 and 99% of HAs with a bipolar head were used (12,13). We have no explanation for this difference; however, this could be a result of tradition and marketing strategies.

Revision Risk for Dislocation

A reason to choose for a bipolar instead of unipolar HA is the expected lower number of dislocations. In our study 1.1% of bipolar HAs were revised because of dislocation and 0.7% of unipolar HAs. This contradicts the original expectation. However, as in most registry studies, closed reductions for dislocation were not registered in our study. Jabory et al. tried to compensate for this by including the International Classification of Diseases 10th Revision Code (ICD10) related to hip dislocation in their National Patient Register in a cohort of 25,678 patients in the Swedish Hip Arthroplasty Register. In this way, dislocations with and

without operation were included, but still no difference between bipolar and unipolar HA was seen (12). This is in accordance with a meta-analysis from Filippo et al., including 27 articles and 4,511 patients, showing no statistically significant difference in dislocation rate between unipolar and bipolar HA (14). However, Jobory et al. and Filippo et al. did not study the amount of revisions for dislocations as we did. In 2014 Kanto et al. published a randomized controlled trial of 175 acute femoral neck fractures treated with a posterolateral approached unipolar or bipolar HA and showed higher dislocation rates for unipolar HA, but no differences in revision rates for dislocation at 8 years follow-up (15). The numbers of revision for dislocation in our study were too small for statistical comparison according to head type.

Other Risk Factors for Revision

Another reason to choose for a bipolar instead of unipolar HA is the expected lower amount of acetabular erosions, which, after longer follow-up, could be a reason for revision. Another study from Farey et al. (16) based on 13,035 unipolar and 8,220 bipolar HA from the AOANJRR, confirmed that acetabular erosion was the most common reason for revision of unipolar HA (22.2% of revision) compared with bipolar HA (13.4%). Unfortunately, in the LROI acetabular erosion is not registered as a separate reason for revision, so we could not analyze this reason for revision. In our study, we found higher revision rates for uncemented stems which is in accordance with the previously published register studies in the Netherlands, United States, Australia, Norway, and Sweden (5,6,18,18,19,20). Furthermore, a higher risk for revision after posterolateral HA compared with other surgical approaches was seen. In accordance with our results, Jabory et al. showed higher risk for revision in posterior approached HA ((odds ratio (OR) = 2.7 (CI 2.3-3.1)) (12). Nevertheless, in the Netherlands, still in half of HAs the posterolateral approach was used. Our results are in accordance with existing guidelines that recommend cemented fixation and anterolateral approach for treatment of hip fractures with HA (21,22).

Strengths and Potential Limitations

A strength of the present study is that it is based on a large real-world population-based (registry) cohort from the LROI including the large majority of patients who received a HA in the Netherlands, including the patients with a higher age, worse health status, and/or lower social-economic status. The risk of selection bias is probably low, since the examined groups had comparable demographic characteristics. However, revision rates might be affected naturally by increasing age with related comorbidity. This was also seen

by Grosso et al. showing lower reoperation and conversion rates in patients >75 years in a cohort of 686 patients who underwent HA for the treatment of femoral neck fractures (23). However, this effect is most likely similar in bipolar and unipolar HA group. Also, unmeasured confounding because of hospital preference for a special type of HA is a factor we could not exclude.

Conclusion

The revision rate for bipolar HA and unipolar HA was comparable. However, after adjustment for potential confounders, the risk for revision showed an estimated 20% increased risk for bipolar heads, although not statistically significant. For both head types, the risk for revision was significantly higher when an uncemented stem was chosen or the posterolateral approach was used.

Author contributions

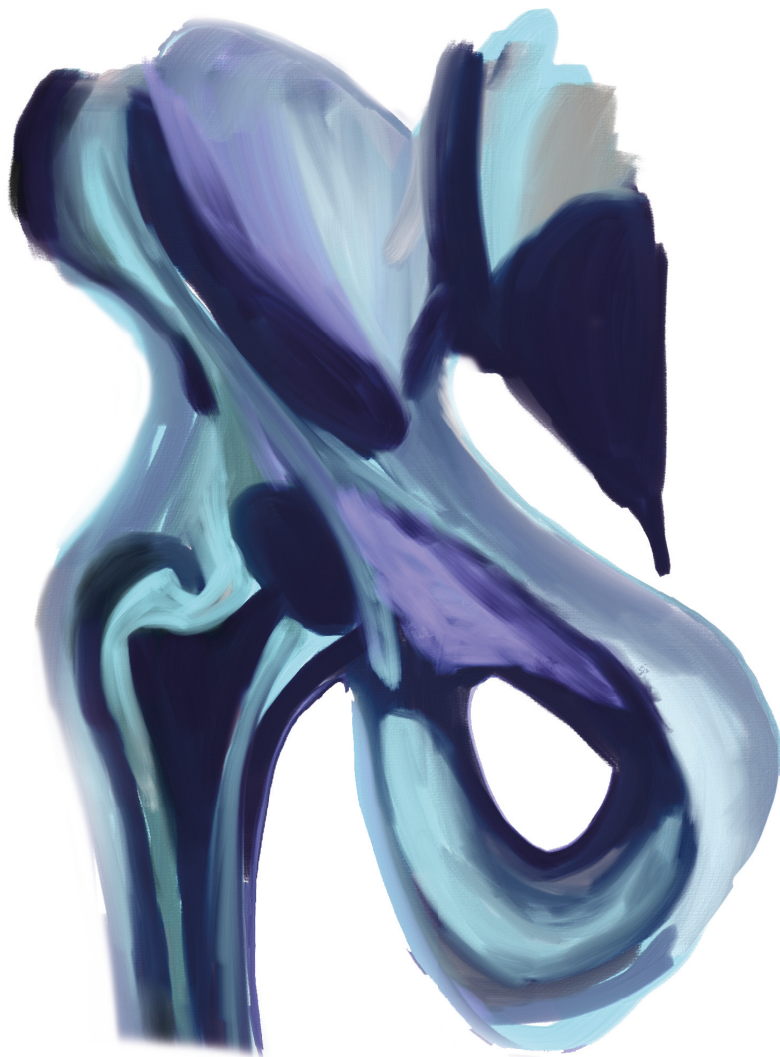
All authors contributed to the conception of the study, data analysis, and preparation of the manuscript.

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Chapter 7



Summary

The objective of this thesis was to investigate mortality and revision rates after hip arthroplasty based on population-based register data in the Netherlands. The focus was on elderly patients and on implants that have been developed to prevent dislocation, a frequent reason for revision surgery. The studies in this thesis are helpful for counselling patients and shared-decision-making before surgery.

This thesis was divided into two sections. In Part 1, implant and patient survival in octogenarians (patients of 80 years and older) after total hip arthroplasty (THA) were investigated. In Part 2, possible implant solutions for dislocations, like dual mobility cups and bipolar heads, were studied and compared with standard implants.

Part 1

Total hip arthroplasty in octogenarians

What is the mortality and prosthesis survival rate of primary total hip arthroplasty for osteoarthritis in patients of 80 years and older in the Netherlands and which patient and implant related factors determine the outcome?

For **Chapter 2** we have included all primary total hip arthroplasties (THAs) for osteoarthritis in patients ≥ 80 years implanted in the period 2007–2019 ($n = 43,053$). Patient mortality and prosthesis revision rates were calculated and risk factors for patient mortality and prosthesis revision were analyzed. Mortality was higher in males and higher ASA class patients, but did not differ between cemented and uncemented fixation. The revision rate after THA was 1.6% (95% CI 1.5–1.7) after 1 year and 2.6% (95% CI 2.5–2.7) after 5 years. Multivariable Cox regression analysis showed a higher risk of revision for uncemented (HR 1.6 CI: 1.4–1.8) and reverse hybrid THAs (HR 2.9 (CI 2.1–3.8)) compared with cemented THAs. Differences in revision rates according to fixation method were largely related to periprosthetic femoral fractures in uncemented stems.

Part 2

Dual Mobility cups in THA for osteoarthritis

What is the use of dual mobility cups in the Netherlands for primary total hip arthroplasty in case of osteoarthritis, what are the patient characteristics and are the survival rates comparable with unipolar cups?

For **Chapter 3** we have included all primary THAs registered in the LROI between 2007 and 2016 (n=215,953) and divided into 2 groups: dual mobility cups (DMC) (n=3,038) and unipolar cups (UC) (n=212,915). The proportion of primary DMC increased from 0.8% (n=184) in 2010 to 2.6% (n=740) in 2016. Patients who underwent a THA in combination with a DMC more often had a previous surgery of the affected hip, a higher ASA class and a diagnosis of acute fracture or late posttraumatic status in comparison with the THA group with a UC. Overall, the 5-year cup revision rate was comparable for DMC (1.5% (CI 1.0-2.3)) and UC THA (1.4% (CI 1.3-1.4)). Stratified analyses for patient characteristics showed no differences. Multivariable Cox regression analyses showed no statistically significantly increased risk for cup revision for DMC THA (HR 0.9 (CI 0.6-1.2)).

Dual Mobility cups in revision-THA

What is the use of dual mobility cups in the Netherlands for secondary total hip arthroplasty and what are the patient characteristics? Are the survival rates comparable with unipolar cups, especially for dislocations?

For **Chapter 4** we have included 15,922 cup revisions performed in the period 2007 and 2016 and divided them into two groups: THA with a DMC (n=4,637) and with an UC (n=11,285). The use of DMC in revision surgery increased from 23% (n=373) in 2010 to 47% (n=791) in 2016. Patient characteristics at time of revision were not comparable between the 2 groups. In the DMC revision group, more cemented cups were placed (89%) and generally the ASA class was higher. The main indication for the index revision was loosening of the cup, but cup re-revision for dislocation was more frequently registered in the UC group. Stratified analyses for cup fixation showed lower cup re-revision rate for DMC in both the cemented and uncemented group. Multivariable regression analysis also showed lower risk for cup re-revision for DMC compared with UC (HR 0.5 (CI 0.4-0.6)).

Dual Mobility cups in primary THA for acute hip fractures

What is the survival rate of total hip arthroplasty with dual mobility cup after an acute fracture of the hip in the Netherlands? What are the reasons for revision? Are the revision rates different between dual mobility cups and unipolar cups?

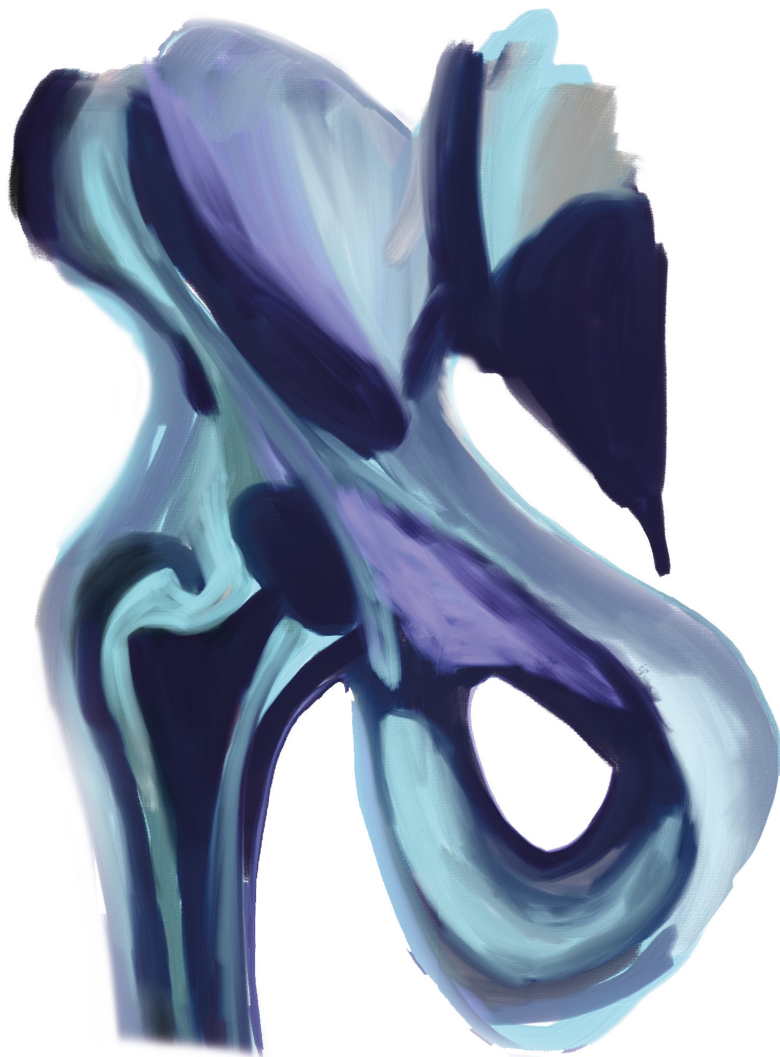
For **Chapter 5** we have included all THAs for an acute hip fracture registered in the LROI during 2007 and 2019 ($n = 11,857$). The use of DMC THA in acute fracture patients increased from $n=15$ in 2009 (3% of all THAs) to $n = 299$ (18% of all THAs) in 2019. Type of cup was divided into DMC ($n = 1,122$) and UC ($n = 10,735$). The 5-year cup revision rate after THA for acute fracture was comparable between DMC and UC THA. However, Multivariable Cox regression analyses showed lower risk of cup revision in DMC compared with UC using a small head (22-28mm femoral head); HR0.4 (CI 0.2-0.8). We found 6 cup revisions within 5 years when a DMC THA was used, 1 of them was revised for dislocation. However, a dislocation with a UC THA can often be reduced without surgery, so possibly the dislocation revisions in DMC THA reflect the number of postoperative dislocations better than the dislocation revisions in UC.

Bipolar heads in hemiarthroplasty for acute fractures

What is the use of bipolar hemiarthroplasty for acute fracture of the hip in the Netherlands? Are the revision rates different between bipolar and unipolar hemiarthroplasty and does this depend on surgical approach?

For **Chapter 6** all hemiarthroplasties (HA) for an acute hip fracture registered in the LROI during 2007 and 2021 were included. In total 44,127 unipolar heads and 6,013 bipolar heads HA. Bipolar heads for HA were used in only 12% of the total number of HA. The percentage of bipolar HA in the Netherlands decreased from 18% in 2015 to 8% in 2020. We have found comparable 1-, 5- and 10-year revision rates for unipolar and bipolar HA. However, after adjustment for potential confounders, the risk for revision showed an estimated 20% increased revision risk for bipolar heads, although not statistically significant (HR 1.2 (CI 1.0-1.4)). Cemented stems showed a lower risk for revision in comparison to uncemented stems. Finally, the anterior, anterolateral and direct lateral approach showed a lower risk for revision compared to the posterolateral approach.

Chapter 8



Nederlandse samenvatting

Het doel van dit proefschrift was meer inzicht te verkrijgen in overleving van patiënt en implantaat na een totale heup arthroplastiek (THA), ook wel 'totale heupvervanging' genoemd, op basis van register-studies in Nederland. De focus is gericht op de oudere patiënt en op implantaten die speciaal ontwikkeld zijn om het risico op luxatie (het uit de kom schieten van de heupprothese), een veel voorkomende reden voor een revisie, te verkleinen. De onderzoeken van dit proefschrift zijn ondersteunend in het informeren van patiënten en kunnen helpen bij het maken van gezamenlijke beslissingen (shared-decision making process) rondom een operatie.

Dit proefschrift is verdeeld in 2 secties. In Sectie 1 is de overleving van patiënt en implantaat bij 80 plussers na een THA onderzocht. In Sectie 2 worden verschillende mogelijke oplossingen voor heupluxaties, zoals dual mobility kommen en bipolaire koppen, onderzocht. De dual mobility heupkom (DMC) wordt gebruikt bij totale heup arthroplastiek en is een 'kom in een kom'. Hierdoor neemt de bewegingsvrijheid toe en de kans op een luxatie af. Een bipolaire kop wordt gebruikt als er sprake is van een fractuur en de kop van de heup vervangen moet worden maar de kom niet. De bipolaire kop bestaat uit twee delen; er is een kleine kop die draait in een kom die vervolgens articuleert in de heupkom van de patiënt. Daardoor is er nog een extra beweging mogelijk in de kop zelf, zodat er mogelijk minder beweging plaatsvindt tussen de buitenkant van de kop en het kraakbeen van de kom van de patiënt zelf. Voor dit proefschrift zijn type 'dual mobility en bipolaire' implantaten vergeleken met de 'standaard' implantaten.

Sectie 1

Totale heupprothesen bij 80 plussers

Wat zijn de overleving en revisie percentages na primaire totale heuparthroplastiek voor artrose bij patiënten van 80 jaar en ouder in Nederland en welke patiënt- en prothesefactoren beïnvloeden deze uitkomsten?

Voor **Hoofdstuk 2** includeerden we alle primaire totale heup arthroplastieken (THAs) bij 80-plussers met artrose in de periode 2007-2019 (n = 43,053). Het revisie percentage en de kans op revisie werd berekend en risicofactoren werden geanalyseerd. De kans op sterfte was hoger bij mannen en bij patiënten met een hogere ASA-classificatie en verschilde niet tussen gecementeerde of

ongecementeerde fixatie. Het revisiepercentage na THA was 1.6% (CI 1.5-1.7) 1 jaar postoperatief en 2.6% (CI 2.5-2.7) 5 jaar postoperatief. Multivariabele Cox regressieanalyse liet een hoger risico op revisie zien na ongecementeerde THAs (HR 1.6 (CI 1.4-1.8)) en reverse hybride THAs (HR 2.9 (CI 2.1-3.8)). De verschillen in revisiepercentage ten nadele van ongecementeerde stelen bleken gerelateerd aan de hogere kans op periprothetische fracturen (fracturen in het bot rondom de prothese).

Sectie 2

Dual mobility kom bij primaire totale heup arthroplastiek

Hoe vaak wordt er gekozen voor een THA met een dual mobility kom in Nederland en bij welke patiënt karakteristieken? Is de kans op revisie vergelijkbaar met unipolaire kom?

Voor **Hoofdstuk 3** includeerden we alle primaire THAs geregistreerd in de LROI tussen 2007 en 2016 (n=215,953) en vervolgens verdeelden we de groep in dual mobility cups (DMC) (n=3,038) en unipolaire cups (UC) (212,915). Het aandeel primaire DMC in verhouding met alle geplaatste cups nam toe van 0.8% (n=184) in 2010 tot 2.6% (n=740) in 2016. Patiënten die een DMC kregen bij een THA waren vaker al eens geopereerd aan diezelfde heup en hadden een hogere ASA-classificatie. Ook was de reden voor operatie vaker een acute fractuur of een post-traumatische status in vergelijking met de UC THA groep. Het 5-jaars revisiepercentage was vergelijkbaar tussen DMC THA (1.5% (CI 1.0-2.3)) en UC THA (1.4% (CI 1.3-1.4)). Gestratificeerde analyse ten aanzien van de verschillende patiëntkarakteristieken liet geen verschillen zien tussen een DMC en UC THA. Multivariabele Cox regressieanalyse liet geen significant verhoogd risico voor cup revisie zien bij DMC THA (HR 0.9 (CI 0.6-1.2)).

Dual mobility kom bij heup revisie operaties

Hoe vaak wordt er gekozen voor een dual mobility kom in Nederland als het gaat om een revisie van de heup arthroplastiek en bij welke patiënt karakteristieken? Is de kans op overleving en revisie vergelijkbaar met een unipolaire kom met name ten aanzien van luxaties?

Voor **Hoofdstuk 4** includeerden we alle revisies van de kom ($n = 15,922$) in de periode 2007 tot 2016 en verdeelden de groep THA in een THA met DMC ($n = 4,637$) en een THA met een UC ($n = 11,285$). Het gebruik van DMC in revisie operaties nam toe van 23% ($n = 373$) in 2010 tot 47% ($n = 791$) in 2016. De patiëntkarakteristieken op het moment van revisie ingreep waren niet vergelijkbaar tussen de 2 groepen. In de DMC revisie groep werd de prothese vaker gecementeerd geplaatst (89%) en meestal was de ASA-classificatie van de patiënt hoger. De voornaamste reden voor revisie was loslating van de cup. Bij de re-revisie (het moment dat de revisie ingreep weer wordt gereviseerd) was de meest voorkomende reden loslating van de cup bij de DMC-groep. In de UC-groep de reden van re-revisie meestal een luxatie. Een gestratificeerde analyse voor type fixatie van de cup liet een lager revisie percentage zien voor DMC THA in de gecementeerde en ongecementeerde groep. Multivariabele Cox regressieanalyse liet ook een lager risico op komrevisie zien in het voordeel van de DMC THA in vergelijking met UC (HR 0.5 THA (95% CI 0.4-0.6)).

Dual mobility kom bij acute heupfracturen

Wat is de overleving van een totale heup prothese bij een acute heupfractuur? Wat zijn de redenen voor revisie en zijn de revisiepercentages verschillend als er gebruik wordt gemaakt van een dual mobility kom of unipolaire kom?

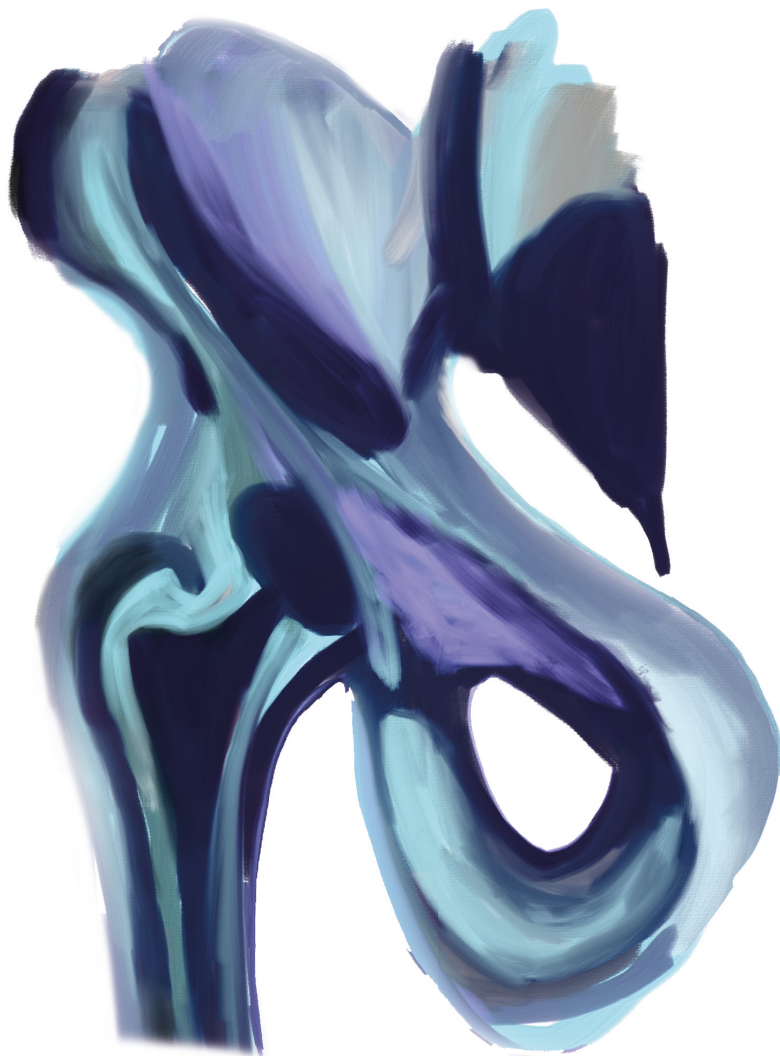
Voor **Hoofdstuk 5** includeerden we alle THAs bij een acute heupfractuur geregistreerd in de LROI tussen 2007 en 2019 ($n = 11,857$). Het gebruik van THA in combinatie met een DMC bij een acute heupfractuur nam toe van $n=15$ in 2009 (3% van alle THAs) tot $n=299$ (18% van alle THAs) in 2019. Het totale aantal THAs na een acute heupfractuur werd verdeeld in 2 groepen: THA met een DMC ($n = 1,122$) en THA met een UC ($n = 10,735$). Het revisie percentage van de kom 5 jaar postoperatief was vergelijkbaar tussen een DMC en UC THA. Multivariabele Cox regressieanalyse liet een lager risico op revisie zien in DMC THA in vergelijking met UC THA met een klein femur kopje (22-28mm diameter); HR: 0.4 (9 CI 0.2-0.8). In totaal waren er 6 cup revisies binnen 5 jaar na de primaire operatie met een DMC THA, 1 daarvan was gereviseerd vanwege luxatie(s). Een luxatie met een UC THA kan vaak zonder operatie (en daardoor zonder registratie in de LROI) hersteld worden, dus mogelijk is het aantal revisies in de DMC THA groep hierdoor hoger.

Bipolaire kop bij kophalsprothese bij acute heup fracturen

Hoe vaak wordt er gekozen voor een bipolaire kophalsprothese bij een acute heupfractuur in Nederland? Zijn er verschillen in revisie percentages tussen bipolaire en unipolaire kophalsprothesen en hangt dit af van het type benadering?

Bij een fractuur van de heup kan een kophalsprothese worden gebruikt, er wordt dan een prothese in het bovenbeen geplaatst met daarop een grote heupkop die direct in de oorspronkelijke heupkom van de patiënt articuleert. Voor **Hoofdstuk 6** zijn alle geregistreerde kophalsprothesen (KHPs) voor een acute heupfractuur in de LROI tussen 2007 en 2021 geïnccludeerd en verdeeld in 2 groepen: n = 44,127 unipolair koppen en n = 6,013 bipolaire koppen. Bij een bipolaire kop is er nog een extra beweging mogelijk in de kop zelf, zodat er mogelijk minder beweging plaatsvindt tussen de buitenkant van de kop en het kraakbeen van de kom van de patiënt zelf. De bipolaire kop werd in 12% van alle KHPs gebruikt. De verhouding tussen bipolaire en unipolaire KHP nam af ten nadele van de bipolaire KHP; 18% in 2015 tot 8% in 2020. We zagen vergelijkbare 1 en 5 jaar postoperatieve revisiepercentages bij bipolaire en unipolaire KHPs. Na correctie voor leeftijd, chirurgische benadering en type fixatie (gecementeerd of ongecementeerd) werd er een hoger risico op revisie gezien in de bipolaire KHP in vergelijking met de unipolaire KHP. Echter was dat verschil niet significant (HR 1.2(CI 1.0-1.4)) Gecementeerde stelen lieten een lager risico op revisie zien in vergelijking met ongecementeerde femurstenen. Tot slot zagen we dat de anterieure, anterolaterale en direct laterale benadering een lager risico op revisie liet zien in vergelijking met de posterolaterale benadering.

Chapter 9



General discussion and future perspectives

In this discussion we will point the four main topics from this dissertation: registry studies, total hip arthroplasty in octogenarians, dual mobility cups and bipolar hemiarthroplasty. We start with discussing these topics in the light of current knowledge and research. Furthermore, we discuss future perspectives of each topic.

Registry studies

Clinical registries are an essential part of the learning healthcare system and have proven to be effective in improving healthcare in many fields. Registries can also be powerful tools for collecting and appraising real-world clinical evidence concerning medical devices. Registries are generally population based, meaning that all patients (including the aged, less healthy and those with a low socioeconomic status) are included. So, the real-world patients without exclusion criteria are included. As mentioned by Lübekke et al. in 2019, a registry, in its best form, is a mission-driven independent stakeholder-registry team collaboration that enables rapid, transparent, open-access knowledge generation and dissemination (1).

The most important medical devices in orthopedic care are joint replacement implants. The value of registries for monitoring these implants has been discussed in the Cumberlege report in 2020 (2). This report was originally commissioned to investigate adverse events of medical drugs, but pointed out that medical implants have different routes to the market in comparison with drugs. The authors concluded that in medical implants, like orthopedic implants, post market surveillance and clinical reports using data collected with registries are of great value. This emphasizes the importance of implant registers.

A registry-based study is based on data collected in a register and can be used to determine factors that are associated with prosthesis outcomes. These data could be helpful to reduce morbidity, mortality and costs. Logically, data quality and data collection are of great importance in registry-based studies using arthroplasty registers as pointed out by Baker et al. (3). The Dutch Arthroplasty Register (LROI) is such a registry, which has a completeness for primary total hips and knees of over 99% (4). The LROI is a full member of ISAR, the International Society of Arthroplasty Registries. To become a full member, the registry must fulfill minimal criteria (5).

Besides data quality, it is important to realize that register data are observational data. Therefore, no causality between variables can be proven. However,

registry data gives insight into real-world observational results and can be used in hypothesis generating research. Furthermore, a selected set of variables is being collected in a registry, to restrict registration burden.

Therefore, registry studies are of great value in the health care system and a great advantage for orthopedic care. For this thesis, all studies are based on data from the LROI. Data were selected and delivered in close collaboration with the LROI.

Total hip arthroplasty in octogenarians

We have shown higher mortality rates in males and higher ASA class in primary THAs for osteoarthritis in patients ≥ 80 years. These results are comparable with other register studies from the Finnish Arthroplasty Register (6) and the Nordic Arthroplasty Register Association (7).

Over the last decades the total amount of THAs worldwide has grown exponentially and will grow further (8). Reasons for this are aging (9), increasing demands of patients and the fact that more countries can now afford such expensive surgery. For the decision to perform a primary THA or revision surgery in an elderly patient it is important to know patient and implant revision risks and survival rates. Register studies could provide us these data.

Many orthopedic surgeons hesitate to perform a THA in patients over 80 years. However, we have shown low mortality and revision rates. We think that, of course on sound indications, these patients can also benefit from this type of surgery just as younger patients. Recently, Schaufelberger et al. (10) have shown good results after primary THA in patients with osteoarthritis aged 90 to 101 years (nonagenarians) after cemented THAs in 1,385 patients from the Swedish Arthroplasty Register (10). Although 30- and 90- day post-operative mortality and reoperation rates were higher in nonagenarians, patient satisfaction and pain relief among nonagenarians were as good as or better than in the younger cohorts.

However, it is still important to realize that the 'older' patient group is more vulnerable and thus at higher risk for complications. It is advisable to operate them in hospitals that are well equipped for this care, as these patients will have a greater need for medical support in the aftermath of the surgery. Geriatrists can be very helpful to optimize the care for these patients. By consulting them before the surgery, they can even play a role in the decision to choose

for the surgery. Also, these specialists can play an important role in the post-operative period.

Important to mention is that in our study, the adjusted results showed a higher risk of revision for uncemented and reverse hybrid THAs compared with cemented THAs. Differences in revision rates according to fixation method were largely related to periprosthetic femoral fractures in uncemented stems. These results are in accordance with the conclusion from Troelsen et al. (11). In their review of current fixation methods in THA and outcomes from the annual reports of 7 national hip arthroplasty registries from 2006 to 2010, their results suggest that cemented fixation in THA has the lowest risk for revision, especially in patients older than 75 years.

In conclusion, primary THA is an option in octogenarians, but good shared decision making is a prerequisite. Furthermore, it is strongly advised to use cemented fixation THA to reduce the revision risk due to periprosthetic fractures.

Dual mobility cups

In primary THA no differences were seen between DMC and UC. Our hypothesis that the DMC would show lower risk of revision due to dislocation was rejected. This was in accordance with a meta-analysis from Jonker et al. in 2020 (12). Their initial search resulted in 702 citations and after in- and exclusion criteria 8 articles were graded: 5 case-control studies and 3 registry studies. One of the 3 registry studies was our study included in this thesis. Remarkable was the fact that all registry studies did not show any significant difference in revision rate between DMC and UC THA, while case-control studies reported overall lower rates of dislocation and revision for DMC cases. However, they pointed out that the existing studies were of medium to low methodological quality with a high risk of bias due to the lack of experimental design.

In conclusion, with the current evidence, a dual mobility cup could be an option in primary THA in specific patients (patients with a high risk for dislocation), but has not been proven to have lower revision rates.

However, our revision THA study, one of the largest population-based studies of almost 16,000 cup revisions, showed lower risks for revision with use of a DMC compared to UC (HR 0.5 (CI 0.4-0.6)). Also, the Swedish register study from Hailer et al. in 2012 showed 7% overall re-revision rates for any reason after a DMC at 2-years follow-up in 228 patients (13). Unfortunately, we cannot

compare their outcome with our results, as our endpoint was cup re-revision and not overall re-revision. Besides, we had no information concerning the type and follow-up of the primary procedure as well as the primary diagnosis.

When discussing revision cases in registry studies, it is necessary to realize when a revision is registered. In our LROI study, a revision was registered if one or more components were exchanged. The LROI does not record reoperations in which no component is exchanged, e.g. debridement for early infection or reoperations for femoral periprosthetic fractures with only osteosynthesis. Moreover, closed reductions for dislocations were not registered. Reductions for dislocated UC THA can often be performed without surgery in contrast to dislocated DMC, so possibly the revision rates in DMC reflect the number of postoperative dislocations better than the number of dislocation revisions in UC.

Finally, when one compares two different cup designs based on register data you have to be aware of residual confounding; are there additional confounding factors that were not considered, or important factors that were not collected? Also selection bias is possible; why did these patients get a DMC in the first place? On which factors was the surgeon's choice made? In registry-nested RCTs with comparable patient groups the risk of residual confounding and selection bias will be lower.

In conclusion, based on the current evidence, a dual mobility cup could be a good option in those THA revisions with a probably higher risk for future revisions, especially when revised for recurrent dislocations.

In case of a primary THA after an acute fracture of the hip, we showed a lower risk for cup revision with use of DMC THA when compared to UC THA with small 22-28 mm femoral head. Also, Jobory et al., based on the Nordic Arthroplasty Register Association dataset, showed a reduced revision risk for DMC in THA for acute femoral neck fracture in 2019 (14), a paper from his thesis about dislocation after hip fracture related arthroplasty (15). For this study propensity score matching was used to match 4,520 hip fractures treated with DMC to 4,520 hip fractures treated with conventional THA. The DMCs showed lower overall risk of revision compared with conventional 32 and 36 mm head THAs (adjusted hazard ratio of 0.75 (CI 0.62-0.92)). Moreover, DMCs had a lower risk of revision due to dislocation (adjusted HR 0.45 (CI 0.30-0.68)). An explanation for this result is that the incidence for dislocations after THA for an acute fracture of the

hip is higher compared with THA performed for osteoarthritis. The DMC could lower this risk in comparison with UC THA.

Currently, only evidence from observational studies has been published about DMC versus standard UC THA in case of acute fractures. We expect that the DUALITY trial from Wolf et al., a multicenter registry-nested randomized controlled trial, will give us more insight (16). In this trial patients with a displaced femoral neck fracture, eligible for THA, are randomized to a DMC or a UC. Inclusion started in January 2020 and they plan to recruit patients for 5 years.

In conclusion, based on the current evidence, a dual mobility cup could be a good option for patients who need a THA in case of an acute hip fracture. Also in specific patient groups, like patients who are difficult to instruct, this is an attractive option.

Finally we like to point out the higher price of the DMC. The DMC is much more expensive than the normal cup. So far, only one cost-effectiveness study has been performed in France by Epinette (17). In 2016 they identified 80,405 patients who had THA in 2009 and collected their outcomes. Cost-effectiveness was assessed based on the costs used for all consequences of prosthetic dislocation and paid for by the health insurance system or other sources. THAs with use of DMC showed 3,283 fewer dislocations per 100,000 patients and a relative risk of 0.2 would yield annual cost savings of 56,28 million Euros suggesting that the DMC may result in cost savings compared with UC (17).

Bipolar heads

The bipolar hemiarthroplasty (HA) showed no significant different revision rates in our study included in this thesis. However, after adjustment for potential confounders the risk for revision showed a tendency to be higher for bipolar heads, although not statistically significant. In the bipolar head group, 41% of revisions were performed for dislocation. In unipolar heads this was 25%. However, we cannot rule out that there were more open reductions necessary in case of bipolar heads, since it is more difficult to reduce dislocation of a bipolar head with close reduction only. The LROI does not record re-operations without component exchange, and therefore these procedures are not included in the LROI.

In 2022, Papavasiliou et al. (18) showed in a systematic review and meta-analysis of randomized controlled studies that bipolar HA have superior hip function, lower erosion rates 6 and 12 months post-operatively and less pain compared to unipolar HA. No differences were seen regarding mortality, re-operation and dislocation rates in a quantitative analysis of 16 studies. However, the total amount of patients in their meta-analysis was 1,814 hips including 908 bipolar hips. Comparably, our study included over 6000 bipolar HAs and 44,000 unipolar HAs.

A recent analysis of hemiarthroplasties from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) (n = 41,949) including 11,494 Exeter V40 cemented bipolar heads (the most commonly used implant (49,9%) in Australia) showed no difference in revision rate 1- and 3-years postoperatively across all designs of hemiarthroplasties (19). However, at 10-years, the bipolar design had the lowest revision rate, although this was not statistically significantly lower.

In conclusion, based on the current evidence, the bipolar head does not show significantly lower revision rates than unipolar heads in HA and not (yet) proven to be better than unipolar HA.

Future Perspectives

Registry studies

After the initial focus of registries on implant revision- and patient survival-rates, also patient reported outcome measures (PROMs) are used to analyze patient reported outcomes (PRO) as endpoints in register studies. PROMs are provided by patients and, in orthopedics, mainly focused on relief of pain, restoration of function and improvement of quality of life. The advantage is that PROMs give us short term results (mostly up to one year postoperatively) without interpretation from a surgeon or other medical professional. The consequence is that it is very subjective.

PROMs are already used in (national) orthopedic arthroplasty registries and studies. In the Netherlands, LROI PROMs studies in THA have been published since 2018 (20,21,22). These studies show patient reported outcomes about pain and physical functioning, as well as quality of life after a total hip arthroplasty for osteoarthritis in a period up to 1 year postoperatively. Though,

as pointed out by Wilson et al. (23), PROMs do have their practical issues for (register) studies. For the patient, PROMs are often long questionnaires which gives implementation challenges. Secondly, at this moment, there are many different ways to report PROMs, so it is quite difficult to link and compare different national registries for international collaboration. International collaboration is especially useful to increase numbers and make it possible to examine less frequent patient groups and implants. Finally, at this moment, PROMs in registries are only collected up to 1 year after surgery. It would be useful if, at least in some patients, PROMs also are collected at e.g. 5 and 10 years after surgery.

Another interesting and important outcome measure to use in registries are complications. These include surgical complications like wound infection, bleeding, and dislocations. In the studies included in this thesis, closed dislocation reductions or surgical reductions without implant exchange, as well as debridement, antibiotics and implant retention (DAIR) procedures in cases of early infections, are not registered in the LROI at that moment. Combining the LROI register with hospital databases containing complications of arthroplasties, it could give a better estimation of the real risk for dislocations after THA. Hopefully this is possible in the near future because since 2023, complications were added to the LROI.

Furthermore, other medical datasets could be linked to implant registries. Hereby, new fields of research can be explored. An example of such a linkage to another registry is the recent project with the pharmacological register. Van Brug et al. (24) linked the LROI with the Dutch Foundation for Pharmaceutical Statistics (SFK). They showed an increased opioid prescription in the Netherlands in general before, but also after THA and total knee arthroplasty from 2013 to 2018. Data linkage is challenging in the Netherlands due to Dutch privacy legislation rules. Therefore they used deterministic data linkage to link data from the SFK to the LROI based on a combination of year of birth, gender and four-digit postcode.

Moreover, data from other medical specialties like microbiological results, are interesting. In the Netherlands the Dutch National Nosocomial Surveillance Network (PREZIES) is a healthcare association infection surveillance network and focuses on the surveillance of surgical site infection such as Prosthetic Joint Infection (PJI) in THAs and Total Knee Arthroplasties. The PREZIES collects there data in a national registration system (25). In 2023, Van Veghel et al.

combined all primary THAs and TKAs between 2012 and 2018 from the LROI and PREZIES and showed that the LROI captures approximately one-third of the PJs as revision within one year for infection or resection arthroplasty (26). We think more collaboration between the LROI and other medical specialties like microbiological registries on infected THAs would result in new and exciting research opportunities, especially in combining these results internationally. Other collaborations could be anesthesiology data and physical therapy data.

As stated before, privacy is a very important issue when one wants to use register data. Especially in the Netherlands, the privacy criteria are quite strict. Fortunately, there is more and more experience within the LROI how to manage these challenges (27).

In conclusion, the above mentioned opportunities can make register studies of even greater value in medical science and lead to further research opportunities in future. Especially combining data with other registries and international collaborations can be very productive for future research.

Dual mobility cups

The idea behind the design of the DMC, to create a larger jumping distance and range of motion, might be not true in a real patient. It is possible that the liner is fixed in the cup and does not move as expected. However, clear data on this possible phenomenon are still lacking. And even if the risk for dislocation remains the same as in a normal cups, there is an additional manner of failure introduced with these new implants: an intraprostatic dislocation. We hope that the REDEP study (28) will shed some light on the questions about this phenomenon. The REDEP study is a single-blinded RCT studying patients >70 years undergoing elective primary THA using the posterolateral approach. 1,100 participants will be randomly allocated to the intervention (DMC) or control group (UC). The recruitment phase started in April 2019. Participants remain traceable in the LROI for evaluation of long-term implant survival and mortality.

Another possible complication of DMCs is higher polyethylene (PE) wear because two articulation surfaces exist in this device. The literature of PE wear in DMCs is sparse, only Tabori-Jensen (29) and Jørgensen (30) tried to calculate PE wear. The results however were not conclusive and longer follow-up has to be awaited. As it stands now, the theoretically high PE wear has not been reflected by higher revision rates.

In conclusion, we expect this thesis could help surgeons to decide whether DMC is a favorable choice for patients in case of primary THA, secondary THA after a revision or a THA after an acute fracture of the hip. To confirm our conclusions more data are still needed and especially registry-nested RCT's are expected to provide further evidence. Also international cooperations are very promising. One example is the international meta-analysis from Farey et al. (31) showing the revision risk of DMC in case of an acute fracture of the hip based on 6 different arthroplasty registries. Unfortunately, there was large variation in use across countries represented and they concluded more research was necessary.

In the meantime, based on our results, we would advise to use a DMC in THA for revision arthroplasty, especially in case of a revision for recurrent dislocations. In primary cases we advise to use a DMC for patients who are difficult to instruct or patients with a hip fracture needing total hip arthroplasty.

Bipolar Hemiarthroplasty

We have shown that the bipolar head hemiarthroplasty is used less frequently in the Netherlands compared to other countries. Our data are in clear contrast with some Scandinavian countries like Sweden (32) and Norway (33) where this implant is widely used, despite lack of clear evidence of lower revision rates and higher costs. The price of a bipolar HA in the Netherlands is 1.5 to 2 times as much as a unipolar HA. As far as we can see now, there is no need to stimulate the use of bipolar heads in the Netherlands, except in some special cases.

When in the near future, complications (like dislocation with closed reduction) are included in the LROI, this will increase the knowledge about complication- and revision rates of bipolar and unipolar HA and might change our view.

Final conclusion of this thesis

Register studies as described in this thesis can be used to get insight into arthroplasty practice. Firstly, we have shown very acceptable patient- and implant survival after total hip arthroplasty in patients 80 years and older, provided that the femoral stem is fixated with cement.

Secondly, we have investigated the revision rates of special implants. Dual mobility cups in case of total hip arthroplasty and bipolar heads in case of hemiarthroplasty. Both have been designed to reduce dislocations after hip arthroplasty. We have shown that these newer designs did not jeopardize implant survival in comparison with conventional implants, especially in revision

cases. Therefore, dual mobility cups are an option in total hip arthroplasty. This holds especially for patients with a high dislocation risk including patients with an acute femoral fracture and an indication for total hip arthroplasty.

The bipolar head is an option in hemiarthroplasty, but we have not shown lower revision risks in comparison with unipolar hemiarthroplasty. Given the higher costs, we think in most cases a standard head is preferred.

This thesis has shown that register studies are of great value to medical science.

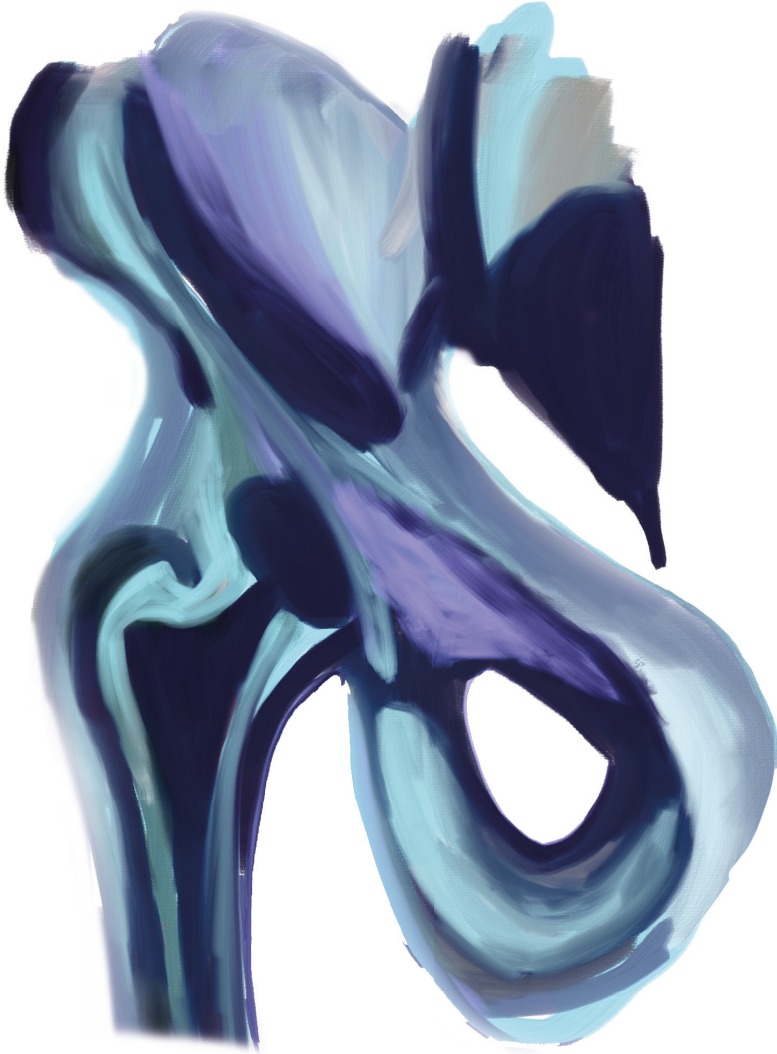
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Chapter 10



Appendices

List of publications

Data Management

Radboud Graduate School Portfolio

Dankwoord

About the author

List of publications

Bloemheugel EM, van Rooij WM, van den Besselaar M. Patella component loosening-A case report. *Acta Orthop Belg.* 2016 Mar;82(1):17-22

Bloemheugel EM, van Steenberg LN, Swierstra BA. Dual mobility cups in primary total hip arthroplasties: trend over time in use, patient characteristics, and mid-term revision in 3,038 cases in the Dutch Arthroplasty Register (2007-2016). *Acta Orthop.* 2019 Feb;90(1):11-14

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Bloemheugel EM, van Steenberg LN, Swierstra BA, Schreurs BW. Revision Risk of Unipolar and Bipolar Hemiarthroplasties in the Dutch Arthroplasty Register. *J Arthroplasty.* 2024 Jan;39(1):118-123

Data Management

Data used within this thesis was collected and stored according to the Findable, Accessible, Interoperable and Reusable (FAIR) principles. This thesis is based on data registered by the Dutch Arthroplasty Register (LROI).

Data from the LROI were received completely anonymous, to ensure the privacy of all patients and hospitals. Data from the LROI was sent via a secured environment used by the LROI. Access to this environment was made possible by receiving a link from the LROI by email, with a password sent in a separate email. Datasets received from the LROI were stored on the server of the department of Orthopaedics (Radboudumc Nijmegen, Rijnstate Arnhem, Sint Maartenskliniek Nijmegen and Máxima Medisch Centrum Veldhoven). When a research project was finished, the dataset, including the syntax from SPSS to produce the final results were uploaded to the LROI, where they are stored into the secure environment of the LROI. When the datasets were sent back to the LROI everything was deleted from the server of the hospital.

The data collected for this thesis will be available at the LROI for further analyses for at least 10 years.

PhD portfolio of E.M. Bloemheuvel

Department: **Orthopaedic surgery, Radboud Institute for Health Sciences**

PhD period: **01/07/2016 – 01/12/2023**

PhD Supervisor(s): **Prof. Dr. B.W. Schreurs**

PhD Co-supervisor(s): **Dr. Ir. L.N. van Steenberg, Dr. B.A. Swierstra**

Training activities	ECTS
Courses	
– Scientific Integrity, Radboudumc (2023)	1.00
– How to search for grants (2023)	0.25
– Grant Writing and Presenting for Funding Committees (2023)	0.25
– Followed course for orthopaedic training (ATLS provider and advanced, AO paediatric trauma, AO trauma basic and advanced, HMIMS, FCCS, DSTC, NVA arthroscopy of the knee, knee arthroplasty, hip arthroplasty, Oxford UKP course, basics osteotomy course, DFAS basic and advanced course, Stralingshygiene, Boerhaave, CCOC-courses (9) (2016-2022)	14.0
– Followed courses for paediatric fellowship (Graf ultrasound course, EPOS motion analysis course, GCI clubfoot part I and II, EPOS Bat trilogy part I and III) (2022-2023)	3.5
Conferences	
– Podium Presentation: NOV congress (2017)	2.0
– Podium Presentation: EFORT congress (2019)	2.0
– Podium Presentation: ISAR congress (2019)	2.0
– Poster Presentation: ISAR congress, online (2021)	2.0
– Podium Presentation: NOF congress (2022)	2.0
– Podium Presentation: NOV congress (2023)	2.0
– Visiting scientific congresses (NOV 10x, Traumadagen 3x, VOCA congress 3x, ISAR congress 2x, EFORT congress 1x, DJS congress 1x EPOS annual meeting 2x, NVA congress 1x, NOF congress 1x, WKO congress 2x)	13.0
Other	
– Visiting weekly seminars and lectures during fellowship (2022-2023)	2.0
– Visiting weekly seminars and lectures during residency (2016-2022)	8.0
Teaching activities	
Lecturing	
– Journal clubs and clinical presentations during residency (2016-2022)	6.0
Total	60.0

Dankwoord

Graag wil ik via deze weg eerst mijn directe 'team' bedanken. Allereerst Bart Swierstra en Liza van Steenberg, want eigenlijk waren wij de drie musketiers waarmee het allemaal begon.

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Liza, ik weet ook nog goed dat wij elkaar voor het eerst zagen op het NOV-bureau in den Bosch. Je bent altijd enthousiast, vooral over statistiek en nieuwe onderzoeks ideeën. Ik vind het heel bijzonder dat we samen alle onderzoeken hebben gedaan. Dankzij jou heb ik heel veel geleerd over statistiek en natuurlijk SPSS. Het leukste vond ik onze dagen in Vilnius tijdens het NOF-congres toen we onder andere samen gingen mountainbiken in de bossen. Hopelijk blijven we elkaar nog veel zien via de NOV!

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About the Author

Esther Bloemheuvel was born in Bergschenhoek on the 21th of April, 1989. After the family moved to Schijndel, she grew up with her parents and two brothers. She graduated Atheneum (Pre-university Education) in 2007 and started Medicine studies at the Maastricht University in Maastricht. In the final year of internships, she decided to focus on orthopedic surgery in the Máxima Medical Center in Veldhoven. During this year she started her first orthopedic research.



After her Master of Science degree, she started working at the Radboudumc orthopedic department in 2014. After one year she became an orthopedic trainee. During her traineeship she started as a surgical resident at the department of orthopedics at the Canisius Wilhelmina Hospital (CWZ) in Nijmegen (dr. F. Polat).

She continued her training at the Sint Maartenskliniek (dr. V.J.J.F. Busch), Rijnstate Hospital (dr. J.L.C. van Susante) and Radboudumc (dr. M.C. de Waal Malefijt). In the meantime the first LROI research studies were initiated and her PhD officially started.

After her traineeship, Esther started as a fellow pediatric orthopedics and trauma surgery at the Máxima Medical Center in Veldhoven in April 2021. In January 2024, Esther started as a staff orthopedic surgeon at the Isala Hospital in Zwolle, the Netherlands.

Esther van der Velden-Bloemheuvel is married to Michiel van der Velden in 2020 and they live together with their three children Sare (2017), Loek (2018) and Tesse (2020).

In her free time Esther likes to do sports, play saxophone, and spend time with her children, family and friends.

