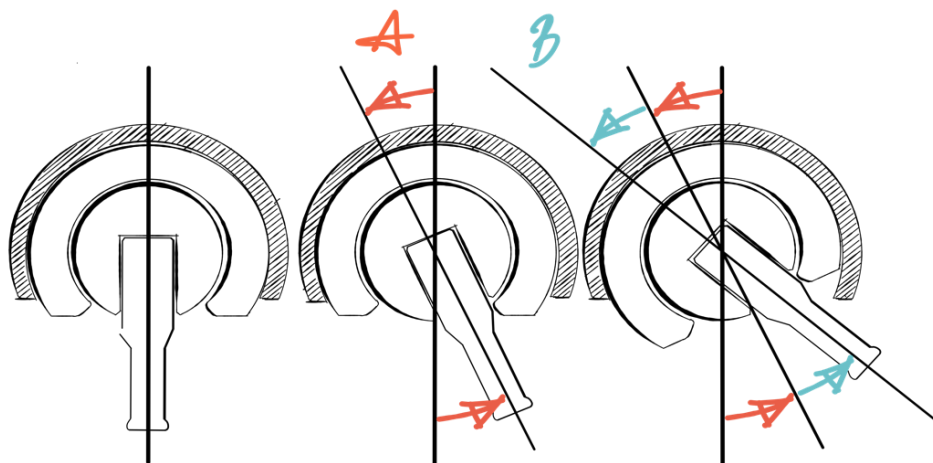# Evaluation of dual-mobility total hip arthroplasty in elderly patients with femoral neck fracture or hip osteoarthritis

PhD thesis

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Faculty of Health Sciences

Aarhus University

2018

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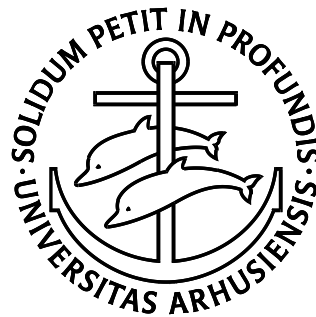
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Steffan Tábori Jensen

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# List of Studies

## This thesis is based on the following studies:

I.      Higher UHMWPE wear-rate in cementless compared with cemented cups with the Saturne® Dual-Mobility acetabular system
Steffan Tabori-Jensen, Christina Frølich, Torben B. Hansen, Søren Bøvling, Morten Homilius, Maiken Stilling.
*Hip Int. 2018 Mar;28(2):125-132.*

II.      Good function and high patient satisfaction 3 years after dual mobility THA following femoral neck fracture. A cross-sectional study of 124 patients.
Steffan Tabori-Jensen, Torben B. Hansen, Søren Bøvling, Peter Aalund, Morten Homilius, Maiken Stilling.
*Clin Interv Aging. 2018 Apr 9;13:615-621.*

III.      Low Dislocation Rate of Saturne®/Avantage® Dual-Mobility THA after Medial Femoral Neck Fracture. A cohort study of 991 hips with a minimum 1.6-year follow-up.
Steffan Tabori-Jensen, Torben B. Hansen, Maiken Stilling.
*Manuscript Accepted, Archives of Orthopaedic and Trauma Surgery*

IV.      Similar Proximal Migration but Inferior Stabilization of Cementless Compared with Cemented Dual-Mobility Cups in Elderly Coxarthrosis Patients. A Blinded Randomized Radiostereometric and Dual-Energy X-Ray Absorptiometry Study with 24-Months Follow-up.
Steffan Tabori-Jensen, Sebastian Breddam Mosegaard, Torben B. Hansen, Maiken Stilling
*Manuscript submitted to Journal of Arthroplasty, November 2018*

The papers of this thesis will be referred to in the text by their Roman numerals (I–V).

# Contents

# Abbreviations

| Abbreviations | Definition |
| --- | --- |
| BMD | Bone mineral density |
| CA | Coxarthrosis |
| CI | Confidence interval |
| CN | Condition number |
| DXA | Dual-energy X-ray absorptiometry |
| DM | Dual mobility |
| EQ-5D | EuroQol - five dimensional |
| FNF | Femoral neck fracture |
| GP | General population |
| GPI | General population index |
| GUR | Granular UHMWPE ruhrchemie |
| HA[a] | Hydroxyapatite |
| HA[b] | Hemiarthroplasty |
| HHS | Harris hip score |
| HRQoL | Health related quality of life |
| HXLPE | Highly crosslinked polyethylene |
| IDP | Intraprosthetic dislocation |
| MTPM | Maximum total point motion |
| NMS | New mobility score |
| OA | Osteoarthritis |
| OHS | Oxford hip score |
| OR | Odds ratio |
| PE | Polyethylene |
| PROM | Patient-reported outcome measure |
| RCT | Randomised controlled trail |
| RLL | Radiolucent line |
| RSA | Radiostereometric Analysis; radiostereometry |
| SD | Standard deviation |
| STS | Sit to stand |
| THA | Total hip arthroplasty |
| TR | Total rotation |
| TT | Total translation |

| | |
|---|---|
| TUG | Timed up and go |
| UHMWPE | Ultra-high molecular weight polyethylene |
| MoP | Metal-on-Polyethylene |
| CoP | Ceramic-on-Polyethylene |
| CoC | Ceramic-on-Ceramic |

# 1. English summary

Although total hip arthroplasty (THA) is one of the most successful procedures in orthopaedics, there are potential disabling complications. To address instability issues, the dual-mobility (DM) THA concept was developed in France in the 1970s and has gained popularity, especially in the treatment of femoral neck fractures (FNF) and revision surgery, but it is also increasingly used in elective surgery for coxarthrosis (CA). Few studies have investigated potential wear issues associated with the DM concept or functional outcomes of DM THA, and no studies have addressed migration profiles in elderly patients. The main aim of this thesis was to investigate the performance of primary DM THA in different clinically relevant settings in elderly patients with displaced FNF and CA. All patients included in studies I–III came from the same study cohort of FNF patients operated on between 2005 and 2016. In studies I–III, we evaluated wear of the plastic polyethylene (PE) liners and the dislocation and revision rate, as well as the postoperative functioning, health status, and satisfaction, of FNF patients. Additionally, in study IV, we wanted to evaluate radiostereometric analysis (RSA) assessed early migration patterns in cemented and cementless fixated DM THA in elderly patients who received surgery for CA.

In Study I a computer-assisted program assessed PE wear in cemented and cementless cups in 132 FNF patients, and radiographic evaluation was performed. We found that both cemented and cementless cups showed high *in vivo* PE wear, and cementless fixated cups had statistically significant higher PE wear compared to cemented cups. Both cup fixation methods had PE wear rates above the established osteolysis limit, but we found very few osteolytic lesions during short-term follow-up period.

Study II was a comparative cohort study in which we investigated 124 FNF patients' functioning, health status, and satisfaction and compared the findings to a matched cohort of CA patients and the general population. At the mean follow-up period of 2.8 years, we found that 89% were satisfied with the operation's outcome; the EQ-5D in DM THA in FNF patients was similar to the matched general population's index, and their Oxford hip scores (OHSs) were similar to those of the matched CA THA group.

In Study III, we evaluated dislocation and revision risk in a large historic cohort of 966 consecutive patients who received DM THA for FNF. We observed 45 (4.7%) large articulation dislocations and 8 (0.8%) cup revisions. There was a non-significant trend of increased

dislocation risk in cognitively impaired patients. We observed eight intraprosthetic dislocations (IPDs), which is a complication only seen in DM THA, and six of the IPDs occurred in relation to a reduction of large articulation dislocation.

Study IV was a randomized, controlled RSA study of 30 cemented and 30 cementless DM cups in elderly patients with CA. We observed generally low migration below the migration threshold limits, which is indicative of later cup loosening. However, at the 2-year follow-up, the cementless cups showed more absolute and continuous rotational migration compared to cemented cups, as well as poorer fixation in patients with preoperartive low bone quality.

There is still much to learn about the performance of DM implants in FNF patients, as well as in patients with DM THA for CA. The findings of this thesis provide novel insights concerning the PE wear profile and functional outcomes. It is currently the single largest evaluation of complications in FNF patients, and we conducted the first RSA cup migration profile of DM THA in elderly patients.

The findings of this thesis provide novel insights concerning about PE wear, functional results, complications as well as prosthetic migration in DM implants. The dissertation highlights important perspectives of treatment and outcome that may help initiate forward progression towards improved patient care.

# 2. Danish summary

Total hofte alloplastik (THA) er en af de mest succesfulde operationer inden for ortopædkirurgi, dog er der potentielle invaliderende komplikationer. For at adressere instabilitet ved konventionel THA, blev dobbelt-mobilitet (DM) THA konceptet udviklet i Frankrig i 1970'erne. DM THA er siden blevet populært, specielt indenfor behandling af brud på lårbenshalsen (*femoral neck fracture*, FNF) og revisionskirurgi, men anvendes også i stigende grad i behandling af hofteslidgigt (*coxarthrosis*, CA). Få studier har undersøgt de funktionelle resultater af DM THA og det potentielle øgede slid af plastkomponenten (PE) associeret med DM THA. Ligeledes foreligger der ingen studier af protesemigrationen af DM THA i ældre patienter.

Det primære formål med denne Ph.D.-afhandling var at undersøge DM THA som primær protesebehandling hos ældre med FNF samt CA. De inkluderede patienter i studie I-III kommer fra den samme kohorte af patienter med FNF opereret mellem 2005 til 2016. I studie I-III undersøgtes PE slid, dislokation- og revisionsraterne samt postoperativ funktion, helbredsstatus og tilfredshed. I studie IV blev der anvendt radiostereometrisk analyse (RSA) til at måle tidlig protesemigration af hhv. cementeret og ucementeret DM THA i ældre patienter opereret pga. CA.

I Studie I blev der anvendt et computerassisteret program til at estimere PE-slid i cementerede og ucementerede DM-hofteskåle i 132 patienter med FNF og røntgenbillederne blev evalueret. Der blev fundet høj PE-slid i såvel cementeret som ucementeret gruppe, men ucementerede hofteskåle viste statistisk signifikant mere PE-slid i forhold til cementerede hofteskåle. Både cementeret og ucementeret fiksation af den kunstige hofteskål havde PE-slid over den fastsatte osteolysegrænse, men vi fandt meget få osteolytiske læsioner i løbet af den korte opfølgning i studie I.

I et komparativt kohortestudie (studie II) undersøgte vi funktion, helbredsstatus og tilfredshed i 124 FNF-patienter og sammenlignede resultaterne til matchede resultater i CA-patienter samt baggrundsbefolkningen. Vi fandt, at 89% var tilfredse med resultatet af operationen. EQ-5D resultaterne i FNF-patienterne var sammenlignelige med den matchede baggrundsbefolkning. Oxford Hip Score (OHS) var sammenlignelig med resultaterne i den matchede CA-THA-gruppe.

I studie III blev dislokation- og revisionsrisiko evalueret i en stor historisk kohorte på 966 FNF-patienter opereret med DM THA. Vi observerede 45 (4.7%) dislokationer i den store artikulation og 8 (0.8%) revisioner af hofteskålen. Der var en ikke-signifikant øget risiko for dislokation i kognitiv svækkede patienter. Intraprostetisk dislokationer (IPD) er en komplikations, som udelukkende opstår i forbindelse med DM THA. Vi observerede i alt 8 IPD, hvoraf 6 opstod i forbindelse med lukket reponering af dislokation af den store artikulation.

Studie IV var et randomiseret kontrolleret RSA-studie af 30 cementerede og 30 ucementerede DM-hofteskåle i ældre patienter med CA. Vi observerede generel lav mikrobevægelse af både cementerede og ucementerede hofteskåle. Migrationerne var under de fastsatte grænseværdier indikativ for senere proteseløsning. Dog fandt vi mere absolut og kontinuert mikrobevægelse i ucementerede hofteskåle i forhold til cementerede hofteskåle ved 24-måneders opfølgning samt dårligere fiksation i patienter med præoperativ lav knoglekvalitet.

Der er stadig meget at lære omkring DM-implantater i behandlingen af FNF- og CA-patienter. Fundene i denne Ph.D.-afhandling bidrager med ny viden omkring PE-slid, funktionelle resultater, komplikationer samt protesemigration i DM-implantater. Afhandlingen fremhæver vigtige perspektiver, som kan hjælpe den fremadrettede udvikling imod forbedret patientpleje.

# 3. Introduction

*"Walking is man's best medicine"*
*Hippocrates c.460 - c.370 BC, 'The father of medicine'*

## Total hip arthroplasty

Total hip arthroplasty (THA) surgery consists of removing the femoral head and the cartilage from the acetabular socket and replacing it with a stem inserted into the femoral bone with a protruding ball of various sizes linking the stem to a liner, which is then located and interlocked inside the cup to form a new acetabulum.

Over the past 120 years, total hip arthroplasty (THA) has grown from an experimental intervention initially designed for severe cases of tuberculosis destruction of the hip joint and hip fracture treatment to being considered one of the most successful orthopaedic treatments of its generation. Initial treatments varied from replacing the destroyed femoral head with ivory in the 1890s to placing various tissues, such as submucosa from pig bladders, between the articulating hip surfaces in the 1910s. In 1925, Marius Smith-Petersen created mold arthroplasty, a ball-shaped hollow glass construction that could fit over the femoral head to simulate cartilage, but problems caused by the glass breaking lead to the use of other materials, such as plastic and steel [4,5].

The basic principles of modern-day THA were developed by Sir John Charnley in the early 1960s with low-friction ball and socket hip arthroplasty with synovial fluid working as natural lubrication between the articulating surfaces [6]. Charnley's invention consisted of a metal femoral stem inserted and fixed with bone cement (borrowed from dentists) and a plastic polyethylene acetabular component in which the small head of the femoral stem articulated, which reduced friction. A typical THA construction is presented in Figure 1.

Current indications for THA are degenerative diseases, such as idiopathic coxarthrosis (CA) and rheumatoid arthritis, as well as hip fractures, traumatic arthritis, benign and malignant bone tumours, and avascular necrosis; CA and hip fractures are the most common indications [7].

Damaged joint cartilage and bone tissue in CA leads to symptoms characterised by pain near the affected hip and leg, stiffness of the hip, and a reduced range of motion, which eventually lead to reduced physical mobility associated with reduced quality of life.

The number of primary THA procedures (all diagnoses) performed in Denmark increased from 5,474 in 2000 to 10,534 in 2015, corresponding to 184 per 100.000 inhabitants in 2018 [7]. Due to a growing proportion of elderly residents and a demand for joint replacement in younger, more active patients, the projected number of THA procedures is expected to increase over the next few decades [8,9]. Increasing the number of THAs inserted while emphasizing longevity, survivorship, and functionality of the implants continue to be key issues in meeting future demands. The most common cause of implant failure is aseptic or mechanical loosening, making good fixation between the prosthesis and the bone one of the most critical factors in securing the new joint's longevity [10,11]. As the aim of this thesis is to evaluate the dual-mobility acetabular cup, the naturel focus of this thesis will be mainly on the acetabular cup component rather than the femoral stem.

**Figure 1** A typical THA design. Stem with a head on top articulating with a plastic liner fixed in the acetabular component, the cup.
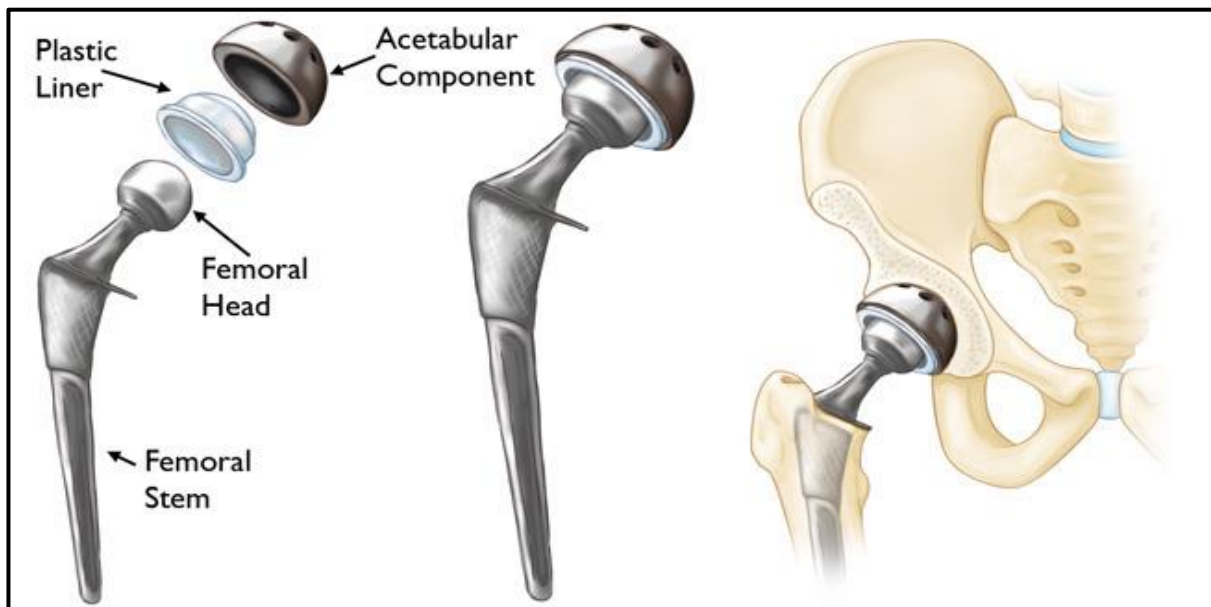
# Principles of bearings and acetabular fixation

Several different hip implant designs are available on the market, and implant components consist of various materials. The implant components must be biocompatible and wear resistant to withstand high mechanical forces during physical movement, which can generate forces up to six times one's body weight across the hip joint [12]. Various metals, such as titanium, stainless steel, and chromium-cobalt, as well as ceramics and plastics, are used in hip implant components, each with different strengths and limitations profile.

Formerly, patients were generally operated on with cemented cup fixation based on the pioneering work of Sir John Charnley, but with the introduction of a variety of different cementless press-fit implants, there has been a shift over the past few decades toward fewer cups inserted with cemented fixation in elderly patients. The fixation principles in cemented implants rely on the cement functioning as a grout rather than a glue, creating an interlocking fit between the bone interstices and the prosthesis, establishing an even distribution of the physical load transmission to the bone and securing firm initial implant stability regardless of bone quality [13,14]. The metals used in cemented components are often stainless steel or cobalt-chromium, as the elastic modulus is higher compared to, for example, titanium, thereby decreasing stresses imposed from the metal to the cement [14]. When inserting a cemented cup, the acetabulum is over-reamed with the removal of the subchondral bone plate, making space for the cement between the bone and the cup [15]. Following a pulse lavage to remove fat, blood, and other material, the cement is introduced and pressurized until ready for implant insertion. Cemented fixation is a more technically demanding and time-consuming procedure compared to cementless techniques, as the surgery team has to wait for the cement to cure around the components before the operation can be completed. When inserting cemented implants, a condition called bone cement implantation syndrome might occur, which is defined by adverse clinical events, such as hypotension, oxygen desaturation, cardiac arrhythmia, and even death. The true incidence of this syndrome is not exactly known, but large studies report incidences between 0.1%–0.4% of cemented hip arthroplasties [16].

The fixation principles in cementless implants rely on a biological fixation where the bone continuously appositions and remodels towards the implant, a process called osseointegration, which happens within weeks to months after implantation [17]. Before the bone can osseointegrate onto the cementless prosthesis, the initial mechanical stability of the press-fit fixation is of utmost importance, as the degree of initial implant micromotion influences the type of tissue

formation between the bone and implant [18]. The osseointegration of a cementless implant is dependent on several factors, such as the host's bone quality, loading conditions, surgical techniques, the implant's surface and design, and whether the implant material is biocompatible [19]. When inserting a cementless cup with a porous surface, the acetabulum is typically under-reamed so that the binding forces of the cup are maximized, creating a tight rim fixation. A bony interlock between the bone and the implant can happen via either on- or in-growth. Grit blasting or plasma spraying hydroxyapatite (HA[a]) onto the implant creates a textured surface onto which the bone can grow, hence on-growth. The surface on which in-growth can happen is created by using sintered beads or porous metals, for example, titanium, thereby forming microscopic pores into which the bone can grow [13].

HA[a] coating has been used since the 1980s and is still used in 20% of cups and 40% of the stems implanted in Denmark [7]. The literature reports divergent results concerning the ability of HA[a] to improve initial stability due to its osteoconductive properties and thereby reducing revision rates caused by implant loosening [20-23]. The major concern is that although HA[a] may enhance osseointegration, the HA[a] might disintegrate and result in excessive HA debris and third-body particulate wear of the PE, leading to periprosthetic osteolysis, and thereby potentially initiating implant loosening [24-29].

**Implant fixation in the elderly**

Traditionally, in Denmark, younger people (i.e., under age 65) have been treated with a cementless arthroplasty due to their general good bone quality and the expectancy that the arthroplasty in young people will have to be revised at some point, bearing in mind that a cementless revision is a less extensive procedure than a cemented revision surgery. With aging, the trabecular bone structure undergoes thinning in men, whereas the number of trabeculae in women is reduced, which is more biomechanically destabilizing. Further, an age-related loss of cortical bone and increased cortical porosity might increase fragility and make bones more susceptible to low impact fractures [30]. The estimated prevalence of osteoporosis in the general population older than age 50 is 40.8% in women and 17.7% in men, while it is 72.2% in women and 33.1% in men in the 70–79 age group and 88.6% in women and 55.3% in men above age 90 [31]. Structural changes in bone architecture lead to decreased bone quality, which might jeopardize the immediate press-fit stability of cementless components [32,33].

Since the introduction of the cementless fixation method in the 1980s, surgeons have overwhelmingly favoured cementless fixation. Although it was first used in North America and Australia, the use of this method has also increased in European countries over the past two

decades. The cause of this shift toward the increased use of cementless fixation seems multifactual, but marketing and the rapid development of durable cementless implants may have affected this change. Furthermore, speculation in the mid-1980s that the use of cement caused 'cement disease' (an adverse reaction to the cement) and the notion that bone cement was thought to be the major catalyst of pelvic osteolysis (although the hypothesis was later refuted) might also have affected this shift [34-36]. Is this change in fixation methods in many countries supported by the superior reported survival of cementless implants, and what is the best method of fixation in elderly patients? A clear answer to the latter is questionable, but according to a large Nordic registry study of 347,899 THAs, the 10-year survival of cemented fixation is higher than that of hybrid (cementless cup and cemented stem) and cementless implants in both the 65–74 and ≥75-year age categories [37]. In a metanalysis of 26,576 primary arthroplasties conducted by Tossi et al., cemented cup fixation was associated with a non-significant lower revision rates (OR 0.7, 95% CI, 0.39–1.25) in the elderly and higher survival (OR 1.49, 95% CI; 0.7–3.2) compared to cementless cups [36]. Furthermore, several other studies have failed to demonstrate the superiority of cementless cups over cemented cups in the elderly [38-42].

## Bearings in total hip arthroplasty

The articulation linking the stem component to the acetabular cup component in a THA is called the bearing surface. Currently, there are different material options available regarding the bearing surface in THA, and the mechanical and wear properties of the bearing is one of the biggest obstacles in securing the prosthesis' longevity. The head on the stem can be made of metal alloys, usually Cobalt-Chromium (CoCr), or ceramics. The head articulates with a liner, which is typically fixed with a locking mechanism inside the metal cup shell (single-mobility), and the most common liner material is polyethylene (PE), but ceramic may also be used. The most commonly used bearing types, which are metal-on-polyethylene (MoP), ceramic-on-polyethylene (CoP), and ceramic-on-ceramic (CoC), are presented in Figure 2, and this thesis will focus on MoP bearings.
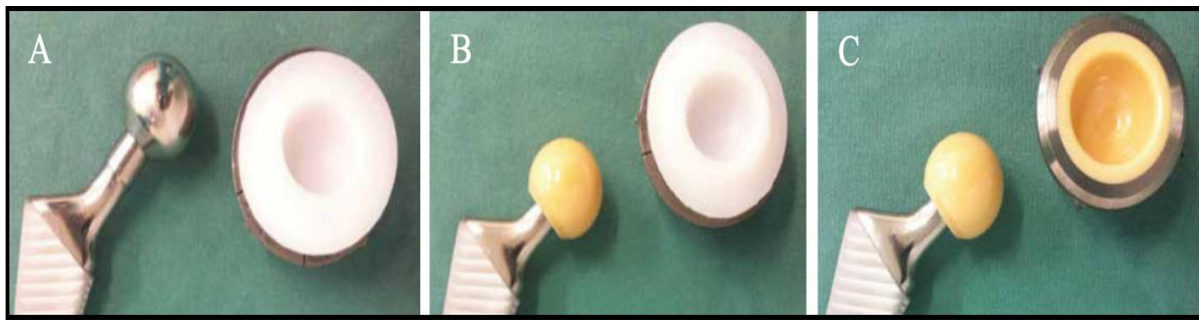
**Figure 2** Different types of THA bearings. A: MoP, B: CoP, C: CoC. [43].

PE is a plastic polymer consisting of a synthetic high molecular-weight compound formed by billions of identical bindings and has many desirable properties, such as low friction, high energy absorption, and excellent abrasion resistance. The first generation of ultra-high molecular weight polyethylene (UHMWPE) used in orthopaedic joint replacement was developed by Sir John Charnley in the early 1960s. After implantation, PE undergoes some changes in which long polymer chains in PE slide over each other, leading to a slow deformation of the PE liner, defined as 'creep.' This creep deformation of the PE liner usually occurs within the first twelve months after surgery and is not related to the production of wear debris [44].

**Wear and wear measurements**

Wear is defined as the removal of material from the implant in the form of particulate debris [45]. It is of great importance to minimize PE wear because wear debris may lead to osteolysis, a type of complex cellular-mediated local bone resorption, adjacent to the implant [46]. The risk of implant loosening is related to the degree of osteolysis, and for UHMWPE, an osteolysis threshold between 0.1 and 0.2 mm/year PE wear-rate has been established [46-48]. Gamma irradiation of the PE liner prior to surgery sterilizes it and increases cross-linking between PE molecules, making it more wear-resistant [49]. In the quest for more wear-resistant PE, the first generation of highly cross-linked polyethylene (HXLPE) by irradiation was developed in the mid-1990s. HXLPE has gradually replaced UHMWPE over the past 15 years, and second-generation HXLPE has proven to be more durable with lower mid- and long-term wear-rates, as well as a lower incidence of osteolysis, compared to conventional UHMWPE [50-53]. When manufacturing HXLPE by irradiation, free radicals are a by-product, which, in the presence of oxygen, facilitates degradation of the polymer. Compared to melting post-irradiated HXLPE, annealing HXLPE preserves its mechanical properties more effectively, but fewer free radicals are removed. To reduce the number of free radicals associated with HXLPE production, vitamin E has been introduced to HXLPE as it possesses antioxidative abilities [54]. The long-term

protective effect of vitamin E-infused HXLPE is unknown, but mid-term evaluations show promising low *in vivo* wear performance [55,56].

There are different ways of estimating PE wear, and as PE undergoes some deforming changes (creep), which is not related to particulate wear, during the first year after implantation, it is desirable to have several years of follow-up to distinguish particulate wear from creep. Radiostereometric analysis (RSA) is a very accurate method of *in vivo* evaluation of PE wear and considered the gold standard; however, it requires an expensive set-up and is not available in routine clinical use [11,57,58]. Commonly, femoral head penetration within the PE liner, measured as total wear (mm) and the wear-rate (mm/year), is the reported outcome measure in computer-assisted methods for plain radiographs. Computer-assisted methods use either the anteroposterior plain radiograph in determining two-dimensional linear wear or both the anteroposterior and the lateral radiographs to evaluate three-dimensional linear wear and volumetric wear between radiographs obtained at different follow-ups [45,59]. The three-dimensional wear assessment method, PolyWare™, introduced by Devane and developed by Draftware developers Inc., requires a CAD model of the implant design to assess wear, and the system can measure wear in metal-backed cups but not all-poly cups. Based on serial radiographs, the computerized program combines image analysis techniques with the determination of bone landmarks and edge-detection algorithms to detect changes in the femoral head's center position with respect to the acetabular cup's center. PolyWare's accuracy and precision are reported at 0.026–0.10mm and 0.006–1.07, respectively [60]; although it has been proven reliable in determining wear measurements in larger cohort studies and in older UHMWPE liners, it may not be sufficient in estimating wear in newer, more wear resistant HXLPE due to inferior accuracy compared to RSA [61]. Computer tomography (CT) has gained interest as a method of assessing PE wear and periprosthetic osteolysis, and recent studies suggest promising results when using CT-based methods as an alternative to RSA or computer-assisted PE wear measurements to determine PE wear [62,63].

# The dual-mobility THA concept

Instability of a THA where the head of the stem dislocates from the PE liner is historically and currently one of the most frequent complications and reasons for revision surgery. The aetiology of instability involves many factors, and although the dislocation rate ranges from 0.2% to 10% in primary THA, it is generally higher in patients treated with THA for displaced FNF and in revision THA [64-66]. To address the instability issue in patients considered to be at high risk for dislocation, a French professor, Gilles Bousquet, introduced the dual-mobility (DM) concept in 1974. The DM THA is a two-articulation design. In the first articulation, the head is mobile inside the PE liner and follows the same mechanical behaviour of MoP as in standard SM THA. The second articulation is between the backside of the PE liner and the metal cup as the DM PE liner is not fixed inside the cup like it is in conventional SM THA. Due to the mobility of the second articulation, the PE liner moves when in contact with the femoral neck until the femoral neck eventually impinges against the rim of the metal cup. Due to a retentive liner construction, the head is 'locked' inside the small articulation. The differences in articulation between conventional SM THA and DM THA are presented in Figure 3.
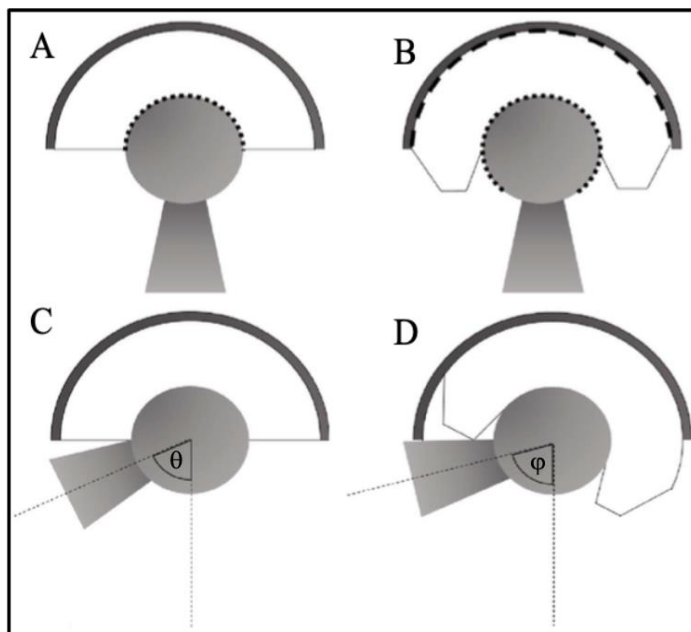


**Figure 3** A: Conventional one articulation SM THA (dotted line). B: Dual mobility cup with two articulations, large articulation (dashed line) and small articulation (dotted line). C and D: Illustrating the greater ROM in DM THA as angle $\varphi > \theta$ [3].

**DM THA advantages**

In an experimental study conducted in 2007, Guyen et al. found the tested DM implant increased the range of motion (ROM) to impingement with increased flexion (30.5°), adduction (15.4°), and external rotation (22.4°) when compared to a standard implant [67]. However, no clinical *in vivo* studies have proven the allegedly increase in ROM in DM implants compared to standard implants. In SM THA, a large femoral head size has proven effective in reducing the risk of dislocation due to the increased jump-distance in 36mm heads compared to 28mm

heads [68,69]. In theory, the head-liner complex in DM THA function as a large-head thereby increasing the jump distance before dislocation [70]. Some DM implant brands have added a cylindric extension that goes beyond the usual hemispheric cup shape for additional joint stability. High dislocation rates are especially a challenge in patients undergoing revision surgery and THA treatment after FNF, but the DM cup has been proven effective in reducing dislocation risk in both categories of high dislocation risk patients [71-74]. The DM THA concept has also gained global interest in primary THA over the last decade [75,76]. Although most published studies on DM in primary THA originate from the DM's country of origin and evaluate patients aged 65 or older, the dislocation rates are reported between 0% to 3.6% [77-81].

**Concerns regarding DM THA implants**

Despite the possible advantages of using DM cups, there are some issues of concern with the concept. The two major concerns are intraprosthetic dislocation (IPD) and the possibility of increased PE wear. IPD is a failure of the retentive properties in the small head-PE articulation, where the head dislocates from the insert and encounters the metallic cup (Figure 4). This complication is seen exclusively in DM implants and possible causes are excessive wear of the retentive rim and the attempted closed reduction of dislocation in large DM articulation. IPD rates are reported to be 0–5% of total DM procedures, potentially jeopardizing the benefit of the DM implants obtained by increased stability of the large articulation [3].



**Figure 4** IPD with an eccentric head position.

DM implants have two articulate sites where PE wear can occur, which has led to speculation regarding whether the convex surface inside the metal cup might increase PE wear and, ultimately, cause more osteolysis and subsequent implant loosening [82]. Prior to the research conducted for this thesis, there were no *in vivo* studies available of PE wear in DM implants. Several retrieval explant and experimental studies have attempted to estimate wear in different types of DM implants. Adam et al. reported linear and volumetric wear in 40 DM PE liners removed due to mechanical or septic failure at a mean of 8 years after implantation. They reported linear and volumetric wear of both the concave and convex surface to be comparable to that found in a wear analysis of MoP with 22mm femoral heads [83]. An experimental hip simulator machine study of one DM implant type under three different conditions (i.e., impingement, abrasion, and immobilized inner or outer diameter) also found similar or lower wear-rates in the DM implant studies compared to conventional SM-THA [84].

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It is not elucidated whether the potential for increased PE wear in DM implants correlates to accelerated osteolysis and subsequent aseptic implant loosening. First-generation DM implants were modified during the 1990s because of a high number of IPD's and poor long-term survival [80,85,86]. Second-generation primary DM implants for CA have shown encouraging medium-term survival in primary THA for CA, ranging 93–95% in two 10-year follow-ups and 94.2% in a 7-year follow-up survival study [78,81,87]. The noted concerns have led to increased caution when implementing DM implants in primary THA surgery and recommendation that DM implants should only be used in revision surgery and patients at extreme risk of instability, for example, patients with FNF and neuromuscular disorders [88]. Thus, most authors warrant long-term prospective investigations concerning the overall performance of DM implants, including *in vivo* PE wear measurements, before advocating the universal use of DM implants [82,88,89].

# Total hip arthroplasty in femoral neck fracture treatment

Hip fractures are defined as extending from the rim of the femoral head to 5 cm below the minor trochanter. Intra-capsular fractures refer to femoral neck fractures (FNFs) with fracture lines located above the insertion area of the hip joint capsule. FNFs are classified according to the Garden I–IV grading system and can be roughly categorized as either undisplaced (Garden I and II) or displaced (Garden III and IV) (Figure 5) [1]. The Garden classification is based on an anteroposterior (AP) radiograph, but Garden type II fractures are regarded as displaced if the lateral radiograph angulation of the femoral head has a posterior tilt >20° [90]. Extra-capsular fractures include intertrochanteric and subtrochanteric fractures. This thesis will only focus on displaced FNFs.
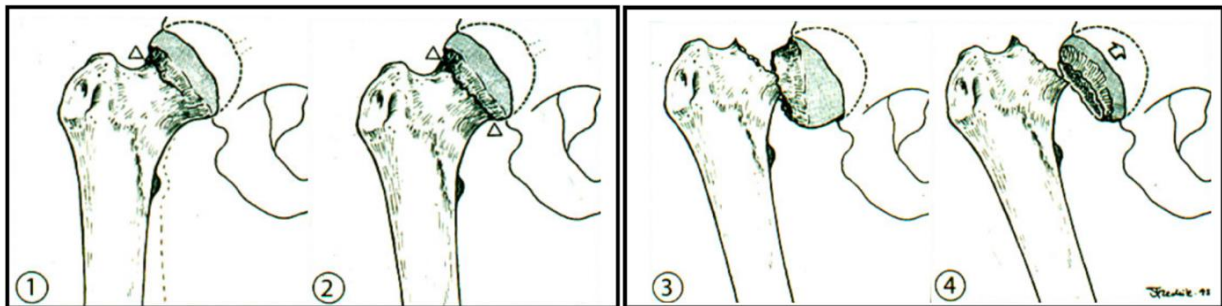


**Figure 5** Garden's classification of femoral neck fractures.
Undisplaced fractures: 1. Garden I, valgus impacted fracture. 2. Garden II, undisplaced fracture.
Displaced fractures: 3. Garden III, partially displaced fracture. 4. Garden IV, fully displaced fracture[1].

Undisplaced FNFs (i.e., Garden types I and II) are usually treated with closed reduction and internal screw-fixation, and displaced (i.e., Garden types III, IV, and type II with a >20° posterior head-on-neck angulation on lateral radiographs) are treated with arthroplasty, either hemiarthroplasty (HA[b]) or total hip arthroplasty [91]. Dislocation and deep infection are the most common early complications within the first five years after the index surgery; after five years, the PE wear process and implant loosening are the most common complications [92-94]. Due to older age, a greater fall tendency, less muscular control, and greater ligament laxity, the dislocation risk in THA may be higher in FNF patients compared to THA in CA [95-97]. Joint stability in THA is influenced by several factors: 1) implant related, including head size and the design of the implant fixation; 2) surgery related, including the implantation technique and positioning of the implant; and 3) patient-related, including gender, age, and the patient's preoperative cognitive status and level of functioning [82]. Numerous studies have reported that SM THA is associated with a higher dislocation risk compared to HA[b] in displaced-FNF treatment [98-100]. However, recent studies of DM implants in the treatment of FNF have shown promising results with reduced dislocations rates [101-104]. In the elderly, who naturally have

progressive deterioration of their cognitive and physical health, a DM THA may prevent dislocation events [105,106]. Furthermore, THA might provide superior postoperative functioning and less pain in addition to lower mortality compared to HA [98,100,107-110]. One factor that supports using THA instead of HA is that during HA[b] procedures, the acetabular socket is not replaced by any component. Therefore, in elderly patients, who have a high probability of pre-existing CA prior to their FNF, the likelihood of post-HA[b] pain due to CA and progressive acetabular degeneration, eventually leading to secondary conversion surgery to THA, increases. The reported conversion from HA[b] to THA due to postoperative pain from pre-fracture CA pain is reported to be between 1% and 10% [111-113]. Nevertheless, HA[b] is an 'easier' procedure that can be performed by less experienced surgeons and traumatologists, whereas the more technically demanding THA procedure often requires a hip surgeon. HA[b] is less expensive than THA, but when the mid-term complication, mortality, revision, and reoperation rates are evaluated, THA might be more cost-effective [65].

**Surgical approach**

The frequency and nature of complications following both HA[b] and THA for CA and FNF are affected by the chosen approach [114]. Compared to the anterior and direct lateral approach, the posterolateral approach is associated with increased dislocation risk in THA for both CA and FNF treatment [114-117]. However, the incidence of nerve damage might be higher in the anterior approach compared to the direct lateral or posterolateral approach [114]. Furthermore, it has been reported that the posterolateral approach might be beneficial regarding postoperative muscular function and gait compared to the direct lateral approach in CA patients, but the pre-fracture functional limitations in FNF patients might outweigh these subtler differences between the two approaches [118,119].

In Sweden, surgeons have reduced the use of the posterolateral approach and increased the use of the direct lateral approach in THA treatment for FNF patients in the last decade, resulting in an apparently lower dislocation risk in the direct lateral approach but also with a possible increase in the deep infection rate related to the direct lateral approach [120]. When HA[b] is used in FNF treatment, the direct lateral and anterolateral approaches have proven superior compared to the posterolateral approach in terms of reduced dislocation risk [116,121-123].

# Radiographic assessment of bone and implant stability

## Radiostereometric analysis (RSA)

RSA was introduced in 1974 by Göran Selvik and is widely used in joint replacement surgery due to its high accuracy and precision for quantifying the motion between the implant and host bone [124]. RSA has also proven valuable in evaluating joint kinematics, fracture stability, and healing and in the wear measurement of femoral head penetration into the PE liner [57,61,125,126]. The high precision and accuracy of RSA make it possible to include a small number of study subjects [126], which makes RSA ideal for pre-marketing evaluations of the migration profile of new implant designs, implant coatings, and bone cement prior to being released to the medical market [127]. The process of evaluating new implants prior to a commercial launch is called a 'stepwise introduction' with the following recommended steps: 1) preclinic mechanical implant testing, 2) early (2-year) clinical RSA trails, 3) large-scale multicenter RSA studies, and 4) postmarked national registry monitoring (Figure 6) [2,128].

Two methods of measuring implant migration are marker-based RSA, where tantalum markers are implemented onto the implant and into the patient's bone during surgery, thereby forming two rigid bodies, and the model-based method, in which a three-dimensional implant model (CAD model) provided by the manufacturer is digitally fitted to the contours of the actual implant on the RSA radiograph. The fitting of the CAD model to the RSA radiograph is done repeatedly by mathematical algorithms until the model fits with minimal discrepancies. Of the marker- and model-based RSAs, the former is reported to be more precise, but model-based is often preferred as occluded implant makers are a non-excising problem in model-based RSA [129].
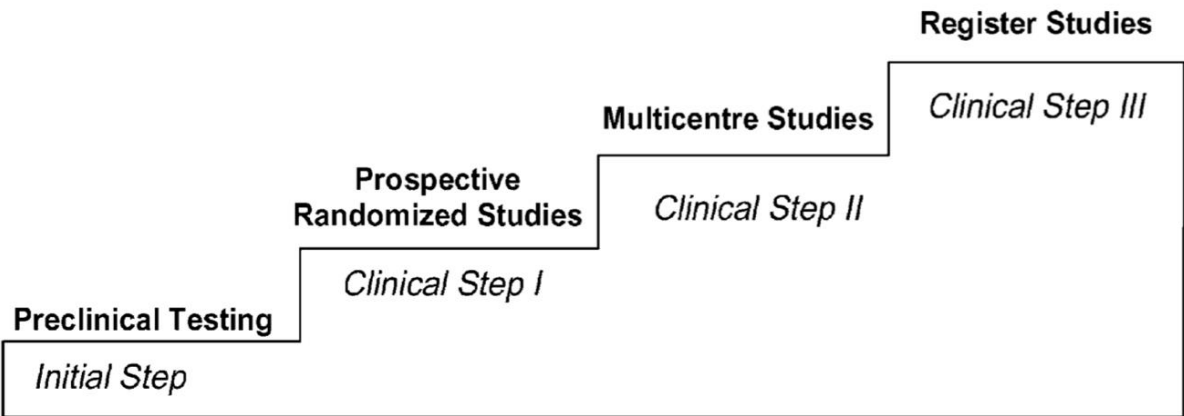


**Figure 6** The staircase "stepwise introduction" of new bearings, cements, and surgical techniques [2]

Several studies have reported a correlation between early implant micromotion and mid- and long-term survival in knee and hip arthroplasties [10,125,128,130,131]. In a systematic review of RSA studies of cup migration, Pijls et al. reported the following early (2-year) risk-thresholds: under 0.2 mm proximal cup translation (designated 'acceptable'), 0.2–1.0 mm proximal cup translation indicative of 10-year revision rates above 5% (designated 'at risk'), and proximal cup translation exceeding 1.0 mm as predictive of 10-year revision rates greater than 5% (designated 'unacceptable') [10]. A study of 39 all-poly cups conducted by Nieuwenhuijse et al. found that in addition to statistically significantly greater proximal cup translation in failed cups (>1.76mm) compared to non-failed cups, rotation around the z-axis exceeding 2.53° was a predictive risk factor for later aseptic cup loosening [131].

**Dual energy X-ray absorptiometry**

Because plain radiographs are not sensitive enough to detect small changes in bone quality adjacent to an implant, dual-energy X-ray absorptiometry (DXA) has become the gold standard in assessing changes in bone mineral density (BMD). Energy from low-dose x-rays used in DXA is absorbed in bone and soft tissue, which the DXA software can subsequently segment and quantify as the mass of bone, fat, and muscle. This makes DXA able to assess small changes in the tissue of interest, and the precision error coefficient of variation (CV%) for BMD measurements of the pelvic bone has been reported to 1.9% and 3.6% for cementless and cemented implants, respectively [132].

Although it is used to measure periprosthetic bone changes, DXA is most often used as a diagnostic tool to detect osteoporosis. Osteoporosis is a 'silent,' progressive systemic disease in which the structural composition of a patient's bones are abnormally porous compared to a normal person of the same age and sex [133]. A significant decrease in bone mass per unit volume makes the bone more brittle and predisposes the affected bone to fractures. Osteopenia is defined as a BMD equal to or less than 1 standard deviation of that of a young reference population (T-score $\leq$ -1), and osteoporosis is less than or equal to -2.5 standard deviations (T-score $\leq$ -2.5) [133,134].

Implant induced alternation of biomechanical forces to the implant adjacent bone structures is believed to cause local bone resorption, which follows Wolff's law from 1892[135], we define as; *"healthy bone will adapt to the loads under which it is placed. When increasing the load on a bone, the bone will remodel itself over time and thereby become stronger to resist that load.*

*The inverse is true as well: if the loading on a bone decreases, the bone will become less dense and weaker due to the lack of the stimulus required for continued remodelling"*.

Bone resorption of the proximal periprosthetic areas (proximal Wilkinson zones) is a commonly reported phenomenon in cementless cup fixation and might be more intense than in cemented cup fixation [136-140]. Monitoring periprosthetic BMD changes around stems might predict implant instability and subsequent loosening, which might also be the case for cups [141-143]. Two studies of postmenopausal women operated on with cementless THA for CA have found that a preoperative low BMD status affects the RSA-measured stability of the femoral stem and cup compared to normal preoperative BMD [32,33].

# Patient-reported outcome measures (PROMs)

Traditionally, outcome monitoring of THA has been limited to tangible data, such as implant survival, revision, reoperation, and mortality rates, as well as radiographic measures. However, interest in patient-centred functional outcomes after rehabilitation has increased over the last decade. THA has proven successful in pain relief, improving patients' functional capacity and health-related quality of life for end-stage CA [144,145]. The primary indication for THA for CA is pain and decreased health-related quality of life, so data collection related to patient-reported outcome measures (PROMs) is preferable. Using outcome measures from more than one of the following five major outcome categories is advised: general health-related quality of life (HRQoL), activity of daily living (ADLs), mobility and physical performance scales, disease-specific scales, and joint-specific scales [146,147].

Sweden routinely collects PROM data (i.e., the Charnley classification, VAS for hip pain, and the health-related quality of life score, EQ-5D) on all patients undergoing THA for CA with almost 90% completeness [120]. A study of almost 35,000 THAs observed statistically significant decreased pain (EQ-VAS) postoperatively, and the postoperative mean EQ-5D increased to above the level of an age- and gender-matched population [148]. PROMs are not routinely collected in Denmark, but a few studies have reported patient-related outcomes in primary THA for CA [149,150]. Contrary to the authors' expectations, Aalund et al. observed greater EQ-5D improvements in older patients compared to younger ones, making older patients with poor preoperative baselines at least as suitable for operations as younger patients [149].

A high number of patients are lost to follow-up due to their poor general physical condition and high mortality rates, which makes mid -and long-term PROM evaluation of FNF patients

particularly challenging. Furthermore, FNF is an acute injury, which is why pre-fracture data is often unavailable for studying pre- and post-fracture outcome differences in patients and between different treatment modalities. Nevertheless, it is expected that FNF patients have reached their postoperative functional outcome peak around one year after surgery; thereafter, functioning may decline due to aging and fragility [151,152].

Although there is a tendency to exclude patients with cognitive impairment in FNF studies [153], several randomized controlled trails studies suggest superior HRQoL and functional outcomes in THA compared to HA in displaced FNF treatment [108,152,154,155]. In addition to considerably lower mortality rates in the THA group compared to internal fixation (IF) and HA[b] for displaced FNF, Leonardsson et al. reported better mean EQ-5D index scores, generally lower mean pain-VAS scores and higher satisfaction ratings in the THA group compared to IF and HA[b] groups [156]. Reported PROMs in DM THA for FNF are scarce, with only two studies reporting PROM outcomes [102,103]. Many hip fracture patients do not fully regain their pre-fracture physical functioning [157]. Physical performance can be measured using a variety of approaches [146], but it is important that physical tests reflect balance and gait maneuvers used in everyday life [158]. The timed 'up and go' (TUG) test is the most commonly identified mobility score used for FNF patients, and the sit-to-stand (STS) test is widely used as a functional performance measure in CA patients after THA [159,160].

# In summary

The following questions arise in terms of evaluating dual-mobility implants in the elderly:

1) There is a lack of *in vivo* evaluations of the wear profiles of DM implants. How will DM implants inserted with different fixation methods, and in comparison, with SM THA, perform in elderly FNF patients with a relatively low physical capacity?

2) THA has been shown to be very beneficial in restoring hip function in coxarthrosis patients, as evidenced by high satisfaction ratings, but can outcomes in FNF patients treated with a DM THA compare to the results of primary SM THA in patients with CA?

3) Will the DM implant inserted in a large unselected group of FNF patients confirm prior reports of its reduced dislocation rate, and what is the extent of other implant-related complications?

4) There is no evidence that DM implants have superior long-term performance as primary THA in elderly patients with CA who have normal and low preoperative bone quality. Furthermore, is the trend towards cementless fixation warranted in elderly patients, and how will DM implants perform in relation to defined migration thresholds when examined by radiostereometric analysis?

# 4. Design, aims, and hypotheses

The overall aim of this thesis was to evaluate the performance of the DM THA concept in the treatment of elderly patients with FNF and CA. The studies described in papers I–III were conducted on patients treated with primary DM THA due to displaced FNF, and the study for paper IV was conducted on patients with CA treated with primary DM THA.

The specific designs, aims, and hypotheses were as follows:

## Study I

*Design:* Cross-sectional clinical cohort follow-up study with a prospective evaluation of the PE wear of the Saturne® DM acetabular component.

*Aim:* To identify potential differences in PE wear-rates of two cup fixation methods (i.e., cemented and cementless) used in surgeries involving a DM acetabular system.

*Hypothesis:* There is an increased PE wear-rate in patients with HA-coated cementless cup fixation.

## Study II

*Design:* Cross-sectional comparative cohort study.

*Aim:* To assess the functioning, health status, and satisfaction of a cohort of patients treated with DM THA and compare the findings to a matched cohort of CA patients, as well as to the general population index.

*Hypothesis:* FNF patients treated with DM THA will gain good function and high satisfaction at the level of gender- and age-matched CA patients treated with primary THA.

## Study III

*Design:* Retrospective follow-up study of an unselected historic cohort.

*Aim:* To investigate the dislocation and revision rate in patients operated on with primary DM THA in our department between 2005 and 2015.

*Hypothesis:* There are low dislocation and revision rates in patients treated with DM THA.

**Study IV**

*Design:* Single-blinded randomized clinical controlled trial with a 24-month follow-up.

*Aim:* To compare RSA-measured early proximal cup migration and the migration pattern of cemented and cementless DM cups, including secondary endpoints, such as changes in the periacetabular BMD and PROMs.

*Hypothesis:* Cemented DM cups will display less migration compared to cementless DM cups.

# 5. Materials and methods

## Ethics and permissions

The protocols for **Studies I–III** were reviewed by the Central Danish Regional Committees on Biomechanical Research Ethics (inquiry 149/2012) and were not regarded as a health research project; therefore, no ethical approval was needed as per the definition in paragraph 2, No. 1 of the Committee Act. Studies I–III were registered with the Danish Data Protection Agency (Protocol no. 1-16-02-64-13).

**Study IV** was approved by the Central Danish Regional Committees on Biomechanical Research Ethics (Journal no. 1-10-72-209-14), and all patients gave their informed content to participate. Study IV was registered with the Danish Data Protection Agency (Protocol no. 1-16-02-16-15). The project was registered with www.clinicaltrials.gov (Clinical Trials Study ID number 02404727). The study was performed in accordance with the ethical principles of the Helsinki Declaration.

# Patients

## Studies I–IV

**Table 1** Demographics study I-IV. Numbers are presented as mean (range). *Adapted from Paper I-IV.*

| Study I | Cemented DM cup | Cementless DM cup |
|---|---|---|
| Number of patients | 56 | 73 |
| Gender, (M/F) | 10/46 | 22/51 |
| Side, (R/L) | 28/28 | 25/48 |
| Age at operation, years | 76.5 (42-93) | 74 (30-95) |
| Follow-up, years | 3.0 (1.1-7.6) | 2.7 (1.0-7.7) |
| **Study II** | **FNF Cases** | **2:1 CA match** |
| Number of patients | 124 | 226 |
| Gender, (M/F) | 29/95 | 49/177 |
| Age at operation, years | 74.7 (30-92.6) | 74.6 (52.6-92.2) |
| Follow-up, years | 2.8 (1.0-7.7) | 1-year FU |
| **Study III** | **Cemented DM cup** | **Cementless DM cup** |
| Number of patients | 415 | 551 |
| Age at operation, years | 81.6 (42-104) | 79.6 (47.3-103.2) |
| Gender, (M/F) | 116/299 | 174/377 |
| Follow-up, years | 6.4 (1.6-12.6) | 4.7 (1.6-12.6) |
| DM implant brand | | |
| *Saturne* | 395 | 389 |
| *Avantage* | 20 | 162 |
| **Study IV** | **Cemented DM cup** | **Cementless DM cup** |
| Number of patients | 29 | 30 |
| Gender, (M/F) | 14/15 | 13/17 |
| Age at operation, years | 75.0 (70.3-81.7) | 75.2 (70.2-82.9) |
| Cup inclination angle° | 49.2 (36.2-61) | 43.5 (28.9-59.7) |
| Cup anteversion angle° | 11.5 (1.2-26.2) | 11.7 (0.7-26.3) |
| Preoperative T-score | -1.01 (-2.9-1.8) | -1.12 (-3.1-2.3) |
| BMI | 28.3 (22.6-39.1) | 28.6 (21.6-38.0) |
| ASA class | 2.0 (1-3) | 1.8 (1-3) |

The FNF patients included in Studies I–III were from the same patient cohort operated on with primary DM THA for displaced FNF between 2005 and 2012 at the University Clinic for Hand, Hip, and Knee Surgery of the Orthopaedic Department at Regional Hospital in West Jutland, Denmark. Patients were given the same treatment regardless of their mental status. The original cohort consisted of 414 patients operated on between 2005 and 2012. At follow-up in December 2013, 155 had passed away, and the remaining 259 were invited for hip radiographs and a clinical examination.

The original follow-up period was extended from 2012–2016 to increase the number of patients in Study III. Studies I–IV's patient demographics are presented in Table 1, and a schematic overview of patients included in the four studies is presented in Table 2. In Study II, 124 DM THA patients were matched 2:1 for comparison on EQ-5D and OHS to a CA group operated on with conventional SM THA at our institution between 2008 and 2013 with reported 1-year EQ-5D and OHS. Furthermore, the 124 DM THA patients in Study II were matched on EQ-5D to general population (GP) norms, which were based on the study of 15,700 respondents (age range 20–79) in the Danish general population [161].

**Table 2** Overview of patients included in study I-IV.

| FNF patients n = 414 | | | | | CA patients n = 90 | |
|---|---|---|---|---|---|---|
| Study I n = 129 | | Study II n = 124 and matching | | Study III n = 966 | Study IV n = 60 | |
| Cemented DM cup n | Cementless DM cup n | DM THA n | Matching | DM THA n | Cemented DM cup n | Cementless DM cup n |
| 56 | 73 | 124 | 226 Matched CA group / Avg. 359 GP match | 966 | 29 | 30 |

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## Study IV

Based on proximal cup translation as the primary effect variable, a pre-study power analysis, which was based on means and standard deviations from the pilot study, was conducted. To conduct a two-sample mean test for a minimal relevant difference of 0.2mm [10] with a power of 90%, 5% significance level, and SD of 0.20 in both groups, 23 patients were needed in each treatment arm. However, we included 30 patients (30 hips) in each group to compensate for potential dropouts.

A CONSORT flow diagram is presented in Figure 7. The eligibility criteria are presented in Table 3. All patients were included during a 12-month period from October 2014 to October 2015.

**Table 3** Eligibility criteria used in Study IV.

| Inclusion Criteria |
|---|
| 1.  Men and women with coxarthrosis. |
| 2.  Age 70 years and above, empowered and capable. |
| 3.  Informed written consent. |
| 4.  The patient may only participate with one hip. |

| Exclusion criteria |
|---|
| 1.  Severe nerve, muscle or vascular disease in the lower extremities |
| 2.  Patients assessed during surgery as unsuitable for treatment with cementless hip prosthesis. |
| 3.  Patients with severe osteoporosis (T-score $\leq$ 4.0) as assessed via a pre-surgical DXA scan. |
| 4.  Patients who previously underwent surgery to correct bone malalignment of the hip or previous hip fractures. |
| 5.  Patients in need of a different type of stem than Exeter (Stryker). |
| 6.  Patients with metabolic diseases of the bone or rheumatoid arthritis. |
| 7.  Patients undergoing corticosteroid treatment ($> 3$ months / year). |
| 8.  Patients with active cancer. |
| 9.  Patients without Danish citizenship / patients who do not speak and understand Danish. |
| 10.  Patients with dementia. |
| 11.  Patients with active alcoholism. |
| 12.  Patients with severe systemic disease affecting gait and mobility (e.g., Parkinson's disease |

**Figure 7** CONSORT 2010 flow diagram. *Adapted from paper IV.*
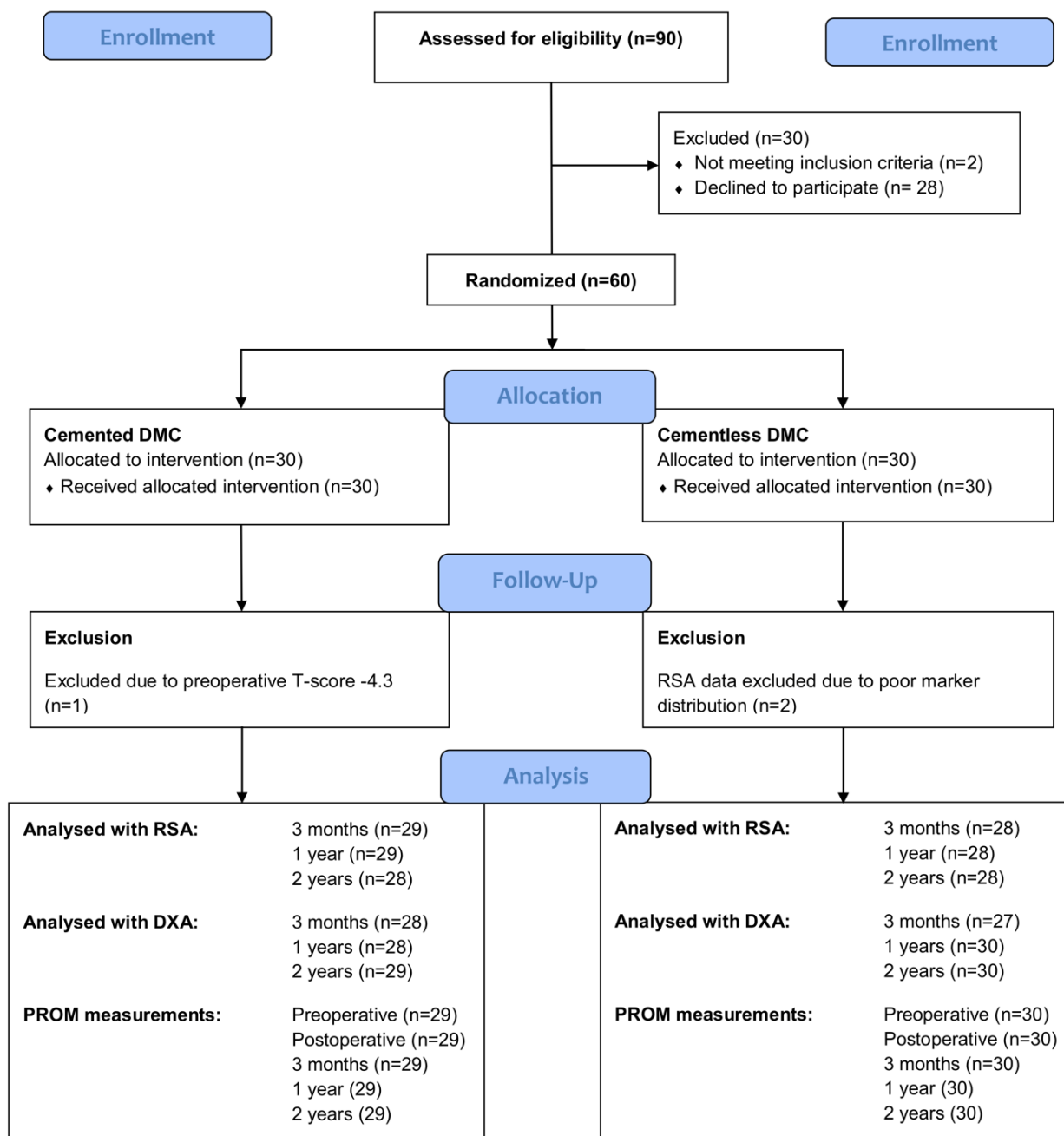


## Randomization

Block randomization was conducted via an online service (www.sealedenvelope.com). Block size of 60 were randomized into two treatment groups (cemented or cementless cup fixation) with a list length of 30. On the day of the operation, a sealed envelope was opened to allow operating-room personnel to prepare the operation theatre for either cemented or cementless cup fixation, depending on the information contained in the envelope. Patients were blinded regarding which cup fixation method they received.

# Intervention and outcomes

## Studies I–III

### General information regarding Studies I–III:

All patients included in Studies I–III had a displaced FNF (Garden III and IV). From 2005 to 2014, the Saturne® (Amplitude, France) DM system was used in combination with a cemented Exeter® (Stryker Corporation, USA) or cementless Corail® (DePuySynthes, USA) stem. Due to a regional tender in July 2014, our department was required to change to the Avantage® DM acetabular cup system (Zimmer Biomet, Warsaw, Indiana, USA), but the stem systems remained unchanged. Cemented or cementless fixation was used according to the surgeon's preference in combination with a preoperative radiograph assessment and the surgeon's intraoperative judgment of bone quality. Surgery was performed by consultants or supervised residents. The surgical approach was posterolateral in all cases.

## Study I

From the original cohort of 414 patients operated on between 2005 and 2012, 129 patients were available for this study. At a mean follow-up of 2.8 (range 1.0–7.7) years, the cross-sectional digital radiograph was used for computerized PE wear measurements and a radiographic assessment of osteolysis and RLL.

### Implants

The DM component was a cemented Saturne® (Amplitude, France) metal shell with an external sandblasted surface and a highly polished articulate surface. The cementless Saturne® (Amplitude, France) metal shell is sandblasted prior to a plasma-spray titanium and synthetic HA[a] dual-coating (80μm+80μm) being applied. Femoral heads were 28-mm chrome-cobalt. The calcium-phosphate ratio of the HA[a] coating was between 1.67 and 1.76. The surface roughness (Ra) of the cementless HA[a] -coated cups was 6.3μm. A UHMWPE liner (GUR 1050) was used in the both cemented and cementless DM THAs. (Product information from Orthotec).

## Polyethylene wear measurement

Baseline postoperative radiographs were taken within 3 days after surgery. At the cross-sectional follow-up, patients were assessed while in the supine position with their feet slightly internally rotated to tighten the head position in the PE/metal bearing and ensure wear measurements were performed on the whole cylinder. Final cross-sectional pelvic AP radiographs were used to analyze PE wear [61]. The inclination and anteversion of the cup and the two-dimensional distance of femoral head displacement (linear wear) could be measured from the digitized radiographs.

Measurements were performed with PolyWare Pro 3D digital version 5.10 software (Draftware Developers, USA). With a digital edge-detection algorithm, circles were fitted on the edges of the cup and the femoral head, creating border-circles on the image (Figure 8), followed by a solid 3D model. Assuming zero wear at the baseline postoperative radiograph, PolyWare measured head penetration into the metal shell (total PE wear, mm), and the wear rate (mm/year) was calculated by the software based on the time from surgery to the date of the final cross-sectional radiograph.



**Figure 8** Digital edge detection of the cup and head.

In order to assess the precision of the method, half (n = 66) of the radiographs were analyzed twice. The same investigator analyzed all radiographs. The wear-rate intra-observer bias was 0.03 mm/year and 0.057 mm for total wear, and the concordance correlation coefficient was 0.91 and 0.90, respectively, which implies a moderate strong correlation between the measurements.

## Radiographic assessment

The occurrence of osteolysis and radiolucent lines were evaluated on the final follow-up radiograph according to the 3 DeLee zones around the cup and the 7 Gruen zones around the stem [162,163]. The formation of ectopic ossification around the cup was evaluated on the final follow-up radiograph using the Brooker classification method [164]. The stem's cementation quality was graded on the postoperative radiographs according to Barrack's grading system [165]. Since no cementation grading system could be found for the acetabular component, we

modified the Barrack grading system to the DeLee zones around the cup, and only RLLs at or above 1mm in width were counted (Figure 9).
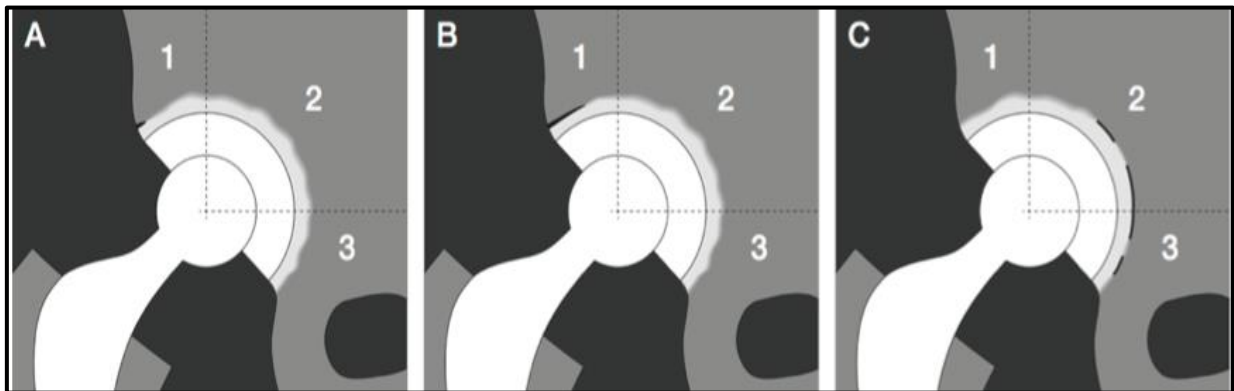


**Figure 9** Classification of cup cementation quality. Grade A: complete filling of the periacetabular cavity by cement, "so-called white-out", or < 4mm long zone 1 lateral RLL (as this is very common) at the bone-cement interface. Grade B: RLL >4mm long in zone 1. Grade C: RLL > 4mm long in zone II or III. Adapted from Paper I

## Study II

At the mean 2.8-year (range 1.0–7.7) follow-up, 124 patients reported EQ-5D, OHS, NMS, and their level of satisfaction with the DM THA treatment. HHS, including a hip examination, was completed. As no preoperative NMS were available, a nurse assisted the patient in recalling the preoperative NMS at the cross-sectional follow-up. A Danish version of the abbreviated 0–9 mental status test was completed; a score of 0–5 on this test is considered to be in the low cognitive functioning range [166]. The patients' functional capacity was tested with TUG and STS tests [158,160].

The FNF patients were matched to CA patients with SM THA on three parameters (i.e., gender, age in 5-year age intervals, and surgery year). Each control patient in the CA group was only used for a single match. There was a full match on all three parameters for 76 patients, and a partial match (age and gender, but not the operation year) for 42 patients. There was no match for six FNF patients. A double match was possible in 88% of full matches and 97% of partial matches. Both full and partial matches were used to compare EQ-5D and OHS (n=226).
FNF cases were divided into 5-year intervals and then matched on gender and age (in 5-year intervals) to GP norms. On average, there were 359 matches in the GP group per FNF case.

## PROMs

*OHS:* The OHS is an entirely self-reported joint specific PROM, measuring the hip-related capability of patients undergoing THA. It consists of 12 multiple choice questions quantifying functional ability, daily activity, and pain, and the score ranges 0–48; a score of > 41 is considered excellent, 34–41 is good, 27–33 is fair, and < 27 is poor. [167-169].

*HHS:* The HHS system is most commonly used by physicians to measure hip function after THA. The 15-item questionnaire evaluates patients' pain level, functional activities, and range of motion [170]. Along with the surgeon-assessed HHS, Danish patients are asked about their overall satisfaction with the operation outcome using a 4-level score (1=very satisfied, 2=satisfied, 3=less satisfied, 4=unsatisfied) [171]. A score of <70 is considered a poor result; 70––80 is fair, 80–90 is good, and 90–100 is excellent [168].

*EQ-5D:* Using a three-level response (i.e., no problem, some/moderate problems, or extreme problems) patients describe their own health status in five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The reliability of comparing EQ-5D to general population norms is reasonable as the study used for comparison is based on a recent study of 15,700 Danish persons [161]

*NMS:* This simple questionnaire measures patients' range of mobility from 0–3 using three questions regarding whether they are able to walk inside and outside, as well as whether they are able to perform grocery shopping tasks. The score ranges from 0–9, with higher scores indicating greater mobility and independence [172]; scores from 0–5 are considered a poor result, and 6-9 is a good result. Evaluating NMS on all FNF patients is recommended at admission and during the postoperative period to evaluate their rehabilitative potential [173].

## Functional capacity tests

*TUG:* Timed 'up and go' (TUG) is a functional test used to quantify mobility. The test is simple and easy to perform in the clinic and requires no special equipment. The test score is roughly divided into 3 groups: <10 secs is considered normal, while < 20 secs is considered to be good mobility, allowing the patient to be outside alone without aid, and 30 secs is considered to be indicative of mobility problems [158]. The TUG test is illustrated in Figure 10.
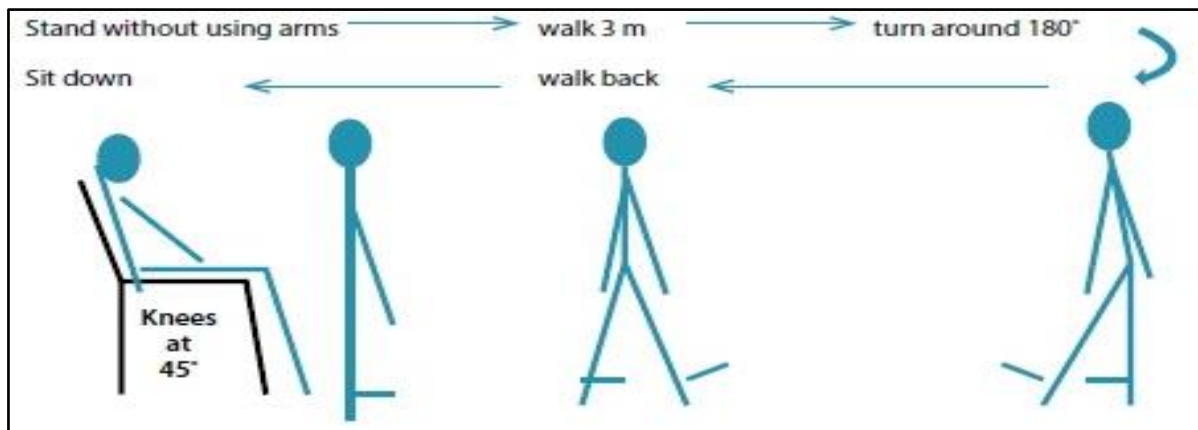
**Figure 10** The TUG test.

*STS:* We used a modified version of the STS test to examine patients. With the patient seated in a standard chair (approx. 43 cm high), we documented the length of time (in seconds) it took them to rise to a full standing position 10 times as quickly as possible.

# Study III

Between 2005 and 2016, 966 patients were operated on in our department with primary DM THA for displaced FNF (Saturne cup: n= 784, Avantage cup: n=182). The mean follow-up period was 5.6 (range 1.6–12.6) years. Complications were recorded until August of 2017 or earlier if the patient died. Since 2011, nurses have used a Danish version of the 0–9 mental status test for FNF patients prior to surgery. A test score between 0–5 is considered low cognitive functioning [166], and mental status scores were available for 65% of the patients (n=634). All files were crosschecked with postoperative radiographs to verify the cup type, fixation type (i.e., a cemented, cementless, or hybrid prosthesis), and DM THA- related complications (e.g., dislocation, cup or stem revision, fracture, and infection). The occurrence of pulmonary embolisms or deep vein thrombosis was recorded for three months after surgery.

## The Danish national patient register

Along with complications recorded while evaluating the cohort's files and radiographs, the Danish National Register was crosschecked for any missed postoperative complications that occurred outside our own department during the follow-up period. The Danish National Register is considered to be largely complete since all admissions to public hospitals are recorded for both in- and outpatient contacts, and ICD-10 diagnostic codes are registered. Extraction from the Danish National Register is based on *a priori* defined variables supplied by the researcher before data were requisitioned from the database.

## Radiographic assessment

All radiographs were evaluated by one observer. Cup inclination was measured manually on postoperative anteroposterior (AP) pelvic radiographs as the angle between the plane through the opening of the cup and the horizontal plane (i.e., the ischial tuberosity line) [174]. The version of the cup was assessed dichotomously to be either anteverted or retroverted in relation to the ischial tuberosity/ischium on the postoperative lateral radiograph [175]. The precision of the cup inclination measurements was evaluated as double measurements by the same observer on 10% of the patients (n = 81). The mean intra-observer inclination difference was -0.42 degrees (SD 1.1), and the concordance correlation coefficient was 0.98, implying excellent intra-observer reproducibility.

# Study IV

## Implants

Both the cemented and cementless DM Avantage® Reload stainless steel acetabular component has a cranial-lateral rim, which increases head-coverage (Figure 11). The external surface of the cemented Avantage® metal shell has a bright polish and the inner articulate surface is highly polished. Vacuum mixed Palacos® R+G bone cement (Zimmer Biomet, USA) was used for fixation. The cementless Avantage® Reload metal shell has a double coating with a projection vacuum plasma (VPS) titanium coating and synthetic HA[a] to create a rough surface finish.



**Figure 11** Left: Cementless Avantage cup. Right: Cementless Avantage cup

The Exeter® highly-polished stem (Stryker Corporation, USA) with vacuum mixed Palacos® R+G bone cement (Zimmer Biomet, USA) were used in all patients. A 28-mm chrome-cobalt femoral head and a Vitamin E-Diffused HXLPE liner were used in all cases. All liners were vacuum packed and gamma-sterilized. (Product information from Zimmer Biomet).

## Surgery and rehabilitation

All patients were operated on by one of two highly experienced orthopaedic hip surgeons. Prophylactic cefuroxime 1.5 g (Zinacef®, GlaxoSmithkline, Sweden) was administrated intravenously before surgery in all patients. After bone preparation, 6-8 tantalum beads (size 1.0 mm) were inserted into the periacetabular bone for subsequent RSA measurements. A bead gun was used to insert the beads (Wennberg Finmek AB, Sweden). To prevent bleeding, 1 g of tranexamic acid was administered at the end of surgery. Hip replacement was carried out using a posterolateral approach with the patient in lateral decubitus. Patients were mobilized with full weight bearing as tolerated immediately after surgery. The rehabilitation goal for the first postoperative day was for the patient to be out of bed for 4 hours, including training with a physiotherapist, and 8 hours per day for the remainder of the hospitalization period.

## Follow-up

The patients were examined according to the intervals given in Table 4. RSA and DXA double examinations were performed at the 3-month follow-up.

**Table 4** Follow-up examinations in study IV.

| Method | Endpoint | Effect parameter | Pre-op | Post-op | 3 mo. | 12 mo. | 24 mo. |
|--------|----------|------------------|--------|---------|-------|--------|--------|
| RSA | Cup fixation | Primary | | x | x | x | x |
| DXA | Bone density | Secondary | x | x | x | x | x |
| PROMs | Function | Secondary | x | | x | x | x |

## Radiostereometric analysis

**RSA setup.**

A standardized RSA setup (Figure 12) was used for obtaining stereoradiographs of the cemented and cementless DM THA in accordance with ISO standards [176]. As no actual RSA system was available at the beginning of the study, an extra x-ray tube was installed in the RSA examination room. The two ceiling-fixed x-ray tubes (Santax Medico, Denmark) pointed directly towards the THA implant and crossed the center at a 20° angle of convergence. A uniplanar carbon calibration box (BOX 19, Medis Specials, Leiden, the Netherlands) was placed under the patient. The stereographs were digitalized images (Fuji CR, 200 μm pixel pitch).

**Figure 12** The set-up of Radiostereometric analysis.
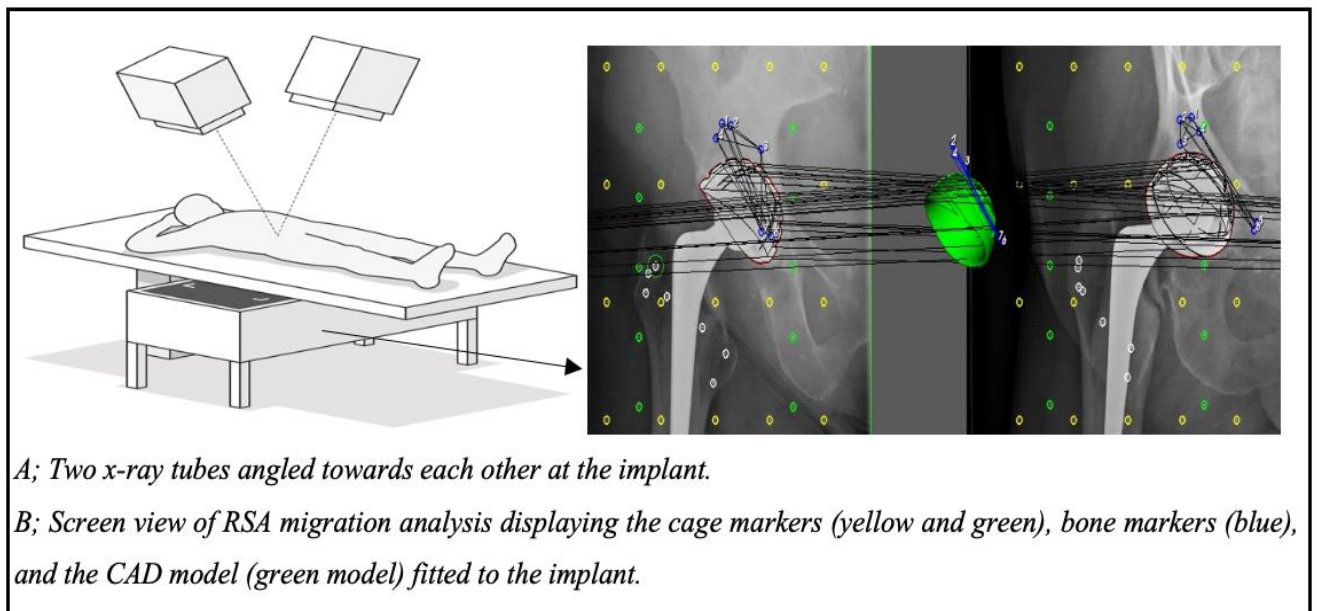


A; Two x-ray tubes angled towards each other at the implant.

B; Screen view of RSA migration analysis displaying the cage markers (yellow and green), bone markers (blue), and the CAD model (green model) fitted to the implant.

The standard roentgen dosage was 95 kV and 16 mAs, but it was dependent on the size of the patient. Due to hardware upgrade in 2016, an automated RSA system (Adora RSA, NRT, Denmark) with ceiling-fixed and synchronized roentgen tubes (Varian Medical Systems, USA) was installed. Hardware update did not require change in the RSA setup, roentgen tube position, patient position, calibration box and exposure setting. The update improved image quality as the stereoradiographs were direct digital with better resolution (Canon CXDI-50RF, 160 μm pixel pitch, 5.9 MP resolution).

## RSA analysis

Translations (i.e., implant movement along the axes) were expressed as x-translation (medial and lateral direction), y-translation (proximal and distal direction), and z-translation (anterior and posterior direction). Rotations were expressed as rotation about the x-axis (anterior and posterior tilt), y-axis (internal and external rotation), and z-axis (abduction and adduction) (Figure 13). To evaluate rotations, a minimum of 3 bone markers had to be visible when analyzing RSA. Total translation (TT) and total rotation (TR) were both calculated using the Pythagorean theorem ($\sqrt{(x^2 + y^2 + z^2)}$).
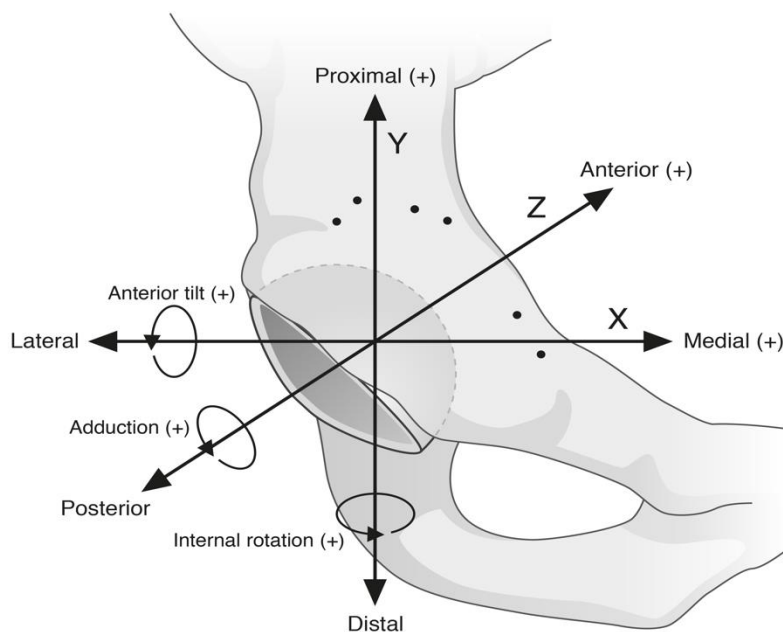


**Figure 13** Illustration of directions, translation, and rotations for Avantage DM cup.

The condition number (CN) was used to assess the distribution of the acetabular bone markers. The mean CN of the markers in the acetabulum was $82.6 \pm 47.1$. The stability of individual markers was evaluated through the mean error of rigid body fitting (ME). The mean ME of the markers in the acetabulum was $0.24 \pm 0.06$. The cut-off points for CN and ME were maintained below 150 and 0.35, respectively [126]. All stereoradiographs were analyzed by one observer using model-based RSA 4.10 (RSAcore, Leiden, the Netherlands) software. Computer-aided design (CAD) implant models were provided by the manufacturer (Zimmer Biomet Inc., Warsaw, IN). Eleven cementless (44–64 mm in diameter) and nine cemented (44–60 mm in diameter) CAD models corresponding to the actual cup size implanted in the patient were available for RSA analysis.

## RSA double examination.

To determine the precision of the model-based RSA system, double examinations were performed at the 3-month follow-up. After the first RSA radiographs were obtained, the patient changed position to either sitting or standing before being repositioned supine on the x-ray table for the second RSA examination. As is it expected that no migrations of the implant would occur between the two examinations, the difference from the first stereoradiograph to the second stereoradiograph should be close to zero. The mean difference (mean dif.) between the double examinations is the systemic error of the system. The standard deviation of the difference between the two examinations (SD dif.) reflects the precision of the RSA results. Coefficient of repeatability (CR) reflect the precision on the individual level (Table 5).

**Table 5** RSA measurement error based on double-examination stereo radiographs. No statistical difference was found between cemented and cementless fixation (p>0.08). *Adapted from Paper IV*

| | Translation, mm | | | | Rotation, ° | | | | MTPM |
|---|---|---|---|---|---|---|---|---|---|
| Axis | X | Y | Z | TT[a] | X | Y | Z | TR[b] | MTPM |
| Mean dif. | 0.02 | -0.01 | -0.01 | 0.00 | -0.23 | -0.05 | 0.09 | 0.07 | 0.01 |
| SD dif. | 0.20 | 0.09 | 0.16 | 0.17 | 0.91 | 0.92 | 0.64 | 0.90 | 0.57 |
| CR* | 0.39 | 0.18 | 0.31 | 0.33 | 1.78 | 1.80 | 1.25 | 1.76 | 1.12 |

*CR was calculated as 1.96 x SD dif.

[a]TT was calculated using the 3-D Pythagorean theorem ($TT=\sqrt{(xt^2 + yt^2 + zt^2)}$)

[b]TR was calculated using the 3-D Pythagorean theorem ($TR=\sqrt{(xr^2 + yr^2 + zr^2)}$)

## Dual-energy X-ray absorptiometry

## DXA set-up

The patient was placed in standard supine position with his or her body parallel to the densitometer table and feet fixed to a device that ensured the big toes pointed straight up. The periprosthetic bone was scanned on the GE Lunar iDXA scanner (General Electric, Chicago, IL, USA). The scans were performed by three nurses educated in DXA examination. Data were analyzed using enCORE version 16 software (General Healthcare, Madison WI, USA) by one research assistant.

## Preoperative DXA scan

All study subjects had their spine and both hips DXA scanned preoperatively to assess their systemic T-score. The lowest T-score from the spine or hip scan was used as the preoperative BMD status. According to the exclusion criteria (Table 3), patients with severe preoperative osteoporosis (T-score < 4.0) were excluded from the study.

## Postoperative DXA scan

The postoperative DXA scan served as a baseline for subsequent scans [177]. BMD of the periacetabular region was measured in the four regions of interest (ROI) as described by Wilkinson [139]. No specialized software was available for creating the acetabular regions; therefore, customized ROIs were created in a template. The template was applied at the baseline scan, and the ROIs were subsequently copied to the follow-up scans. ROIs 2 and 3 were adjusted depending on the cup size to represent respectively half of the cup height and ROIs 1 and 4 with fixed sizes respectively proximal and distal to the cup (Figure 14).

When analyzing the DXA scans, the software used a dynamic tissue detection algorithm to automatically identify bone, tissue, and artefacts. As the software's automatic detection was incorrect in some cases, manual adjustments were performed

## PROMs in Study IV

The follow-up points for HHS, OHS, and EQ-5D were performed according to Table 3. A detailed description of the measurements is presented in the section describing Study II.

**Figure 14** Wilkinson regions of interest (ROI) 1-4 in a cemented cup (left image) and cementless cup (right image). Only area within yellow lines are included in the measurements.
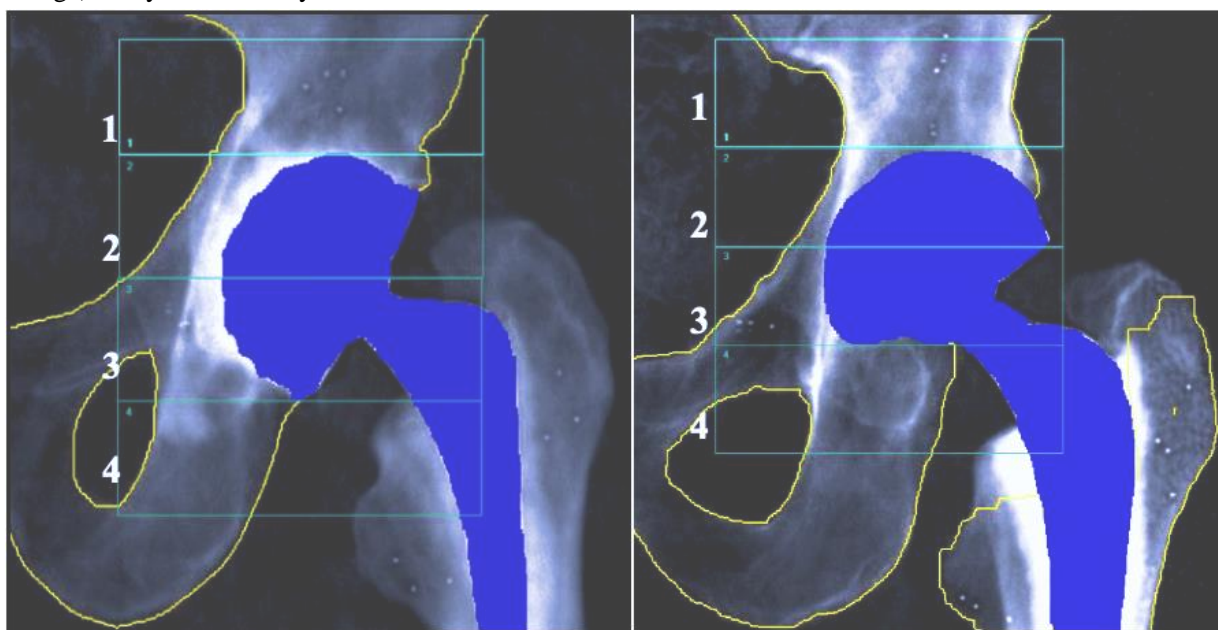


## DXA double examination.

To determine the iDXA scanner's precision level, double examinations were performed at the 3-month follow-up. After the first DXA scan was obtained, the patient changed position to either sitting or standing before being moved to a supine on the x-ray table for the second DXA examination. The precision was calculated according to the coefficient of variation (CV) formula: $CV\% = 100 \times [(\delta/\sqrt{2})/\mu]$ for each ROI for cemented and cementless cup fixation, where $\delta$ represents the SD of the difference between the paired BMD measurements, and $\mu$ is the overall mean of all BMD measurements for each ROI. The precision ranged from 3% to 12.5% in cemented cup fixation and 3% to 6% in cementless cup fixation (Table 6).

**Table 6** DXA measurement error based on double-examination DXA scans for cemented and cementless cup fixation.

|  | Cemented | | | | Cementless | | | |
|---|---|---|---|---|---|---|---|---|
|  | ROI1 | ROI2 | ROI3 | ROI4 | ROI1 | ROI2 | ROI3 | ROI4 |
| Mean dif. | -0.02 | -0.01 | -0.05 | -0.01 | 0.02 | -0.01 | 0.00 | 0.01 |
| SD dif. | 0.07 | 0.31* | 0.13* | 0.07 | 0.07 | 0.11* | 0.07* | 0.05 |
| CV% | 3.02 | 12.50 | 8.20 | 5.40 | 3.20 | 6.26 | 5.83 | 4.14 |

* Denotes significant difference between cemented and cementless cups using the F-test.

# Statistics

For all studies, statistical significance was set at the 5% level. Stata version 13.1 (StataCorp, College Station, TX, USA) was used for statistical analysis.

## Study I

The primary endpoint was PE wear-rates in cemented and cementless DM THA. Secondary endpoints were radiographic and PROM evaluations. Non-parametric statistics for continuous data were used, as data were not normally distributed according to a Shapiro-Wilks test. Mann-Whitney U-tests were used to test for differences in the PE wear-rate, mean PE wear, age, follow-up time, and gender between the cemented and cementless groups. Correlations were evaluated using a Spearman's correlation test. Chi-squared and Fisher's exact tests, as appropriate, were used for categorical data. For comparability and interpretability reasons, the mean values for data without a Gaussian distribution were presented.

## Study II

The primary endpoint was the patients' level of functioning as assessed by OHS, EQ-5D, and HHS compared to matched CA patients and the GP index. Secondary endpoints were NMS, TUG, and STS test scores. Non-parametric (Mann–Whitney) statistics were used for continuous data when data were not normally distributed according to a Shapiro–Wilks test, and parametric (Student's $t$-test) statistics were used when data were normally distributed. Linear regression was used to compare the FNF group's and the matched CA group's EQ-5D scores, and likewise linear regression was used to compare OHS between FNF patients and the matched CA group. Correlations were evaluated using a Spearman's correlation test. For comparability with the literature, as well as for interpretability reasons, the mean values for data without a Gaussian distribution (TUG, STS, EQ-5D, HHS, and OHS) were presented.

## Study III

The primary endpoint was dislocation. The secondary endpoints were cup/stem revision and periprosthetic fractures with or without needed fracture fixation/component revision. Revision was defined as the replacement of either the cup or stem component and all other complications requiring secondary surgery as reoperation. Non-parametric (Mann-Whitney) statistics were used for continuous data when data were not normally distributed according to a Shapiro-Wilks test, and parametric (student's $t$-test) statistics were used when data were normally distributed. Chi-squared and Fisher's exact tests (used for expected cell counts lower than 6) were used for

categorical data, and odds ratios for two dichotomous variables were calculated using a Woolf approximation.

## Study IV

The primary endpoint was the degree of cup migration at the 2-year follow-up. The secondary endpoints were measurements of periprosthetic BMD, clinical outcomes of HHS, OHS, and EQ-5D, and VAS (rest and activity) for pain. Subgroup analyses (mixed model) were performed between cup fixation (cemented/cementless) and proximal translation (y-axis) when stratified to normal (T-score $\geq$-1.0) or low (T-score < -1.0) preoperative BMD. In the cup migration analysis, BMD was conducted using a linear mixed model to account for repeated measurements and missing values. Model estimates are reported as means with 95% confidence intervals (CIs). The Student's t-test was used for normally distributed data. When data were not normally distributed according to the Shapiro-Wilks test, a non-parametric (Mann-Whitney) test was used. Data were analyzed as of the date of the last data collection (January 2018).

# 6. Main results

## Study I
### Polyethylene wear

At the mean 3.0-year follow-up, cemented cups (n=56) had an annual penetration rate (i.e., wear rate) of 0.3 mm/year (range 0.06–1.71, SD 0.27), which was statistically significantly less ($p$=0.004) than in the cementless cups (n=73) with a mean wear rate of 0.43 mm/year (range 0.08–1.9, SD 0.3) at the mean 2.7-year follow-up. The total liner head penetration was statistically significantly lower ($p$<0.001) in the cemented cups than in the cementless cups during the whole follow-up period with a mean of 0.66 mm (range 0.17–1.9, SD 0.3) and 0.94 mm (range 0.26–4.5, SD 0.6), respectively. The patients' age at the time of the index surgery correlated with the length of follow-up ($r$= -0.26; $p$=0.003). Hence, older patients had shorter follow-up periods. Furthermore, the patients' age at the time of the index surgery correlated with the PE wear rate ($r$=0.19; $p$=0.04), indicating higher PE wear rates in older patients.

### Radiological results

Cemented cups had statistically significantly ($p$=0.002) more radiolucent lines compared to cementless cups, but we found similar rates of osteolytic lesions in the two fixation methods ($p$=0.56). Radiological cup results are presented in Table 7.

**Table 7** Radiology cup results at follow-up. *Adapted from Paper I.*

|  | Cemented DM cup | Cementless DM cup | *p*-value |
|---|---|---|---|
| DeLee 1 RLL (progressive RLL) | 7 (5) | 1 (1) | 0.02 |
| DeLee 2 RLL (progressive RLL) | 4 (4) | 0 (0) | 0.033 |
| DeLee 2 RLL (progressive RLL) | 5 (5) | 1 (1) | 0.085 |
| Total cups with RLL | 9 | 1 | 0.002 |
| Postoperative cementation grading A/B/C | 45/6/5 |  |  |
| Osteolysis | 0 | 2 | 0.56 |
| Brooker 1/2/3/4 | 4/2/1/0 | 11/2/5/0 | 0.083 |

# Study II

## FNF patients compared with CA patients and GPI groups

Results are presented in Table 8 and Figure 15. The adjusted (i.e., gender, age, and operation year) estimate of the mean difference in EQ-5D between FNF patients and CA patients was 0.06 (95% CI=0.01–0.1, $p$=0.01), and the adjusted (i.e., gender, age, and operation year) estimate of the mean difference in OHS between FNF patients and CA patients was 1.66 (95% CI= -4.1–0.8, $p$=0.18). At the mean 2.8-year follow-up, 89.5% ($n$=111) scored their overall satisfaction with the operation outcome as either very good ($n$=71) or good ($n$=40). Patient satisfaction was moderately and statistically significantly ($p$<0.0001) correlated with EQ-5D ($r$= -0.47), OHS ($r$= -0.42), and HHS ($r$= -0.49).

**Table 8** Results for patient outcome measures and clinical tests. *Adapted from Paper II.*

|  | FNF Cases | 2:1 CA match | $p$–value |
|---|---|---|---|
| EQ-5D (range, SD) | 0.79 (0.37–1.0, 0.15) | 0.85 (0.47–1.0, 0.13) | 0.01 |
| OHS (range, SD) | 36.4 (9–48, 9.5) | 38.5 (16.5–48, 6.9) | 0.18 |
| HHS (range, SD) | 78.7 (31–100, 15.5) |  |  |
| NMS (pre/post-operative) | 8.2/7.2 |  | <0.001 |
| TUG, seconds (range, SD) | 13.5 (4.5–30.1, 4.9) |  |  |
| STS (range, SD) | 38.0 (16–101,15.4) |  |  |
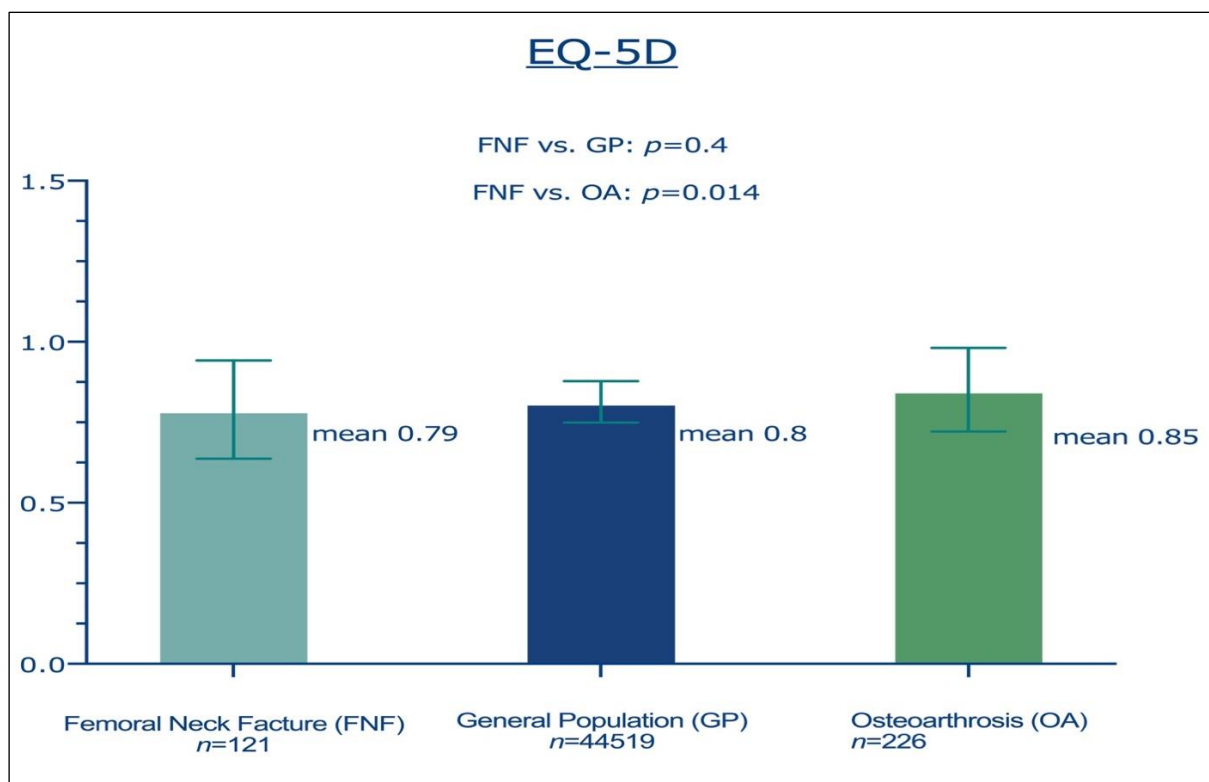
**Figure 15** Mean EQ-5D scores of FNF, GP, and osteoarthrosis of the hip patients (OA). There was an average of 359 GP matches per FNF patient. Error bars represent standard deviation. *Adapted from Paper II.*

Although there was no difference in EQ-5D between FNF patients and the gender- and age-matched GP index ($p$=0.04) (Figure 15), we found strong correlations between HHS and EQ-5D ($r$=0.60; $p$<0.0001) and between HHS and OHS in FNF patients ($r$=0.65; $p$<0.0001).

# Study III

## General

The mean follow-up period was 5.4 (range 1.6–12.6) years. Of the 966 patients included in the study, 415 (43%) cups and 741 (76.7%) stems were fixed using the cemented technique. By the end of the follow-up period, 533 (55.2%) patients had died. The 30-day and 1-year mortality rates were 9.2% and 22.1%, respectively.

## Dislocation

In this cohort, 4.7 % of patients (n=45) experienced dislocation of the large articulation in the DM THA. Of the 45 patients with large articulation dislocation, 33 (73%) were treated with closed reduction, and 18 patients underwent open surgery with either open reduction with/without implant replacement, a Girdlestone procedure, or cup revision. Patients who experienced a hip dislocation had a mean 3° higher cup inclination, which was associated with dislocation risk (p=0.04). Likewise, cup retroversion was associated with higher hip dislocation risk ($p<0.001$). There was a trend toward higher dislocation risk in cognitively impaired patients compared to patients with a normal mental status (OR=2.0, CI=0.96–4.34, $p=0.06$). Kaplan-Meier survival curves for time to the first dislocation according to the preoperatively-assessed mental status are presented in Figure 16.
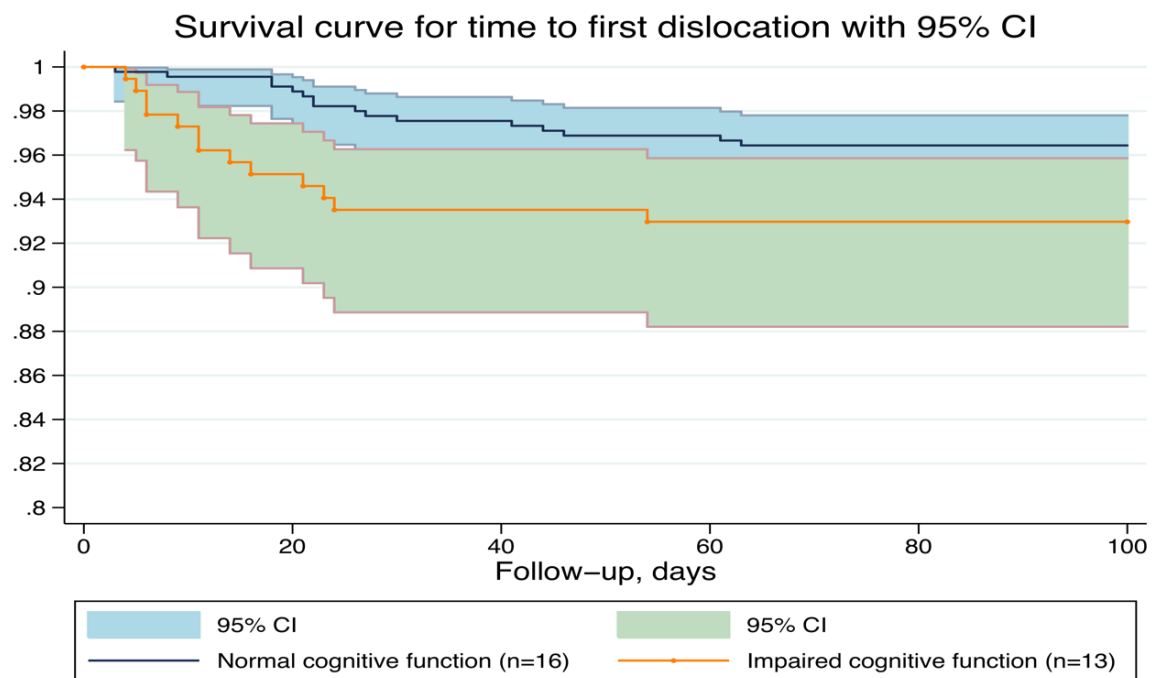


**Figure 16** Kaplan-Meier curve for time to first dislocation according to preoperative cognitive functioning. Follow-up is 100 days since all first-time dislocations occurred within 63 days after the index surgery.

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We observed eight patients (0.8%) with IPD; six occurred during attempt of closed reduction of large articulation dislocation, and two were related to a fall (9 days and 5 years after the index surgery). All IPDs required open surgery with femoral head and liner replacement. IPS was not related to the DM system type used in the index surgery (*p*=0.66). DM cup dislocation data are presented in Table 7.

**Table 9** DM cups dislocation by various possible risk factors. *Adapted from Paper III.*

| | Dislocation | No dislocation | *p*-value |
|---|---|---|---|
| Number of patients (range, dislocations) | 45 (1–4) | 918 | |
| Time to dislocation, mean days (SD, range) | 21 (16.3; 1–63) | | |
| Age at index surgery (SD, range) | 80.4 (10.8; 49–98) | 80.5 (9.5; 42–104) | 0.97 |
| Gender (M/F) | 10/35 | 280/641 | 0.24 |
| Cognitive status (impaired/normal) | 13/16 | 172/433 | 0.06 |
| Stem fixation (cemented/cementless) | 30/15 | 711/210 | 0.10 |
| Cup fixation (cemented/cementless) | 17/28 | 398/523 | 0.47 |
| Inclination, degrees (SD, range) | 45.6 (9.1; 31.7–67.2) | 42.6 (8.4; 15.3–69.4) | 0.04 |
| Version (anteversion / retroversion) | 35/10 | 860/29 | <0.001 |
| Surgeon (resident/consultant) | 10/35 | 158/763 | 0.37 |
| Cup Revision | 3 | 5 | <0.001 |

## Cup revision

Of the 966 DM cups, eight (0.8%) were revised (i.e., an exchange of the cup, femoral head, and liner). Four revisions were due to aseptic loosening, while three were due to recurrent dislocations caused by either retroversion of the cup ($n=2$) or very steep inclination ($n=1$), and one was due to septic loosening. DM cup revision was not associated with the fixation type of the cup ($p=0.75$) or stem ($p=0.91$). All incidences of DM cup loosening (aseptic or septic) sum up to 0.9 % ($n=9$) in this cohort (Figure 17).

## Reoperation of the cup and stem

In total, 2.7% ($n=26$) of the patients underwent hip-related reoperation (i.e., IPD, infection, Girdlestone, dislocation). Reoperation was not associated with the cup fixation method ($p=0.32$). Postoperative deep infection occurred in 1% ($n=10$) of patients, who underwent either cup revision, cup reoperation, or a Girdlestone procedure. All THA-related complications are presented in Figure 17. In total, 3.1% ($n=30$) underwent stem-related reoperation. All postoperative stem fractures were related to a new fall event, and the 24 periprosthetic stem fractures were operated on with plate and wire-cable fixation. Cementless stem fixation was associated with a statistically significant higher risk of conservative and operative-treated stem complications ($p=0.002$).
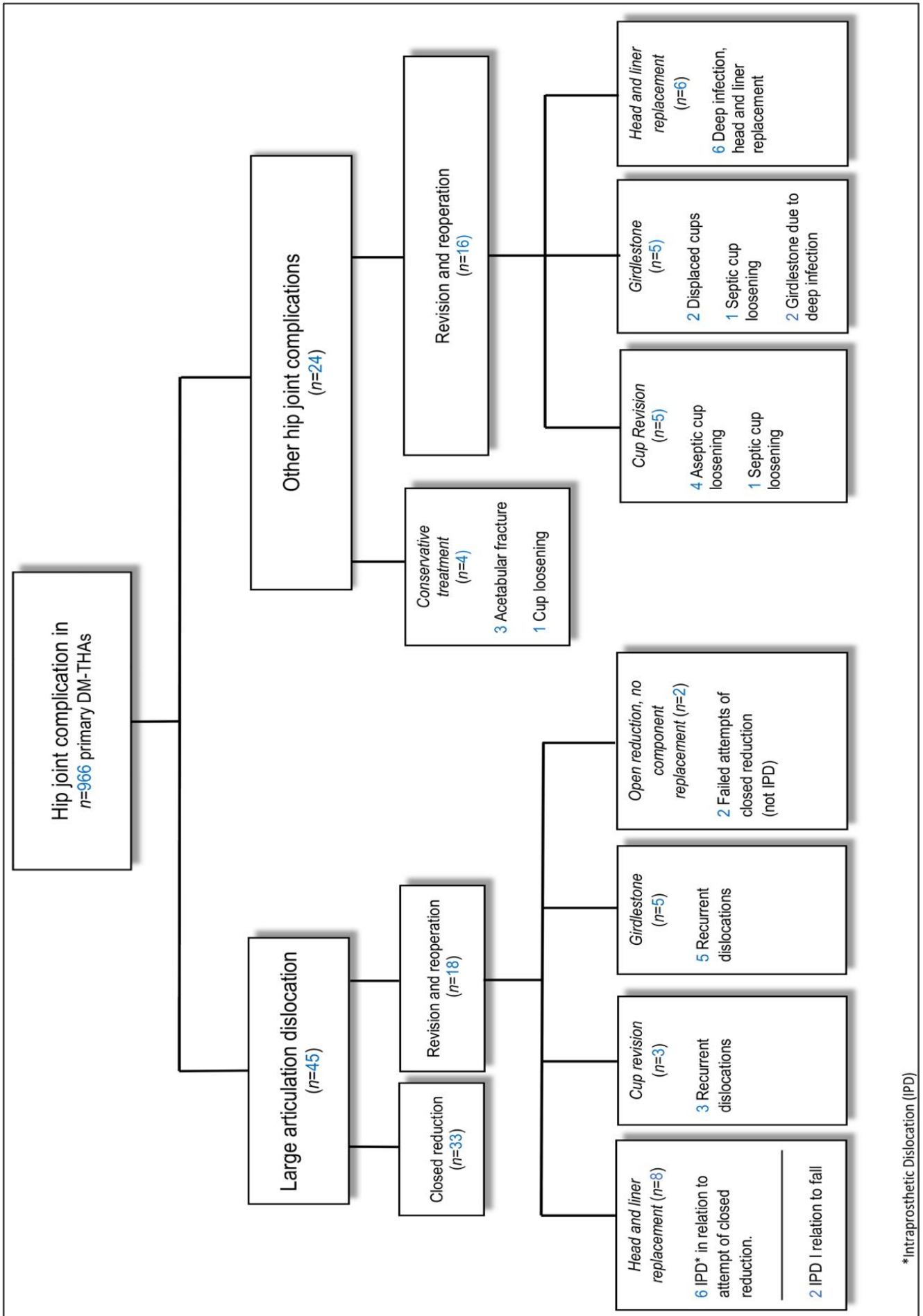
**Figure 17** All THA-related complications. *Adapted from Paper III.*

# Study IV

## Migration patterns

When migration in cemented and cementless cups was compared, the cementless cups' migration was statistically significant for y-axis rotation, TR, and MTPM (Table 10).

**Table 10** Translations along and rotations about the x-, y-, and z-axis for cemented and cementless cups, presented as mean and 95% CI. *Adapted from Paper IV.*

| Axis | Cemented | Cementless | *p*-value |
|---|---|---|---|
| **Translations, mm** | | | |
| x-axis | | | |
| 3 mos. | -0.01 (-0.17–0.14) | 0.08 (-0.19–0.36) | 0.61 |
| 12 mos. | -0.03 (-0.21– 0.15) | 0.16 (-0.20–0.51) | 0.47 |
| 24 mos. | -0.01 (-0.22–0.20) | 0.23 (-0.20–0.66) | 0.32 |
| y-axis | | | |
| 3 mos. | 0.08 (0.00–0.16) | 0.15 (0.02–0.27) | 0.44 |
| 12 mos. | 0.09 (0.01–0.18) | 0.12 (-0.02–0.26) | 0.75 |
| 24 mos. | 0.11 (0.00–0.23) | 0.09 (-0.09–0.28) | 0.79 |
| z-axis | | | |
| 3 mos. | 0.16 (0.00–0.32) | 0.31 (0.00–0.62) | 0.41 |
| 12 mos. | 0.15 (-0.01–0.31) | 0.36 (0.03–0.69) | 0.31 |
| 24 mos. | 0.23 (0.02–0.44) | 0.39 (0.03–0.75) | 0.42 |
| TT | | | |
| 3 mos. | 0.49 (0.34–0.64) | 0.79 (0.49–1.10) | 0.17 |
| 12 mos. | 0.56 (0.37–0.76) | 0.88 (0.51–1.25) | 0.13 |
| 24 mos. | 0.65 (0.44–0.87) | 0.98 (0.54–1.42) | 0.12 |
| **Rotations,°** | | | |
| x-axis | | | |
| 3 mos. | 0.34 (0.01–0.66) | 0.01 (-0.48–0.51) | 0.35 |
| 12 mos. | 0.52 (0.15–0.89) | 0.64 (-0.01–1.30) | 0.72 |
| 24 mos. | 0.29 (-0.05–0.63) | 0.04 (-0.63–0.70) | 0.47 |
| y-axis | | | |
| 3 mos. | 0.23 (0.26–0.72) | 1.08 (0.34–1.82) | 0.06 |
| 12 mos. | 0.30 (-0.25–0.85) | 1.74 (0.91–2.57) | 0.002 |
| 24 mos. | 0.18 (-0.37–0.73) | 1.10 (0.42 – 1.78) | 0.04 |
| z-axis | | | |
| 3 mos. | -0.35 (-0.60–0.03) | -0.07 (-0.60–0.46) | 0.48 |
| 12 mos. | -0.40 (-0.75– -0.05) | -0.33 (-0.92–0.26) | 0.84 |
| 24 mos. | -0.35 (-0.76–0.05) | -0.01 (-0.69–0.68) | 0.37 |
| TR | | | |
| 3 mos. | 1.52 (1.12–1.90) | 2.23 (1.55–2.92) | 0.08 |
| 12 mos. | 1.80 (1.40–2.24) | 3.00 (2.20–3.80) | 0.003 |
| 24 mos. | 1.72 (1.30–2.13) | 2.57 (1.83–3.30) | 0.04 |
| **MTPM** | | | |
| 3 mos. | 1.14 (0.86–1.42) | 1.81 (1.26–2.36) | 0.06 |
| 12 mos. | 1.30 (1.00–1.60) | 2.24 (1.64–2.85) | 0.005 |
| 24 mos. | 1.36 (1.00–1.73 | 2.16 (1.44–2.87) | 0.02 |

The postoperative inclination angle was higher in cemented cups compared to cementless cups ($p$=0.01; Table 1). However, the postoperative anteversion angle did not differ between the two fixation methods ($p$=0.87; Table 1). We observed a moderate positive correlation between cup inclination and proximal cup migration in cementless cups ($r$ =0.38, $p$=0.04), and a moderate negative correlation between cup inclination and proximal cup migration in cemented cups ($r$ = -0.48, $p$=0.01).

**Migration (proximal cup translation) in relation to threshold guidelines**

Cemented cups: At the 24-month follow-up, 75% ($n$=21) had proximal cup translation (y-axis) < 0.2mm, and 25% ($n$=7) were between 0.2–1.0mm. No cemented cups had proximal cup translation (y-axis) > 1.0mm.

Cementless cups: At the 24-month follow-up, 64% ($n$=18) of the cementless cups had proximal cup translation < 0.2 mm, and 32% ($n$=9) were between 0.2–1.0mm. One cementless cup had > 1.0 mm proximal translation at 24 months.

### Continuous migration within fixation groups

Cemented cups: within the cemented group we found no statistically significant continuous translation ($p > 0.27$) or rotation ($p > 0.15$) during the 24-months follow-up time.

Cementless cups: no statistically significant continuous translations ($p > 0.20$) during 24-months follow-up, but showed continuous rotation in all axes including TR and MTPM during the 2-year follow-up (MTPM stabilizing from 12-24 moths), Table 11.

**Table 11**: Rotational and MTPM migration within cemented and cementless cups during follow-ups. Presented as mean difference and 95% CI. *Adapted from Paper IV.*

| Axis | Cemented | *p-value* | Cementless | *p*-value |
|---|---|---|---|---|
| **Rotations,°** | | | | |
| x-axis | | | | |
| 3 mo. - 12 mo. | -0.18 (-0.49 – 0.13) | 0.25 | -0.63 (-0.95 – 0.31) | <0.001 |
| 12 mo. - 24 mo. | 0.23 (-0.08 – 0.55) | 0.15 | 0.61 (0.28 – 0.93) | <0.001 |
| y-axis | | | | |
| 3 mo. - 12 mo. | -0.07 (-0.44 – 0.29) | 0.69 | -0.66 (-1.03 – -0.28) | 0.001 |
| 12 mo. - 24 mo. | 0.14 (-0.22 – 0.51) | 0.45 | 0.64 (0.26 – 1.01) | 0.001 |
| z-axis | | | | |
| 3 mo. - 12 mo. | 0.09 (-0.15 – 0.32) | 0.48 | 0.26 (0.01 – 0.50) | 0.04 |
| 12 mo. - 24 mo. | -0.08 (-0.32 - 0.15) | 0.49 | -0.33 (-0.60 – -0.08) | 0.01 |
| TR | | | | |
| 3 mo. - 12 mo. | -0.25 (-0.62 – 0.12) | 0.16 | -0.75 (-1.13 – -0.36) | <0.001 |
| 12 mo. - 24 mo. | 0.07 (-0.31 – 0.44) | 0.73 | 0.42 (0.04 – 0.80) | 0.03 |
| **MTPM** | | | | |
| 3 mo. - 12 mo. | -0.12 (-0.36 – 1.12) | 0.31 | -0.43 (-0.68 – -0.18) | 0.001 |
| 12 mo. - 24 mo. | -0.08 (-0.32 – 1.16) | 0.52 | 0.08 (-0.16 – 0.33) | 0.51 |

**Net periprosthetic BMD**

In the cemented group, the mean measured BMD in each of the 4 regions ranged from 0.91 to 1.78 g/cm$^2$, and from 0.84 to 1.55 g/cm$^2$ in the cementless group. The net measured BMD was 19% greater around the cemented cups compared to the cementless cups and was greater in the zones central-medial to the cup (ROIs 2 and 3) than in the cup zones proximal and distal to the cup (ROIs 1 and 4) ($p \leq 0.05$; Table 12).

**Table 12** Mean Bone mineral density (g/cm$^2$) for the Net and individual ROIs around the cemented and cementless cups.

| Characteristic | Region of interest (ROI) | | | | |
| --- | --- | --- | --- | --- | --- |
| | Net** | 1 | 2 | 3 | 4 |
| Cemented cup | | | | | |
|   Mean BMD, g/cm$^2$ | 1.37 | 1.65 | 1.78 | 1.14 | 0.91 |
|   SD | 0.26 | 0.34 | 0.44 | 0.34 | 0.23 |
| Cementless cup | | | | | |
|   Mean BMD, g/cm$^2$ | 1.11 | 1.55 | 1.23 | 0.85 | 0.84 |
|   SD | 0.26 | 0.30 | 0.38 | 0.35 | 0.26 |
| Difference in measured BMD between groups, % | 19.0 | 6.3 | 31.2 | 25.5 | 7.7 |
| *p* value between groups* | <0.001 | 0.02 | <0.001 | <0.001 | 0.05 |

*Analysis is cemented vs cementless prosthesis by t-test.
** Net: mean of all 4 ROIs.

**Migration (proximal cup translation) in relation to preoperative BMD**

Proximal cup translation did not differ ($p > 0.34$) between cementation methods when patients were stratified into either normal or low preoperative BMD (Figure 18).

**Figure 18** Proximal translation in the two fixations methods when stratified according to normal/low BMD
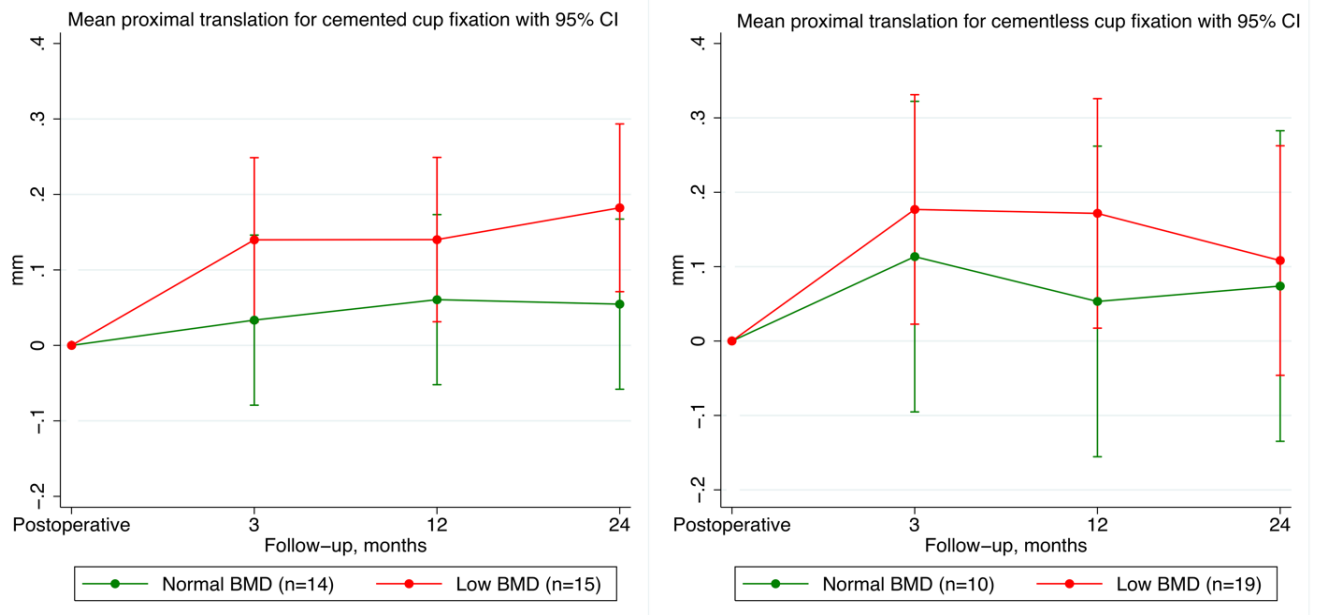


When the BMD subgroups (i.e., normal and low BMD) were divided based on cemented or cementless cup fixation, we found no difference in proximal cup translation between normal and low preoperative BMD ($p > 0.18$) and no continuous proximal cup translation in normal and low BMD groups in cemented or cementless cup fixation ($p > 0.19$), See Figure 19.

**Figure 19** Proximal translation in normal and low BMD when stratified according to fixation method
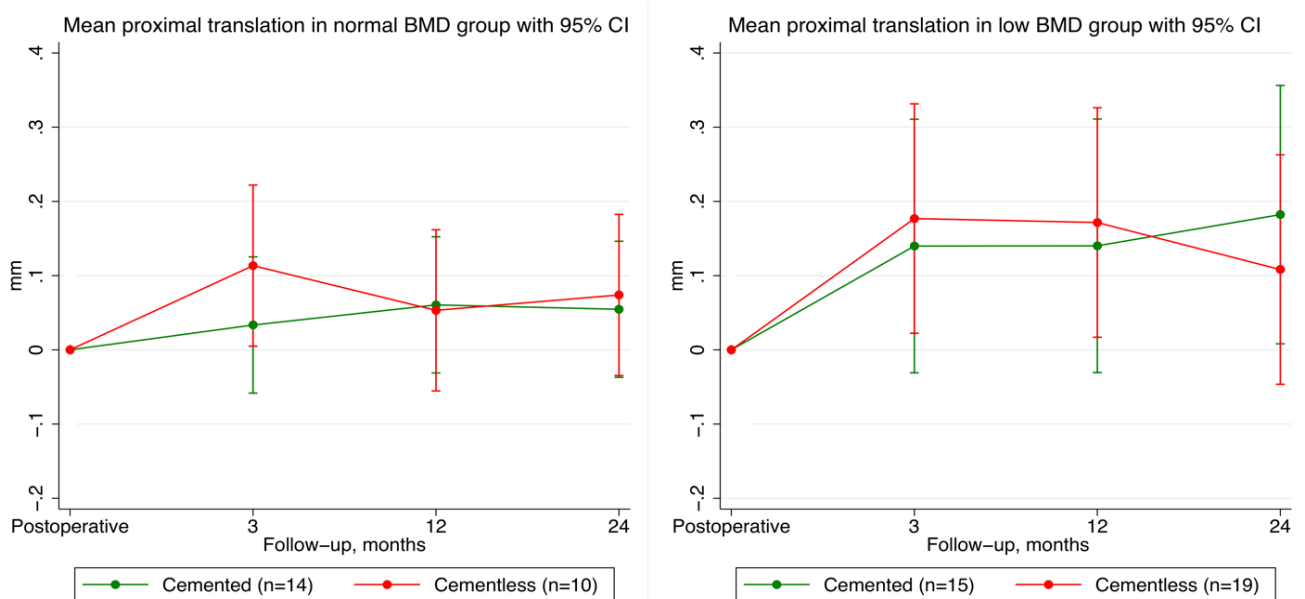
Sub-analyses showed statistically significantly higher MTPM at the 12- and 24-month follow-up in cementless cups compared to cemented cups in the low BMD group ($p$=0.01; Figure 20), which could be explained by higher cup migration in the x-translation ($p$=0.04 at 24 months), y-rotation ($p$<0.001, $p$=0.03, at 12 and 24 months, respectively), and z-rotation ($p$=0.04 at 24 months). Likewise, TT and TR were higher for cementless cups compared to cemented cups in the low BMD group at 12 and 24 months ($p$<0.03). (Figures for x-translation, y- and z-rotations, TT and TR in appendix 1).
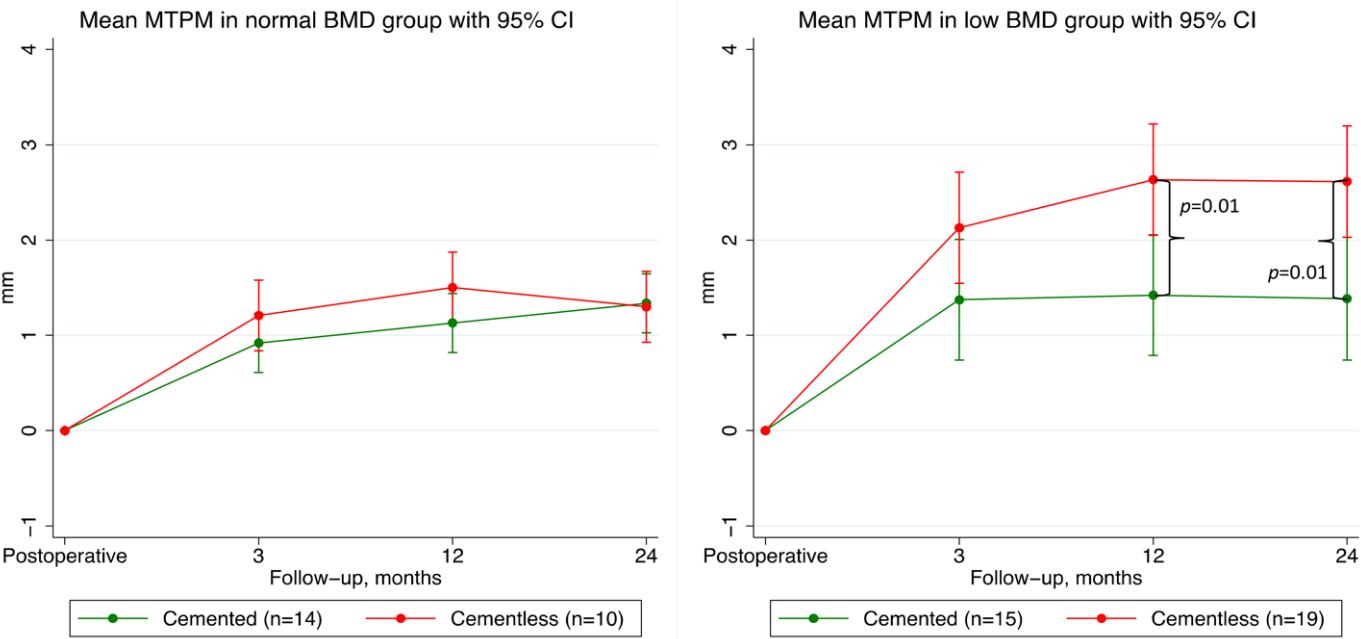


**Figure 20** MTPM migration in normal and low BMD groups based on cup fixation.

## Percentage of change in periprosthetic BMD

Percentage BMD changes were calculated as the percentage change in BMD from the individual follow-up point in relation to the postoperative BMD, serving as baseline measure
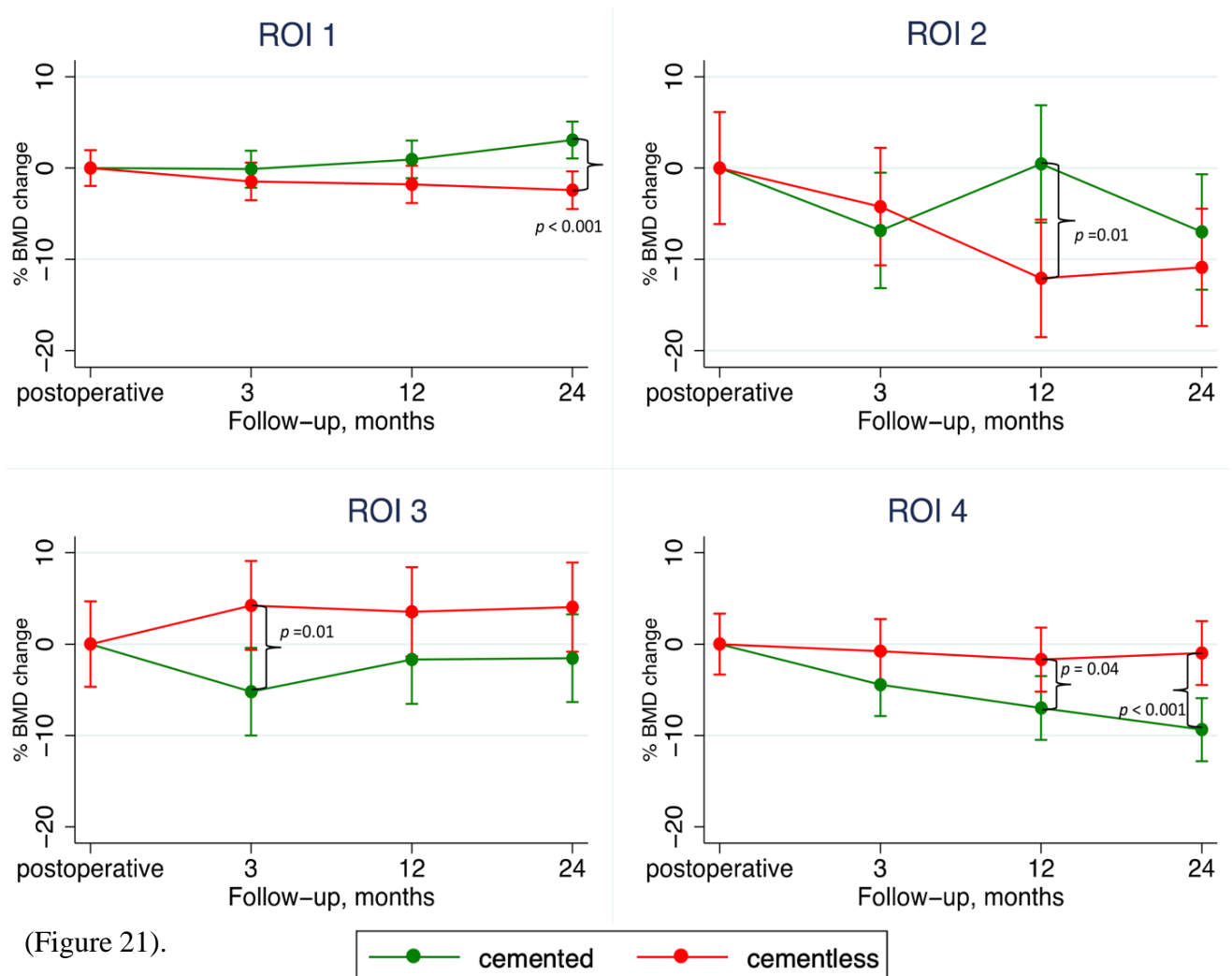


(Figure 21).

**Figure 21** Percentage BMD change in cemented and cemented cup fixation in Wilkinson's ROI 1-4. *Adapted from Paper IV.*

ROI 1: At 24 months, the BMD increased by 3% in the cemented group, whereas a small 2% decrease was noted in the cementless group ($p=<0.001$).

ROI 2: The cemented group showed less BMD loss at 12 months ($p=0.01$), but at 24 months, the BMD loss was similar ($p=0.4$).

ROI 3: The increase (4%) in BMD in the cementless cups was statistically significant ($p=0.01$) at 3 months compared to the decrease (-5%) in cemented cups but not at 12- and 24-months follow-up ($p > 0.11$).

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ROI 4: The loss of BMD in the cemented cups (-9%) was statistically significant compared to the decrease in the cementless cups (-1%) at 24 months ($p$=0.001).

**Percentage change in periprosthetic BMD and migration**

We found no correlation between the percentage BMD change and proximal translation in cemented or cementless cups during the follow-up period ($p$>0.06).

**Clinical outcome measures**

We found no differences in clinical outcomes between cup fixation, HHS, OHS, EQ-5D, and VAS at neither the preoperative stage nor during the 3-, 12-, and 24-month follow-ups ($p$>0.31; Table 13). Furthermore, we observed no differences in improvement in either of the outcome scores between cup fixation methods from the preoperative stage to the 24-month follow-up ($p$>0.07).

**Table 13** Scores for HHS, OHS, EQ-5D, and VAS for pain

| Outcomes | Cemented | Cementless | $p$-values [a] |
|---|---|---|---|
| HHS | | | |
|     Preoperative | 55.6 (12.4) | 56.0 (15.5) | 0.59 |
|     3 mos. | 80.2 (13.2) | 81.4 (13.7) | 0.60 |
|     12 mos. | 92.3 (6.5) | 89.1 (10.1) | 0.31 |
|     24 mos. | 92.1 (8.7) | 89.9 (10.9) | 0.72 |
| OHS | | | |
|     Preoperative | 25.1 (6.5) | 25.2 (6.2) | 0.79 |
|     3 mos. | 37.0 (8.0) | 38.7 (5.6) | 0.82 |
|     12 mos. | 44.8 (3.9) | 43.0 (4.9) | 0.08 |
|     24 mos. | 44.6 (4.3) | 43.2 (5.5) | 0.30 |
| EQ-5D | | | |
|     Preoperative | 0.63 (0.15) | 0.66 (0.10) | 0.92 |
|     3 mos. | 0.88 (0.13) | 0.90 (0.10) | 0.62 |
|     12 mos. | 0.93 (0.10) | 0.92 (0.11) | 0.83 |
|     24 mos. | 0.94 (0.10) | 0.92 (0.10) | 0.44 |
| VAS for hip pain (rest) | | | |
|     Preoperative | 3.2 (2.7) | 2.9 (2.0) | 0.74 |
|     3 mos. | 0.9 (1.3) | 0.7 (0.8) | 0.57 |
|     12 mos. | 0.03 (0.2) | 0.2 (1.1) | 0.54 |
|     24 mos. | 0.1 (0.6) | 0.2 (0.8) | 0.63 |
| VAS for hip pain (activity) | | | |
|     Preoperative | 6.8 (1.9) | 5.5 (2.1) | 0.02 |
|     3 mos. | 1.0 (0.9) | 0.9 (0.8) | 0.66 |
|     12 mos. | 0.17 (0.5) | 0.5 (1.4) | 0.46 |
|     24 mos. | 0.4 (1.0) | 0.1 (0.3) | 0.36 |

All values are mean (SD).

[a] Two-sample Wilcoxon Rank-sum (Mann-Whitney) test.

# 7. Discussion of results and comparison with the literature

## Study I

Polyethylene wear is an important limiting factor for THA longevity. The DM design concept has two wear surfaces on the PE and, therefore, presents a potentially greater risk of wear than in regular SM THA. The HA coating on the implants and older types of less wear-resistant PE may also increase PE wear. With a lack of previously reported *in vivo* PE wear of DM implants in FNF patients, our primary aim was to assess the PE wear rate in elderly patients with cemented and cementless cup fixation. We found statistically significantly higher total wear and wear rates of the UHMWPE in cementless HA[a]-coated cups compared to cemented DM cups, and both fixation methods had a 2–3-fold wear rate above the established osteolysis limit for UHMWPE of 0.1–0.2 mm/year [46,47]. Periprosthetic osteolysis may lead to implant failure by aseptic implant loosening; however, we did not find high wear rates associated with the formation of osteolytic bone lesions in this short-term study [24,178]. A wear rate exceeding 0.4 mm/year was associated with greater risk of cup failure and revision in a long-term study of titanium- and HA[a]-coated cementless cups [28]. Applying this wear rate limit to our study would make the cementless cups associated with greater risk of failure and revision compared to cemented cups.

Several factors might have influenced the generally high wear rate and the greater wear rate observed in cementless compared to cemented cups. Initial PE deformation, such as creep (i.e., non-particulate wear), might lead to a proportionally larger impact in our wear analysis due to a shorter follow-up period, thereby obscuring the true wear rate. Due to the formation of third-body abrasive PE wear, HA[a]-coated SM cups have been associated with increased PE wear when compared to non-HA[a] SM-coated cups, which might have contributed to the greater PE wear and wear rate observed in cementless DM cups [24,28,179,180].
Furthermore, any motion of the mobile articulation between the liner and the metal cup might lead to excessive PE wear due to the contact surface of the convex side of the PE, which could explain the observed PE wear rates. A recent *in vivo* study of HXLPE wear in 34 DM implants inserted in patients with a high risk of instability (n=11) and revision (n=24) found high wear rates that exceeded the penetration rate reported in SM THA by a factor of two [181]. Although the study was limited by the use of two different bearings, MoP and CoP, they still reported a high wear rate in both groups of elderly patients with low activity levels, and they speculated the additional convex wear surface of the DM implant was a plausible explanation for the

elevated wear rates. Although HXPLPE has proven to be more wear resistant, and mid- and long-term studies have suggested lower wear-related failure rates compared to conventional UHMWPE [5,52,182-184], the study conducted by Deckard et al. supports our findings of high wear rates in a DM THA, even with HXLPE liners [181].

The biomechanics of DM implants and their PE wear profiles remain incompletely understood [88]. Recently, *in vitro* retrieval and experimental studies have attempted to estimate the PE wear profile of DM implants [185,186]. In an experimental set-up of DM THA vs. SM THA, Gaudin et al. reported similar wear of the UHMWPE liner after 5 million cycles [185]. Boyer et al. reported wear data of 98 retrieved UHMWPE liners due to implant failure; when 3D scanning, head penetration measurements, center of rotation shifts, and linear penetration rate measurements were analysed, they found no relationship between linear head penetration into the DM liner and wear of the liner, making the DM wear profile truly three-dimensional [186]. Whilst the results provide some degree of confidence, the *in vitro* set-up of these studies is separated from patient factors, surgical techniques, and exposure to the anatomical properties of bone and tissue, making their *in vivo* applications limited. To date, only two studies were conducted *in vivo*, including the present study of PE wear of DM implants [181,187]. Recent review studies provide no clear recommendation as to which methodological approach should be used when evaluating PE wear in DM implants, and some authors suggest that DM implants should be used with prudence in primary THA for CA due to the unsolved PE wear issue [82,88,188,189].

Longer follow-up periods provide better data for more precise PE wear rate estimates, and performing at least three years of follow-up has been recommended to minimize the risk of overestimating the PE wear rate [44]. However, considering the high natural mortality rate and that many patients were not even fit enough for an outpatient clinical examination, we would likely have lost more patients if the follow-up period had been longer. Thus, the patients we examined provided a good estimate of PE wear in the most active and physically fit FNF patients operated on in our institution; these patients are also the most likely to use the DM THA for a long duration and, thus, to encounter PE wear-problems, if this should happen to be a clinical problem.

## Study II

We believe that this is the first study to report PROM, physical performance, and treatment satisfaction among FNF patients receiving DM implants. The aim was to investigate PROMs from 3 of the 5 major outcome categories defined by Hutchings et al.[146]. In summary, we found that patients followed for 2.8 (1.0–7.7) years after an FNF treated with DM THA regained HRQoL (EQ-5D) compared to the age- and gender-matched general population index, but they had slightly lower EQ-5D scores compared to similar age- and gender-matched CA patients with primary SM THA with a one-year follow-up period. In comparison to CA patients with SM THA, we found similar OHS scores. FNF patients reported excellent patient satisfaction with their surgical treatment.

FNF has a substantial, long-lasting impact on HRQoL and recovery to the physical and psychosocial pre-fracture level, and for some patients, the pre-fracture level is never reached [190]. The observed EQ-5D score of 0.79 (range 0.37–1.0) in this study was comparable and, in serval cases, higher than reported in studies of patients with displaced FNF who were treated with THA, in which the reported EQ-5D ranged from 0.61–0.71 [108,152,191,192]. In a study of 664 hip fracture patients who received a questionnaire sent by mail one year after the index surgery, the reported EQ-5D score was 0.46 in patients ranging from 70–80 years in age [193]. This difference might be related to case mixing, as Hansson et al. investigated all types of hip fractures (i.e., displaced/non-displaced FNF, cervical, stable/unstable trochanteric, and subtrochanteric fractures). Furthermore, in Study II, only patients fit enough for outpatient clinic services were examined, which may limit the study's generalizability and explain the statistically significant difference in EQ-5D scores.

It is questionable whether a statistically significant difference of 0.06 score points in EQ-5D between FNF patients and the matched CA patient group is clinically relevant [194]. Furthermore, the FNF patients had a longer follow-up period (mean=2.8 years) compared to the 1-year follow-up period used in the CA group, which might contribute to the small difference since FNF patients generally have more comorbidities, and their functioning and health status may decline at a considerable rate after the initial recovery and rehabilitation period [192]. Importantly, EQ-5D in the FNF group was comparable and at the level of the large age- and gender-matched Danish GP index. Moreover, EQ-5D scores in the FNF group were at the level of the reported one-year postoperative scores of 0.76 in men (n=4760) and 0.81 in women (n=7205) in the 70–

80 age category in CA patients with SM THA reported in the Swedish Hip Arthroplasty Register [148].

The mean OHS of 36.4 translates to good results in the FNF patients [168], which was similar to the age- and gender-matched CA patient group. The reported GP OHS index in the 70–79 age category in a combined Australian and Canadian GP reference was 42.5 [195]. The basis for the Canadian GP reference was only a total of 70 persons, which might increase the risk of selection bias, and the cross-national norm data might also be different.

TUG scores were expectedly higher for the FNF patients than for the normative reference value of 9.2 sec. for the 70–79 age group [196], but more than 90% of the FNF patients had TUG scores < 20 secs. (mean=13.5 secs.), which translates to good mobility without the need for gait aids [158]. Furthermore, the FNF patients TUG scores were below the predictive cut-off fall value for community-dwelling older adults of 14 sec and that of 24 sec within the first six months after the index surgery [197]. Considering the substantial healthcare expense associated with fall-related trauma, we regard our results as promising [198].

A mean HHS of 78.7 (range 31–100) in the FNF group translates to a fair result, which is lower than the HHS reported in other studies [108,152,199]. Only two recent studies other than the current one have reported patient-related outcomes after treatment with DM THA in FNF patient [200,201]. A short-term (22-month) retrospective study of DM THA (n=84) vs. bipolar HA (n=214) reported superior clinical outcomes in the DM THA group with HHS of 84.3 compared to 79.3 in the HA group [200]. A small-scale, short-term retrospective study of 31 FNF patients (mean age=66.4) reported HHS of 92.8 at the one-year follow-up after DM THA [201]. The shorter follow-up time in both studies could possibly be the reason for the higher HHS than in our Study I because patients' physical functioning and health status decline with the passage of time [192]. Furthermore, the low mean inclusion age of 66.4 years in the study conducted by Rasheda et al. could be associated with a better initial health status and physical functioning than the FNF patients in Study II, with a mean age at operation of 74.7 (range 30–92.6) years.

Nich et al. reported mean NMS of 6.8 (SD 2.3) preoperative and 6.1 (SD 2.7) postoperative (*p*=0.32) in 45 FNF patients treated with DM THA at a mean follow-up of 23 months (range 12.1–42.0 months) [103]. We observed both higher preoperative and postoperative NMS levels in the FNF patients treated with DM THA than the Nich et al. [103] study. Similarly, we observed lower postoperative NMS scores than preoperative scores; these differences may be due to the

patients being unable to regain their preoperative NMS level, normal aging processes, or recall bias.

One of the major limitations of Study II is the selection of patients. As stated previously, we only included patients who were physically able to attend the out-patient clinic. Hence, the true outcome of the remaining patient cohort still living at the end of the follow-up period is potentially overestimated. Furthermore, as in many cases of PROM data collection among traumatic injury patients, it was impossible to perform a pre-fracture PROM assessment, which prevented us from assessing differences in pre-intervention versus post-intervention outcomes.

## Study III

To our knowledge, Study III is the single largest consecutive cohort study with the longest follow-up period to report dislocation and complications of primary DM THA in the treatment of displaced FNF. In summary, Study III showed an acceptably large articulation dislocation risk (4.7%) and a low revision rate in fragile elderly FNF patients (mean age=80.5 years). Furthermore, we reported a relatively high occurrence of IPD, a unique complication only associated with DM implants, which requires immediate surgery with open reduction.

The concern of higher dislocation rates in conventional SM THA compared to HA[b] in FNF is contradictory. Several studies conducted in the past decade have associated SM THA with an increased dislocation risk compared to HA[b] [99,202-206], with reported dislocation rates in SM THA ranging between 2.9% and 18%. A recent systematic review and metanalysis compared DM THA to SM THA in primary surgery for CA and in FNF and revision treatment and found DM THA to have a lower dislocation risk in all three treatment groups [207].

Two case-control studies reported dislocation rates in DM THA vs. bipolar HA[b] (BHA) [101,208]. Bensen et al. investigated 172 FNF patients and found significantly lower dislocation rates of 4.6% in the DM THA group and 14.6% in the BHA group at the mean 25.3-month follow-up [101]. Missing data concerning cognitive functioning, as well as the BHA patients being nine years older on average than the DM THA patients, could have confounded the reported difference. Boukebous et al. [208] recently reported three dislocations in 90 FNF patients treated with DM THA and ten dislocations in 101 FNF patients treated with BHA at the mean 24-month follow-up. Dislocation rates were not significantly different after adjusting for age, activities of daily living, and the Charlson Comorbidity Index score. A recent matched study of DM THA versus

BHA (84 in each group) in patients treated for FNF reported three dislocations (3.6%) in the BHA group and two (2.4%) in the DM THA group (p=1.0) at the 22-month follow-up [200]. In a study conducted by Kim et al.[200], severe dementia and inability to walk independently prior to the trauma were exclusion criteria. In non-comparative cohort studies, Adam et al. [103] reported a dislocation rate of 1.4% in 214 FNF patients with DM THA at the 9-month follow-up (mean age=83 years), and Nich et al. [104] reported a dislocation rate of 4.4% in 83 patients with DM THA at the 24-month follow-up (mean age=86.7 years). In comparison to the posterolateral approach, the anterior and direct lateral approaches have both been associated with lower THA dislocation rates in FNF patients [116,117]. As in 96% of the primary THAs performed in Denmark, we only used the posterolateral approach, while others report a dislocation rate for a mix of surgical approaches [104], making direct comparisons problematic.

There is a tendency to exclude patients with cognitive impairment in FNF studies, which may contribute to a lower incidence of complications [153]. Although our study was limited by the lack of a control group, we showed a similar dislocation rate with DM THA, with the longest reported follow-up and in an unselected cohort of FNF patients; mentally impaired patients were *not* excluded, and HA[b] was not used at all in our institution. Cognitive impairment is associated with greater risk of dislocation [209], and we observed that cognitively impaired elderly has a trend, however statistically insignificant, toward a higher dislocation than patients with normal cognitive functioning.

Although the mean inclination of both our dislocation group (45°) and non-dislocation group (42°) was within the suggested safe zones of cup positioning defined by Lewinnek et al. [210], both groups had extreme cup inclination outliers ranging between 32°–67° and 15°–69°, respectively. However, the small difference in cup inclination supports the common finding that higher cup inclination increases dislocation risk [211,212]. However, a recent systematic review of the Lewinnek safe zones concluded that placing the cup within an inclination safe zone may not eliminate dislocation risk, but the risk might be minimized [213].

We observed six IPD (0.8%), which mainly occurred in relation to closed reduction for large articulation dislocation due to the 'bottle-opener effect' described by De Martino et al.[214]. In the literature, IPD is also ascribed to excessive wear of the retentive rim [214,215]. This unique complication is only seen in DM implants and is a significant complication because it requires open reduction and additional surgery for the patient, which could compromise the dislocation protective abilities of the large articulation [3].

While we did not assess cup migration, radiolucencies, or osteolysis in this study, and symptomatic cup loosening led to only eight incidences (0.8%) of revision surgery. There are no published studies available regarding the long-term survival of DM THA in FNF patients. A recent systematic review conducted by Batailler et al.[89] reported good mid-term follow-up outcomes of third-generation DM THA for the primary treatment of CA, with reported 93–95% 10-year cup survivorship rates [81,87,89]. Many of the studies on DM THA used as the primary treatment for CA are retrospective, and Vahedi et al. conclude that although the data are encouraging, there is a need for long-term evaluations, including socioeconomic evaluations [88].

We found cementless stem fixation is associated with a statistically significant higher risk of postoperative stem complications, and our results support the use of cemented stem fixation in elderly fragile, and often osteoporotic FNF patients [216-218]. Although we did not observe any fatal incidences associated with the cemented technique in the study, six perioperative embolic events were significantly and exclusively associated with cemented stems [219]. FNF patients are a heterogeneous group, and the treatment is complex with several different factors that may affect the outcome, including patient-related, implant-related, and surgical factors. Perhaps the treatment modalities used in hospitals for displaced FNF should not be either SM THA, HA[b], or DM THA but a combination where patients that are either bedridden, minimally ambulatory, or cognitively impaired are treated with HA[b], and all other patients with displaced FNF are treated with THA [220].

## Study IV

Ideally, all new implant brands should be investigated prior to market release according to the principles of stepwise introduction. RSA is the second step on the staircase intended for randomized evaluations of new implants against the gold standard. RSA has been validated as a surrogate marker for long-term primary THA outcomes [2,125,130,221]. However, Study IV is the first RSA study of the DM concept in CA patients to compare cemented and cementless cup fixation.

The relationship between RSA-measured early, high proximal cup translation and an increased risk of aseptic loosening and later cup revision has been reported in several papers [10,131,222,223]. Pijls et al. suggested an acceptable proximal cup translation threshold of 0.2mm at 24 months, and the mean migration of the cemented and cementless cup fixation groups in our study was below this limit [10]. We identified seven cemented cups and nine cementless cups 'at risk' of later revision and observed no cemented cups and only one cementless cup with 'unacceptable' proximal cup translation [10]. In relation to Nieuwenhuijse's defined limits for later cup translation in terms of proximal cup translation of >1.76 mm and sagittal (z-axis) rotation >2.53°, we observed no cups exceeding the translational limit and only one cementless cup exceeding the sagittal rotation above the limit [131]. Although no continuous translation was observed in either cemented or cementless cups, cementless cups showed statistically significant continuous rotation over time in opposite directions before and after 12 months when compared to cemented cups. Patients with cup migration above the acceptable risk levels were asymptomatic, and when combining all patients (i.e., both cup fixation types) in one group, we found no difference in 24-month PROM outcomes (i.e., OHS, HHS, EQ-5D, and VAS for pain at rest and during activity) between patients with <0.2mm and those with 0.2–1.0mm proximal cup migration. These findings indicate that early but excessive cup migration is asymptomatic, which supports using RSA-measured cup migration as an important surrogate marker for later cup loosening. Two additional studies of tibial knee components [125] and hip stems [130] also found that later implant failure was not associated with any early warning signs.

Cemented cups had a statistically significant higher inclination than cementless cups, which may be explained by our surgeons inserting all the cemented Avantage DM cups without using the guide system because they observed that when disconnecting the guide system, this could negatively affect the cement mantle before it was fully cured. However, our findings suggest that the migration of cemented cups is less sensitive to a steeper cup inclination than cementless

cups, which was in line with the findings in a study on all-poly cemented and cementless cups [224].

Using the 24-month proximal cup migration rate as an indicator for secondary stability, the results for cemented and cementless cup fixation in Study IV are comparable, as well as with lower proximal cup migration, than reported in other studies of cemented and cementless cup fixation in CA patients treated with primary THA [33,136,225-231].

A study of 34 women treated with primary THA for CA reported proximal cup translation to be higher in patients with low BMD than in patients with normal BMD at the 24-month follow-up [33]. Furthermore, they reported continuous proximal cup migration in patients with low BMD between 3 and 12 months but not from 12 to 24 months [33]. We observed similar proximal cup migration in normal and low BMD patient groups, but in contrast to Finnilä et al.[33], we found no continuous proximal cup migration during all follow-ups in normal and low BMD groups when they were stratified by cup fixation. In Study IV, the mean 24-month proximal cup migration was 0.11mm (CI= -0.07–0.29) in the cementless cup group in patients with low BMD, which was lower than the 0.29 mm (CI=0.20–0.39) reported by Finnilä et al.[33] for patients with low BMD, suggesting early initial proximal cup stability, even in the low BMD patient group with cementless and cemented cup fixation. However, cementless cups had significantly more migration in MTPM, x-axis translation, y-axis rotation, TT, and TR than cemented cups in the low BMD patient group, which warrants the use of cemented cup fixation in patients with preoperative low systemic BMD. No previous studies have reported proximal migration of cemented cups when patients were stratified according to their preoperative BMD status (normal or low). One study [231] reported statistically significant TT migration in cemented cups inserted in patients with osteoporosis when compared to non-osteoporosis, but the authors' definition of osteoporosis was based on a diagnosis of either rheumatoid arthritis, a failed femoral neck fracture, or cortisone treatment, make direct comparisons difficult.

We found higher periprosthetic BMD for cemented cups than cementless cups at all follow-ups in all 4 Wilkinson ROIs and in all ROIs, which is similar to findings in previous studies [132,138,140]. The cement penetrated deep into the subchondral bone plate, and in the transition zone between bone and cement, it was difficult for the human eye, as well as the DXA software, to distinguish between the two on scan images. Consequently, some of the cement is measured as bone in the periprosthetic regions of the cemented cups, leading to a false increase of the measured BMD and higher variation (i.e., lower precision) in BMD measurements when compared with cementless cups [132]. We consider this to be the most important explanation for

the observed differences in periprosthetic BMD between cemented and cementless cups in Study IV.

Different load transfer mechanisms in cemented and cementless fixation may lead to different bone remodelling profiles [140]. The forces are transmitted sideways rather than proximally in cementless cups, which leads to a reduced load transfer in the most cranial/proximal areas [136,138,140,143]. This may lead local bone resorption caused by stress-shielding, which might explain the observed greater bone loss in ROI 1 and ROI 2 in cementless cups than cemented cups. Conversely, the pattern of increased BMD in ROI 3 and lower BMD loss in ROI 4 in cementless cups than cemented cups might be attributed to the increased traction forces in cementless cups in these areas acting as a stimulus for bone preservation or even an increase in BMD [225]. We found no correlation between BMD changes and proximal migration in the 24-month follow-up period for either of the two fixation methods, which suggests that early cup stability is not compromised even with substantial bone loss around the cup.

We found no significant difference in clinical outcome scores on postoperative evaluations (i.e., quality of life measured by EQ-5D or hip status measured by HHS and OHS) between cup fixation methods. Furthermore, there was no difference in postoperative VAS of pain at rest and during activity between cemented and cementless cup fixation patient groups. The 24-month clinical evaluations of cemented and cementless fixation translate to either very good or excellent end-results [168]. Early cup loosening often produces very few symptoms, and the observed differences in migration between cemented and cementless cup fixation are small; both of these factors make measurable differences in clinical outcomes unlikely.

National Registry reports from the UK, Australia, Sweden, Norway, and Denmark reveal no clear overall tendency regarding cup fixation methods in the elderly. Although registry reports and systematic reviews show a tendency toward more cups being inserted with cementless press-fit fixation in general and in the elderly, their superiority is not supported [13,36,37,40,42]. A newly published Dutch registry study [76] compared mid-term revision rates in 3,038 CA patients with DM THA (mean age=70 years) to 212,915 CA patients with SM THA (mean age=79 years) and reported an overall similar 5-year revision rate of 1.5% and 1.4%, respectively. Furthermore, revision due to dislocation was lower in the DM THA group (0.2%) than the SM THA group (0.5%).

# Methodological considerations and limitations

**Study I**

Study I was designed as a cross-sectional clinical cohort follow-up study. One of the study's limitations is patient selection since almost 30% of the patients were deceased by the end of the follow-up period, and only 50% of the remaining patients participated in the radiological and clinical evaluations. Thus, we probably evaluated only the most physically fit patients at the mean 2.7-year follow-up. However, taking the naturally high mortality rate and comorbidities in FNF patients into consideration, we would likely have lost even more patients with a longer follow-up period. Furthermore, PE wear in the weakest patients with a short life expectancy might not be of great importance.

While PE wear measurements were based on a well-established method proven sufficient with mean PE wear exhibiting a minimum of 0.5 mm, an SM THA control group for PE wear comparison would have strengthened the study [61,188]. We assessed the precision of the PolyWare system by double PE wear examination (assessed by the same observer) on half (n=66) of the FNF patients. Intra-observer wear rate bias was 0.03 mm/year and 0.057 mm for total wear, with a concordance correlation coefficient of 0.91 and 0.90, respectively, which implies moderate strength of agreement between double measurements [232]. Some (n=7) of the double-examined patients showed a mean wear rate bias of 0.61 mm/year, and further investigation suggested that poor radiographic quality in these cases could have influenced precision. Furthermore, poor quality of radiographs increases the risk of observer bias since the system might not be able to auto-detect the head contours why the investigator manually has to add head points – and this inevitably reduce the precision.

We could not distinguish non-particulate wear (i.e., creep) of the PE liner from true PE wear, which poses a risk of overestimating true wear in short-term follow-up studies because the creep effect is greatest within the first year after the index surgery [44]. Furthermore, the PolyWare system did not allow us to distinguish back-side from front-side PE wear, which would have been preferable in the assessment of whether DM implants have substantial PE wear of the mobile convex surface (back-side) as suggested by some authors [181,188]. All radiograph assessments of migration and radiolucent lines were evaluated based on consensus between two observers: an experienced orthopaedic surgeon (SB) and an orthopaedic resident (ST). Neither inter- nor intra-observer reliability was investigated, which limits these evaluations.

**Study II**

As in Study I, patient selection is one of the major limitations as almost 40% of the patients were deceased by the end of the follow-up period, and only 50% of the remaining patients were in adequate physical condition and willing to come to the hospital for clinical examination. This probably caused an overestimation of the true PROM outcomes for the cohort as a whole. It would have strengthened the study if all patients in the cohort, or a greater percentage of them, could have been examined or could have at least completed the PROM evaluations at home and return these to the hospital by mail. Furthermore, for a more accurate PROM comparison to other FNF studies, our study would have benefitted from assessing the patients' comorbidity status, because we are unable to document whether the good outcomes in Study II are related to the DM THA fracture treatment or whether we examined patients in better physical condition than other FNF studies.

Most hip joint-specific outcome scales were designed and validated for evaluating patients with CA after primary THA surgery, which makes the PROMs less useful for evaluating arthroplasty treatment of hip fractures and less reflective of the complexity of the FNF population [146,233]. Although there are four hip specific scores (i.e., the functional recovery score, hip fracture functional rating scale, lower extremity measure [LEM], and new mobility score) validated for use in FNF patients, none of these four scores are widely used [146].

The cross-sectional study design and the fact that FNF is an acute condition did not allow for preoperative mobility and physical performance (i.e., TUG and STS) or PROM (i.e., EQ-5D, HHS, and OHS) data collection. The absence of repeated measurements to detect post-intervention changes in relation to preoperative status limits the study's ability to estimate the true potential of the specific implant. For the NMS, there was an evident risk of recall bias as the patients reported their pre-fracture status when examined in the outpatient clinic at the mean 2.8-year follow-up.

When comparing PROMs of FNF patients treated with THA at the mean 2.8-year follow-up with PROMs from CA patients treated with THA at the mean 1-year follow-up, there is a potential risk that the longer follow-up period in FNF patients might have been accompanied by significant deterioration, making the basis for comparison skewed in favour of CA patients.

The OHS, EQ-5D, and VAS for hip pain assessments were completed by the patient themselves, whereas the HHS assessment was completed by four different surgeons during follow-up. We did not evaluate the inter-observer reliability of HHS scores in this study.

**Study III**

Unlike Studies I and II, there is no potential selection bias in study III as all patients operated on for displaced FNF with a THA in our department during the follow-up period were included in the evaluation of complications. Furthermore, the Danish National Register, which is considered to be largely complete, was cross-checked for complications that might have occurred outside our own department. However, one limitation of our study is the lack of a control group (i.e., a group treated with HA[b]). It would have been rather difficult to do so since HA[b] was not used at all in our institution during the study period; DM THA was used exclusively in treating patients with displaced FNF. Another limitation of the study is that we were unable to retrieve information on PROMs for more than 13% of the cohort (Study II). Furthermore, we did not estimate the comorbidity level, which would have been preferable for comparison to other FNF studies.

For the radiological assessment of cup inclination, intra-observer reliability was assessed by double examination of 10% of the patients (n=81) evaluated by the same observer. The intra-observer bias was -0.42°, and the concordance correlation coefficient was 0.98, implying substantial intra-observer strength of agreement [232]. Ideally, the radiological assessments would have been performed by at least two independent investigators to assess inter-observer reliability.

**Study IV**

The randomized controlled study design and a large group available for migration analysis is the strength of this study. RSA is a validated surrogate measure of later implant loosening, but other complications (e.g., fractures in the cement mantle or wear-induced osteolysis) may not be detectable with RSA [131]. We used a mixed model statistical analysis, which enabled us to use all the available data for all patients. A large number of radiographs were available for analysis, and we excluded two patients in the cementless group due to poor marker distribution [176], and one patient with cemented cup fixation was excluded due to a mistake made in identifying severe preoperative osteoporosis (preoperative T-score= -4.3).

*Model-based RSA*

To obtain an estimate of the precision of the RSA measurements, the patients should be subjected to a double examination on at least one occasion during the follow-up period [11,126]. RSA has been proven very accurate (i.e., results are close to the true value) and precise (i.e., the closeness of agreement between repeated independent test results), which allows the RSA method to be used in small patient groups [126,234]. Several studies have reported precision in a similar fashion as we did (i.e., the coefficient of repeatability), and we find the precision of the double examinations in this study comparable [33,222,227,235]. Furthermore, there were no statistically significant differences in precision between cemented and cementless cup fixation.

*DXA scans*

There was no dedicated software available for assessing periacetabular bone. Instead, we used ortho hip scan mode, designed for scanning the bone region around a femoral stem, and created a template of the four ROIs (i.e., Wilkinson Zones) that we used to evaluate the BMD measurements around the Avantage DM cups in cemented and cementless cup fixation. The same template was used for each patient with some manual adjustment of the first (post-operative) scan of zones 2 and 3, and thereafter, the template and bone-border of the first scan was copied to subsequent scans. In every DXA scan, some manual adjustments of the tissue point-typing and zone adjustment had to be performed, which inevitably introduced some measurement errors in addition to the patients' position changes from one follow-up to the next.

The precision of the DXA double examinations varied from 3–12.5 (CV%) in cemented cup fixation and between 3–6 (CV%) for cementless cup fixation. These findings correspond with the reported CV% for cemented cups between 5–11 % and between 4–9 % for cementless cups in a study conducted by Digas et al. [140] and the CV% between 3–6% in cementless cups [225]. It is well known that periprosthetic pelvic BMD measurements around cementless cups are more precise than those of cemented cups [132]. The poorer precision for cemented cups may be attributable to the intrusion of cement into the marrow space, thereby artefactually altering the measured BMD and subsequently limiting the visual contrast between cement and bone [132].

# 8. Conclusion

**Study I**

The study showed statistically significant greater PE wear and a higher PE wear rate in the cementless DM cups than cemented cups, and but both fixation methods had a wear rate above the osteolysis limit at the short-term follow-up. It is unlikely that the high wear rates will lead to osteolysis and subsequent aseptic loosening in FNF patients with a short life expectancy. The DM hip concept is also used in younger, more active patients, and we advise close follow-up of both short- and long-term *in vivo* PE wear in these patients.

**Study II**

DM THA following displaced FNF showed good functional and patient satisfaction results. Approximately 90% of the patients were satisfied with the surgical outcome. EQ-5D was similar to the age and gender-matched general population index but slightly lower compared to matched CA patients with SM THA. We found good functional and mobility TUG, STS, and NMS outcomes in the FNF patients. The hip-specific outcome measures revealed good results, and the OHS results were at the same level as the age and gender-matched CA patient with SM THA.

**Study III**

In DM THA following displaced FNF inserted via a posterior approach, we observed an acceptable dislocation rate and a low revision rate in elderly, fragile patients. Cognitively impaired patients had a higher dislocation risk than patients with normal cognitive functioning. The unique complication IPD was fairly high, and it mainly occurred in relation to closed reduction for large articulation dislocation, which led to immediate open reduction surgery.

**Study IV**

Model-based RSA-evaluated migration data reveals that both cemented and cementless cup fixation in CA patients with DM THA showed early cup migration below threshold limits indicative of later loosening. The findings do not support the superioríty of cementless cup fixation over cemented cups in the elderly. However, we found indications that cementless cup fixation might not provide the same level of cup stability as cemented cup fixation, especially in terms of continuous rotational migration and poorer fixation in patients with low bone quality.

# 9. Perspectives and future research

The eligibility of DM implants as primary DM THA for coxarthrosis, femoral neck fracture management, and revision surgery is still widely debated. In Study I, which is one of only two *in vivo* studies of PE wear in DM implants, we demonstrated considerable PE wear in FNF patients with relatively low physical activity levels and significantly greater PE wear in cementless cups compared to cemented cups. There is an evident need for *in vivo* (preferably RCT) studies comparing PE wear of HXLPE in physically active patients treated with DM THA and SM THA to determine whether DM implants are associated with greater adverse PE wear and subsequent higher failure rates. In an extension of the RSA-assessed migration used in Study IV, we plan to study 5-year RSA-measured PE wear in elderly patients from study IV with low comorbidity.

As the area of patient-reported outcomes is quite new, future research should focus on determining which PROMs are most suitable for evaluating patient-related outcomes in both CA and FNF surgery. Unfortunately, PROM data are not collected from CA or FNF patients at the national level in Denmark. Collecting this data would be of great value in elucidating treatment intervention outcomes from the patients' perspective, and furthermore, collecting pre-surgery PROM data would minimize recall bias and provide a clearer perspective of actual PROM improvements related to surgery.

In Study III, which is the largest follow-up of an unselected cohort treated with DM THA, we demonstrated an acceptable dislocation rate and a low revision rate. The major limitation of the study was the lack of a comparative control group. Regarding DM implants in FNF treatment, future studies will preferably utilize randomized controlled trials to evaluate outcomes in DM THA versus SM THA and HA[b]. Furthermore, is has been suggested that our current one-treatment arm for all displaced FNF might not be suitable for all FNF patients as they are a very heterogeneous group. Possibly, the treatment should rely on a more individualized assessment of the patients' physical and cognitive functioning. Future studies should evaluate a new treatment algorithm specifically for FNF fractures in which x-ray results and the patient's chronological age, as well as the patient's biological age and activity level, are considered when making treatment decisions.

Our finding in Study IV showed more migration in cementless DM cups than cemented DM cups in patients treated with arthroplasty for CA, and the preoperative systemic BMD status

influenced migration in cementless cups when compared to cemented cups. These results confirm the importance of using a 'stepwise introduction' approach to the release of new devices. At the University Clinic for Hand, Hip, and Knee Surgery in the Orthopaedic Department of Regional Hospital in West Jutland, Holstebro, we plan to continue our investigation of the DM implant we investigated in Study IV. The 56 patients included in Study IV will be followed with RSA measurements 5-year postoperatively in relation to potential differences in migration profiles between cemented and cementless DM cups, as well as with a closer focus on the long-term effect of low preoperative systemic BMD on implant migration. I believe this thesis has highlighted important perspectives of treatment and outcomes in DM implants used in patients with femoral neck fractures and coxarthrosis, and the studies included in this thesis contribute important, useful knowledge in the quest to improve patient care.

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# Appendices

## Appendix 1
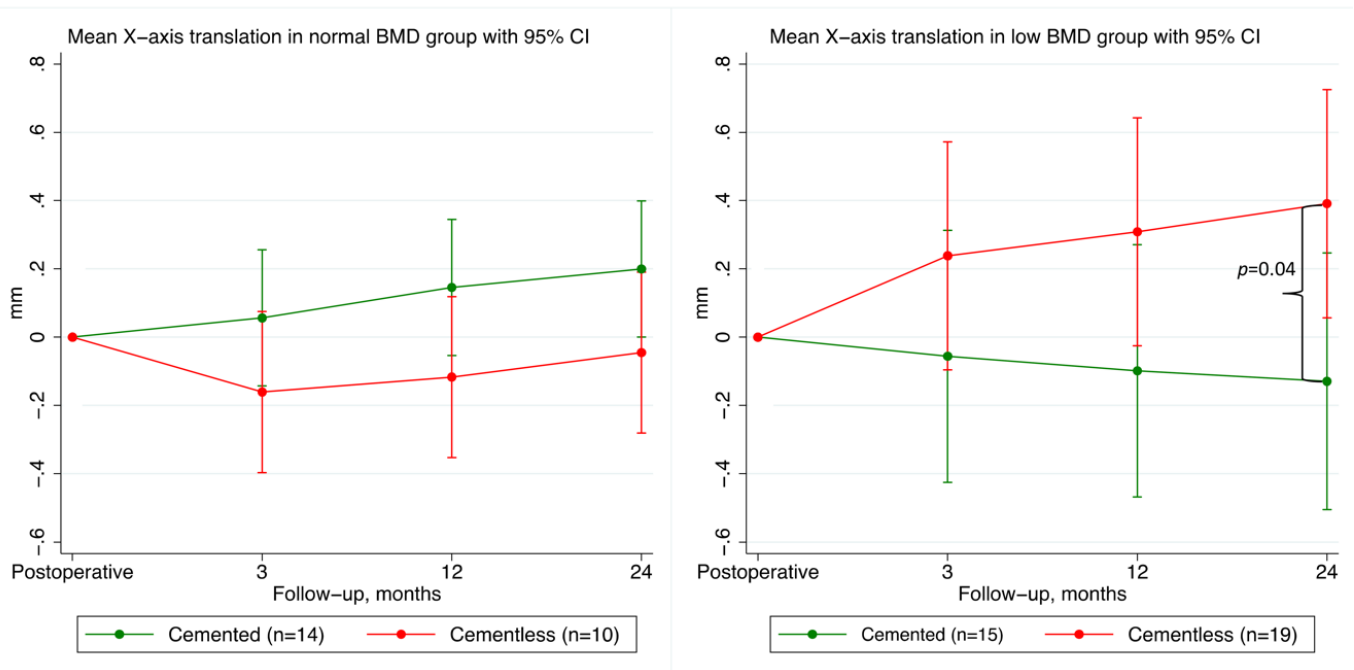


**Figure** 1 x-translation in normal and low BMD groups based on cup fixation.
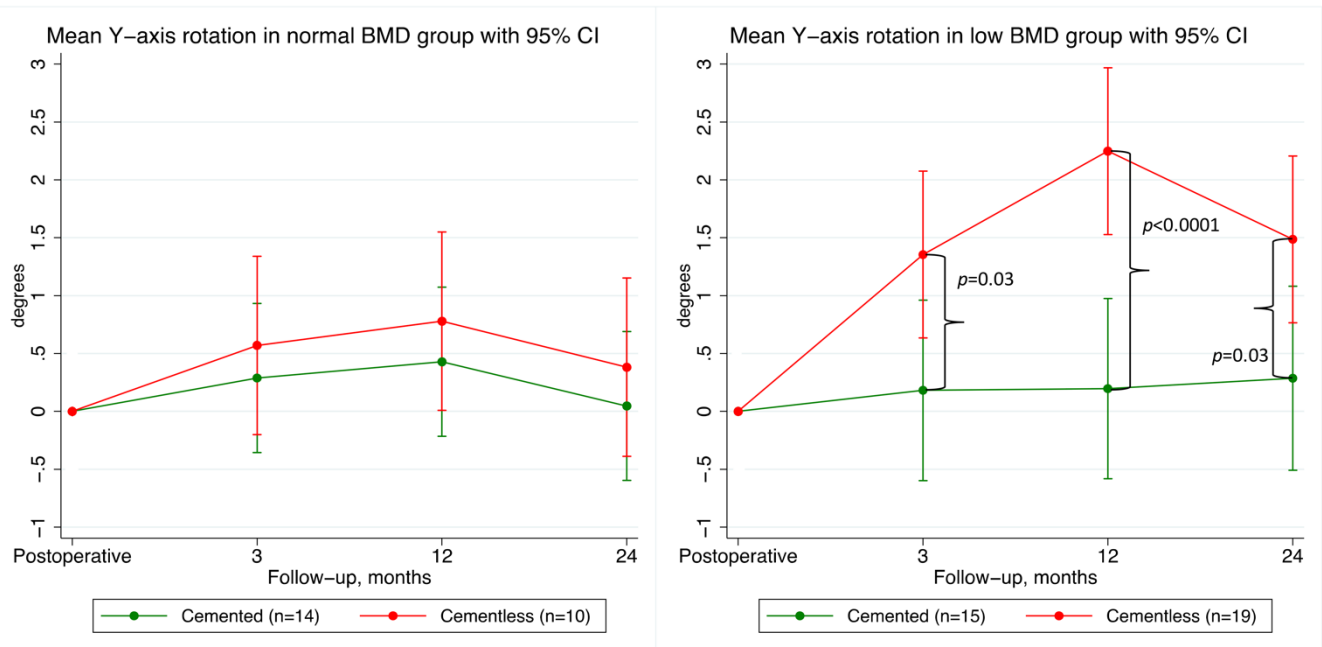


**Figure 2** y-rotation in normal and low BMD groups based on cup fixation.

**Figure 3** z-rotation in normal and low BMD groups based on cup fixation.
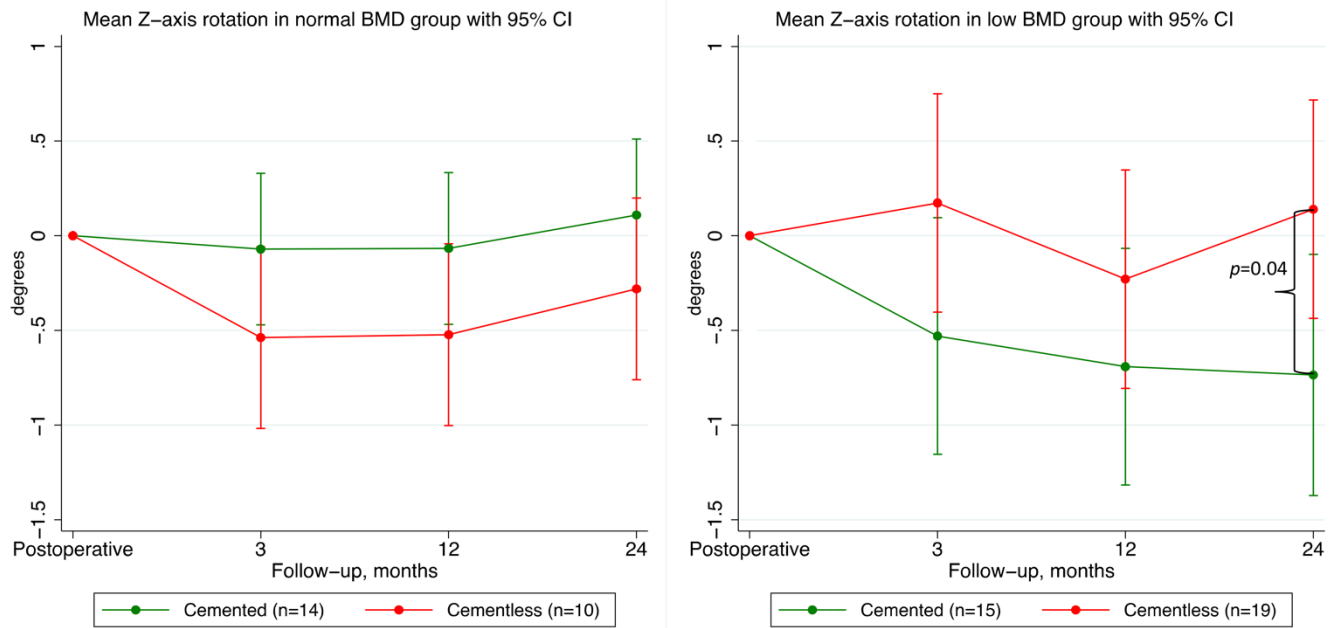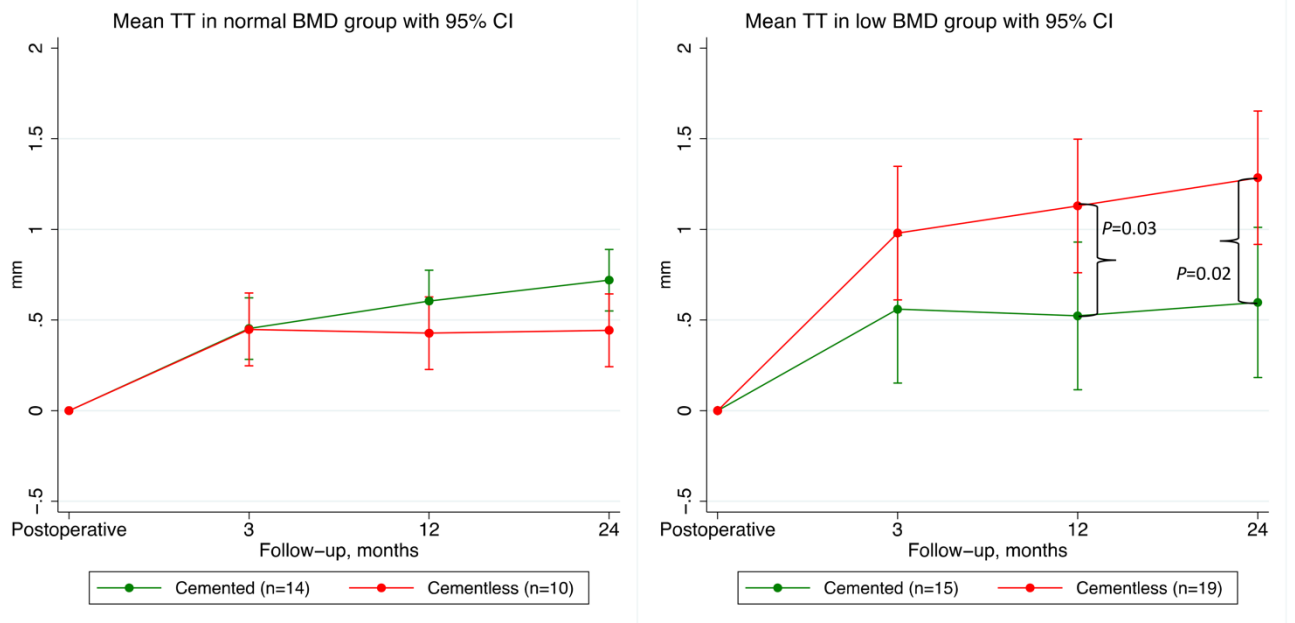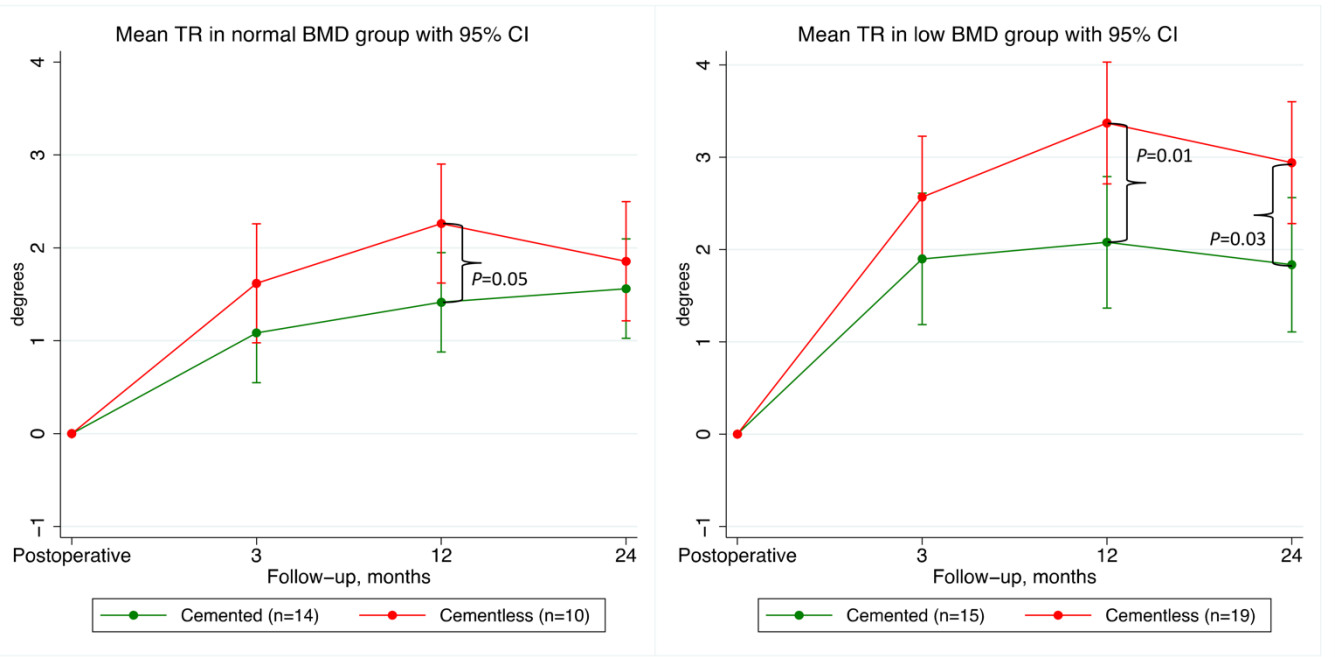


**Figure 4** TT-translation in normal and low BMD groups based on cup fixation.

**Figure 5** TR-rotation in normal and low BMD groups based on cup fixation.

# Paper I-IV

# Paper I

**ORIGINAL RESEARCH ARTICLE**

# Higher UHMWPE wear-rate in cementless compared with cemented cups with the Saturne® Dual-Mobility acetabular system

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## ABSTRACT

**Introduction:** Dual mobility (DM) total hip arthroplasty (THA) may reduce dislocation risk, but might increase the risk of high polyethylene (PE) wear due to double wearing surfaces.
**Methods:** 127 patients (97 female) with 129 hips operated with THA after displaced femoral neck fracture FNF between 2005 and 2011, were seen for a cross-sectional clinical follow-up. Acetabular components were Saturne® DM cups with 28mm chrome-cobalt heads in UHMWPE. Cementless cups (n = 73) were hydroxyapatite coated. Radiographs were obtained for analysis of cup placement, 2D polyethylene wear and wear-rate (PolyWare 3D), and further radiological evaluation. Activity measurements included Timed Up and Go test (TUG) and walking distance from Harris Hip Score (HHS).
**Results:** At a mean follow-up of 2.83 (1.0-7.7) years the mean wear was 0.82 mm (range 0.17-4.51, SD 0.50), and the wear-rate was 0.37 mm (range 0.06-1.90, SD 0.29). Wear-rate of 0.43 mm/year (SD 0.30) in cementless cups was higher (p = 0.004) than 0.30 mm/year (SD 0.27) in cemented cups. Mean age at time of surgery was 75.1 years (range 30-95). There was no correlation between age at time of surgery and wear (p = 0.56). There was no correlation between cup inclination and wear-rate (p = 0.35). TUG was mean 13.4 seconds (range 4.5-30.1) and correlated with wear rate (p = 0.03).
**Conclusions:** At short term follow-up, the mean wear-rate in old and low demand patients was high, correlated to activity, and was above the generally accepted osteolysis threshold (0.1 mm/yr.). Cementless HA-coated cups had higher wear-rate than cemented cups.

**Keywords:** Dual mobility cup, Femoral neck fracture, Hip arthroplasty, Hydroxyapatite, Polyethylene wear, UHMWPE

## Introduction

The dual-mobility (DM) hip articulation concept is based on a mobile femoral head in a non-locked polyethylene (PE) liner, which can move freely within the acetabular metal cup. These hip systems typically have large head/liner components with an outer diameter similar to that of the anatomical/native femoral head. Large head-size DM total hip systems increase the range to impingement and improve stability compared with conventional hip implants (1, 2).

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Patients with femoral neck fractures (FNF), dementia, and high risk of falling have increased THA dislocation risk, and might have a safer treatment with DM THA over conventional THA (3, 4).

Stability based on large head size and dual articulation may come at a prize of increased PE wear, which may limit implant survival (5). Cementless as well as cemented fixation options are available for DM THA, however, hydroxyapatite (HA) coating on acetabular components may cause excessive 3rd-body PE wear due to formation of particulate HA debris. PE wear may lead to periprosthetic osteolysis, aseptic component loosening, and shorter implant survival. The osteolysis threshold for ultra-high molecular weight polyethylene (UHMWPE) has been established at a PE wear-rate between 0.1mm/year and 0.2 mm/year (6-9).

PE wear in terms of femoral head penetration into the metal acetabular shell may be measured with acceptable precision on conventional hip radiographs by automated computer software (10). In approximately the 1st 6-12 months after surgery, the PE deforms (creep) and shapes into articulation with the femoral head (bedding-in). For

practical reasons, post-operative radiographs are often used as baseline for PE wear-analysis, which consequently include non-particulate PE deformation that cannot be separated from true particulate PE wear in the wear analysis (11-13). Preferably, estimation of PE wear-rates should be based on some years of follow-up in order to evaluate the "true wear-rate" (particulate wear), especially with more modern and wear-resistant highly cross-linked polyethylene (HXLPE) (14). In old and fragile fracture patient's long follow-up may not be possible due to high morbidity and mortality in the first years after hip fracture. However, when the measured mean wear is large (>0.5 mm) shorter follow-up is acceptable for precise measurements with digitised methods on plain radiographs (10).

The aim of the present study was to investigate the PE wear-rate (primary effect parameter) with cemented and cementless fixation of the Saturne® DM Acetabular System used for primary treatment in patients with dislocated medial FNF. We hypothesised increased PE wear-rate in patients with HA-coated cementless implant fixation.

## Methods

### Patients

The study design was a cross-sectional clinical cohort follow-up study with prospective evaluation of PE wear of the Saturne® DM acetabular component.

In 2005, the Saturne® DM Acetabular System (Amplitude) became the standard treatment in our department for displaced medial FNF, in terms of Garden type III and IV fractures and Garden I and II fractures with a posterior angulation >20° (15). Regardless of mental status patients were given the same treatment.

We identified all patients operated with the Saturne® DM Acetabular System in the period from January 2005 to December 2011 and invited them for follow-up. 127 patients (97 female) with 129 hips were investigated (Flowchart in Fig. 1).

All patients were operated through a posterolateral approach and were offered the same postoperative rehabilitation programme.

The Central Danish Regional Committees on Biomechanical Research Ethics reviewed the study and judged it as a quality control, and therefore according to Danish law no approval was necessary (inquiry 149/2012 of October 01, 2012).

### Components

Both the cemented and cementless Saturne® chrome-cobalt acetabular component (Amplitude) is symmetrical with a cranial-lateral rim, which increase head-coverage and reduce the dislocation risk.

The cemented Saturne® metal shell has an external sand-blasted surface and the articulate surface is highly polished. Vacuum mixed Palacos® R + G bone cement was used for fixation. The cementless Saturne® metal shell is sand-blasted before plasma-spray titanium and synthetic HA dual-coating (80 µm + 80 µm). Calcium–phosphate ratio in the HA coating was between 1.67 and 1.76. The surface roughness
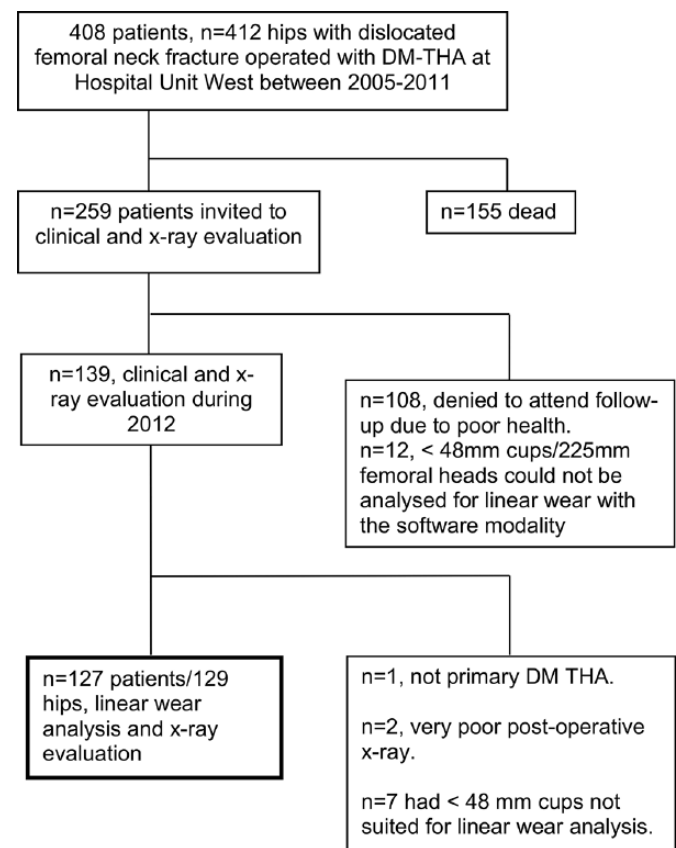


**Fig. 1 -** Flowchart of patients available for study evaluation.

(Ra) was 6.3 µm for the HA-coated cups. Line-to-line press-fit fixation was used. An UHMWPE liner (GUR 1050) was used in both cemented and cementless cups. Both cup types and the UHMWPE liners were sealed in vacuum packaging and sterilised by gamma irradiation with a minimum of 25kGy (product information from Orthotec). Femoral heads were 28-mm cobalt-chromium.

The Exeter® highly-polished stem (Stryker) with vacuum mixed Palacos® R + G bone cement were used in all cemented stem cases (n = 90) (Zimmer). The Corail® HA-coated stem (n = 34) was used in most cementless cases (DePuy Synthes, Warsaw, IN, USA), and the porous coated Synergy® cementless stem was used in (n = 5) cases (Smith & Nephew).

### Radiographic assessment and polyethylene wear analysis

All radiographs were digital (TIFF file format) and non-weight-bearing. The postoperative baseline radiographs were taken within 3 days after surgery after partial weight bearing and mobilisation. At the cross-sectional follow-up the patient was positioned supine with the feet slightly internally rotated to tighten the head-position in the PE/metal-bearing, and ensure wear-measurement of the whole wear cylinder (Fig. 2) (16). We used only the final cross-sectional pelvic AP radiographs to analyse PE wear as has formerly been described (10).

PE wear-analysis, and cup anteversion and inclination measures was performed in consensus between 3 observers
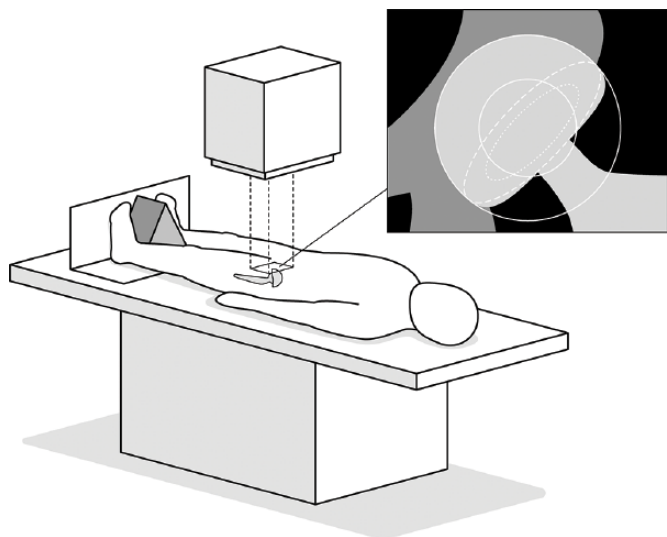
**Fig. 2 -** Follow-up radiograph and polyethylene wear measurement. The patient is positioned supine with slightly internally rotated feet. During PE wear analysis the cup dome, the cup opening and the femoral head is marked and the PE wear including front-side and back-side PE wear is calculated by the software (PolyWare).

with a computerised method (PolyWare Pro 3D Digital Version 5.10; Draftware Developers).

In the software, the location of the central ray was estimated by pencilling diagonals between the corners of the rectangular exposure on the pelvic radiograph. With a digital edge-detection algorithm circles were fitted to the peripheries of the femoral head and the acetabular cup thereby creating a 3-D model of the acetabular component and femoral head on the basis of back-projection of the radiographs and computer assisted design knowledge of the components. PolyWare measured the head penetration into the metal shell (total PE wear) assuming zero wear at the time of surgery, and, with assumption of linear wear, the wear-rate was calculated by the PolyWare software based on the time from surgery to the date of the final follow-up radiograph for each individual patient.

Double measurements were performed on 1/2 the patients (n = 66) in order to assess the precision of the method. Wear-rate intraobserver bias was 0.03 mm/year (SD 0.13) and 0.057 mm (SD 0.24) for mean wear. Double measurements with discrepancy of >0.4 mm (n = 7) was re-analysed a 3rd time for assurance.

Osteolysis and radiolucent lines (RLL) were evaluated in the 3 DeLee zones around the cup (17) and in the 7 Gruen zones around the stem at the cross-sectional follow-up x-ray (18). Only progressions in osteolysis and RLL form the postoperative to follow-up x-rays were counted. The stem cementation quality was graded on the immediate postoperative radiographs according to Barrack's grading system (19). Since no cementation grading system could be found for the acetabular component, we modified the Barrack grading system to the DeLee zones around the cup, and only RLLs at or above 1 mm in width were counted (Fig. 3).

Migration of the cup was judged visually by comparing the postoperative and follow-up x-ray. Subsidence of the cementless femoral components were measured as the difference in
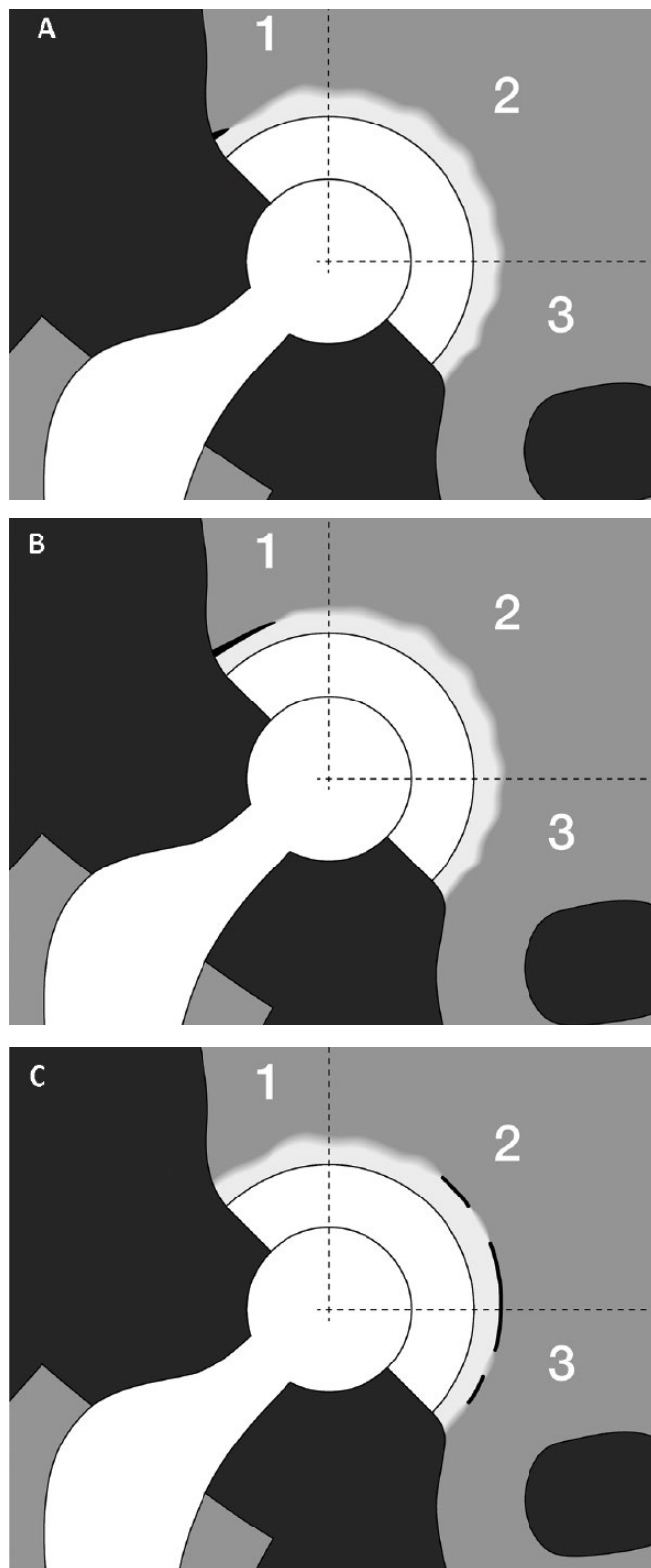


**Fig. 3 -** Classification of cup cementation quality. Grade A: Complete filling of the acetabular cavity by cement, so called "white-out", or <4-mm long lateral RLL (as this is very common) at the bone-cement interface in DeLee zone I. Grade B: RLL >4-mm long in DeLee zone I. Grade C: RLL >4-mm long in DeLee zone II or zone III.

the distance from the shoulder of the prosthesis to the tip of the greater trochanter between the postoperative and follow-up x-ray. For cemented femoral components subsidence was measured as the distance difference from the distal tip of the stem to the cement mantle between the postoperative and follow-up x-ray. Valgus, varus or neutral positioning of the femoral component was graded visually. Ectopic ossification was classified according to Brooker et al (20).

All radiographic assessment was performed in consensus between 2 observers.

### Patient-reported outcome measures (PROMs)

Oxford Hip Score (OHS) was completed by the patients and Harris Hip Score (HHS) was completed by the physician at the cross-sectional outpatient visit (21, 22). Timed Up and Go test (TUG) and HHS were used to evaluate activity and mobility (23). HHS question 12 categorise walking distance into 5 categories: 1) Unlimited, 2) 1.5-2.0 km, 3) 0.5-1.0 km, 4) Only indoor, 5) Bound to bed/wheelchair.

### Statistics

The primary endpoint was PE wear-rate of cemented vs. cementless Saturne DM acetabular components. We used non-parametric statistics for continuous data, as data were not normally distributed according to a Shapiro-Wilks test. Mann-Whitney U-test was used to test for differences in PE wear-rate, mean PE wear, age, follow-up time and gender between the cemented and cementless groups. Correlations were evaluated by Spearman's correlation test. Chi squared and Fischer Exact tests, as appropriate, were used for categorical data. Statistical significance was assumed at $p<0.05$.

Intercooled Stata version 13.1 (StataCorp, CollegeStation) was used for statistical computations.

### Results

The demographic results are summarised in Table I. At the mean 2.7 years (range 1.0-7.7 years) cross-sectional follow-up patients reported OHS of mean 36.4 (range 9-48) and HHS of mean 78.8 (range 31-100). There was no difference in PROMs between cemented and cementless cups for HHS (p = 0.68) and OHS (p = 0.44).

### Wear analysis

The head penetration rate (wear-rate) for the cemented cups (n = 56) at a mean of 3.0 years was 0.3 mm/year (range 0.06-1.71, SD 0.27) which was significantly less (p = 0.004) compared with a wear-rate of 0.43 mm/year (range 0.08-1.9, SD 0.3) at a mean of 2.7 years for the cementless cups (n = 73). Mean linear head penetration in the cemented cups at a mean of 3.0 years was 0.66 mm (range 0.17-1.9, SD 0.3) compared with 0.94 mm (range 0.26-4.5, SD 0.6) in the cementless cups at a mean of 2.7 years (p = 0.0001).

There was no correlation between length of follow-up and mean PE wear (rho = 0.05; p = 0.59).

Age at time of surgery correlated with length of follow-up (rho = -0.26; p = 0.003), hence there was shorter follow-up of older patients. Furthermore, age at time of surgery correlated with PE wear-rate (rho = 0.19; p = 0.036) indicating that older patients had higher PE wear-rates than younger patients.

There was no association between gender and PE wear-rate (p = 0.97), and no correlation (p = 0.35) between cup inclination and PE wear-rate, even when correlation was tested

**TABLE I -** Patients demographics included in the radiological wear analysis

| | Cemented cup | Cementless cup | p value |
|---|---|---|---|
| n | 56 | 73 | |
| Gender (M/F) | 10/46 | 22/51 | 0.11 |
| Side (R/L) | 28/28 | 25/48 | 0.072 |
| Age, years, mean/median (range) | 76.5/78 (42-93) | 74/75 (30-95) | 0.097 |
| Follow-up, years (range, SD) | 3.0 (1.1-7.6, 1.7) | 2.7 (1.0-7.7, 1.4) | 0.28 |
| Cup inclination, mean° (range, SD) | 42.1 (29.1-70.7, 8.6) | 43.8 (25.5-62.3, 8.6) | 0.21 |
| Cup anteversion, mean° (range, SD) | 16.3 (-2.3-37.7, 8.4) | 14.7 (-25.2-46.1, 10.9) | 0.96 |
| Wear-rate, mm/year (range, SD) | 0.30 (0.06-1.71, 0.27) | 0.43 (0.08-1.9, 0.3) | 0.004 |
| Mean wear, mm (range, SD) | 0.66 (0.17-1.9, 0.3) | 0.94 (0.26-4.5, 0.6) | 0.0001 |
| Mean TUG, seconds (range, SD) | 14.3 (4.5-28.5, 5.0) | 12.8 (6.3-30.1, 5.0) | 0.13 |
| Mean OHS (range, SD) | 37.2 (14-48, 9.1) | 35.8 (9-48, 9.8) | 0.44 |
| Walking distance (applied from HHS) | | | |
| 1 (unlimited) | 23.4% | 21.2% | 0.98 |
| 2 (1.5-2.0 km) | 29.8% | 33.3% | |
| 3 (0.5-1.0 km) | 31.9% | 31.8% | |
| 4 (only indoor) | 14.9% | 13.6% | |
| 5 (bound to bed/wheelchair) | 0.0% | 0.0% | |

HHS = Harris Hip Score; OHS = Oxford Hip Score; SD = standard deviation; TUG = Timed Up and Go test.

**TABLE II -** Follow-up radiological cup results

|  | Cemented cup (n = 56) | Cementless cup (n = 73) | p value |
|---|---|---|---|
| DeLee 1 RLL (progressive RLL) | 7 (5) | 1 (1) | 0.02 |
| DeLee 2 RLL (progressive RLL) | 4 (4) | 0 (0) | 0.033 |
| DeLee 2 RLL (progressive RLL) | 5 (5) | 1 (1) | 0.085 |
| Total cups with RLL | 9 | 1 | 0.002 |
| Postoperative cementation grading A/B/C | 45/6/5 |  |  |
| Osteolysis | 0 | 2 | 0.56 |
| Brooker 1/2/3/4 | 4/2/1/0 | 11/2/5/0 | 0.083 |

**TABLE III -** Follow-up radiological stem results

|  | Cemented stem (n = 90) | Cementless stem (n = 39) | p value |
|---|---|---|---|
| Gruen 1 RLL (progressive RLL) | 18 (7) | 6 (6) | 0.54 |
| Gruen 2 RLL (progressive RLL) | 28 (14) | 1 (1) | <0.001 |
| Gruen 3 RLL (progressive RLL) | 18 (10) | 1 (1) | 0.01 |
| Gruen 4 RLL (progressive RLL) | 18 (8) | 3 (3) | 0.12 |
| Gruen 5 RLL (progressive RLL) | 12 (8) | 1 (1) | <0.001 |
| Gruen 6 RLL (progressive RLL) | 16 (9) | 3 (3) | <0.001 |
| Gruen 7 RLL (progressive RLL) | 12 (6) | 2 (2) | <0.001 |
| Total stems with RLL | 35 | 11 | 0.25 |
| Subsidence, mm (SD) | 1.84 (1.1) | 1.24 (4.9) | <0.001 |
| Postoperative cementation A/B/C | 50/29/11 |  |  |
| Stem position valgus/ varus/neutral | 4/15/71 | 0/10/29 | 0.67 |
| Osteolysis | 0 | 0 |  |

separately in relation to cup fixation (p>0.25), and also when correlation was tested between wear-rate and inclination >50°(p = 0.42).

There was a positive but weak correlation between the TUG time and wear-rate (rho = -0.21; p = 0.03). TUG time was similar between cup fixation methods (p = 0.06). At follow-up, 54% of patients reported good walking distance, unlimited walking capability, or walking distance in the range of 1.5-2.0 km, but there was no difference in self-reported walking distance between patients with cemented and cementless cup fixation (p = 0.98). No patients seen for clinical follow-up were immobile and bound to bed/wheelchair.

Characteristics of the study group are summarised in Table I.

### Radiological results

The radiological results for the cups and stems are summarised in Tables II and III.

In total the cemented cups had significantly more radiolucent lines (p = 0.002) compared to cementless cups, but there was no difference in the occurrence of osteolytic lesions between cup fixation (p = 0.56). We found no correlation between postoperative cup cementation quality and later occurrence of RLL in cemented cups (p = 0.11). Further, there were no differences in ectopic ossifications between cemented or cementless cup fixation (p = 0.083).

In total, there was no difference in RLL between cemented and cementless cups (p = 0.25). The cemented stems had significantly more RLL than the cementless stems in Gruen zone 2 (p<0.001) and 5-7 (p<0.001). Also, cemented stems subsided more than cementless stems (p<0.001). We found no correlation between postoperative stem cementation quality and the occurrence of RLL in cemented stems (p = 0.81). There was no difference in stem position (valgus/varus/neutral) between cemented and cementless stems (p = 0.67).

### Complications

During the follow-up period 1 hemiplegic patient sustained a fall 17 days after surgery and had a single hip dislocation, which was treated by closed reduction.

1 patient with a cemented cup had aseptic loosening at 5 years follow-up and underwent cup-revision with good result. 1 patient had stem revision because of a fall related stem fracture 58 days after primary surgery. At 4.2 years follow-up 1 patient had severe stem subsidence of 30 mm, but had no pain or complaint and never underwent additional operation. 1 patient with a lesser trochanter avulsion after a fall was treated conservatively.

### Discussion

To the best of our knowledge, this is the first in vivo study of PE wear in total hip arthroplasty exclusively in hip fracture patients. The key findings were more PE wear in cementless HA-coated cups compared with cemented cups, and a short-term wear-rate which was 2- to 3-fold above the UHMWPE osteolysis threshold of 0.1-0.2 mm/year (5, 7-9).

### PE wear measurement

PE wear-measurement of THA on plain radiographs is recommended at mid-term follow-up in order to be able to measure a sufficient amount of PE wear (higher than the detection limit of the wear measurement method). The PE used in the DM Saturne cup was of standard UHMWPE type, which generally has higher wear than more modern crosslinked types of PE, and the measured wear was above the method precision level (intraobserver bias 0.03mm/year wear). We only used the cross-sectional (last follow-up) radiograph for wear analysis, all of which were obtained with a standard protocol, and the digital wear measurement method presumed zero wear at the time of surgery. This method is sufficient when the mean linear wear measurement is above 0.5 mm,

and has precision at the level of model-based RSA, and the mean wear in both groups was above this limit (10).

A machine measured explant study suggest that retrieved PE liners from DM articulations have wear similar to conventional constrained liners, and report mean wear-rate of 0.082 mm/year (0.002-0.282, SD 0.072) and mean total wear of 0.625 mm (0.036-2.803, SD 0.671) after mean 8 years follow-up (24). We find considerably higher wear rates and mean wear, which may be partially explained by different wear measurement methodology and a proportionally larger effect of creep and bedding-in (non-particulate wear) in our wear analysis due to a shorter follow-up.

The shorter follow-up seen in older patients may be explained by natural higher mortality at older age and an initial phase-in period to operate older FNF patients with THA, when we started using the Saturne cup for displaced FNF in 2005.

### Inclination

We did not find a correlation between wear-rate and cup inclination. In support of this, a short term in vitro hip joint simulation study tested wear of 2 sizes of highly crosslinked dual-mobility bearings but found no significant effect on PE wear when increasing the cup inclination angle from 50°-65° (25). However, in single-mobility/standard hip articulations retrospective clinical studies have shown steeper cup angles to lead to increased PE wear (26-28). Thus, it seems that DM articulation might protect against increased wear with poor cup position, as well as reduce the risk of dislocation (3, 29, 30).

### Activity and wear

The TUG test is a quick and easy test to perform. TUG test on 60 geriatric patients (mean age 79.5 years) suggested a TUG time <10 seconds to be normal, TUG time <20 seconds to be good mobility, out alone, mobile without aid, and TUG time >30 seconds to be related to mobility problems (23). The patients in the present study had a mean TUG time of 13.4 seconds (range 4.5-30.1 seconds) which indicates good mobility, balance and functional level.

We found a positive but week correlation between TUG time and wear-rate for the whole group, but the clinical importance is questionable. Importantly, there was no difference in activity measures between cup fixation groups.

### Osteolysis

An osteolysis threshold has been established to be between 0.1 and 0.2 mm/year PE wear-rate for UHMWPE (6, 31), which is important since osteolysis may lead to implant failure by aseptic component loosening (32).

In a study of single-mobility cups with 15 years follow-up high UHMWPE wear-rate (>0.4 mm/year) was associated with cup failure and cup revision in cementless cups with and without HA (9). At short-term follow-up in our study we did not see signs of osteolysis. However, we did find the short-term PE wear-rate 2- to 4-fold above the osteolysis threshold, and the long-term effects on implant survival related to this could be a problem.

Fortunately, UHMWPE has generally been replaced by more durable highly crosslinked PE (HXLPE), which has up to 87% lower incidence of osteolysis compared to UHMWPE at midterm follow-up (33-36).

### Hydroxyapatite and third-body wear

HA-coating on cementless cups has not been associated with positive long-term survival as for HA coating on cementless femoral stems (37). Rather HA coating seems to have adverse effects in terms of increased PE wear compared with cementless non-HA-coated cups (9, 38). Likewise, in our study, HA coating on the cementless Saturne cups may explain the higher PE wear-rate in this group as compared to a lower wear-rate with cemented fixation.

The concern is that the HA coating leads to excessive 3rd-body PE wear when it disintegrates into the joint (7, 8, 38-40). The DM concept has 2 wearing PE surfaces. The majority of the hip joint motion is believed to occur in the small joint (metal head/liner), which should have good wear properties due to the small femoral head. However, any motion in the large joint (liner/shell) may lead to excessive PE wear due to the large contact surface/big head (41, 42). The wear measurement method used in our study includes both front-side and backside PE liner wear, and if the PE liner does wear significantly in the large joint, this may explain the generally higher wear-rate in our study compared with single-mobility PE wear. Further, eventual third-bodies from HA may accelerate PE wear even more when present in a double-mobile joint with non-crosslinked UHMWPE.

### Limitations

The primary limitation of the study is the potential patient selection since 30% of patients were dead at the time of the follow-up and only 50% of remaining patients (n = 127) participated in radiological evaluation and clinical examination. Thus, we probably evaluated only the best of the patients at follow-up, and OHS of mean 36.4 and HHS of mean 78.7 also indicate that the patients had a fair functional level, comparable to other functional outcome studies after FNF operated with THA (43-46). Taking into account the naturally high mortality rate and comorbidities in FNF patients, we would likely have lost even more patients at an eventual longer follow-up. However, it could be argued that PE wear is not important in the weakest patients with a short life expectancy.

## Conclusion

The DM hip concept is now recommended for younger and active patients because of stability safety. Since the expected lifespan and activity level of these patients are expectedly larger than in our patient group it is important to keep attention on in vivo PE wear of DM articulations in the future and explore further differences between cemented and cementless cups. Currently, no in vivo studies on PE wear and on the actual large-joint motion in DM are available.

In conclusion, we found higher UHMWPE wear in cementless over cemented Saturne® DM cups in patients operated with THA after displaced femoral neck fracture. Longer term

in-vivo studies in older as well as in younger patients with different DM implant brands/HXLPE are warranted.

## Disclosures

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# Paper II

ORIGINAL RESEARCH

# Good function and high patient satisfaction at mean 2.8 years after dual mobility THA following femoral neck fracture: a cross-sectional study of 124 patients

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**Aims:** Our aim was to investigate function, health status and satisfaction in patients treated with primary dual mobility (DM) total hip arthroplasty (THA) after displaced femoral neck fracture (FNF).

**Patients and methods:** From 2005–2011, 414 consecutive FNF patients received Saturne DM THA. At a minimum of 1-year follow-up, 124 (95 women) were evaluated with Oxford Hip Score (OHS), Harris Hip Score (HHS), health-related quality of life (HRQoL) measure (EQ-5D) and two functional tests: Timed Up and Go (TUG) and Sit to Stand 10 times (STS). The FNF patients were matched 1:2 by age, sex and surgery date with patients receiving THA due to osteoarthrosis (OA group) and 1-year OHS and EQ5D were compared. FNF patients were matched by age and sex with the general population index (GPI) for EQ-5D comparison.

**Results:** Patient age at surgery after FNF was mean 74.8 (range 30–92) years. At mean follow-up of 2.8 (range 1.0–7.7) years, mean EQ-5D score was 0.79 (SD 0.15) in the FNF group, which was similar to the matched GPI ($p = 0.4$), but lower ($p = 0.014$) compared to the OA group. Mean OHS was 36.4 (SD 9.5) in the FNF group and 38.4 (SD 7.2) in the OA group ($p = 0.18$). HHS in the FNF group was 78.7 (SD 15.5). Mean TUG time was 13.5 (SD 4.9) secs, and mean STS was 37.9 (SD 15.3) secs. Eighty nine percent (n = 111) of FNF patients were satisfied with the operation result.

**Conclusion:** DM THA following displaced FNF provides a good functional result and quality of life in addition to high patient satisfaction.

**Keywords:** dual mobility cup, femoral neck fracture, hip arthroplasty, EQ-5D, Oxford Hip Score, patient reported outcome measures

## Plain language summary

The proportion of older people in the world is increasing. Total hip arthroplasty (THA) is a common and well-established procedure for displaced femoral neck fractures (FNFs) due to the risk of femoral head necrosis after osteosynthesis with approximately 600 surgeries performed annually in Denmark. The demand for well-functioning implants that not only have low implant complications profile but also maintain the patients function and mobility after surgery is essential. In this cross-sectional study, we investigated the function, mobility and satisfaction in patients receiving a dual-mobility (DM) THA. A total of 414 patients were operated on between January 2005 and December 2011. In 2012, we evaluated 124 patients with two questionnaires (Oxford Hip Score [OHS] and Harris Hip Score [HHS]) regarding their postoperative function, health-related quality of life (HRQoL) and we did two functional capacity tests, Timed Up and Go (TUG) and Sit to Stand 10 times (STS). The patients were

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matched 1:2 to a patient group receiving a THA due to osteoarthritis (OA group). For the HRQoL, results were matched to the general population index (GPI). The mean follow-up time was 2.8 years and the mean age was 74.8 years. Of the 124 FNF patients investigated, 89% were satisfied with the operation. We found slightly lower HRQoL results in the FNF patients compared to the matched OA group, but HRQoL was similar to the large matched GPI group. OHS results for the FNF patients were comparable to the OA group. The functional capacity tests translate into good function. We concluded that using DM THA in the treatment of FNF patients provides good functional results and quality of life in addition to high patient satisfaction.

## Introduction

Hip fracture is one of the biggest health care challenges in the 21st century. The reason is the reversing aging pyramid and longer life expectancy, which increases morbidity, mortality and socioeconomic costs related to hip fractures.[1] Displaced femoral neck fracture (FNF) is a common injury in the elderly, and treatment with total hip arthroplasty (THA) has low complication and revision rates compared to internal fixation and hemiarthroplasty.[2,3] The dual-mobility (DM) hip articulation has a mobile femoral head captured in the polyethylene (PE) liner so that the large diameter PE essentially functions as a large femoral head similar to that of the anatomical/native femoral head. This design, theoretically increases range to impingement and improves stability compared to conventional hip implants.[4] The DM articulation has proven effective in reducing the THA dislocation risk in fragile FNF patients, demented and patients with a high risk of falling.[5]

Traditionally, the outcome after surgery has been measured in relatively tangible data such as mortality, reoperation, surgical implant success and radiographic results. Less is known about the patient-centered and functional outcome after ended rehabilitation in fragile FNF patients.[6,7] There is increasing focus on patient-related outcome measures (PROMs) but little consensus among professionals on which measures to use, and which outcomes patients see as important. There are five major categories in assessing outcome measurements; general health-related quality of life (HRQoL), activities of daily living (ADLs), mobility and physical performance scales, disease-specific scales and joint-specific scales.[7] It is advised to use scales from more than one category to assess outcome.

In Denmark, 568 THA out of 9,674 annual THA (all diagnoses, 2015) are performed due to FNF. There is no national follow-up on patient-reported outcomes after THA for treatment of FNF in Denmark.[8]

The aim of the present study was to investigate the function, health status and satisfaction in patients treated with primary DM THA after displaced FNF in comparison with 1) an age- and gender-matched group of patients treated with THA due to hip osteoarthritis (OA) and 2) the background population. We hypothesized that FNF patients treated with DM THA gain good function and high satisfaction at the level of hip OA patients treated with primary THA.

## Patients and methods
### Patients

The study design was a cross-sectional clinical cohort follow-up study with prospective evaluation of the function, health status and satisfaction in patients treated with primary THA after displaced FNF compared to 1) a matched group of patients treated with THA inserted due to OA, and 2) the age-matched background population.

In 2005 the Saturne® DM Acetabular System (Amplitude, Valence, France) became the standard treatment in our department for Garden type III and IV displaced FNF[9] in combination with a cemented Exeter stem or a cementless Corail stem. Cemented or cementless fixation according to bone quality and the surgeon's preference. Regardless of mental status, patients were given the same treatment.

Between January 2005 and December 2011, 414 consecutive FNF patients received a Saturne DM THA at the time of follow-up 155 were dead. The etiology of the FNF was low velocity mechanical fall in all cases. At a minimum of 1-year follow-up, 124 patients (95 women) with a mean age of 77.6 age (range 37.2–94.3) responded to an invitation and were evaluated in our outpatient clinic. Of the 124 patients, 56 cups and 83 stems were cemented.

All patients surgeries were through a posterolateral approach and they received the same postoperative rehabilitation program as OA patients. To prevent infection 1 g Diclocil® (dicloxacilline) was administrated preoperatively as well as three times during the first 24 postoperative hours. From the first postoperative day, the mobility goal was for the patient to be out of bed 4 hours including training with the physiotherapist and occupational therapist, and 8 hours per day for the rest of the hospitalization period.

At the cross-sectional follow-up, and after informed consent, all FNF patients reported their quality of life EQ-5D, Oxford Hip Score (OHS), New Mobility Score (NMS) and satisfaction with the DM THA treatment.[10–14] A nurse assisted the patient in recalling the preoperative NMS. Harris Hip Score (HHS) including a hip examination was completed.[15]

Functional capacity was tested with Timed Up and Go (TUG) time as well as Sit to Stand 10 times (STS).[16]

Patients had their cognitive function tested at follow-up with a Danish version of the abbreviated 0–9 mental status test, where a test score between 0 and 5 is considered low cognitive function.[17] For those participants with cognitive impairment (n = 10), the journal and questionnaire was reassessed and in total five patients were excluded because we felt their cognitive function was too impaired for the answered questionnaires to be valid and useful.

All the patients were offered a standard package of postoperative clinical controls from our standard clinical pathway, and by attending the controls the patients gave their consent to participate and no written consent was needed.

FNF patients were matched 1:2 by age, sex and surgery date with patients receiving THA due to hip osteoarthrosis (OA) where all had been followed to 1 year with OHS and EQ-5D. The FNF patients were further matched to the general population index (GPI) for comparison of EQ-5D scores.

## Matching

We performed matching with two different control groups for comparison of PROM data with our FNF case group.

1) 2:1 matching on EQ-5D and OHS to the hip OA group receiving THA at the Hospital Unit West between the years 2008 and 2013 (n = 1,250). The FNF patients were matched on three parameters (gender, age in 5-year age intervals and surgery year). A control patient was only used for a single match. We obtained a full match on all three parameters for 76 patients, and a partial match (gender and age, but not on operation year) for 42 patients, where we further attempted to minimize the difference in operation year. Six FNF patients could not be matched at all. Double match was possible in 88% of full matches and in 97% of partial matches. All full and partial matches were used for comparison of EQ-5D and OHS (n = 226).

2) EQ-5D scores of the FNF patients was matched to the general population norms based on the study of 15,700 respondents in the Danish general population.[18] FNF cases were divided into 5-year intervals and thereafter matched on gender- and age-related (5-year intervals) population norm. On average, there were 359 matches in the general population group per FNF case, but all possible matches were used for the comparison of life quality (n = 44,519).

The Central Danish Regional Committees on Biomechanical Research Ethics reviewed the study and judged it as a quality control, and therefore according to Danish law no approval was necessary (inquiry 149/2012 of October 1, 2012).

## Statistical analysis

Non-parametric (Mann–Whitney) statistics was used for continuous data, where data were not normally distributed according to a Shapiro–Wilks test, and parametric (Student's $t$-test) statistics where data was normal distributed.

Linear regression was used to compare the FNF group to the matched OA group for scores in EQ-5D, and likewise linear regression was used to compare OHS between FNF patients and the matched OA group. Correlations were evaluated by Spearman's correlation test.

For comparability with the literature, and for interpretability reasons, we present the mean values for data without a Gaussian distribution (TUG, STS, EQ-5D, HHS and OHS).

Statistical significance was set at the 5% level and all statistical computations were undertaken with Intercooled Stata version 13.1 (StataCorp LP, College Station, TX, USA).

## Results

The demographics for the FNF group are summarized in Table 1.

## Comparison with matched OA THA group

FNF patients had a mean EQ-5D of 0.79 (range 0.37–1.0, SD 0.15). The adjusted (gender, age and operation year)

**Table 1** Demographic results for FNF and OA patients

| Demographic | FNF cases | 2:1 OA match | p-value |
|---|---|---|---|
| n | 124 | 226 | |
| Gender (m/f) | 29/95 | 49/177 | 0.7 |
| Age at operation, mean (range, SD) | 74.7 (30–92.6, 9.5) | 74.6 (52.6–92.2, 8.7) | 0.6 |
| Age at FU, mean (range, SD) | 77.6 (37.2–94.3, 9.1) | 75.6 (53.6–93.2, 8.7) | <0.001 |
| Follow-up, years (range, SD) | 2.8 (1.0–7.7, 1.6) | 1-year FU | <0.001 |
| TUG, seconds (range, SD) | 13.5 (4.5–30.1, 4.9) | | |
| STS (range, SD) | 38.0 (16–101, 15.4) | | |
| NMS (pre/postoperative) | 8.2/7.2 | | <0.001 |
| HHS (range, SD) | 78.7 (31–100, 15.5) | | |
| EQ-5D (range, SD) | 0.79 (0.37–1.0, 0.15) | 0.85 (0.47–1.0, 0.13) | 0.014 |
| OHS (range, SD) | 36.4 (9–48, 9.5) | 38.5 (16.5–48, 6.9) | 0.18 |

**Abbreviations:** FNF, femoral neck fracture; OA, osteoarthrosis; m, male; f, female; FU, follow-up; TUG, Timed Up and Go; STS, Sit to Stand; NMS, New Mobility Score; HHS, Harris Hip Score; EQ-5D, EuroQol-5D; OHS, Oxford Hip Score.

estimate of the mean difference of EQ-5D from FNF patients to OA patients was 0.06 (95% CI 0.1, 0.01, $p = 0.014$).

The statistical difference between the FNF patients and the OA patients was found to be in question 1 concerning mobility ($p = 0.002$) and question 4 concerning pain/discomfort ($p = 0.0043$).

The adjusted estimate of the mean OHS difference between FNF patients and OA THA patients was 1.66 (95% CI −4.10, 0.78, $p = 0.18$). There was no difference in OHS score between genders in the FNF group ($p = 0.74$).

## Comparison with matched GPI

There was no difference in EQ-5D between FNF patients and the gender- and age-matched general population norm ($p = 0.40$). EQ-5D results for FNF, GP and OA patients are shown in Figure 1.

The age matched (age > 75 years) HHS for the general population has been reported to be 93.7 (SD 7.1),[19] and the HHS of the FNF patients in our study was lower than the reported population level ($p < 0.0001$), but 20% of the FNF patients had a score at or above the general population level at follow-up. In the FNF group, there were similar HHS between genders ($p = 0.98$).

There was a good correlation between HHS and EQ-5D (rho = 0.60, $p < 0.0001$) and between HHS and OHS in the FNF patients (rho = 0.65, $p < 0.0001$).

At follow-up, 89.5% (n = 111) scored their overall satisfaction with the operation outcome as either very good (n = 71) or good (n = 40). Satisfaction had a moderate correlation to EQ-5D (rho = −0.42), OHS (rho = −0.52) and HHS (rho = −0.48), all significant ($p = <0.0001$).
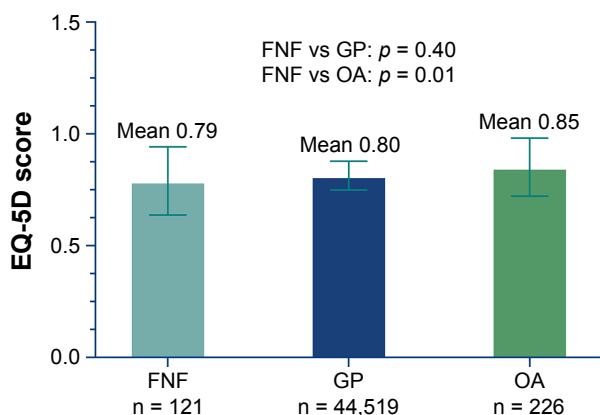


**Figure 1** Mean EQ-5D score of the FNF, GP and OA patients. Average of 359 GP matches per FNF patient. Error bars represent standard deviation.
**Abbreviations:** EQ-5D, EuroQol-5D; FNF, femoral neck fracture; OA, osteoarthrosis; GP, general population.

## Complications

Of the FNF patients, four underwent revision surgery during follow-up. One patient had stem-revision because of a fall-related stem fracture 58 days after primary surgery. One patient in immunosuppressive therapy was successfully revised to debridement, washout and arthrotomy because of a *Staphylococcus epidermidis* acute deep infection, and no components were replaced. Two patients underwent revision surgery because of aseptic loosening, one with cup loosening and one with femoral stem loosening. One hemiplegic patient sustained a fall 17 days after surgery and had a hip dislocation, which was treated with closed reduction.

The patients who experienced complications all had below average scores in the follow-up PROMS and functional tests compared to the other FNF patients.

## Discussion

To the best of our knowledge, this is the first study of mobility, physical performance, PROMs and treatment satisfaction exclusively in hip fracture patients treated with DM THA.

It is recommended to use scales from more than one of the five overall categories when measuring outcome after FNF, as there is no single unifying scale for assessing outcome after FNF.[6,7] In this cross-sectional study, we focused on three out of the five categories, namely, general quality of life (EQ-5D), mobility and physical performance (TUG, STS) and hip-specific scores (OHS, HHS).

## EQ-5D

The FNF patients in this study had a mean EQ-5D score of 0.79 (range 0.37–1.0) with follow-up between 12 and 90 months, which was better than reported in other studies of FNF patients treated with THA, with EQ-5D scores ranging from 0.61 to 0.71 with follow-up length between 12 and 48 months.[20–23] We found a slightly lower EQ-5D score compared with the matched OA THA group, but the clinical relevance is questionable. In general, OA patients have fewer comorbidities than FNF patients and the follow-up time was mean 1.8 years longer for the FNF patients than for the matched OA THA patients, which may also have contributed to the difference, as function and health status decline with the passage of time especially in comorbid FNF patients.[21] Positively, the EQ-5D for the FNF patients in our study were comparable or slightly better than EQ-5D values 6 months after surgery in British patients receiving THA for OA, which is reported to be 0.76 in the age range 70–80 in 2010/2011.[24]

We found no difference to the age- and gender-matched large general population group in EQ-5D.[18]

## OHS

We expect both FNF and OA patients to have reached peak hip function 1 year after surgery, but possibly function may also decline again after 1 year due to aging and fragility.[20,22] In spite of the longer follow-up in FNF patients, we found no difference in OHS score between the FNF patients and the age- and gender-matched OA THA group, and the mean OHS score of 36.4 translates to a good result in the FNF patients.

A combined normal population OHS reference in the age range 70–79 from Australia and Canada was 42.5.[25] This score was based on a quite low total number of 70 persons from the two countries, which bears a risk of selection bias, and further cross-nation norm data might also be different.

## HHS

HHS of 78.7 in the FNF patients of this study translates to a fair result which is lower than other studies of FNF patients.[22,23,26,27] We found a lower HHS compared to the age (>75)-matched general population level by Lieberman et al, and to the reported HHS values of 93.1 for the age range 70–79 years in McLean et al.[19,25] Both studies were based on a low number of respondents, 44 and 70, respectively, and Lieberman et al used telephone administrated questionnaire and no clinical assessments. Furthermore, both studies might have cultural composition differences that may not be comparable to that of our study group.

## Time Up and Go test and Sit to Stand test

The TUG score of 13.5 secs (range 4.5–30.1) in the FNF patients is below the predictive cutoff fall values for community-dwelling older adults of 14 secs and that of 24 secs within the first 6 months after discharge after hip fracture operation.[28,29] TUG score <20 secs translates to good mobility in terms of "can go out alone, mobile without gait aid," and this was found in 90.5% of the FNF patients in our study.[16]

## STS

STS 10 times repeated time measure has not been reported for FNF or OA patients before. The more widely used STS test is either 5 times STS or 30 secs STS.[30] We found that a correlation between TUG and STS in the FNF patients was moderate to strong correlation (rho = 0.58), and we cautiously interpret this as a fairly good performance although we do not have directly comparative studies.

## NMS

Of the FNF patients, 84.5% (n = 70) had a NMS higher than 6 at follow-up which translates into a high score with good mobility and functional level.[29] Patients scored their recalled preoperative NMS higher than their postoperative score. This difference could potentially be recall bias, as the preoperative NMS evaluation was collected at a postoperative cross-sectional follow-up interview in the outpatient clinic at a mean follow-up of 2.8 years. The difference could also be attributed the general functional decline elderly experience over time.

## Limitations

Elderly sustaining a FNF is a heterogeneous patient group ranging from healthy independent subjects, to patients demanding a high level of functional assistance, to even institutionalized and bedridden subjects. As a result, there is a natural high loss to follow-up to consider in any hip fracture study, which also was the case in this study.

The current study has several limitations that should be considered. Patient selection is one of the primary limitations of this study, as 37% (n = 155) patients were dead at follow-up, and of the remaining patients only 47% (n = 124) were sufficiently fit and willing to participate in the clinical examination. Thus, we probably evaluated only the best of the FNF patients. Longer follow-up would most likely have resulted in greater loss of patients available for evaluation, as the mortality rates and comorbidities of FNF patients are high.

The cross-sectional study design did not option data collection of preoperative mobility and physical performance data (TUG and STS) and PROM data (EQ-5D, OHS and HHS), and the absence of repeated measurements to detect change before and after intervention might not generate a true outcome.[31] It is questionable that the PROMs developed for the evaluation of specific joints and HRQoL are suitable for evaluation after a proximal femoral fracture. The reason for this is that most of these scales were developed to evaluate patients after operation due to OA. Furthermore, older and fragile FNF patients may tend to view their limitation causality to aging, making it challenging to evaluate the FNF impact from the comorbidities patients may experience.[6] The existence of four suitable validated scores for hip-related outcome scales for the use in patients with proximal femoral fractures calls for a shift in the widely used scales when evaluating the complex patient group that proximal femoral fracture patients represent.[7] The need for implementing more robust and rigorous scoring systems is evident for clearer recommendations for future investigations.

## Conclusion

At short-term follow-up, patients with DM THA following displaced FNF had a good functional and satisfaction result.

Some 89% (n = 111) of the patients were satisfied with the surgical outcome. EQ-5D was similar to the age/gender-matched population index, but lower compared with OA THA patients. We found good functional and mobility outcomes on TUG test, STS and NMS for FNF patients. Hip-specific questionnaires revealed good results for FNF patients, and for OHS, the results were at the same level as the age, gender and surgery time-matched OA THA patients.

## Acknowledgments

## Author contributions

All authors contributed toward data analysis, drafting and critically revising the paper and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no conflicts of interest in this work.

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# Paper III

**ORTHOPAEDIC SURGERY**

CrossMark

# Low dislocation rate of Saturne®/Avantage® dual-mobility THA after displaced femoral neck fracture: a cohort study of 966 hips with a minimum 1.6-year follow-up

Steffan Tabori-Jensen[1,2] · Torben B. Hansen[1,2] · Maiken Stilling[1,2]

## Abstract

**Introduction** Dislocation is a serious and common complication and a great concern with the use of total hip arthroplasty (THA) when treating displaced femoral neck fracture (FNF). Dual-mobility (DM) THA might reduce the dislocation risk. We aim to report the dislocation and revision rate of primary DM THA in patients with displaced FNF.

**Materials and methods** Between 2005 and 2015, 966 consecutive patients (676 women) at mean age 80.5 years (range 42–104) with displaced FNF were operated with DM articulation THA by posterolateral approach (PLA). Patient files and radiographs were evaluated for dislocations, revisions, and other complications until death of the patient or August 1st, 2017. Data were crosschecked with the National Patient Registry. Patient's mental state was tested upon admissions. Surgeon's educational level was noted and post-operative cup position was measured.

**Results** At minimum 1.6-year follow-up, there were 45 (4.7%) dislocations and eight (0.8%) cup revisions. The 30-day mortality was 9.2% and 533 patients (55.2%) were dead at the time of last follow-up. We observed eight intraprosthetic dislocations (IPD); six occurred in relation to closed reduction. Cementless stem fixation was associated with higher dislocation risk ($p = 0.04$) and higher rate of stem complications ($p = 0.002$). There was no significant association between cognitive impairment and dislocation (OR 2.0, 95% CI 0.96–4.34, $p = 0.06$).

**Conclusion** Overall, DM THA inserted via PLA results in an acceptable dislocation risk and low revision rate in fragile, old patients with acute FNF fracture, regardless of mental status. A unique complication in DM THA is IPD, which requires an immediate open reduction surgery.

**Keywords** Femoral neck fracture · Total hip arthroplasty · Dislocation · Dual-mobility cup

## Introduction

Hip arthroplasty has proven superior in terms of lower complication and reoperation rates, and better functional outcome compared to internal fixation (IF) in the treatment of displaced femoral neck fractures (FNF) [1–3]. However, there is no clear consensus if the best treatment choice is total hip arthroplasty (THA) or hemiarthroplasty (HA), and

if the patient age and preoperative ambulatory status and mental status should be considered [4]. Some suggest that THA results in better functional outcome, lower mortality and reduced reoperation risk compared to HA [1, 5, 6]. Dislocation is a serious and common complication, and the greatest concern with use of THA in displaced FNF, and the biggest concern in using THA over HA is the greater dislocation risk associated with THA [7, 8]. Prosthetic joint stability is influenced by several factors including (1) patient-related factors: age, gender, preoperative function and cognitive status, (2) implant factors: design, head size, component fixation, and (3) surgical factors: technique, approach, implant positioning [9]. The theoretical benefit of the original dual-mobility (DM) implant was to increase stability and range to impingement as the large mobile femoral PE head is not constrained inside the cup as in conventional single-mobility (SM) THA [10, 11]. Patients with femoral

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neck fracture (FNF) treated with primary THA do have a higher dislocation rate than patients treated with THA due to osteoarthritis, which can likely by reasoned by higher age, fragility, comorbidity, cognitive impairment and poor ambulation/fall incidents I FNF patients [12, 13].

The aim of this cohort study is to report the rate of dislocation, reoperation and revision for DM THA used as the primary treatment for displaced medial FNF.

## Methods

### Patients

The study design was a retrospective follow-up study of an unselected historic cohort treated with primary DM THA after displaced medial FNF in terms of Garden III, Garden IV, or Garden I–II with > 20° posterior tilt [14, 15]. According to the Danish hip fracture reference program, primary HA or THA is the standard treatment in patients aged > 70 years and in younger patients where the fracture cannot be satisfactorily reduced for osteosynthesis [16]. Patients with impaired mental function or poor ambulation were also included and treated with primary DM THA. Patients with secondary DM THA after failed osteosynthesis were not included. In our department, we introduced the DM THA as primary treatment for all displaced medial FNF in 2005 reasoned by a wish to elude conversion from HA to THA due to acetabular erosion, an expected reduction in dislocation rate with DM THA, and evidence of lower mortality and reoperation rate in general in SM THA compared to HA [6, 17–20]. Daily on-call hip surgeons at our institution offer FNF patients treatment with DM THA at highest specialist standards within recommended time limits.

From 2005 to 2014, the Saturne® DM Acetabular System (Amplitude, Valence, France) was used in combination with a cemented Exeter stem or a cementless Corail stem [15]. Due to a regional tender in July 2014, our department was obliged to change cup system to the Avantage® DM acetabular system (Zimmer Biomet, Warsaw, Indiana, USA), while the stem systems stayed unchanged. Cemented or cementless fixation was used according to surgeon's preference, preoperative evaluation of radiographs and intraoperative judgement of bone quality. Gentamycin-loaded Palacos bone cement (Haereus Medical GmbH, Wehrheim, Germany) was utilized.

The cohort consisted of 966 consecutive hips (31 bilateral hips), including 676 women and 290 men, with a mean age of 80.5 (SD 9.5, range 42–104) years. All patients were admitted and treated in the Department of Orthopedics, Hospital Unit West, Holstebro, Denmark between January 2005 and December 2015.

Patients were operated by consultants highly experienced in hip surgery ($n=798$) and supervised residents ($n=168$). Reflecting every day's real-world acute surgery management, a number of surgeons were involved in operating of the large number of patients during the operation period from 2005 to 2015. All surgeons were either orthopedic consultants ($n=13$) or orthopedic residents ($n=12$) supervised by senior a surgeon. The surgical approach was posterolateral in all cases and the external rotators were resutured in all cases. All received prophylactic antibiotics as 1 g Diclocil® (dicloxacillin) administrated intravenous preoperatively as well as two times during the first 24 post-operative hours.

All patient files were crosschecked with post-operative radiographs to verify cup type, fixation type (cemented/cementless/hybrid prosthesis), and complications. Pulmonary embolism and deep vein thrombosis were considered to be in relation to THA surgery when occurring within 3 months after the operation.

We further crosschecked the data with The Danish National Patient Register for any missed postoperative complications outside our own department (dislocation, fracture, infection, cup or stem revision). The Danish Patient Register is considered to be largely complete since all activities in public hospitals are included. All diagnoses for every admission are recorded including non-operative procedures, e.g. closed reduction of dislocated THA [21]. This ensures that all complications registered at other hospitals are recorded and were available for evaluation in this study.

Since 2011, as a standard in our department, nurses have completed a Danish version of the abbreviated 0–9 mental status test for admitted FNF patients prior to surgery. A test score between 0 and 5 is considered low cognitive function [22]. Mental status test results were available for 65% of the patients ($n=634$).

All radiographs were taken using a standardized set-up at our radiology department. Postoperative radiographs include a radiograph of the pelvis, and an anteroposterior and lateral view of the hip. Radiographs of the pelvis and the affected hip were taken with the patient in supine position. All radiographs were taken with 15–20 degrees internal rotation of the legs. Lateral view was taken with 90 degrees flexion of the hip and knee of the non-affected side. All radiographs were evaluated by one observer (ST-J). Cup inclination was measured manually on digital postoperative standard anteroposterior (AP) pelvic radiographs, as the angle between the plane through the opening of the cup and the horizontal plane (ischial tuberosity line) [23]. Due to missing postoperative pelvic radiographs, we could only measure inclination in 38 of the 45 patients who suffered hip dislocation. The reason for missing post-operative radiographs was poor physical condition of the patients so that they were not able to get post-operative radiograph. The version of the cup was assessed dichotomously to be either anteverted or retroverted

based on relation to the ischial tuberosity/ischium on the postoperative lateral radiographs as described by Paterno et al. [24].

Precision of the cup inclination measurements was evaluated as double measurements on 10% of the patients ($n = 81$). The average intra-observer inclination difference was $-0.42$ degrees (SD 1.1) and concordance correlation coefficient was 0.99 implying excellent intra-observer reproducibility.

The protocol for the study was reviewed by The Central Danish Regional Committees on Biomechanical Research Ethics (inquiry 149/2012).

## Statistical methods

The primary endpoint was dislocation. The secondary endpoints were cup/stem revision and periprosthetic fractures with or without needed fracture fixation/component revision. Revision was defined as replacement of either cup or stem component, and all other complications requiring secondary surgery as reoperation.

Non-parametric (Mann–Whitney) statistics was used for continuous data, where data were not normally distributed according to a Shapiro–Wilk test, and parametric (Student's $t$-test) statistics where data were normal distributed. Chi-squared test and Fisher's exact test (used for expected cell count of 5 and less) for categorical data and odds ratios for two dichotomous variables were calculated using Woolf approximation. The Kaplan–Meier survival curve for time to first dislocation was made. Statistical significance was set at the 5% level.

## Results

Mean follow-up time was 5.4 (1.6–12.6) years. Of the total 966 patients, 415 (43%) cups and 741 (76.7%) stems were fixed with cemented technique. At the time of last-available follow-up 533 (55.2%) patients were dead. There were more women ($n = 676$) than men ($n = 289$) in the cohort

($p < 0.001$). 30-Day mortality was 9.2% and 1-year mortality was 22.1%.

Demographic data are presented in Table 1.

### Primary fracture augmentation

Eight patients had trochanteric fractures in combination with the FNF, and these were fixed intraoperatively with wire-cables or wires in combination with a trochanteric plate at the primary DM THA surgery.

### Dislocation

There were 45 patients with large-articulation dislocations (4.7%), with a mean time to dislocation of 21 days (median 18, range 1–63) and the number of dislocations was between one and four. Most dislocations $n = 33$ (73%) were treated with closed reduction, but 18 patients underwent operation with either open reduction with/without component replacement, cup revision, or Girdlestone procedure. Age at the time of THA insertion and gender did not jeopardize the risk of dislocation or revision ($p = 0.97$ and $p = 0.24$, respectively). Neither cup nor stem fixation was associated with higher dislocation risk ($p = 0.4$ and $p = 0.1$, respectively). Cup inclination was 3° higher in patients with hip dislocation, which was associated with risk of dislocation ($p = 0.04$). Cup retroversion was likewise associated with higher dislocation risk ($p < 0.001$). The educational level of the primary surgeon was unrelated to the dislocation risk ($p = 0.42$). The Saturn® and Advantage® DM cup systems had similar dislocation risk ($p = 0.84$). Of the 65% patients who underwent mental testing, 29% were categorized as cognitive impaired ($n = 185$). There was no significant association between cognitive impairment and dislocation (OR $= 2.0$, 95% CI 0.96–4.34, $p = 0.06$). Kaplan–Meier survival curves for time to first dislocation according to preoperative assessed mental status are presented in Fig. 1.

Eight patients (0.8%) experienced intraprosthetic dislocation (IPD). Six IPD occurred during an attempt of closed reduction, and two IPDs occurred in relation to a fall (9 days

**Table 1** Patient demographics by cup fixation

| Variables | Cemented DM, $n = 415$ | Cementless DM, $n = 551$ |
|---|---|---|
| Age at operation, years (SD; range) | 81.6 (8.9; 42–104) | 79.6 (10; 47.3–103.2) |
| Gender M, F | M 116, F 299 | M 174, F 377 |
| Follow-up years (SD; range) | 6.4 (2.4; 1.6–12.6) | 4.7 (2.3; 1.6–12.6) |
| Cup inclination (SD; range) | 43.8 (7.3; 24.4–68) | 42 (9.1; 15.3–69.4) |
| Cup version, (anteversion/retroversion) | 389/9 | 506/30 |
| DM implant | | |
| Saturne | 395 | 389 |
| Avantage | 20 | 162 |

*DM* dual mobility

**Fig. 1** Kaplan–Meier curves for time to first dislocation according to preoperative normal or impaired cognitive status. Follow-up is 100 days since all first time dislocations occurred within the first 63 days after index surgery
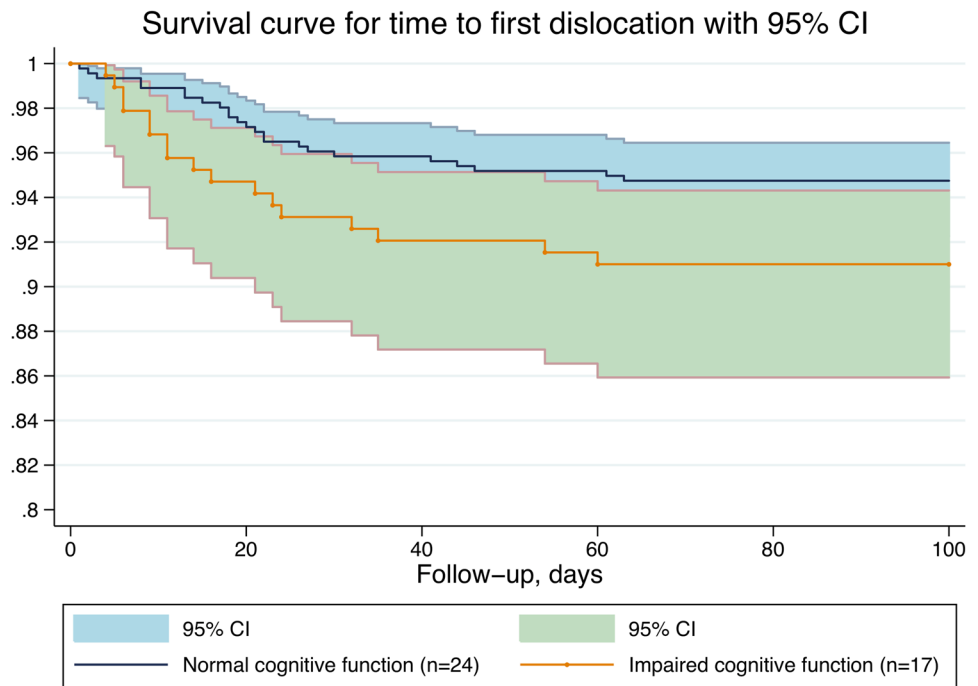


and 5 years after surgery). Mean days to IPD for seven of the eight IPD was 37.6 days (range 6–97). All IPD required open surgery with femoral head and liner replacement. IPD was not related to DM system type ($p = 0.66$).

Dislocation data are presented in Table 2.

## Cup revision

Eight (0.8%) of the 966 DM cups were revised (exchange of cup, femoral head and liner). Four revisions were due to aseptic loosening, three were due to repeated dislocations due to either retroverted cup ($n = 2$) or very steep inclination ($n = 1$), and one was due to septic loosening. Revision of the DM cup was not associated with the fixation type of cup

($p = 0.75$) or stem ($p = 0.91$). All aseptic or septic DM cup loosenings sum up to 0.9% ($n = 9$) in this cohort.

## Reoperation, cup and stem

In total there were 2.7% ($n = 26$) hip related reoperations. Two DM cups were revised to Girdlestone due to aseptic cup loosening. Three patients sustained a fall-related acetabular fracture around the inserted DM cup postoperatively and were treated conservatively; one of these also had an IPD. Within all DM cup revisions and reoperations (IPD, infections, Girdlestone, dislocations), cup fixation was not associated with higher risk ($p = 0.32$), but cementless stem fixation was ($p = 0.018$). We observed post-operative deep infection in 1% ($n = 10$), and these

**Table 2** DM cup dislocation by various possible risk factors

| Variables | Dislocation | No dislocation | $p$-value |
|---|---|---|---|
| Number of patients (range, dislocations) | 45 (1–4) | 918 | |
| Time to dislocation, mean days (SD, range) | 21 (16.3; 1–63) | | |
| Age, mean (SD, range) | 80.4 (10.8; 49–98) | 80.5 (9.5; 42–104) | 0.97 |
| Gender (M/F) | 10/35 | 280/641 | 0.24 |
| Cognitive status (impaired/normal) | 13/16 | 172/433 | 0.06 |
| Stem fixation (cemented/cementless) | 30/15 | 711/210 | 0.10 |
| Cup fixation (cemented/cementless) | 17/28 | 398/523 | 0.47 |
| Inclination, degrees (SD, range) | 45.6 (9.1; 31.7–67.2) | 42.6 (8.4; 15.3–69.4) | 0.04 |
| Version (anteversion/retroversion) | 35/10 | 860/29 | <0.001 |
| Surgeon (resident/consultant) | 10/35 | 158/763 | 0.37 |
| Cup revision | 3 | 5 | <0.001 |

patients were reoperated with either cup revision, cup reoperation or Girdlestone procedure. All THA-related complications are presented in Fig. 2.

In total there were 3.1% ($n = 30$) stem-related stem reoperations. All stem fracture complications after primary DM THA were related to new fall events, and 24 periprosthetic stem fractures were operated with plate and wire-cable fixation. Six patients with stem loosening, of which five were aseptic and one septic, were all revised with a new stem. Nine patients were treated conservatively for post-operative stem complications. These were six trochanteric fractures, two periprosthetic stem fractures, and one stem subsidence. Cementless stem fixation was associated with a higher risk of conservative- and operative-treated stem complications ($p = 0.002$).

## Other complications

We observed six pulmonary embolisms within the first 3 months after surgery. All occurred in patients with cemented cup and cemented stem fixation. Cemented cup fixation was associated with higher risk of pulmonary embolism ($p = 0.03$), whereas cemented stem fixation was not ($p = 0.18$). We observed one deep vein thrombosis, which was not associated with cup or stem fixation (respectively, $p = 0.4$, $p = 0.6$).

## Discussion

To our knowledge, this is the largest consecutive single cohort study to report dislocations and complications of DM in the treatment of FNF. We observed dislocations in 4.7% of DM cups (large articulation) at mean 5.4-year follow-up. Cognitive impairment showed a two times higher insignificant tendency toward higher dislocation risk compared to patients with no cognitive impairment.

A case–control series of 172 hips found significantly lower dislocation rate in DM THA (4.6%) compared to bipolar HA (14.6%) at mean follow-up of 25.3 months [25]. A study of 83 FNFs in patients older than 75 years treated with a DM cup (Avantage, Zimmer Biomet) reported dislocation rate of 4.4% at mean follow-up of 24 months. Of the 83 patients 50 (60%) suffered from at least one severe medical conditions such as Alzheimer's disease, dementia or chronic heart failure [26]. Tarasevicius compared two consecutive groups of FNF patients operated via posterior approach, 42 DM THA and 56 SM THA at mean age 75 and 74 years, respectively, and reported no dislocations at 1 year postoperatively in the DM THA group but eight dislocations in the SM THA group [27]. We show similar dislocation rate with DM THA, but at longer follow-up, and in an unselected cohort of FNF patients—that is mental status was not an exclusion criteria and HA was not used at all in our institution. Furthermore, the mean age at time of surgery is at least 5 years older in our study compared to Bensen
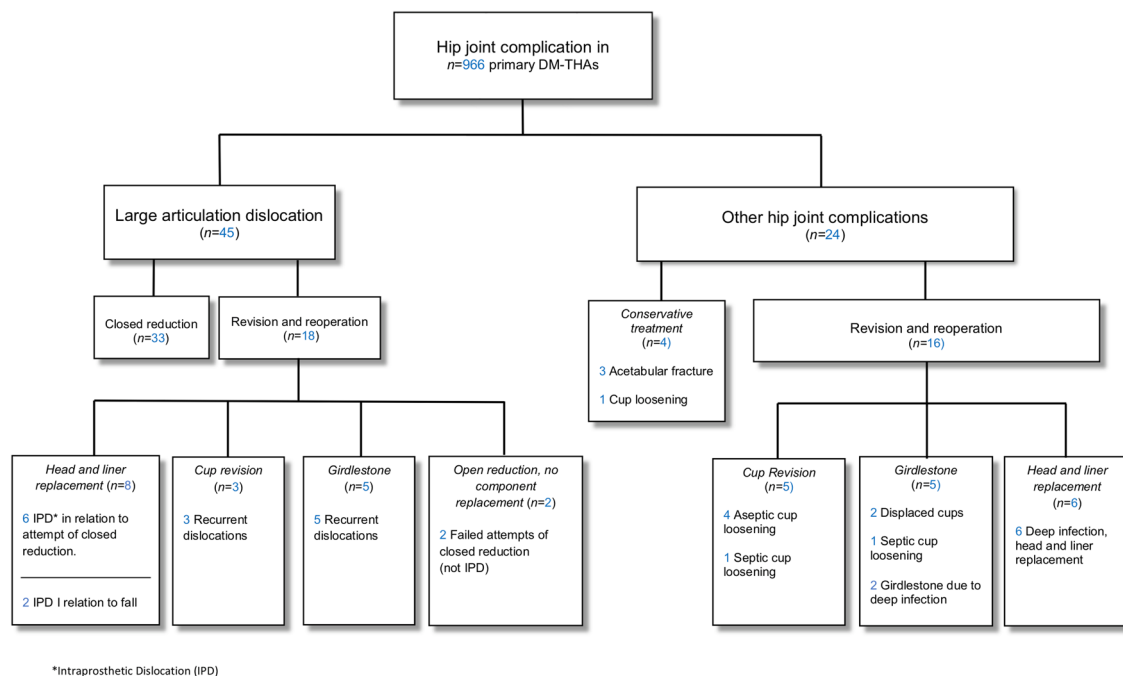


**Fig. 2** All DM THA-related complications

et al. and Tarasevicius et al. [25, 27]. Anterior or direct lateral approach has lower reported dislocation rate in THA compared to the posterolateral approach [28, 29]. We only used the posterolateral approach, which is used in 96% of primary THA in Denmark, while others report a dislocation rate for a mix of surgical approaches with THA [30, 31]. Direct comparisons may, therefore, be troublesome. Furthermore, approximately 20% of the DM THAs in our series were inserted by supervised residents, but we found no association between surgeon's experience level and risk of dislocation.

The dislocation rates in FNF patients treated with conventional SM THA vary between 2–18% [8, 32–34], which on average is higher than in all reports of dislocations in DM THA. The reason is most likely that the DM THA design is forgiving on cup positioning and patient factors predisposing to dislocation. This is supported by the fact that we only found a modest average 3° higher inclination in the dislocation group, which is hardly of clinical significance. Although the mean of both our dislocation group (45°) and non-dislocation group (42°) was within the safe zones of cup position defined by Lewinnek et al., both groups had extreme cup inclination outliers between 32°–67° and 15°–69°, respectively.

However, the small inclination difference supports common findings that higher cup inclination increases dislocation risk [35]. We also found that retroversion of the cup was associated with higher dislocation risk, which is in line with a study that showed anteversion of less than 10° or even retroversion of the cup to result in higher risk of posterior dislocation [36]. However, the literature on cup placement is not definite, and the commonly referenced Lewinnek safe zones have been disproven in a recent (2017) systematic review on non-fracture SM THA [37]. Most likely, the dislocation safe zone for cup positioning in DM THA is more liberal than outlined by Lewinnek et al [38].

IPD is a consequence of failure of the retentive rim-locking abilities where the femoral head is linked in the small articulation in the liner. IPD may occur with excessive retentive rim (small articulation) and PE wear or in attempts of closed reduction of dislocation in the large DM articulation. IPD is a unique complication for the DM cup design and rates are reported to be between 0 and 5% of total DM procedures [39, 40]. In our cohort, we observed six IPD, 13.5% of the total number of dislocations, which mainly occurred in relation to closed reduction due to the "bottle-opener" effect described by De Martino et al. [40]. This early complication occurs iatrogenic when the outer PE liner engages the rim of the metal cup or pelvic bone prominence subsequently causing dissociation of the femoral head from the small articulation during a closed reduction maneuver. Focus and attention should be given when attempting to reduce a DM cup large-articulation dislocation, and appropriate sedation and muscle relaxation or even neuroaxial anaesthesia had been advised when reducing large-articulation DM dislocations [40].

The first DM cup generation was associated with aseptic loosening and the original design by Bousquet had to be redesigned because of unacceptable revision rates due to acetabular component loosening [12, 39]. The newer DM cup designs have shown more reliability and are comparable to the survival of other well-documented THA systems [41, 42]. Although we did not assess cup migration, radiolucencies and osteolysis systematically in this study, we observed only eight symptomatic cup loosenings (0.8%) that led to revision.

Studies have shown that cemented stem fixation is preferable in FNF patients compared to cementless fixation because of the lower incidence of complications such as periprosthetic fractures and superiority in terms of pain relief [43–45]. We view our findings of a strong association of stem complications in cementless stem fixation as supportive for the use of cemented stem fixation technique. A disadvantage of the cemented technique is the risk of cardiovascular complications during pressurized stem cementation [46]. Even though no fatal incidences occurred, all six perioperative embolic events in this study were exclusively associated with cemented stems.

In Denmark, the National Guideline for Hip Fracture Treatment aims at a mortality rate below 10% at 30 days after hip fracture in general (all types of fractures including FNF, intertrochanteric fractures, and subtrochanteric fractures) [47]. The mortality rate in the current study of only displaced FNF treated with DM THA was 9.2% at 30-day and 22.1% at 1-year follow-up. We find these rates comparable to international studies on mortality of all types of hip fractures where the 30-day mortality rates range between 7.3 and 13.3% [47].

One limitation of our study is the lack of a control group, i.e. a control group treated with HA. Several studies have reported good survival, lower mortality, lower reoperation rates and superior functional outcome when treating FNF patients with THA compared to HA [1, 6, 8]. The great concern is higher dislocation rates of THA compared to HA [7, 8]. In this study, we report low DM cup dislocation and revision rates, even lower compared to conventional SM THA when treating FNF patients and the authors believe that the DM cup design is warranted as a standard in the treatment of displaced FNFs.

In a short-term follow-up study, we reported function, health status and satisfaction in a subgroup investigation of 124 patients treated with DM THA for FNF between 2005 and 2011. Oxford Hip Score in the FNF patients was comparable to age- and gender-matched osteoarthritis patients operated at our institution with SM THA. Further, we found no difference in EQ-5D when FNF patients were age and gender matched to a large general population group.

Although we only had patient-reported outcome measures (PROM) and clinical follow-up of patients at sufficient health for an outpatient clinic follow-up, our findings suggest good functional results and quality of life in addition to high satisfaction in patients treated with DM THA [48].

The generalizability of the results from this consecutive unselected large cohort DM cup study in the general context of FNF management is probably very high, but multiple factors unrelated to the cup design, surgical approach and position also pose a risk for THA dislocation including patient factors such as cognitive and ambulatory abilities. We saw a two times of higher dislocation risk, although not statistically significant, in patients with cognitive impairment at the time of surgery—but the majority of patients with cognitive impairment had no hip dislocations. We observed several IPDs in relation to closed reduction of DM THA dislocations, which is a specific and severe complication related to the DM cup design that may lead to immediate open surgery intervention.

Although we believe that the DM THA concept is warranted in the treatment of FNF, future treatment plans might need to include more than one all-inclusive arthroplasty treatment arm. One possible solution could be a combination of THA and HA where patients that are either bedridden have low walking abilities or severe impaired cognitive function and are treated with a cemented HA, and all other patients with displaced FNF are treated with THA [4]. However, this may challenge the local organization as well as trauma surgeons who may have no experience with the technically more demanding THA procedure. Future high-quality prospective studies investigating several treatment arms are needed to evaluate arthroplasty treatment in the heterogenous FNF patient population.

## Compliance with ethical standards

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# Paper IV

**Similar Proximal Migration but Inferior Stabilization of Cementless Compared with Cemented Dual Mobility Cups in Elderly Coxarthrosis Patients. A Blinded Randomized Radiostereometric and Dual-Energy X-Ray Absorptiometry Study with 24 months follow-up.**

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## Abstract

### Background

Dual-mobility (DM) articulation is a well-proven concept in total hip arthroplasty, but it is currently unknown if cemented or cementless cup fixation is preferential in elderly patients with coxarthrosis (CA).

### Methods

In a prospective patient-blinded randomized clinical trial 60 patients (33 female) with CA were allocated to cemented (*n*=30) or cementless (*n*=30) Avantage® DM cup fixation. Criteria were age 70 years and older, and T-score above -4. We investigated DM cup migration, systemic and periprosthetic bone mineral density (BMD), and PROMs (HHS, OHS, EQ-5D, VAS hip pain) until 24 months follow-up.

### Results

At 24 months proximal cup migration was 0.11mm (CI95% 0.00-0.23) for cemented cups and 0.09mm (CI95% -0.09-0.28) for cementless cups (*p*=0.79). But generally, cementless cups migrated more than cemented cups at 12 and 24 months. Cemented cups had no measurable migration from 3 months follow-up, while cementless cups had not yet stabilized at 24 months in all rotations. Cementless cups showed significantly more maximum total point motion (MTPM) at 12- and 24-months follow-up compared to cemented cups in low BMD group (*p*=0.01). Periprosthetic BMD changes did not correlate to proximal migration in either cup fixation group (*p*>0.06). PROMs improved similarly in both groups.

### Conclusion

We found similar 24-months proximal cup migration in cemented and cementless fixation. However, cementless cups migrated more on absolute measures and had not stabilized at 24 months, whereas cemented cups were stable from 3 months. Cemented fixation of the Avantage® DM cup seems safer in elderly patients with preoperative sub-normal systemic BMD.

## Introduction

Almost one million total hip arthroplasties (THAs) are performed annually worldwide, and a projected doubling during the next two decades is expected [1]. In Denmark in 2015, approximately 50% of primary THAs with coxarthrosis (CA) as the indication were performed on elderly patients above 70 years. The implant fixation method (i.e., cemented or cementless) seems mainly based on the surgeon's preference and national trends. In Denmark, only 20% of acetabular cups in CA patients above 70 years are inserted with cemented technique [2]. The same change towards cementless cup fixation has been described in the United Kingdom (UK) and Australia, while in Sweden and Norway, cemented cup fixation is still the preferred fixation method in elderly patients [3-6].

According to registry reports, the most common indication for revision of a conventional primary THA is aseptic loosening of the components [2, 3, 5], and other common reasons for THA revision are dislocation, fracture, and infection. [2, 3, 6].

The DM concept, with two articulation surfaces and increased jumping distance, thereby decreasing the dislocation rate, and has a better theoretical range of motion (ROM) than standard single mobility (SM) THAs [7]. In the elderly, which naturally have a progressive deterioration of cognition and physical health, a DM THA may prevent dislocation events [8, 9]. The long-term survival and the best fixation method of the newer Avantage® Reload DM cup in elderly patients is currently unknown but retrospective studies on other types of primary DM THAs (different etiology) have reported acceptable survival rate of 95.4% and 95.9% at mean 12- and 15.3-years follow-up, respectively [10, 11].

Radiostereometric analysis (RSA) quantifies micromotion between an implant and the host bone with high accuracy and precision. Excessive early (2 year) implant micromotion is a strong predictor for later implant loosening and poor survival [12-15]. RSA has been suggested as an important primary step in phased clinical introduction of new implants to the common market. For knee arthroplasty, phased introduction of implants by use of RSA has shown 22–35% reduced revision rate in national registries as compared to knee arthroplasties introduced without prior RSA testing [16].

The primary aim of this study was to investigate the early fixation of cemented and cementless Avantage® DM Reload cup in elderly (> 70 years old) CA patients without severe osteoporosis (T-score >-4) until 24-months follow-up. Secondary endpoints included

periprosthetic Bone Mineral Density (BMD) measurements, clinical outcome scores and complications. We hypothesized that cemented fixation would result in lower migration compared to cementless fixed of the Avantage® Reload DM cup system.

## Methods

*Design and Patients*

Between November 2014 and January 2018, a prospective, randomized, patient-blinded, parallel group trial was performed at Hospital Unit West, Holstebro, Denmark. Inclusion criteria were primary coxarthrosis, patients at 70 years of age and older, and informed written consent. Exclusion criteria were vascular or neuromuscular disease in the operated leg, fracture sequelae, avascular necrosis of the femoral head, alcohol abuse, daily intake of nonsteroidal anti-inflammatory drugs, and severe osteoporosis (T-score $\leq$ -4.0). Sixty patients (27 males) were included and block randomized (using a computerized algorithm) to surgery with either cemented (n=30) or cementless (n=30) fixation of Avantage® Reload DM acetabular cup system (Zimmer Biomet Inc., Warsaw, IN). All patients were included between November 2014 and December 2015, and follow-up was 24-months.

*Prosthesis, Surgery, and Rehabilitation*

The Avantage® Reload cemented and cementless DM cup (Zimmer Biomet Inc., Warsaw, IN) has been commercially available since 2005. Both the cemented and cementless DM Avantage® Reload stainless steel acetabular component has a cranial-lateral rim, which increases head-coverage. The external surface of the cemented Avantage® Reload metal shell has a bright polish (Ra max 0.4$\mu$m), and the inner articulate surface is highly polished. Vacuum-mixed Palacos® R+G bone cement (Heraeus Medical, Wehrheim, Germany) was used for cemented fixation. The cementless Avantage® Reload metal shell has a double coating with a projection vacuum plasma (VPS) titanium coating (Ra>15$\mu$m) and synthetic hydroxyapatite (HA) (150 $\pm$ 50$\mu$m) to create a rough surface finish (Ra>11$\mu$m). Exeter® highly-polished stems (Stryker Corporation, Kalamazoo, MI) with vacuum mixed Palacos® R+G bone cement (Heraeus Medical, Wehrheim, Germany) were used in all patients. A 28-mm chrome-cobalt femoral head was used in all cases. Vitamin E-infused highly cross-

linked polyethylene (HXLPE) liner (GUR 1050) was used in both cemented and cementless cups. All liners were vacuum-packed and Gamma sterilized with a minimum of 25kGy.

All patients were operated by one of two highly experienced orthopedic hip surgeons. Sealed envelopes were hidden from investigators until directly prior to surgery to prevent bias. On the day of surgery, a sealed randomization envelope was opened to allocate the patient to either cemented or cementless cup fixation. Prophylactic cefuroxime 1.5 g was administrated intravenously before surgery in all patients. After bone preparation, 6–8 tantalum beads (1 mm) were inserted into the periacetabular bone during surgery for subsequent RSA measurements. Tranexamic acid 1 g was given at the end of surgery to prevent bleeding. All patients were operated by a posterolateral approach and received the same rehabilitation program, allowing full weight bearing immediately after surgery.

*Radiostereometric Analysis*

Stereo-radiographs were obtained within the first postoperative two days (mean 1.1, range 1-14) and at 3, 12, and 24 months after surgery. All examinations were performed with the patient in a supine position with a uniplanar calibration box (Carbon Box 19, RSAcore, Leiden, The Netherlands) located underneath the examination table. The anatomical axis of the leg was parallel to the y-axis of the calibration box. Cup migration was evaluated on all three follow-up stereo-radiographs with the postoperative stereo-radiograph as the baseline reference.

The radiostereometric analysis was performed with Model-Based RSA version 4.10 software (RSAcore, Leiden, The Netherlands) using computer-aided design (CAD) implant models provided by the manufacturer (Zimmer Biomet Inc., Warsaw, IN). The translations and rotations along the x, y and z axes are presented in figure 2. Total translation (TT) and total rotation (TR) were both calculated using Pythagoras theorem (sqrt ($x^2 + y^2 + z^2$). The condition number (CN) was used to assess the distribution of the acetabular bone markers. The mean CN of the markers in acetabulum was $82.6 \pm 47.1$. The stability of individual markers was evaluated through the mean error of rigid body fitting (ME), which was $0.24 \pm 0.06$ in the acetabulum. A minimum of 3 bone markers was accepted and the cut-off points for CN and ME were maintained at 150 and 0.35, respectively [17]. All patients were subject to double examinations at the 3-month RSA examination, which were performed according to the guidelines [17, 18]. The standard deviation of the difference between the two examinations (SD dif.) reflects the precision of the RSA results. The coefficient of

repeatability (CR) (±1.96 × SD dif.) reflects the lower limit within which it is possible to detect prosthetic migration on the individual basis of the system [18] (Table 2).

The position of the fitted implant CAD model on the postoperative stereo-radiograph pose estimation served as inclination and anteversion estimates and were read from the Model-Based RSA software (RSAcore, Leiden, The Netherlands).

*Dual-Energy X-Ray Absorptiometry (DXA) Scans*

Preoperatively all patients underwent spine and dual hips DXA scan to determine preoperative systemic T-score. Postoperatively (within 4 days after surgery) and at 3, 12, and 24 months after surgery, quantitative measurements of the periprosthetic BMD (g/cm$^2$) was acquired with DXA scans using a GE Lunar iDXA scanner (General Electric, Chicago, IL), and analyses were performed using enCORE version 16 software. Patients were placed in a standard supine position with the body parallel to the examination table and the feet fixed to a device that kept the halluces pointing straight up. The postoperative DXA scan served as a baseline for the subsequent scans [19]. The BMD of the periacetabular region was measured in the four regions of interest (ROI) as described by Wilkinson [20] by use of a customized four region template. The template was applied to the baseline scan, and the ROIs were subsequently copied to align with the bone-border on follow-up scans. ROIs 2 and 3 were adjusted in height on the baseline scan depending on the cup size (each ROI was one half cup height) and ROIs 1 and 4 had fixed sizes (Fig. 3).

The double examination at 3-months follow-up was used to determine the reproducibility (intra-observer) variation performed by the same person on identical equipment and was calculated as coefficient of variation (CV%) as described by Bonnick: SD/X (100), where SD is the standard deviation of the paired measurements and X is the mean value of the first and second measurement (Table 3)[21].

*Clinical Outcome Measures and Complications*

Clinical outcome measures were assessed by Harris Hip Score (HHS) [22], Oxford Hip Score (OHS) [23], patient-reported quality of life (EQ-5D) [24], and visual analog scale (VAS) [25] for hip pain preoperatively and at 3, 12 and 24 months after surgery. The scores were subsequently evaluated for differences between the cemented and cementless groups

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during follow-ups. Postoperative complications were documented until 24-months post-surgery.

*Ethics*

The study was conducted in accordance with the Helsinki Declaration. All patients gave informed consent before entering the study. The study was approved by The Central Danish Regional Committees on Biomechanical Research Ethics (Journal no. 1-10-72-209-14; issue date June 24, 2014) and the Danish Data Protection Agency (Protocol no. 1-16-02-16-15; issue date February 12, 2015). The project was registered with www.clinicaltrials.gov (Study ID number; 02404727).

*Statistics and Sample Size*

The cup migration analysis was conducted using a linear mixed model to account for repeated measurements and missing values [26]. Model estimates are reported as means with 95% confidence intervals (CIs). The Student's t-test was used for normally distributed data. When data were not normally distributed according to the Shapiro-Wilks test, the Non-parametric (Mann-Whitney) test was used. The primary endpoint was proximal cup migration at the 24-months follow-up[27]. The secondary endpoints were measurements of periprosthetic BMD, clinical outcomes of HHS, OHS, and EQ-5D, and VAS (rest and activity) for pain.

Patient subgroups with normal BMD (T-score $\geq$ -1) and low BMD (T-score $<$ -1 $\geq$ -4) were generated on the bases of preoperative systemic BMD measurements (spine/dual hip). Subgroup analyses (mixed model) were performed for proximal migration (y-axis) comparing cup fixation (cemented/cementless) within each BMD subgroup. Pearson pairwise correlation analysis was used to examine correlation between percentage change BMD and proximal migration at all follow-ups.

In a systematic review of RSA studies, a 24-months risk-threshold of 0.2-1.0 mm proximal cup migration was found to indicate a revision rate above 5% at 10-years postoperative (designated "at risk") and proximal migration above 1.0mm predicted that 10-year revision rate would exceed 5% (designated "unacceptable") [27].

The proximal cup migration was used as the primary effect variable in the pre-study power analysis based on a pilot study including both cemented and cementless Avantage DM cups.

Sample size calculation using two-sample mean test for a minimal relevant difference of 0.2mm[27] with a mean cup migration of 0.1mm and a standard deviation of 0.2 (pilot study), power of 0.90, and 5% risk of type-1 error, 23 patients were needed in each group. To compensate for potential dropouts, we decided to include 30 hips in each treatment arm. Statistical significance was set at the 5% level. Stata version 13.1 (StataCorp, College Station, TX, USA) was used for statistical analysis.

## Results

The baseline demographics of all patients are presented in Table 1. A CONSORT flowchart is presented in Figure 1.

*Radiostereometric Analysis*

Translations and rotations, including TT, TR, and MTPM (mean and 95% CI), are presented in Table 4, and significant migrations are presented in Figure 4. Cemented cups showed no statistically significant translation ($p>0.27$) or rotation ($p>0.15$) during the 24-months follow-up time. Cementless cups had no statistically significant translations ($p>0.20$) during 24-months follow-up, but showed continuous rotation about all orthogonal axes and in TR and MTPM during the 24-months follow-up (Table 5).

By 24 months, 75% ($n=21$) of the cemented cups showed proximal cup migration < 0.2 mm, 25% ($n=7$) were between 0.2–1.0mm, and no cemented cups had proximal cup migration (y-axis) > 1.0mm. By 24 months, 64% ($n=18$) of the cementless cups showed proximal cup migration < 0.2 mm, 32% ($n=9$) were between 0.2–1.0mm, and one cementless cup showed > 1.0 mm proximal cup migration. When migration data for the two cup fixation groups was pooled, we found no association ($p > 0.12$) between patient-related outcomes (i.e., HHS, OHS, EQ-5D, and VAS at rest and activity) and dichotomized 24-months proximal cup migration to either 'acceptable' (under 0.2mm) or 'at risk' (0.2–1.0mm) according to Pijls et al.'s classification [27].

The postoperative inclination angle was higher in cemented cups compared to cementless cups ($p=0.01$) (Table 1). The postoperative anteversion angle did not differ between the two fixation methods ($p=0.87$) (Table 1). We found a moderate positive correlation between cup inclination and proximal cup migration in cementless cups (r = 0.38, p=0.04), and a moderate

negative correlation between cup inclination and proximal cup migration in cemented cup fixation ($r$ = -0.48, $p$=0.01).

At the 24-month follow-up, 10 patients in the cemented group and 17 in the cementless group had measurable TR above the detection limit of 1.76° (Table 2). Additionally, 4 patients in the cemented group and 8 in the cementless group had measurable y-axis rotation above the detection limit of 1.80 ° at the 24-month follow-up (Table 2).

When stratifying patients into two subgroups based on preoperative systemic BMD (normal and low BMD), we found no within subgroup difference in proximal cup migration between cemented and cementless cup fixation ($p$ > 0.34; Fig 5). The mean 24-months proximal cup migration in the normal BMD group was 0.05mm (CI: -0.08 - 0.18) for cemented cups and 0.07 mm (CI: -0.17 - 0.32) for cementless cups (Fig 5). The mean 24-months proximal cup migration in the low BMD group was 0.18mm (CI: 0.05 - 0.31) for cemented cups and 0.11mm (CI: -0.07 - 0.29) for cementless cups (Fig 5).

Further sub-analyses revealed significantly higher MTPM at 12- and 24-months follow-up in cementless cups compared to cemented cups in the low BMD group ($p$=0.01; Fig 6), which could be explained by a higher cup migration in x-translation ($p$=0.04 at 24-months), y-rotation ($p$<0.001, $p$=0.03, at 12 and 24-months respectively), and z-rotation ($p$=0.04 at 24-months). Likewise, TT and TR was higher for cementless cups compared to cemented cups in low BMD group at 12 and 24 months, all $p$<0.03.

When the BMD subgroups (normal and low BMD) were divided based on cemented or cementless cup fixation, we found no difference in proximal cup migration ($p$>0.18) at any follow-up and no continuous proximal cup migration ($p$>0.19, Fig 7) at any follow-up between normal and low preoperative BMD patients.


*Net and Percentage Change in Periprosthetic BMD*

In the cemented group, the mean measured BMD in each of the 4 regions ranged from 0.82 to 1.89 g/cm$^2$, and from 0.69 to 1.85 g/cm$^2$ in the cementless group. The net measured BMD was 19% greater around the cemented cups compared to the cementless cups and was greater in the zones central-medial to the cup (ROIs 2 and 3) than in the cup zones proximal and distal to the cup (ROIs 1 and 4) ($p \leq 0.05$).

In ROI 1 at 24-months, the BMD increased by +3% in the cemented group, whereas a small -2% decrease was noted in the cementless group ($p<0.001$). In ROI 2 the cemented group showed less BMD loss at 12 months ($p=0.01$) compared to cementless cups, but at 24-months the BMD loss was similar ($p=0.40$). Cementless cups showed significant BMD loss from 3 to 12 months in ROI 2 ($p=0.02$). The increase (+4%) in BMD in ROI 3 in the cementless cups was significant ($p=0.01$) at 3 months compared to the decrease (-5%) in cemented cups, but not at 12- and 24-months follow-up ($p>0.11$). In ROI4, the BMD loss at 24 months in the cemented cups (-9%) was greater as compared to the cementless cups (-1%) ($p=0.001$). Cemented cups showed significant BMD loss from postoperative to 3 months follow-up in ROI 4 ($p=0.03$). Percentage BMD changes are presented in Fig 8. There was no correlation between the percentage BMD change and proximal cup migration in cemented or cementless cups during follow-up ($p>0.06$).

*Clinical Outcome Measures and Complications*

There was no difference in clinical outcome scores between cup fixation method on HHS, OHS, EQ-5D, and VAS at preoperative, 3-, 12-, and 24-month follow-ups ($p > 0.31$; Table 6). We found no statistical difference in HHS, OHS, EQ-5D and VAS improvements between cup fixation from preoperative to 24 months follow-up ($p>0.07$).

One patient (male, 72 years) with cementless cup fixation underwent revision surgery three months after the primary surgery. Due to extensive osteophyte formation anterior to the cup, an intraprosthetic dislocation (IPD) occurred, which led to liner and femoral head change. Two weeks after cup revision surgery, the patient had clinical signs of deep infection, and was successfully one-stage revised with debridement, washout, femoral head and liner exchange, and antimicrobial treatment for six weeks. Cultures showed a deep *Staphylococcus aureus* infection, but after soft tissue revision surgery, the patient had a well-functioning hip and continued the regular RSA follow-up.

## Discussion

To our knowledge, this is the first RSA study of the DM concept in elderly CA patients comparing cemented and cementless cup fixation. We hypothesized that the cemented in comparison with cementless DM Avantage® Reload cups would have lower migration up to 24-months follow up, and this was confirmed in the clinical randomized trial.

*Radiosteremetric Analysis*

Several papers have described the relationship between early high proximal cup migration and the elevated risk of aseptic cup loosening and later revision [13, 27-29]. In relation to Pijls' thresholds for proximal cup migration, we identified seven cemented cups (range 0.23-0.71mm) and nine cementless cups (range 0.2-0.75mm) 'at risk' of later revision in the present study, but we observed no cemented cups and only one cementless cup (1.16mm) with 'unacceptable' proximal migration [27]. In relation to Nieuwenhuijse's definition we observed no cups exceeding 1.76mm proximal migration and only one cementless cup (6.39°) with abduction (z-axis) above 2.53° [13]. Patients with cup migrations above the recommended risk-levels were asymptomatic, and when all patients were combined in one group, we found no difference in 24-months reported PROM outcomes (HHS, OHS, Eq-5D, and VAS at rest and activity) between those with <0.2mm and those with 0.2-1.0mm proximal cup migration. These findings support that early but excessive cup migration is asymptomatic, and therefore RSA measured cup migration is an important early proxy-measure for later cup loosening.

Cementless cups are inserted by under-reamed technique, and the initial rim-fit may be lost over time resulting in a final bottoming in the acetabulum [30]. However, we only saw one cementless cup with large proximal migration, and in general no measurable translation over time in the cementless group. Cementless cups did however have more rotation overall, over time, and in opposite directions before and after 12 months, as compared with cemented cups.

We found that cemented cups were inserted with significantly higher inclination angle compared to cementless cups. The higher inclination in cemented cups may be explained by the fact that our surgeons inserting the cemented Avantage® DM cups by free-hand, because they experienced that disconnection of the guide affected the cement before it was cured. However, our findings suggest that bone fixation of cemented cups is less sensitive to increased cup angulation compared to cementless cups. This is also in line with a study on all-poly cemented and cementless cups [31].

RSA evaluations of elderly with CA treated with a primary THA are scarce. Direct comparisons with previous RSA reports are difficult due to alternative ways of presenting data, methods of fixation, marked differences in patient demographics, implant design, surgical approach, and follow-up time. Based on 24 months proximal migration as an

indicator for primary stability our findings for cemented and cementless fixation methods are comparable, and in many cases lower than reported in other studies on cemented and cementless cup fixation in primary THA [32-40].

*Radiosteometric Analysis and Preoperative BMD Status*

In the study by Finnilä et al., 34 women received cementless ceramic-on-ceramic THA and they reported significantly higher proximal migration in low BMD (lower T-score limit of -3.5) patients compared to normal BMD patients at 24 months follow-up. Furthermore, they found continuous proximal migration in the low BMD group between 3 and 12 months, but not from 12 to 24 months [36]. These findings are inconsistent with our findings where we observed no difference in proximal migration in normal BMD and low BMD group and no continuous migration during follow-ups when stratified according to cup fixation. Our mean 24-months proximal migration in the cementless group with low BMD of 0.11mm (CI: -0.07 - 0.29) was lower than reported in the study by Finnilä et al. of 0.29 mm (CI:0.20 - 0.39), suggesting early initial proximal cup stability even in the low BMD group both in cemented and cementless cup fixation. However, cementless cups showed significantly more migration in MTPM, x-axis translation, y-axis rotation, TT and TR compared to cemented cups in low BMD group, suggesting that cementless cup fixation is not preferable in patients with preoperative low BMD. There are no studies reporting proximal cup migration in cemented cups when stratified to normal and low BMD. One study reported greater three-dimensional migration in cemented cups with osteoporosis compared to non-osteoporosis, but their definition of osteoporosis according to diagnosis of either rheumatoid arthritis, failed femoral neck fracture or cortisone treatment, make direct comparison troublesome[40].

*Periprosthetic BMD Measurements*

Like previous studies, we observed greater mean BMD in each of all 4 ROIs and totally in all ROIs in the cemented group compared to the cementless group during all follow-ups[41-43]. The cementing procedure introduce a cement penetration zone below the subchondral bone plate where it is difficult for the human eye as well as for DXA software to distinguish between bone and cement. Consequently, some cement is measured as bone in the periprosthetic region of cemented cups, and this will falsely increase the measured BMD and result in a higher variation of BMD measurements with a lower precision[41]. We believe

that this also explains the differences in periprosthetic BMD between cemented and cementless cups found in the present study.

Differences in BMD change in cemented and cementless fixation may be a result of different load transfer mechanisms leading to different bone remodeling profile [43]. In cementless cups, forces are transmitted sideways to the periphery, rather than proximal, which leads to reduced load transfer in the most cranial/proximal area [35, 42-44] with local bone resorption caused by stress-shielding. This might explain the greater bone loss observed in ROI 1 and 2 of cementless cups compared to cemented cups in our study. Conversely, the increased BMD in ROI 3 and lesser BMD reduction in ROI 4 in cementless cups compared to cemented could be due to the increased traction forces in cementless cups acting as a stimulus for preservation of bone or even increase in BMD [32].

When all patient data was pooled, initial pairwise correlation testing showed correlation between BMD change in ROI 4 at 24-months follow-up and proximal cup migration, but with sub-analysis based on fixation method this correlation was no longer significant possibly due to type 2 error. These findings suggest that cup stability until 24-months follow-up is not compromised even with substantial bone loss around the cup.


*Clinical Outcome Measures and Complications*

There was no statistically significant difference in postoperative evaluations (quality of life measured by EQ-5D, or hip status measured by HHS and OHS) between cemented and cementless cup groups. The 2-year clinical evaluations of cemented and cementless fixation translates to either very good or excellent end-results [45]. Early cup loosing often produces very few symptoms, and the observed differences in migration between cemented and cementless cup fixation are small. Both makes measurable differences in clinical outcome unlikely.

IPD is solely related to the DM concept, and is a consequence of dissociation of the femoral head from the retentive liner (small articulation). IPD usually occurs after years of extensive wear of the retentive liner or in relation to closed reduction of large articulation dislocation [11, 46]. The IPD was an isolated case attributed to extensive osteophyte formation which was not recognized during primary surgery.

*Cup Fixation Method in the Elderly*

There is no clear consensus on the choice of the cemented or cementless cup fixation method in elderly patients and registry reports from the UK, Australia, Sweden, Norway, and Denmark reveal no clear overall tendency regarding cup fixation methods in the elderly [2-5]. While many registries report a tendency towards more cups being inserted with cementless fixation, their superiority is not supported in the literature [47-50]. A recent register study compared mid-term revision rate in 3,038 DM THA for CA (mean age 70) to 212,915 SM THA for CA (mean age 69) and they reported overall similar 5-year revision rate of 1.5% and 1.4%, respectively[51]. Furthermore, revision due to dislocation was lower in DM THA group (0.2%) compared to SM THA group (0.5%).

We found continuous (statistically significant) cup rotation (x, y, z-axis, and TR) within the cementless group during 24-months follow-up. However, 24-months end-results in the cementless and the cemented group showed overall very low proximal migration (maximum 0.11mm) and abduction (maximum -0.35°) below the described risk-zone levels, and therefore we generally expect both fixation methods of the Avantage Reload cup to have good survival in patients above 70 years with normal/low bone quality.


*Limitations and Strengths*

The strength of this study is the randomized controlled study design and a large group available for migration analysis. RSA is a validated surrogate measure of later implant loosening, but other complications i.e. wear-induced osteolysis or fractures in the cement mantle may not be detected with early RSA [13].

Mixed model statistical analysis enabled us to use all the available data for all patients. A high number of radiographs were available for analysis, and we only excluded two patients in the cementless group due to poor marker distribution, and one patient in the cemented group was excluded due to a mistake in identification of severe preoperative osteoporosis (preoperative T-score of -4.3).


**Conclusion**

Both cemented and cementless DM cups in our study showed short-term migration below recommended proximal cup migration thresholds limits. However, cementless cups showed more overall rotational migration and did not show rotational stability at 24 months, whereas

cemented cups were stable from 3 months. Furthermore, cementless cup fixation was associated with generally poorer stability in patients with preoperative low BMD as compared to cemented cup fixation. Both cemented and cementless DM cups showed excellent patient-reported outcomes, and no cups failed for reasons related to the cup fixation method within the 24-months study period. Cemented fixation lead to less bone loss proximal to the cup compared to cementless cups and vice versa in the most distal regions of the cup. The percentage BMD changes in the two cup fixation methods did not correlate to proximal cup migration.

In conclusion, cemented cup fixation of the Avantage® DM cups seems to be a safer treatment in elderly patients regardless of their preoperative systemic T-score assessed by DXA. Patients will be followed for mid- and long-term results.

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**Table 1** Descriptive Baseline Characteristics of the Patients, Implants, and Surgery.

| | Cemented | Cementless |
|---|---|---|
| Sex (male / female) | 14/15 | 13/17 |
| Age at operation, mean | 75.0 | 75.2 |
| Implant side, right / left | 16/13 | 15/15 |
| Cup size mm, mean (range) | 48.7 (44-54) | 52.8 (48-58) |
| Cup inclination angle°, mean (range) | 49.2 (36.2-61) | 43.5 (28.9-59.7) |
| Cup anteversion angle°, mean (range) | 11.5 (1.2-26.2) | 11.7 (0.7-26.3) |
| Preoperative T-score, mean (range) | -1.01 (-2.9-1.8) | -1.12 (-3.1-2.3) |
| BMI, mean | 28.3 | 28.6 |
| ASA class, mean | 2.0 | 1.8 |

**Table 2** RSA measurement error based on double-examination stereo radiographs. No statistical difference between cemented and cementless fixation (p>0.10).

| Axis | Translation, mm | | | | Rotation, ° | | | | MTPM |
|---|---|---|---|---|---|---|---|---|---|
| | X | Y | Z | TT[a] | X | Y | Z | TR[b] | MTPM |
| Mean dif. | 0.02 | -0.01 | -0.01 | 0.00 | -0.23 | -0.05 | 0.09 | 0.07 | 0.01 |
| SD dif. | 0.20 | 0.09 | 0.16 | 0.17 | 0.91 | 0.92 | 0.64 | 0.90 | 0.57 |
| CR (1.96 * SD dif.) | 0.39 | 0.18 | 0.31 | 0.33 | 1.78 | 1.80 | 1.25 | 1.76 | 1.12 |

[a]TT was calculated using 3-D Pythagorean theorem (TT= sqrt $(xt^2 + yt^2 + zt^2)$)

[b]TR was calculated using 3-D Pythagorean theorem (TR= sqrt $(xr^2 + yr^2 + zr^2)$)

**Table 3** DXA measurement error based on double-examination DXA scans for cemented and cementless cup fixation.

| | Cemented | | | | Cementless | | | |
|---|---|---|---|---|---|---|---|---|
| | ROI1 | ROI2 | ROI3 | ROI4 | ROI1 | ROI2 | ROI3 | ROI4 |
| Mean dif. | -0.02 | -0.01 | -0.05 | -0.01 | 0.02 | -0.01 | 0.00 | 0.01 |
| SD dif. | 0.07 | 0.31* | 0.13* | 0.07 | 0.07 | 0.11* | 0.07* | 0.05 |
| CV%[a] | 4.26 | 17.61 | 11.61 | 7.61 | 4.52 | 8.90 | 8.32 | 5.90 |

[a] Calculated as CV%=(SD/X) x 100.

* Denotes significant difference between cemented and cementless using F-test.

**Table 4** Translations along and rotations about the x-, y-, and z-axis for cemented and cementless cups presented as mean and 95% CI.

| Axis | Cemented | Cementless | *p*-value |
|---|---|---|---|
| Translations, mm | | | |
| x-axis (*n*=57) | | | |
| 3 mo. | -0.01 (-0.17 – 0.14) | 0.08 (-0.19 – 0.36) | 0.61 |
| 12 mo. | -0.03 (-0.21 – 0.15) | 0.16 (-0.20 – 0.51) | 0.47 |
| 24 mo. | -0.01 (-0.22 – 0.20) | 0.23 (-0.20 – 0.66) | 0.32 |
| y-axis (*n*=57) | | | |
| 3 mo. | 0.08 (0.00 – 0.16) | 0.15 (0.02 – 0.27) | 0.44 |
| 12 mo. | 0.09 (0.01 – 0.18) | 0.12 (-0.02 – 0.26) | 0.75 |
| 24 mo. | 0.11 (0.00 – 0.23) | 0.09 (-0.09 – 0.28) | 0.79 |
| z-axis (*n*=57) | | | |
| 3 mo. | 0.16 (0.00 – 0.32) | 0.31 (0.00 – 0.62) | 0.41 |
| 12 mo. | 0.15 (-0.01 – 0.31) | 0.36 (0.03 – 0.69) | 0.31 |
| 24 mo. | 0.23 (0.02 – 0.44) | 0.39 (0.03 – 0.75) | 0.42 |
| TT (*n*=57) | | | |
| 3 mo. | 0.49 (0.34 – 0.64) | 0.79 (0.49 – 1.10) | 0.17 |
| 12 mo. | 0.56 (0.37 – 0.76) | 0.88 (0.51 – 1.25) | 0.13 |
| 24 mo. | 0.65 (0.44 – 0.87) | 0.98 (0.54 – 1.42) | 0.12 |
| Rotations,° | | | |
| x-axis (*n*=54) | | | |
| 3 mo. | 0.34 (0.01 – 0.66) | 0.01 (-0.48 – 0.51) | 0.35 |
| 12 mo. | 0.52 (0.15 – 0.89) | 0.64 (-0.01 – 1.30) | 0.72 |
| 24 mo. | 0.29 (-0.05 – 0.63) | 0.04 (-0.63 – 0.70) | 0.47 |
| y-axis (*n*=54) | | | |
| 3 mo. | 0.23 (0.26 – 0.72) | 1.08 (0.34 – 1.82) | 0.06 |
| 12 mo. | 0.30 (-0.25 – 0.85) | 1.74 (0.91 – 2.57) | 0.002 |
| 24 mo. | 0.18 (-0.37 – 0.73) | 1.10 (0.42 – 1.78) | 0.04 |
| z-axis (*n*=54) | | | |
| 3 mo. | -0.35 (-0.60 – 0.03) | -0.07 (-0.60 – 0.46) | 0.48 |
| 12 mo. | -0.40 (-0.75 - -0.05) | -0.33 (-0.92 – 0.26) | 0.84 |
| 24 mo. | -0.35 (-0.76 – 0.05) | -0.01 (-0.69 – 0.68) | 0.37 |
| TR (*n*=54) | | | |
| 3 mo. | 1.52 (1.12 – 1.90) | 2.23 (1.55 – 2.92) | 0.08 |
| 12 mo. | 1.80 (1.40 – 2.24) | 3.00 (2.20 – 3.80) | 0.003 |
| 24 mo. | 1.72 (1.30 – 2.13) | 2.57 (1.83 – 3.30) | 0.04 |
| MTPM (*n*=54) | | | |
| 3 mo. | 1.14 (0.86 – 1.42) | 1.81 (1.26 – 2.36) | 0.06 |
| 12 mo. | 1.30 (1.00 – 1.60) | 2.24 (1.64 – 2.85) | 0.005 |
| 24 mo. | 1.36 (1.00 – 1.73 | 2.16 (1.44 – 2.87) | 0.02 |

**Table 5** Cup migration between follow-ups within each group presented as mean difference and 95% CI.

| Axis | Cemented | *p-value* | Cementless | *p-value* |
|---|---|---|---|---|
| Rotations,° | | | | |
| x-axis | | | | |
| 3 mo. - 12 mo. | -0.18 (-0.49 – 0.13) | 0.25 | -0.63 (-0.95 – 0.31) | <0.001 |
| 12 mo. - 24 mo. | 0.23 (-0.08 – 0.55) | 0.15 | 0.61 (0.28 – 0.93) | <0.001 |
| y-axis | | | | |
| 3 mo. - 12 mo. | -0.07 (-0.44 – 0.29) | 0.69 | -0.66 (-1.03 – -0.28) | 0.001 |
| 12 mo. - 24 mo. | 0.14 (-0.22 – 0.51) | 0.45 | 0.64 (0.26 – 1.01) | 0.001 |
| z-axis | | | | |
| 3 mo. - 12 mo. | 0.09 (-0.15 – 0.32) | 0.48 | 0.26 (0.01 – 0.50) | 0.04 |
| 12 mo. - 24 mo. | -0.08 (-0.32 - 0.15) | 0.49 | -0.33 (-0.60 – -0.08) | 0.01 |
| TR | | | | |
| 3 mo. - 12 mo. | -0.25 (-0.62 – 0.12) | 0.16 | -0.75 (-1.13 – -0.36) | <0.001 |
| 12 mo. - 24 mo. | 0.07 (-0.31 – 0.44) | 0.73 | 0.42 (0.04 – 0.80) | 0.03 |
| MTPM | | | | |
| 3 mo. - 12 mo. | -0.12 (-0.36 – 1.12) | 0.31 | -0.43 (-0.68 – -0.18) | 0.001 |
| 12 mo. - 24 mo. | -0.08 (-0.32 – 1.16) | 0.52 | 0.08 (-0.16 – 0.33) | 0.51 |

**Table 6** Mean (SD) scores for the HHS, OHS, EQ-5D and VAS for pain.

| Outcomes | Cemented | Cementless | p-values [a] |
|---|---|---|---|
| **HHS** | | | |
| Preoperative | 55.6 (12.4) | 56.0 (15.5) | 0.59 |
| 3 mo. | 80.2 (13.2) | 81.4 (13.7) | 0.60 |
| 12 mo. | 92.3 (6.5) | 89.1 (10.1) | 0.31 |
| 24 mo. | 92.1 (8.7) | 89.9 (10.9) | 0.72 |
| **OHS** | | | |
| Preoperative | 25.1 (6.5) | 25.2 (6.2) | 0.79 |
| 3 mo. | 37.0 (8.0) | 38.7 (5.6) | 0.82 |
| 12 mo. | 44.8 (3.9) | 43.0 (4.9) | 0.08 |
| 24 mo. | 44.6 (4.3) | 43.2 (5.5) | 0.30 |
| **EQ-5D** | | | |
| Preoperative | 0.63 (0.15) | 0.66 (0.10) | 0.92 |
| 3 mo. | 0.88 (0.13) | 0.90 (0.10) | 0.62 |
| 12 mo. | 0.93 (0.10) | 0.92 (0.11) | 0.83 |
| 24 mo. | 0.94 (0.10) | 0.92 (0.10) | 0.44 |
| **VAS for hip pain (rest)** | | | |
| Preoperative | 3.2 (2.7) | 2.9 (2.0) | 0.74 |
| 3 mo. | 0.9 (1.3) | 0.7 (0.8) | 0.57 |
| 12 mo. | 0.03 (0.2) | 0.2 (1.1) | 0.54 |
| 24 mo. | 0.1 (0.6) | 0.2 (0.8) | 0.63 |
| **VAS for hip pain (activity)** | | | |
| Preoperative | 6.8 (1.9) | 5.5 (2.1) | 0.02 |
| 3 mo. | 1.0 (0.9) | 0.9 (0.8) | 0.66 |
| 12 mo. | 0.17 (0.5) | 0.5 (1.4) | 0.46 |
| 24 mo. | 0.4 (1.0) | 0.1 (0.3) | 0.36 |

All values are mean (SD).

[a] Two-sample Wilcoxon Rank-sum (Mann-Whitney) test.
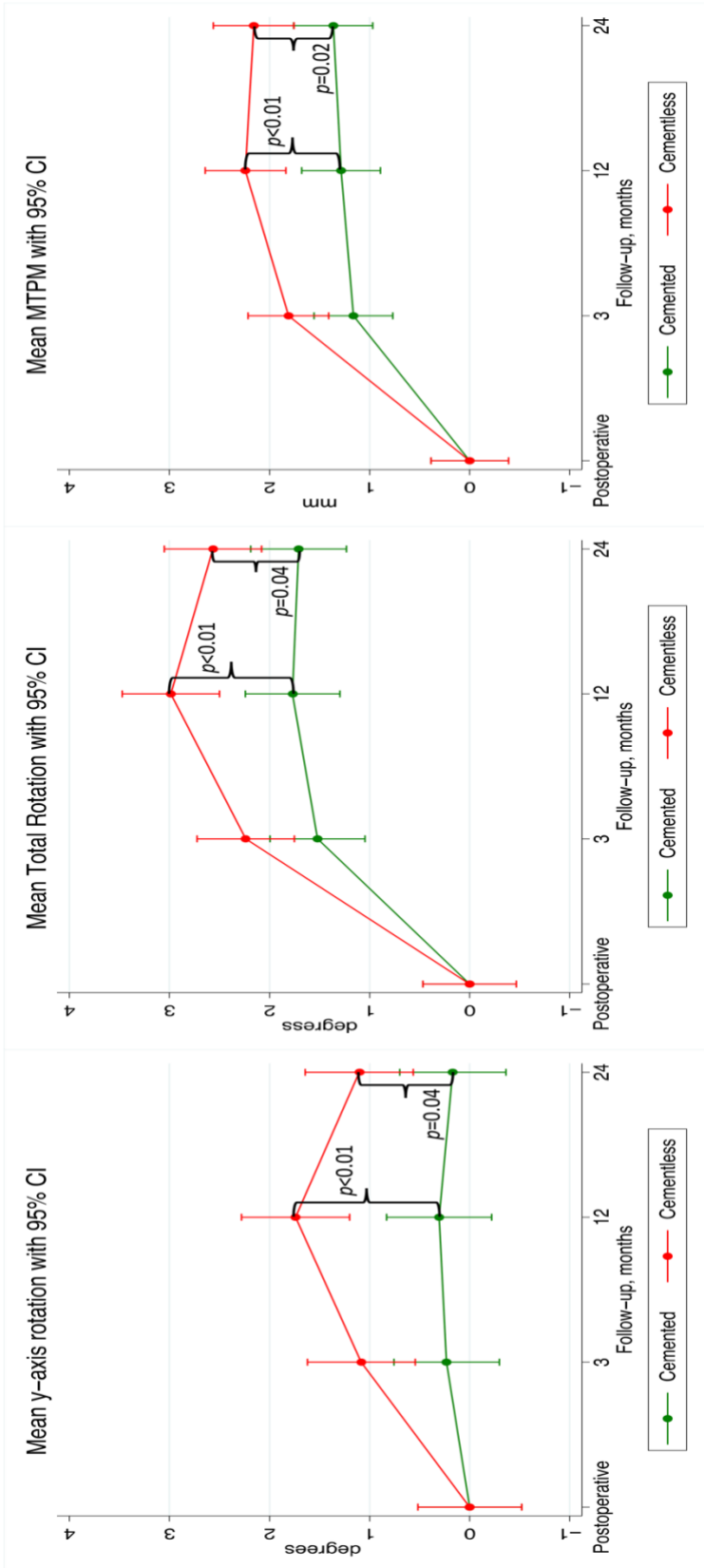
**Figure 7** CONSORT 2010 flow diagram.
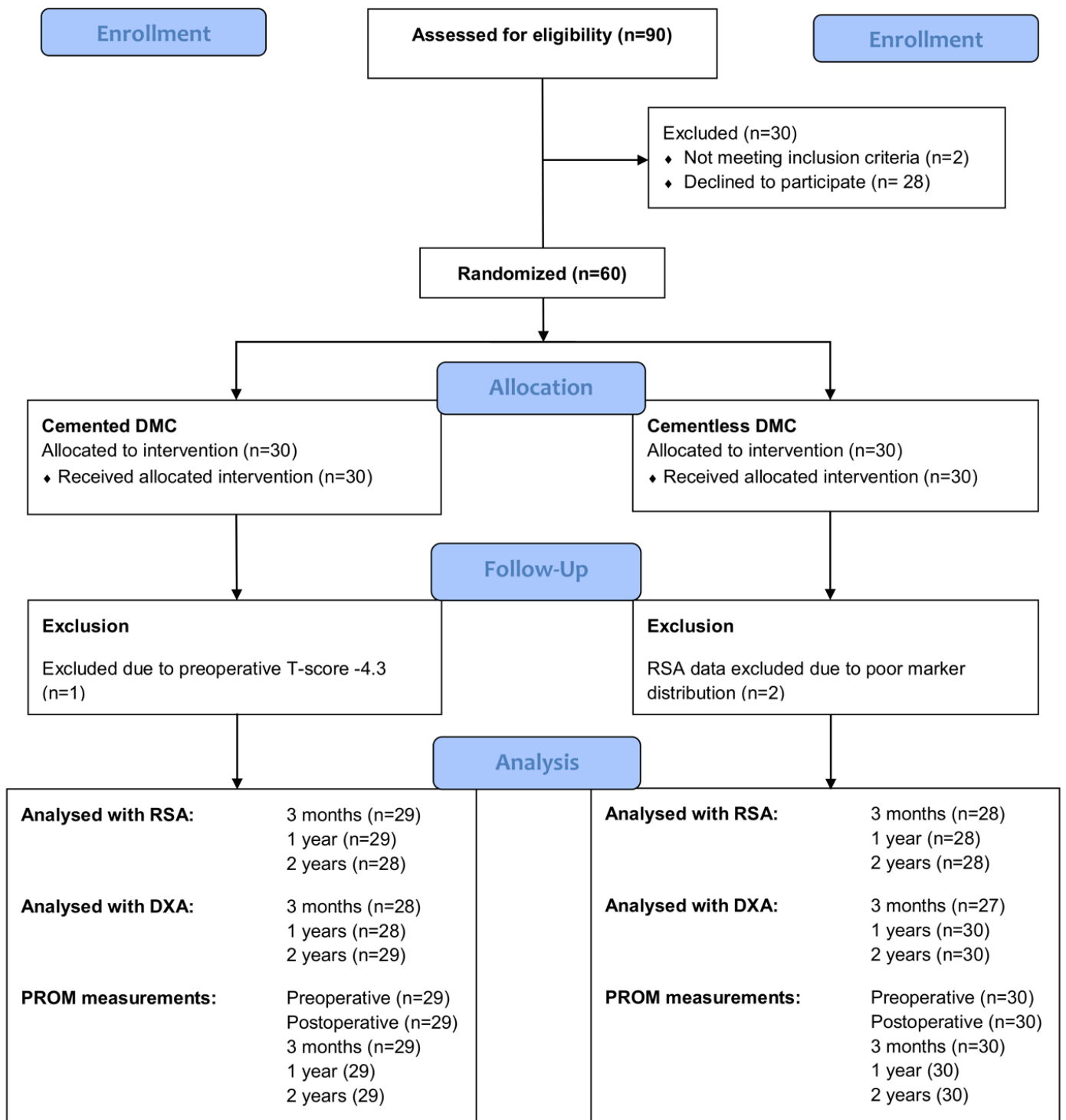
**Figure 2** Illustration of directions, translation, and rotations for Avantage DM cup.
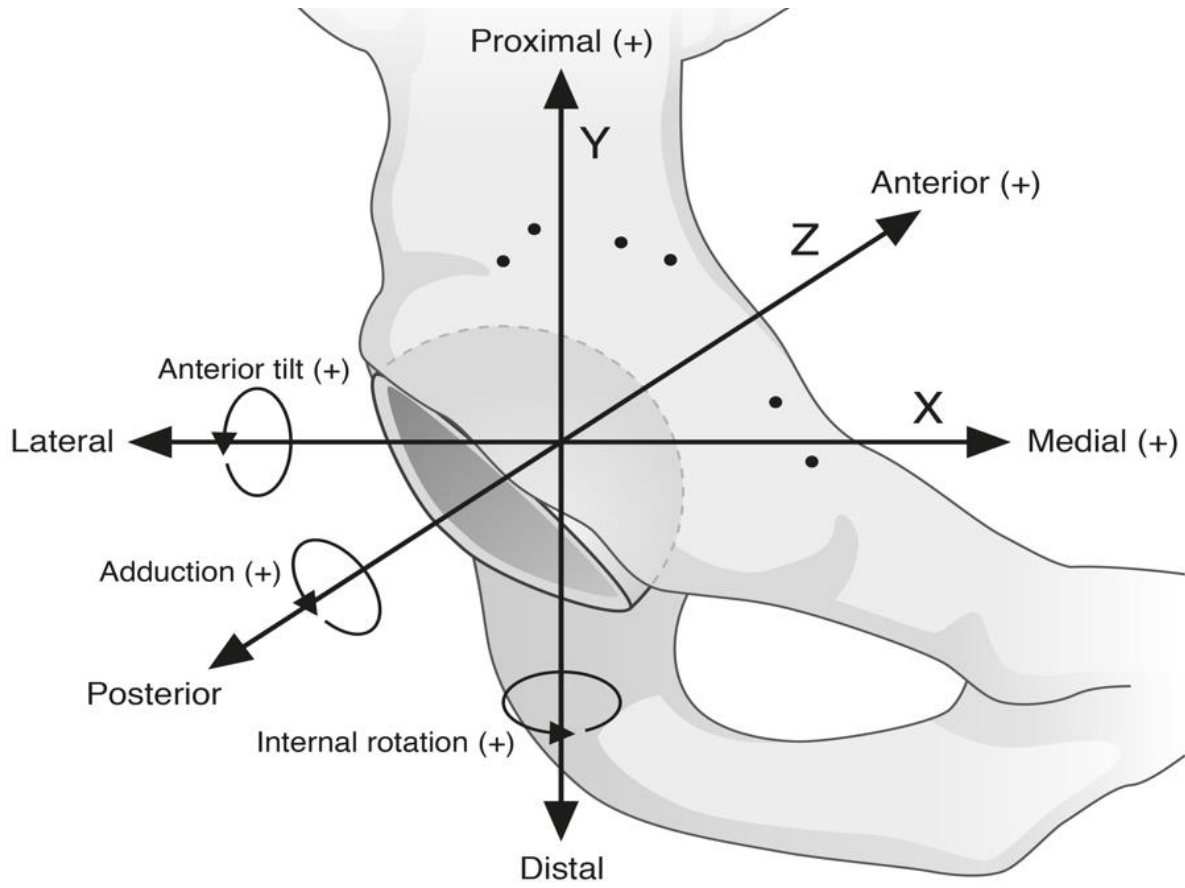
**Figure 3** Wilkinson regions of interest (ROI 1-4. Only area within yellow lines are included in the analysis
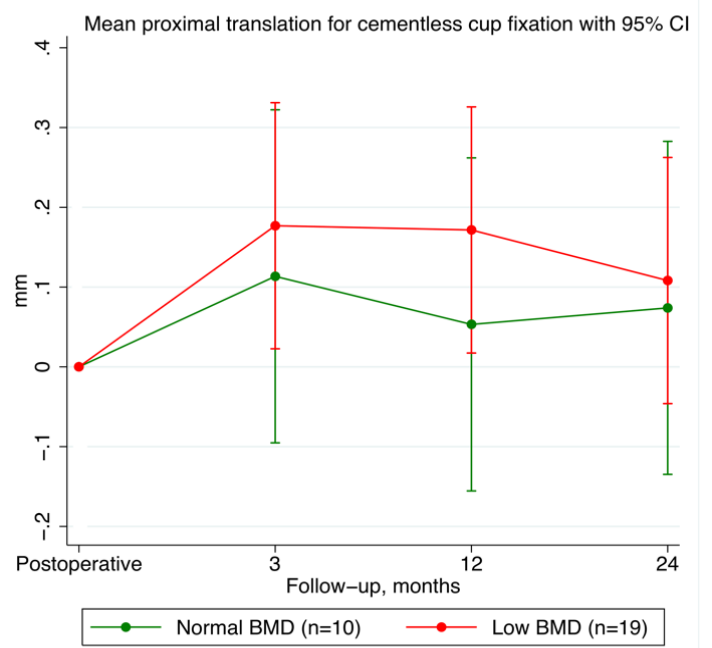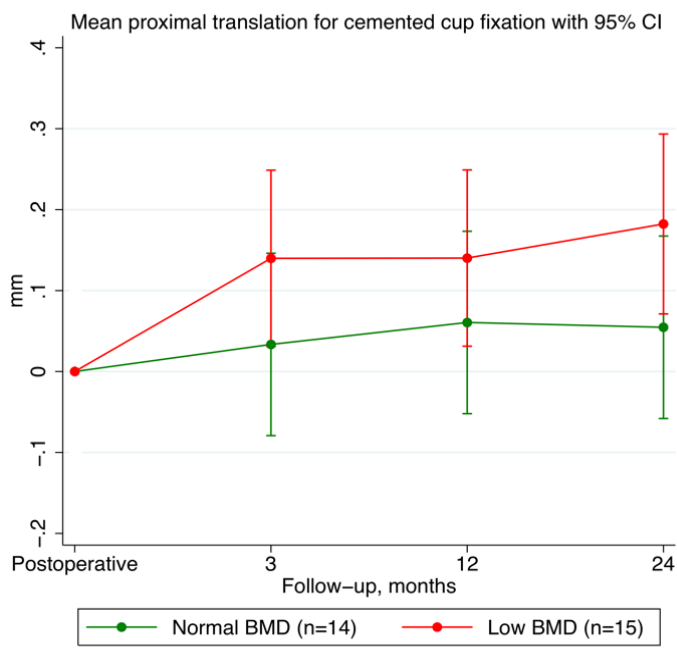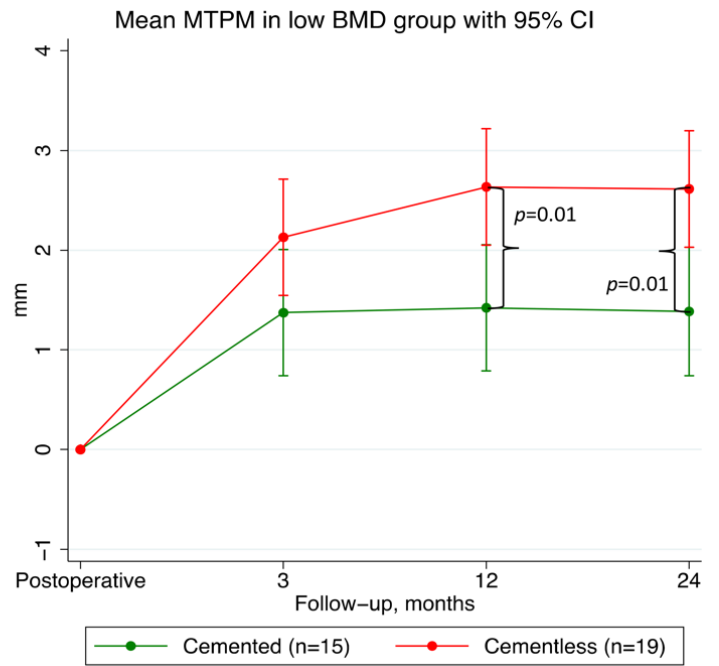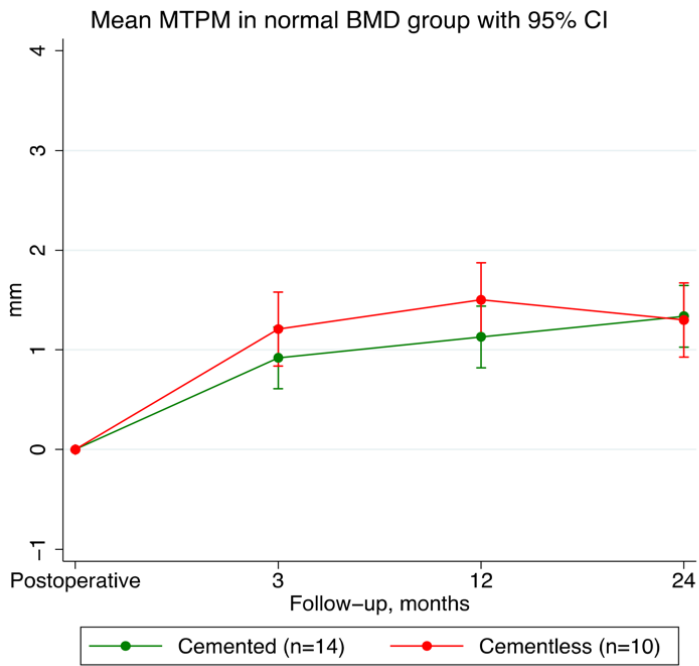
**Figure 4** Significant migration in cementless cups compared to cemented cups in y-axis, TR and MTPM
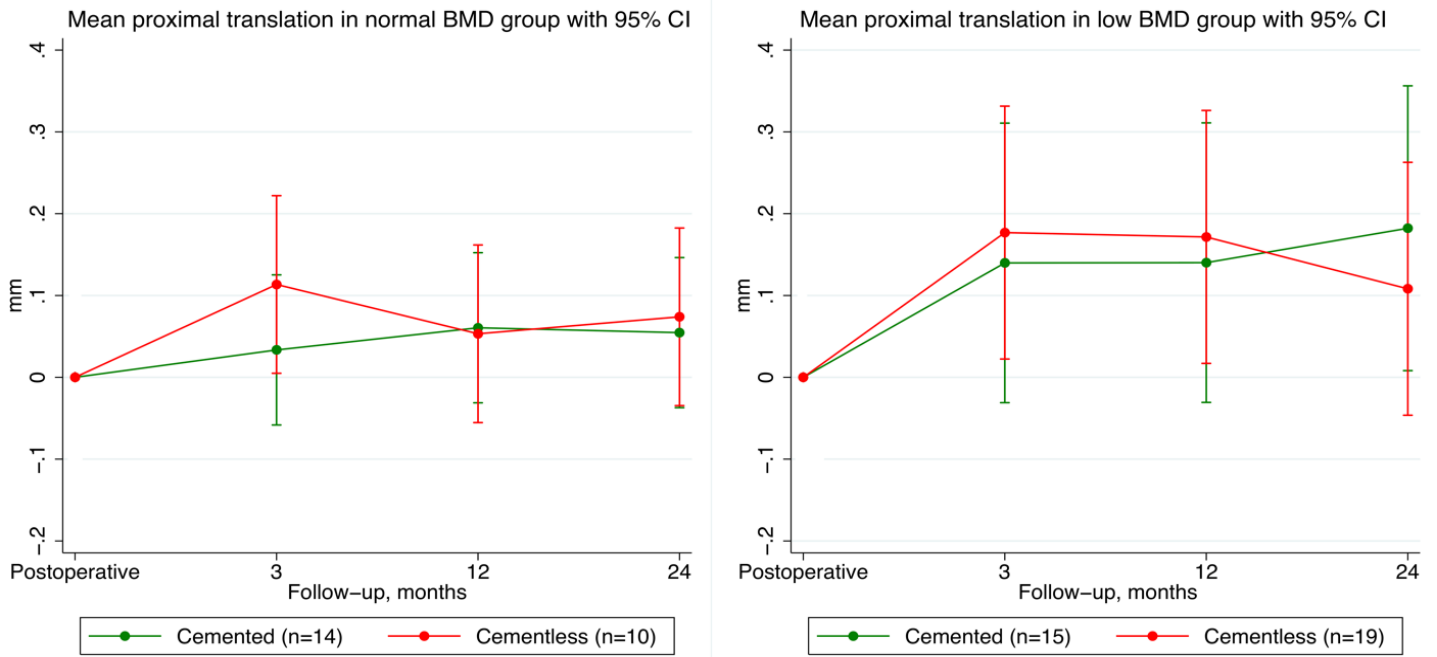
**Figure 5** Proximal translation in the two fixations methods when stratified according to normal/low BMD.

**Figure 6** MTPM migration in normal and low BMD groups based on cup fixation.

**Figure 7** Proximal translation in normal and low BMD when stratified according to fixation method

**Figure 8** Percentage BMD change in cemented and cemented cup fixation in Wilkinson's ROI 1-4.