Influence of Stem Design on Total Hip Arthroplasty

Clinical and radiological assessment based on randomized controlled trials and register data

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Det är konstigt med mig. Jag kan så mycket!

Ur "Visst kan Lotta nästan allting" av Astrid Lindgren

ABSTRACT

Since the 1960s, total hip arthroplasty has revolutionized the care of patients with end-stage osteoarthritis. Results after surgery using contemporary implants are usually good. Nevertheless, new implants are constantly being developed and introduced to the market. In recent years, there has been a trend towards shorter femoral implants, to save proximal bone and thereby facilitate any future revision surgery.

This thesis aimed to evaluate three different stem design, comparing them with a reference stem (Papers I–III). In Paper IV, register data were used to study and compare survival rates and first-time revisions of short stems versus stems of standard length.

Small differences in outcome were found between implants as regards patient-reported outcome measures and migration as seen through radiostereometric analysis. In contrast to the aim of the design, two of the studied implants had more pronounced loss of proximal bone stock. In Paper IV, the short stems showed survival rates equalling those of standard stems. In first-time revisions, short stems were, more frequently than standard stems, exchanged with stems of standard length as opposed to longer revision stems.

In conclusion, there were small differences in outcome between the implant designs studied and reference stems. Two of the studied stems were associated with increased loss of proximal bone density, this stands in contrast to the aim of the design. However, if revision becomes necessary, a short stem seems to allow for replacement with a stem of standard length, which may be advantageous in younger patients with risk of repeated revision surgery.

Keywords: total hip arthroplasty, radiostereometric analysis, patient-reported outcomes, bone mineral density loss, revision

SAMMANFATTNING PÅ SVENSKA

Höftproteskirurgi har ansetts vara en av de mest framgångsrika ortopediska operationerna som presenterats under 1900-talet. Majoriteten av patienterna med höftartros upplever minskad smärta samt förbättringar i rörelseomfång och livskvalitet. Sedan introduktionen av höftproteser på 1960-talet har en mängd nya typer av implantat introducerats och även återkallats från marknaden. De implantat som idag används har en bevisat lång överlevnad och goda kliniska resultat. Trots detta introduceras ständigt nya implantat på marknaden. Det är av största vikt att dessa har lika bra eller bättre resultat än de implantat som redan används. Nya implantat kan också ha andra egenskaper som gör dem överlägsna redan förekommande implantat. I denna avhandling utvärderas endast implantat avsedda för lårbenet, så kallade stammar. Alla stammar som har utvärderats är fixerade utan användning av bencement, ocementerad fixation. Under de senaste åren har det funnits en trend att göra stammarna kortare, detta i syfte att spara benmassa i lårbenet samt att förenkla en eventuell framtida omoperation. De korta implantaten är i dagsläget inte väl utvärderade – varken i kliniska studier eller i registerbaserade studier. Trots detta används de allt oftare.

Den här avhandlingen har utvärderat tre typer av implantat i randomiserade kontrollerade studier, där vi jämfört dem med välbeprövade implantat som har dokumenterat goda långtidsresultat i nationella protesregister. Både kliniska och radiologiska utfall har registrerats och utvärderats.

I Studie I jämfördes en anatomisk stamdesign (SP-CL) med en vanligt förekommande stam (Corail). Primärt utfallsmått var patientrapporterad funktion vid 2 år. Sekundära utfallsmått var mikrorörelser, bentäthet och radiologiska förändringar på sedvanliga röntgenundersökningar. Ingen statistisk signifikant skillnad kunde ses mellan implantaten, förutom att SP-CL var kopplat till förlust av mer benmassa i de övre delarna av lårbenet. Denna skillnad var statistiskt signifikant.

I Studie II jämfördes en kort stam, CFP, med Corail. Målet med CFP är att bevara så mycket benmassa i de övre delarna av lårbenet som möjligt. Studien hade ett liknande upplägg som Studie I. I den kliniska utvärderingen syntes ingen skillnad mellan implantaten; båda grupper rapporterade god funktion med höga poäng i olika utfallsmått. Radiologiskt syntes små skillnader mellan implantaten. Det fanns en statiskt signifikant skillnad i förlust av benmassa i de övre delarna av lårbenet, där CFP var kopplat till större förlust av benmassa än Corail. Detta trots att målet med stamdesignen är att spara benmassa.

I Studie III opererades patienter bilateralt vid samma operationstillfälle med två olika implantat. Stammen som studerades var Fitmore-stammen, en kort stam med huvudsaklig metafysär förankring. CLS Spotorno användes som referensstam. Primärt utfallsmått var vilken höft som patienterna ansåg vara bäst vid 2 år. Ingen statistiskt signifikant skillnad kunde ses mellan implantaten även om fler patienter föredrog CLS-stammen. Radiologiskt kunde ingen skillnad noteras mellan implantaten. De hade liknande mönster av mikrorörelser och förändring av benmassa. Inte heller vid konventionell röntgenundersökning sågs någon skillnad.

I Studie IV studerades risken för omoperation av så kallade korta stammar med hjälp av registerdata. En jämförelsegrupp med patienter opererade med en protes av standardlängd valdes också ut. Risken för omoperation upp till 12 år efter den primära operationen beräknades såväl som risken för ytterligare omoperationer efter den första omoperationen. Vidare analyserades val av implantat vid omoperation av lårbenskomponenten och kategoriserades som standardlängd eller revisionslängd. Detta för att, om möjligt, bekräfta teorin att de korta stammarna sparar ben i den övre delen av lårbenet och därför är lättare att omoperera. I studien framkom ingen ökad risk för omoperation med de korta stammarna jämfört med stammar av standardlängd. Fler patienter med korta stammar omopererades med hjälp av en stam av standardlängd. Trots detta var risken för ytterligare omoperationer inte högre i den gruppen.

Sammanfattningsvis upptäcktes inga eller endast små skillnader i resultat som patientrapporterade utfall, stammigration, bentäthet och röntgenförändringar. Anmärkningsvärt är dock att två av de stammar vars

design syftar till att bättre fördela belastningen i benvävnaden (SP-CL och CFP) var kopplade till större förlust av benmassa i de övre delarna av lårbenet. Detta talar för en motsatt effekt av dessa implantat. I den registerbaserade studien noterades att korta stammar i en högre utsträckning revideras med en standardstam vilket skulle kunna vara fördelaktigt, framför allt vid operation av yngre patienter.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

I. Rilby, K., Nauclér E., Mohaddes, M., Kärrholm J., Similar outcome with a new anteverted or a straight standard stem: a randomized study of 72 total hip arthroplasties evaluated with clinical variables, radiostereometry, and DXA up to 2 years. *Acta Orthopaedica*. 2022; 93: 59-67.

II. Rilby, K., Nauclér E., Mohaddes, M., Kärrholm J., No difference in outcome or migration but greater loss of bone mineral density with the Collum Femoris Preserving stem compared with the Corail stem: a randomized controlled trial with five-year follow-up. *The Bone & Joint Journal*. 2022; 104-B(5): 581-588.

III. Rilby, K., Nauclér E., Mohaddes, M., Kärrholm J., Similar results after five years with the use of the Fitmore or the CLS femoral components. *The Bone & Joint Journal Open.* 2023; 4(5): 306-314.

IV. Rilby, K., van Veghel M., Mohaddes M., van Steenbergen L., Lewis P., Kärrholm J., Schreurs W., Hannink G. Does choice of primary stem influence choice of revision stem? Evaluation of 591 first time femoral stem revisions in 16,258 primary short-stem Total Hip Arthroplasties (THA) and 32,515 matched standard-stem THAs from the Australian, Dutch and Swedish Arthroplasty Registers. In manuscript.

CONTENTS

ABBREVIATIONS

AOANJRR	Australian Orthopaedic Association National Joint Replacement Register
ASA	American Society of Anaesthesiologic
BMD	Bone Mineral Density
BMI	Body Mass Index
CCD angle	Caput Collum Diaphyseal angle
CFP	Collum Femoris Preserving
CI	Confidence Interval
CRR	Cumulative Revision Rate
DAA	Direct Anterior Approach
DXA	Dual X-ray Absorptiometry
EQ-5D	EuroQol 5 Dimensions
FJS	Forgotten Joint Score
HHS	Harris Hip Score
IQR	InterQuartile Range
LROI	Landelijke Registratie Orthopedische Interventies
MCID	Minimal Clinical Important Difference
MIC	Minimal Important Change

OHS   Oxford Hip Score

PJI   Periprosthetic Joint Infection

PROM   Patient-Reported Outcome Measures

RCT   Randomised Controlled Trial

ROM   Range Of Motion

RSA   RadioStereometric Analysis

SAR   Swedish Arthroplasty Register

SP-CL   Status Physiologicus - CementLess

THA   Total Hip Arthroplasty

VAS   Visual Analogue Scale

DEFINITIONS IN SHORT

ASA Classification	Morbidity scale assessing patients' overall health prior to surgery, grading from I (healthy) to VI (organ donor).
Aseptic loosening	Implant failure due to continuous motions at the bone-implant interface without the presence of microbes. In National Registers more types of failures may be included.
Cup	Acetabular implant of the THA.
Dual energy X-ray Absorptiometry (DXA)	Radiologic method measuring bone mineral density and body composition.
National Arthroplasty register	Registries covering almost all arthroplasty operations in a specific country.
Revision surgery	A new surgical intervention where any part of the implant was removed or exchanged.
RadioStereometric Analysis	Radiologic method measuring micromovements between e.g. implant components and bone.
Stem	Femoral component of the THA.

01

1 PROLOGUE

Throughout my professional career, my focus has been to provide high-quality care to patients crossing my path. I've considered myself a clinician first – research being too tedious and slow.

In the last four years, my opinion has changed. Not only do I now consider myself a researcher (in her infancy), but I have also realised that through science I can help provide high-quality care to patients who do not cross my path. The studies in this thesis, along with future projects, might change the care of patients for the better. And it is a scientist's responsibility, together with the manufacturers, to ensure the safe introduction of new implants.

Therefore, I'm truly glad that Johan Kärrholm asked me in the winter of 2020 if I wanted to write a thesis, not mentioning how much of my hair that would turn grey during the process. However, I'm glad that I took the bait.

And now, here we are – four years later, the thesis is finished. Or, as I see it, my work has only just started.

02

2 INTRODUCTION

2.1 TOTAL HIP ARTHROPLASTY

Humans have always been at risk of hip osteoarthritis. Several attempts have been made throughout history to restore hip anatomy and function. Until the early 1960s, clinical results were generally poor. In 1961, Sir John Charnley first introduced low-friction arthroplasty, revolutionizing the treatment of end-stage hip arthrosis. (1) Since then, many types of implants have been introduced – and many have been withdrawn from the market. Total hip arthroplasty (THA) has been called the surgery of the century due to its cost effectiveness and good long-term results. (2) Contemporary implants often show survival rates exceeding 95% at 10 years. Many patients who were formerly doomed to a crippled and painful life can now have almost normal joint function without pain.

2.1.1 ANATOMY

A THA requires two implants fixed in bone: the stem and the cup. The stem is fixed in the femur, whereas the cup is fixed in the acetabulum. Together, the implants make up the artificial joint. Fixation can be achieved either using bone cement or by direct fixation to bone (osseointegration) without use of cement (uncemented). This thesis will focus on uncemented stems.

Most contemporary stem designs are modular with several different options in sizes, caput-collum-diaphyseal (CCD) angle, neck length, offset and sometimes femoral component curvature, to enable restoration of the patient's individual anatomy **(Figure 1)**.

Figure 1. Stems in different sizes, CCD-angles, and off-set.

2.2 EPIDEMIOLOGY

In 2022, a total of 18,339 primary elective THAs were performed in Sweden. The median patient age was 69 years and more women (57.2%) than men underwent surgery. (3) Approximately 30% of the patients (all ages) receive an all uncemented THA (both cup and stem); the distribution differs substantially between age groups. For patients younger than 65 years of age,

uncemented THAs are most common. Among the youngest patients (< 45 years), uncemented THAs dominate completely **(Figure 2)**.
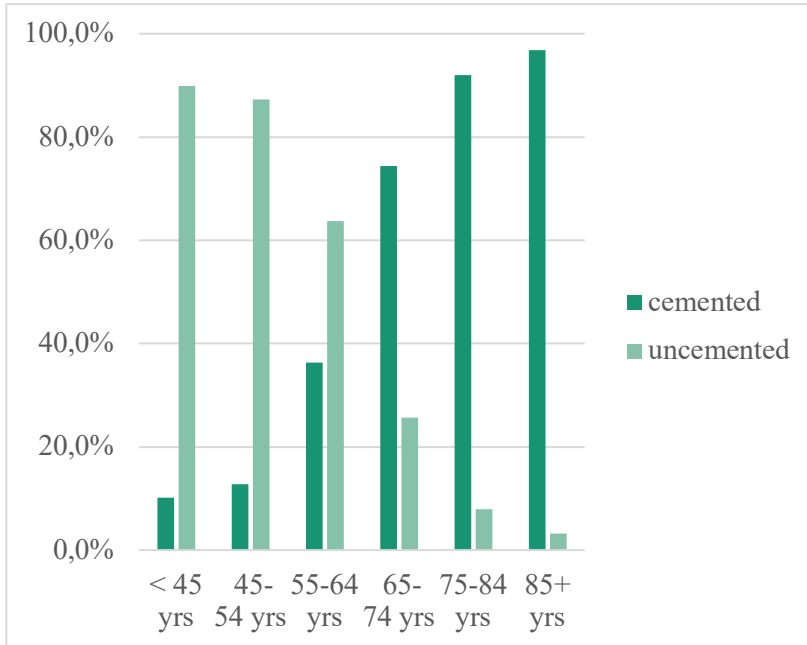
Figure 2. Distribution of stem fixation based on age. Data from the SAR.

Thanks to improvements in surgical technique, better implants and materials, the survival of THAs has improved over the years. Several national arthroplasty registries report the risk for revision (all reasons) at 10 years to be approximately 5% for uncemented stems. (4-6)

Today, patients live longer and have higher expectations of physical activity than in the past. This has led to a sharp rise in demand for THA. Also,

overweight and obesity have increased in the last decades, leading to a higher incidence of osteoarthritis, which further increases the need for THA. (7-9)

Due to surgical improvements and excellent results, more younger patients are assessed as eligible for THA. Even if several studies report excellent surgery outcomes in younger patients, the risk of revision is larger in this population due to higher levels of activity and longer life expectancy. (10-14)

2.2.1 UNCEMENTED STEMS

2.2.1.1 CLASSIFICATION

In 2011, Khanuja et al. (15) proposed a classification system for uncemented stems based on implant shape. In 2020, Kheir et al. upgraded this classification with an additional category. (16) The classification now includes 7 categories separated by appearance and length **(Figure 3)**. The short stems (category 1) are divided into 4 subcategories depending on fixation and bone-sparing properties. Although there is no maximal length limit for the short stems, the majority are shorter than 120 mm, designed for proximal fixation above the diaphysis. The remaining six categories are different kinds of conventional stems. The stems examined in this thesis fall into category 1B (Fitmore, collum femoris-preserving (CFP)) and category 7 (Status Physiologicus Cementless (SP-CL)).

Short stems

Type 1: Short and ultra-short stems

Type 1A: Femoral neck | *Type 1B: Calcar loading* | *Type 1C: Calcar loading with lateral flare* | *Type 1D: Shortened tapered stem*

Conventional stems

Type 2: Single-wedge | Type 3: Double-wedge

Type 4: Gradual taper, metadiaphyseal filling
Type 4A: Tapered round | *Type 4B: Tapered rectangle*

Type 5: Diaphyseal-engaging
Type 5A: Tapered spline/cone | *Type 5B: Cylindrical fully-coated*

Type 6: Modular
Type 6A: Modular neck | *Type 6B: Modular body*

Type 7: Anatomic

Figure 3. *Categorization of uncemented stems according to Kheir. © The Trustees of Indiana University.*

2.2.1.2 RATIONALE FOR FIXATION

Fixation of uncemented stems depends on osseointegration of the stem in the femoral canal. Osseointegration of titanium implants was first described in 1981 by Albrektsson. (17) For osseointegration to occur, the implant needs to be stable during the first months postoperatively. Continuous migration will lead to fibrous anchorage and higher risk of future loosening. A tight press-fit is also of importance to allow bone formation in the bone-implant interface. (18-20) Osseointegration can be achieved through either on-growth or in-growth to the implant; the characteristics of the implant surface determine what type of fixation will occur **(Figure 4)**. Most uncemented stems rely on on-growth. A rough surface is achieved through grit-blasting or plasma spraying. The roughness should be 3-5 µm for optimal conditions. (21)

Figure 4. *Osseointegration, by in-growth, into the porous surface of an acetabular implant. (22)* http://creativecommons.org/licenses/by/4.0/ *With permission from Thor Balkhed, Linköping University.*

Osseointegration must occur circumferentially to prevent joint fluid with debris and particles from entering the femoral canal, which would result in osteolysis and aseptic loosening. (23, 24) In early designs of uncemented stems, a lack of rough or porous surface or non-circumferential coating likely contributed to less favourable results.

2.2.1.3   INFLUENCE ON BONE MINERAL DENSITY

According to Wolff's law, bone will adapt to the mechanical forces to which it is exposed. Bone that is not loaded will be resorbed, leading to a loss in bone mineral density (BMD) and, eventually, total disappearance. The part of the bone to which load is redistributed will increase in density. All orthopaedic implants will alter loading, leading to areas with decreased BMD; this phenomenon is known as stress shielding. For most THAs, load will pass through the proximal femur and increase in the diaphyseal area. A proximal loss of BMD will be seen and the femur will gain in BMD distally. (25) This corresponds to BMD loss in Gruen zones, 1, 6 and 7 and BMD gain in zones 2, 3, 4 and 5 **(Figure 5)** .

Figure 5. *Gruen zones in the frontal and lateral plane.*

This pattern can be seen with many different stem designs. (26-28) The diameter and stiffness of the implant will influence the amount of loss. A stiffer implant will unload the proximal femur to a greater degree than an implant better mimicking the elasticity of the femur. (28-31) However, stem length seems to have limited influence on the pattern of BMD changes. (32-34)

Bone remodelling and loss of BMD will usually occur during the first months postoperatively but then stabilizes and further bone loss will often be at the same level as in the contralateral native hip. (35-37)

2.2.1.4   PROS AND CONS OF UNCEMENTED STEMS

Uncemented implants (both stems and cups) are gaining popularity globally. Operation times are shorter than for cemented implants, there are no risks for cementation-related adverse events and the implants are easy to handle. Due to these benefits, the majority of stems used for elective THAs are uncemented in many countries. (5, 6, 38, 39) Although results are very good in general, there are some drawbacks with uncemented stems compared with cemented designs.

Uncemented stems have a higher risk of revision surgery due to the higher risk of periprosthetic fractures in the early postoperative period. This is particularly true for elderly women, due to the higher incidence of osteoporosis or osteomalacia. (40) In order to obtain good initial fixation, adequate femoral bone stock is a prerequisite. (41) Leg-length discrepancy is also more common with uncemented stems than with cemented stems. (42)

2.2.2   INTRODUCTION OF IMPLANTS

Over time, numerous implants have been introduced to the market. In the 1990s, Malchau et al. proposed an algorithm for introducing implants. (43) This algorithm was to base introduction on the results of preclinical studies followed by randomized controlled trials (RCTs) where radiostereometric analysis (RSA) played a central part. If an implant had favourable results, a larger multi-centre trial could be performed before the implant was used in a wider setting. Post-market surveillance is achieved through continuous evaluation in national arthroplasty registries **(Figure 6)**. This algorithm has

been supported by several other researchers when introducing new surgical techniques and is widely accepted. (44, 45)

Figure 6. Algorithm for introducing implants, Nelissen et al. 2011. (46)

Despite this, some implants have been introduced without proper evaluation. The large metal-on-metal surface replacements are one example where large-scale usage occurred without proper prior testing. (47-49) A register-based study conducted in Australia showed no benefits with the newer design compared with established implants. On the contrary, the revision rates were higher with some newly introduced implants. (50) For the individual patient, the consequences might be disastrous, with multiple surgery and inferior results.

In 2021, new legislation on medical devices was adopted in the European Union. (51) This will hopefully encourage more standardised testing of medical devices and more controlled introduction of implants.

2.2.3 ASEPTIC LOOSENING – REASONS AND OUTCOME AFTER REVISION SURGERY

Aseptic loosening is one of the major reasons for revision surgery. In several national registries, it is the leading reason for revision. (3-6, 39) Reasons for aseptic loosening of the femoral implant are multifactorial and are probably a combination of patient- and implant-related factors. Micromotions continuing for 6 to 12 months after the operation will result in fibrous fixation with increased risk of clinical loosening. Low preoperative BMD indicating osteoporotic bone with few and thin bone trabeculae is one reason for failure to achieve sufficient implant stability. (41, 52) The risk of loosening may also be related to design factors such as implant shape and type of surface structure or coating. Use of proper surgical technique is also of importance. Malposition and under-sizing of the stem may jeopardize osseointegration, with increased risk of aseptic loosening. (53, 54) Medications, such as corticosteroids, and diseases like rheumatoid arthritis are other factors that affect bone remodelling and fracture healing, and may also increase the risk of aseptic loosening (52) **(Figure 7)**.

Figure 7. Aseptic loosening of uncemented stem, 2 years after insertion, with radiolucent lines, distal welding spot and evident subsidence.

An initial instability of the implant may later become aggravated by debris and particles from the articulation surfaces which will infiltrate the bone implant interface creating an inflammatory response. This will drive bone remodelling in osteoclastic direction, which in turn hastens loosening and osteolysis.(55, 56) The outcome after revision surgery is known to be worse than after primary THA. (57, 58) The risks of infection, dislocation, second revision and mortality are also significantly higher than after primary THA. (59, 60)

2.3 FACTORS INFLUENCING OUTCOME AFTER TOTAL HIP ARTHROPLASTY

2.3.1 SURGICAL FACTORS

2.3.1.1 INCISION

All approaches to the hip joint have advantages and drawbacks. In Sweden, the two most common incisions are the direct lateral and posterior approaches. One or the other is used in 90% of all THA operations. (3) Globally, the direct anterior approach (DAA) is gaining in popularity, with increasing numbers in Europe and Australia. (61, 62)

With the direct lateral approach, the anterior third of the gluteus medius is detached from the femur and the joint is accessed from the anterior aspect. In the posterior approach, the external rotators and the joint capsule are released from the posterior aspect of the femur, after which the joint is accessed. Both incisions give good access to the acetabulum as well as the femoral canal. Historically, the posterior approach has been known for a higher risk of dislocation compared with the lateral approach. However, a recent register-based study found no difference in risk of revision due to dislocation between those two approaches in patients operated for osteoarthritis in Sweden after 2006. (63) With proper soft tissue repair and component positioning, the risk of revision due to dislocation seems to be the same for both approaches. The direct lateral approach is associated with more pain, less satisfaction but not with increased frequency of limp due to creating weakness in the abductor muscles. (64-66)

The DAA has gained in popularity in recent years due to its atraumatic access to the joint. The interval between tensor fascia lata and rectus femoris is

identified and used for gaining access through the ventral capsule. No muscles need to be released and the joint is accessed from the anterior aspect. However, past studies have shown a steep learning curve for surgeons and a higher risk of early complications. (61, 67) Patients operated with DAA report better scores for patient-reported outcome measures (PROMs) during the first three months postoperatively compared to patients operated with a posterior approach, but the difference then levels out and becomes insignificant. (68-70)

2.3.1.2 HIGH-VOLUME CENTRES AND SURGEON EXPERIENCE

Few studies have explored the association between high-volume centres and functional outcomes. In the systematic review conducted by Malik et al. in 2018, (71) only two studies were found (72, 73). These dated back to the beginning of the century and the patients in the studies had been operated in the 1990s. It is unclear if the conclusions from these studies are still relevant. In these studies, no difference could be seen in outcome measured with PROMs between high-volume hospitals (> 100 operations annually) and hospitals with lower volumes. However, the complication rates seemed to correlate inversely with surgical volume, with hospitals and surgeons reporting higher volumes having fewer complications. (74-77)

The experience of the individual surgeon seems not to influence the clinical outcome of THA as measured with PROMs. Studies in which more experienced surgeons have been compared to surgeons in training reveal limited differences in revision rates and clinical outcomes. (78-81) In the registry-based study by Jolbäck et al. in 2018, patients operated by a senior surgeon were more satisfied at 1 year postoperatively than those operated by a trainee. No other PROMs recorded in the Swedish Arthroplasty Register (SAR) showed any difference depending on the experience of the surgeon. No evaluation of revision rates or adverse events was carried out in the study **(Figure 8)**.

Figure 8. Young surgeons have similar clinical outcome as more experienced ones.

2.3.2 PATIENT FACTORS

2.3.2.1 PREOPERATIVE MENTAL HEALTH AND OPIOID USE

Although results after THA surgery are generally good and most patients report excellent or good results, a subgroup of patients report inferior results. In a study based on data from the SAR, approximately 10% were not satisfied at 1 year post surgery. (82) In the last decade, the focus has shifted to preoperative mental health status in relation to postoperative outcome after THA. Evidence is growing that preoperative anxiety and depression result in less satisfied patients. (83-88) The exact mechanism for this is unknown, but preoperative mental status is important to acknowledge as a factor in patient satisfaction and pain relief after surgery.

Despite little evidence for opioids to be used in chronic arthritic pain, prescription still occur. (89) In a recent Swedish study, 18% of patients eligible for THA had > 4 prescriptions issued during the year prior to surgery. (90) In the US, a similar study showed that 39% of patients undergoing knee arthroplasty surgery were prescribed opioids for more than 3 months prior to surgery. (91) Preoperative opioid use is correlated with inferior outcome, higher periprosthetic joint infection and revision. (90, 92, 93) Opioid use also seems to be related to worse mental status preoperatively. (92) In a study on shoulder arthroplasty, opioid users improved their functional and pain scores in absolute numbers after surgery at approximately the same level as non-opioid users, but from a lower starting point. Hence, they never reach the same function or pain relief as non-opioid users. (94) Although this was a study on shoulder arthroplasty, the same pattern could be true for hip arthroplasty as well.

2.3.2.2 DEMOGRAPHIC AND SOCIOECONOMIC FACTORS

Socioeconomic factors influence the results of many types of medical treatment, e.g., colon cancer and acute myocardial infarction. (95, 96) THA is no exception. Low socioeconomic status and low education level negatively influence pain and function. (97-99) Age and gender do not seem to affect functional outcome, although younger men have a higher risk of revision surgery. There is conflicting evidence on the influence of obesity and overweight. (100-102) It is not clear if body mass index (BMI) influences the patient reported outcome of THA, but patients with obesity have a higher risk of complications following surgery. (102)

2.4   EVALUATION   OF   TOTAL   HIP ARTHROPLASTY

2.4.1 PROMS

2.4.1.1 GENERAL CHARACTERISTICS

Since the early 2000s, evaluation of THA has shifted from radiological and technical endpoints (such as migration or revision) to patient satisfaction. Numerous PROMs have been developed and are now generally included in national registries and clinical assessments of THA. (103) PROMs are often divided into subcategories measuring different aspects of health and joint function. Generic scales such as the 36-item Short Form Health Survey (SF-36) and the EuroQol 5 dimensions (EQ-5D) measure general health. Disease-specific scores, as the Oxford Hip Score (OHS) or the Forgotten Joint Score (FJS), measure function and pain in the affected joint. The use of symptom-

specific scoring, such as visual analogue scales (VAS) for pain and satisfaction, is also common. A combination of scores is often used, e.g., the SAR uses EQ-5D, the Hip dysfunction and Osteoarthritis Outcome Score, as well as VAS scores, to evaluate the effect of surgery on general health, pain and joint-specific function. (3, 103) Unsurprisingly, patients suffering from end-stage arthritis often score their general physical and mental health low and the majority report substantial improvement after a hip replacement. (82)

2.4.1.2   DEFINITIONS

A few different concepts are used for assessing the quality of PROMs. (104)

- Reliability: The degree to which the measurement is free from measurement error – if the patient status does not change, neither should the score.
- Validity: The PROM should reflect the severity of the condition it is supposed to assess. Does the PROM measure what it supposed to?
- Responsiveness: A change in the PROM score should reflect an actual change in outcome.

There are various ways to report on improvement in PROMs; one important measurement to consider is the minimal clinical important difference (MCID). It is used for assessing change *between* two cohorts. It was first introduced in 1989 and is defined as the smallest difference in score which patients perceive as beneficial. (105) It is also important to acknowledge the Minimal Important Change (MIC) which is the minimum change in health status *within* a group or individuals over time. (106) The MCID and MIC varies between PROMs and is also dependent on population and diagnosis. It can be calculated in different ways (anchor-based or distribution-based); both methods have benefits and disadvantages. (106-108) Most MCIDs for PROMs used in evaluation of orthopaedic surgery in the lower extremities are calculated using anchor-based questions. (109) When analysing PROM results it is of most importance to know the MCID and MIC for the PROM used to interpret the results correctly. There might be statistically significant

differences both within and between groups but without meaningful clinical change.

Some joint-specific scores, such as the OHS or the Harris hip score (HHS), were not constructed for evaluation of outcomes, but rather for preoperative measurement of the severity of symptoms. Therefore, they suffer from ceiling effects, making it difficult to differentiate between good and excellent results. This is especially when evaluating young patients with high physical demands (110, 111) **(Figure 9).**
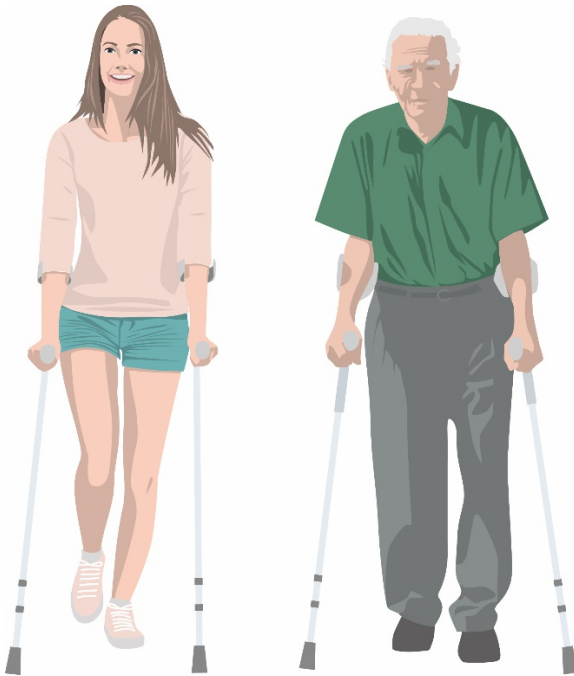

Figure 9. PROMs evaluate patients' perception on general health and joint function which may differ between age groups.

2.4.2 RADIOLOGICAL EVALUATION

2.4.2.1 RADIOSTEREOMETRIC ANALYSIS

The RSA method now considered standard was initially developed by Göran Selvik (1974). (112) During the 1980s and 1990s, RSA became the backbone of implant research and THA evaluation. It is known for its high precision, allowing evaluation of implants in small cohorts. (113)The theory behind the method is that the magnitude of migration during the first two years postoperatively may predict later aseptic loosening.(114, 115)

For closed-shaped cemented stems, there are clearly defined thresholds for acceptable initial migration. Migration above these thresholds is indicative of worse outcome and risk for revision. (114) In polished cemented stems, continuous migration is part of the design concept. (116) With uncemented stems, there are no defined thresholds for migration and the migration pattern differs between stems. (117) Even an excessive migration during the first months postoperatively can be followed by stabilization. (118) However, most uncemented stem design migrate only moderately during the first three months postoperatively, a process followed by stabilization. Evidence is mounting that initial migration can be accepted without jeopardizing long-term results. (34, 119-124)

When RSA was first developed, markers were used on implants to ensure reliable points of measurement. However, after attachment of markers, a new CE approval was necessary which increased the costs. Further, marking will weaken the implant, with increased risk of corrosion and subsequent implant fracture. To address this problem, more recent methods use computer-aided design models or mathematical algorithms based on implant geometry fitted to the image obtained. (125) The femoral head centre may also be used as a reference, resulting in an evaluation with high precision. (114, 126, 127) As an alternative, computer tomography-based examinations, which provides high precision, can be used. The use of this method is increasing, probably because it requires neither bone markers nor specific

calibration equipment and has a resolution of the same magnitude as marker-based RSA. (128-130)

2.4.2.2 DUAL ENERGY X-RAY ABSORPTIOMETRY/BONE MINERAL DENSITY LOSS

Dual energy X-ray absorptiometry (DXA) is used for evaluating BMD in the body. X-ray beams with different energies are used when scanning the patient. Software can calculate the density of different tissues in the body based on the differences in absorption. It is widely used for diagnosis of osteoporosis and is regarded as the gold standard for measuring BMD. (131) DXA has been proven to accurately measure BMD around THA, even in the presence of an implant. (132-134) To describe changes in BMD, results are correlated to the Gruen zones (**Figure 4**).

2.4.2.3 RADIOGRAPHIC EVALUATION

Plain radiographs (or X-ray pictures) have been used for evaluation since the introduction of THA. X-ray is a cheap and readily available technique used in everyday orthopaedic practice. The images are easy to interpret, and every orthopaedic surgeon can do a first assessment of the result.

Subsidence can be detected using plain radiographs, but the precision is low, and the subsidence must usually exceed 4 mm to be detectable. To precisely measure migration, more accurate methods must be used. (135, 136)

Radiolucent lines occur where there is no osseointegration between implant and bone. This may be due to a mismatch between metaphyseal and diaphyseal diameter leading to unloading of the proximal femur. (137) Widespread lines exceeding 50% of the total bone to implant interface indicate poor fixation and implant loosening. To describe the position of the radiolucent lines they are correlated to the Gruen zones, see **Figure 4**.

However, isolated radiolucent lines in Gruen zones 7 and 8 do not seem to be related to clinical outcome.(138)

When THA alters the strain distribution in the femora, proximal bone is resorbed, whereas BMD is increased distally in the cortex. In X-ray pictures this can be seen as welding spots or thickening of the cortex (cortical hypertrophy). (139) However, there is little evidence that cortical hypertrophy affects clinical outcomes. (140, 141)

2.4.2.4 BIOMECHANICAL EVALUATION AND RETURN TO SPORTS

Although patients usually report good clinical outcomes, hip joint motions and moments do not return to normal after operation with a THA. Stride length and walking velocity are also negatively affected. (142, 143) The type of implant used for surgery does not seem to significantly influence gait pattern postoperatively. (144-146)

Many patients, especially younger ones, want to return to the same activity level as before onset of their osteoarthritis or as their peers. Return to sports is a loosely defined outcome, as the level of activity may vary greatly between different kinds of sporting activities. Younger males with higher activity levels before surgery seem to have a greater chance to return to sports than other groups, irrespective of the type of arthroplasty performed in the lower extremities. (147, 148)

2.4.3 PROS AND CONS OF REGISTER-BASED EVALUATION

National registries offer a unique opportunity to evaluate large numbers of patients. If implants exhibit high rates of rare adverse events, such as aseptic loosening, they can be detected thanks to the large numbers of patients. The registries also provide the opportunity to follow patients for a long period of time, often until death, making long-term follow-up possible. National registries play an important role in the evaluation of implants, revealing implants or surgical techniques with inferior results. (149, 150)

The downside of register-based research is the inability to go into detail for each individual patient. A patient may have a loose implant but only minor symptoms, not qualifying for revision surgery, may be too diseased for a procedure, or may not want to undergo further surgical interventions.

High coverage and completeness are important factors in addition to data validation. Missing or incorrectly reported data may skew the results and make interpretation difficult. (149)

2.5 CURRENT GAPS IN KNOWLEDGE

- Clinical and radiographic outcomes of new stem designs. Are they superior to existing stem designs? (Papers I–III)
- Does use of a short stem influence outcome after THA? (Papers II and III)
- What is the revision rate of short stems compared with that for stems of standard length? (Paper IV)
- Can short stems be safely revised using stems of standard length? (Paper IV)
- Have short stems beneficiaries over stems of standard length stems that can justify their use? (Paper II-IV)

03

3 AIMS

The specific aims of this thesis were the following.

- To investigate the clinical and radiological outcomes of a recently introduced anatomical uncemented stem and compare them with those of a well-evaluated reference stem. (Paper I)
- To compare the clinical and radiological outcomes of a short stem aiming to save proximal bone stock with those of a reference stem of standard length. (Paper II)
- To assess differences in clinical and radiological outcomes in patients bilaterally operated with one short stem and one reference stem of standard length. (Paper III)
- To establish cumulative revision rates and choice of implant in first-time revisions of short stems and compare with those for stems of standard-length using data from three national hip arthroplasty registries. (Paper IV)

04

4 PATIENTS AND METHODS

Papers I, II and III were prospective randomized studies using similar methods, accounted for below. Study-specific methods and patient selection will be described under the subheading for each paper. Paper IV was a register-based study including patients from three different national arthroplasty registries.

4.1 CLINICAL EVALUATION

In Studies I–III, questionnaires were sent out by post by study nurses, to be filled in prior to the patient's visit to the outpatient clinic. The forms were collected by the physicians and returned to the study nurses. The Harris Hip Score (HHS) was filled out and completed during the visit.

4.1.1 HIP-SPECIFIC SCORES

4.1.1.1 OXFORD HIP SCORE (OHS)

The OHS consists of 12 questions assessing pain and functional outcome in hips both pre- and postoperatively. Originally, it was designed as a tool to be used prior to a decision on surgical treatment or not. Today, it is a well-established and validated instrument also used in the follow-up of THA. (151, 152) Each question is scored 0 to 4, where 4 is the best possible outcome and 0 is the worst. The answers are added up without any weighting. The best possible total score is 48 and the worst 0. The MCID has been estimated at 5 points. (106)

4.1.1.2 HARRIS HIP SCORE (HHS)

The HHS is a joint-specific evaluation tool consisting of four domains covering pain, function, absence of deformity and range of motion. The first two

domains encompass 8 questions on pain, walking ability and function. The other two domains are assessed by a physician examining deformities and range of motion (ROM). There is a fully patient-administered version where the patient self-assesses ROM and deformities. (153) In these studies, a clinician performed the physical examinations. The answers are weighted and added up in accordance with the test key. The best possible total score is 100, the worst is 0. The HHS was first introduced in 1969 and is today widely used for evaluation of THA. (154, 155) In recent years, questions have been raised on its usefulness due to ceiling effects. (111)

4.1.1.3   FORGOTTEN JOINT SCORE 12 (FJS-12)

The FJS-12 was introduced in 2012. The rationale behind this instrument is to obtain better discriminatory power in patients with any subtle remaining symptoms. (156) The form consists of 12 questions on pain and functional outcome. Each question is scored 1 (never) to 5 (mostly). The answers are then added up, and the raw score is transformed to a 0–100 scale, where 100 is the best possible outcome and 0 the worst. The instrument is gaining popularity due to its ability to differentiate between a good and excellent result. (110, 157) The Swedish version has been validated and is frequently used. (158)

4.1.1.4   MY HIP

My hip was designed by the research group specifically to assess patients undergoing bilateral, one-stage THA. This far, it has not been validated. The questionnaire encompasses 4 questions evaluating strength, pain and general hip function. The two hips are compared with each other, and patients rank the function and pain in one hip against that in the other hip. (Appendix)

4.1.2 GENERAL HEALTH SCORES

4.1.2.1 EQ-5D-3L

EQ-5D-3L stands for EuroQol 5 dimensions 3 levels. It is used for evaluation of general health. (159) It consists of 5 questions covering mobility, hygiene, activities, pain and depression or anxiety. Responses are given on a scale 1 to 3. The answers are then weighted based on a health index which has been validated in several countries. Since the studies included herein were conducted, a 5-level version of EQ-5D has been developed, but the 3-level version was used in this thesis. The 5-level version is known to have smaller ceiling effects than the 3-level version. (160, 161) The UK tariff was used for all three studies. The best possible outcome is 1 and the worst is -0.594.

4.1.2.2 EQ-VAS

EQ-VAS is a simple grading system for general health. The patient grades their perceived health on a VAS ranging from 0 to 100, where 100 indicates best possible health.

4.1.2.3 SF-36

The SF-36 is a comprehensive tool for evaluation of general health. (162) It consists of 36 questions in 8 dimensions, with both physical and psychological aspects of health and well-being being considered. The score is calculated using an algorithm weighting the answers. The score ranges from 0 to 100, where 100 indicates the best possible health. The form is well-validated in multiple patient categories and clinical settings. (163) In this thesis, SF-36 version 1 was used. The Swedish version has been validated. (164, 165) The SF-36 is also available as a shorter version, SF-12. Studies in this thesis used the full-length version.

4.1.2.4 VAS PAIN AND SATISFACTION

VAS pain and satisfaction are commonly used for evaluation in various settings. The scale usually spans from 0 to 10, where 0 is the best possible outcome and 10 is the worst. VAS pain and satisfaction has been found to correspond to THA outcome. (166, 167)

4.1.2.5 UCLA ACTIVITY SCORE

The UCLA activity score measures physical activity on a scale from 1 to 8 (English version). (168) A high number indicates high physical activity whereas a low score indicates low activity. It is commonly used for evaluation after THA. (169, 170) There are two versions of the UCLA activity score, one ranging from 1 to 10 and one ranging from 1 to 8. In these studies, the 8-point version has been used.

4.2   RADIOGRAPHIC EVALUATION

4.2.1   RADIOSTEREOMETRIC ANALYSIS (RSA)

In this thesis, patients were examined with so-called marker-based RSA (171, 172) To obtain distinct bony landmarks, 7–9 0.8 mm tantalum beads were inserted into the proximal femur during surgery with the use of a dedicated instrument. At follow-up, patients were examined with a calibration cage (Cage 77, RSA Biomedical, Umeå, Sweden) placed beneath the examination table. Two X-ray tubes were used, angled at about 40 degrees in relation to each other and with the central beams crossing each other in the hip region. Translation of the femoral head was used to represent migration of the stem. The examinations were analysed using UMRSA software (RSA Biomedical, Umeå, Sweden).

The patients were examined postoperatively and after 3 months, 6 months, 1 year, 2 years and 5 years.

When analysing RSA examination, it is important to evaluate the stability and distribution of markers. Mean error of body fitting is a measurement of the stability of markers, where the movement of the individual markers within a defined segment is calculated between examinations. The condition number describes the distribution of markers within the studied segment. Upper limits for mean error of rigid body fitting and the condition number were set at 0.35 and 150, respectively, in all three studies. Examinations with less than three bone markers visualized or with a mean error of rigid body fitting/condition number above the limits described were excluded from the analyses. The precision of the examinations was calculated using double examinations. The calculations were based on a 0-mean value between the examinations and corresponded to the standard deviation of the error x 2.66 based on a t-table and the available number of observations. In the precision calculation, a 99% reference interval was used in all three studies.

Migration of the femoral head centre along the three cardinal axes was accounted for. Y-axis translations correspond to proximal (+) or distal (-) migration, X-axis translations to medial (+) or lateral (-) migration and Z-axis translations to anterior (+) or posterior (-) migration of the right hip. Stem rotations were not analysed **(Figure 10).**
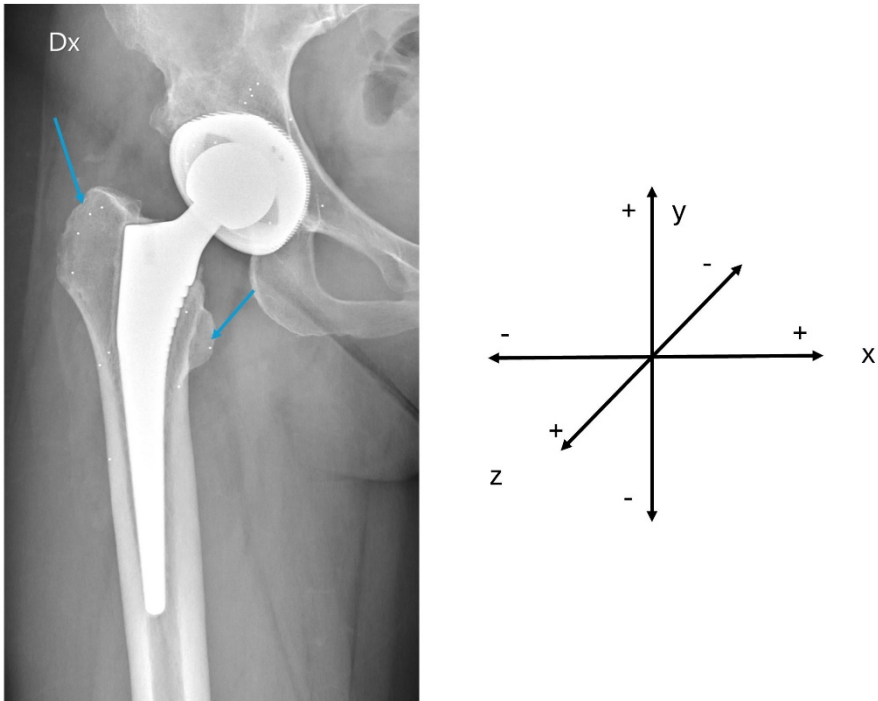
Figure 10. *Left: Frontal view of a total hip arthroplasty. Blue arrows indicate tantalum markers in the trochanteric and calcar region. Right: The coordinate system with origo in the femoral head centre.*

4.2.2 DXA

DXA was performed using a Hologic Discovery QDR DXA scanner and Hologic Apex software (v. 12.7.3; Hologic, Mississauga, Canada). The metal removal scan mode was used. Patients were examined postoperatively and at intervals stated in the study-specific sections below. BMD was analysed and related to Gruen zones. At follow-up, percentage-based change of BMD was calculated in relation to the postoperative value **(Figure 11)**.

Figure 11. DXA image and position of Gruen zones 1–7.

4.2.3 PLAIN RADIOGRAPHS

Patients were examined with plain radiographs (anteroposterior, lateral and pelvic views) 1–3 days postoperatively and at intervals stated in the study-specific sections. The radiographs were analysed by one author (KR) with respect to length of radiolucent lines, presence of welding spots and cortical hypertrophy on both the anteroposterior and lateral views **(Figure 12)**. The lengths of the radiolucent lines were related to the total length of the stem-bone interface and calculated as percentage. For the CFP stem, the remaining neck length was also evaluated. All examinations were analysed using the Mdesk software (UMRSA, Biomedical, Umeå, Sweden).

Figure 12. Plain radiograph, 6 years after insertion, showing cortical hypertrophy surrounding a CFP stem.

4.3   PAPER I

4.3.1   GENERAL CHARACTERISTICS

Study I was a prospective RCT comparing the SP-CL stem (Waldemar LINK, Hamburg, Germany) with the well-established Corail stem (DePuy Synthes, Raynham, MA, USA). In this study, the 2-year results were presented.

Patients were recruited from the outpatient clinic at Sahlgrenska University Hospital, Mölndal, Sweden.

4.3.2   PATIENT SELECTION

Patients were recruited between 1 April 2013 and 31 May 2017. A total of 301 patients planned for uncemented THA were assessed in the outpatient clinic during this period. A total of 80 patients were recruited. At 2 years, 71 patients (72 hips) remained in the study. One patient with both hips included received a SP-CL stem on one side and a Corail stem on the other **(Figure 13)**.

Randomization was done using envelopes. A study nurse managed the randomization process; neither the surgeons nor the patients were blinded. No stratification was used.

Inclusion criteria were anatomy suitable for both implant designs, age between 35 and 75 years, and primary or secondary osteoarthritis. Exclusion criteria were ongoing treatment with corticosteroids, active cancer disease, known osteoporosis or osteomalacia, inflammatory arthritis, or difficulties speaking or understanding the Swedish language.

A total of 16 surgeons performed the operations. The approach was decided based on the preference of the surgeon in question. A majority of the operations (51; 32 SP-CL, 19 Corail) were performed with a posterior approach (Moore); 24 operations (5 SP-CL, 19 Corail) were performed in a

direct lateral approach (Gammer). All operations were performed in the lateral position. Full weight bearing was permitted postoperatively.
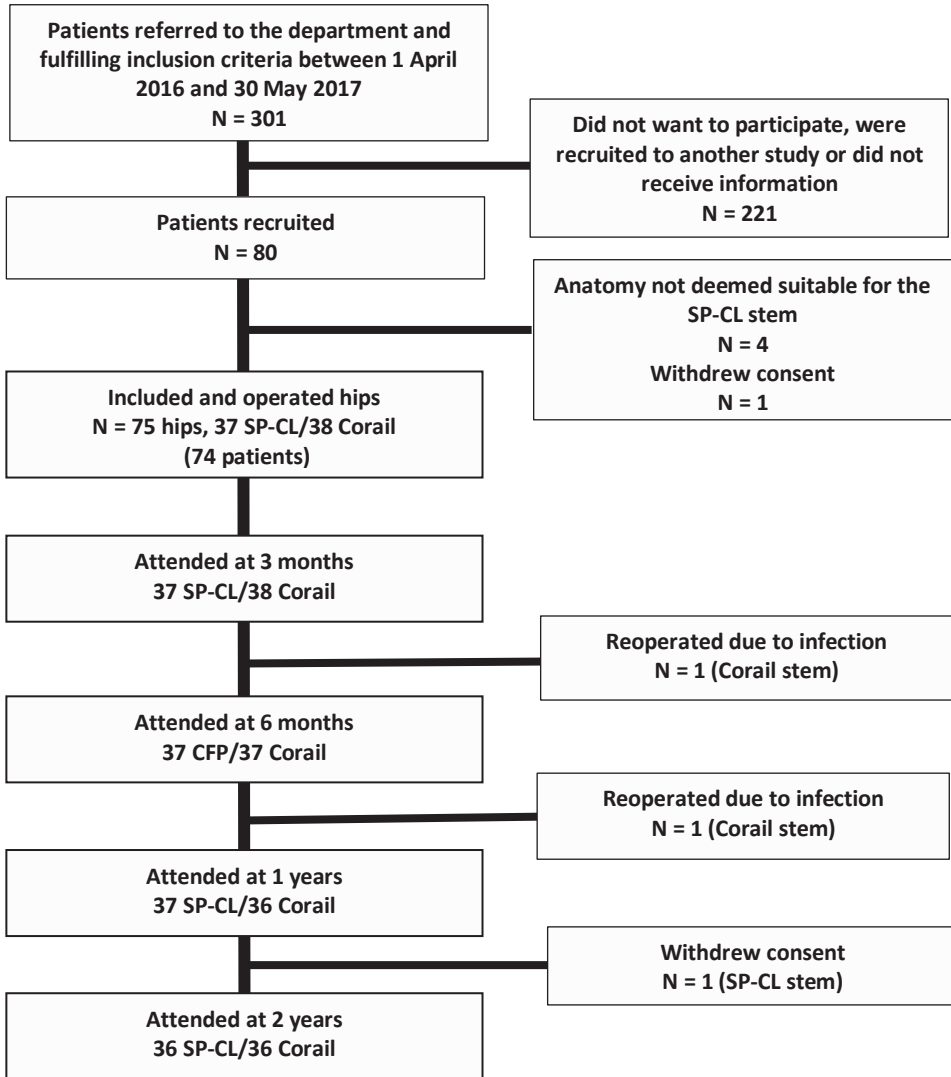
Figure 13. Flowchart Study I.

4.3.3 IMPLANTS

4.3.3.1 SP-CL

The SP-CL stem (Waldemar LINK, Hamburg, Germany) was introduced in 2014. It is defined as an anatomical stem with a slight curvature in the frontal plane and with an anteversion of 5 degrees. Proximally, it is plasma-sprayed with calcium phosphate (HX coating) and distally it is polished **(Figure 14)**.

*Figure 14. The SP-CL stem ©
Waldemar Link.*

4.3.3.2 CORAIL

The Corail stem (DePuy Synthes, Raynham, MA, USA) is an uncemented straight stem. It is fully covered with a hydroxyapatite coating. It was first introduced in the 1980s and has excellent results in several national arthroplasty registers. It has been the most used uncemented stem in Sweden since 2009 **(Figure 15) .**

Figure 15. The Corail stem. © Depuy Synthes.

4.3.3.3 ACETABULAR IMPLANT

All patients received an uncemented Delta TT-cup (Trabecular Titanium, Lima Corporate, Milan, Italy). Highly crosslinked polyethylene liners (X-lima) were used in both groups.

4.3.4 FOLLOW-UP PROTOCOL

4.3.4.1 CLINICAL OUTCOME

Patients filled out PROMs preoperatively and at 3 and 6 months and 1 and 2 years. The HHS was filled out by physicians at patient visits to the outpatient clinic, see **Table 1.**

Table 1. Number of examinations at follow-up. SP-CL/Corail

Score	Preop	3 m.	6 m.	1 y.	2 y.
OHS	36/33	34/35	30/33	34/28	33/35
EQ-5D	31/31	36/35	32/36	34/30	34/36
EQ-VAS	36/33	37/37	33/36	34/31	33/36
Pain-VAS	34/36	37/37	33/36	34/30	34/36
Satisfaction-VAS		37/37	33/36	34/31	34/36
FJS	35/33			34/31	34/36
HHS	38/36			36/37	35/36
UCLA	36/34			34/31	34/36

4.3.4.2   RADIOGRAPHIC EVALUATION

Radiographic evaluations (RSA, DXA and conventional radiographs) were carried out postoperatively, as shown in **Table 2** below.

In the RSA examinations, the median mean error of body fitting was 0.22 (interquartile range (IQR) 0.16–0.27) at 2 years, the median condition number was 30 (IQR 24–35), and the median number of markers used in the reference segment was 7 (IQR 6–8). All examinations fulfilled the RSA guidelines at each follow-up. Precision was determined using double examinations in 71 hips. Translation of the femoral head centre could be measured with a precision of 0.16 (medial (+) or lateral (-)), 0.16 (proximal (+) or distal (-)) and 0.41 (anterior (+) or posterior (-)). The first RSA examination was performed on median 1 day (range 0–2) after the operation.

Table 2. Number of examinations at follow up. SP-CL/Corail

Examination	*Post op*	*3 m.*	*6 m.*	*1 y.*	*2 y.*
RSA	37/38	37/38	37/36	37/36	36/36
DXA	36/35		37/38	36/34	36/32
Radiographs	37/38				34/34

4.3.5 STATISTICS

Our primary outcome was the OHS at 2 years. Secondary outcomes were proximal-distal migration based on RSA, the FJS and the EQ-VAS, BMD change in percent at 2 years, and revision for any reason within 2 years. We hypothesized that there would be no difference between groups.

Sample size calculations were based on the hypothesis that a 5-point difference in the OHS at 2 years could be detected at 80% power based on a

sample size of 32 observations in each group and an assumed standard deviation of 7. In total, 80 patients were recruited, to allow for dropouts. Recalculations of power based on 72 patients resulted in a power of 78% (difference of 5 points, true SD SP-CL=7.5, Corail=7.2.

All variables except BMD changes had non-normal distribution. Hence, the Mann-Whitney U-test and Wilcoxon's signed rank test were used for comparison between groups. For the BMD data, the T-test was used. All tests were two-sided and p-values <0.05 was assessed as significant. Mean values and 95% confidence intervals (CIs) or medians and IQRs are presented.

The mean difference in migration, measured with RSA, over the whole study period was evaluated using linear mixed models. In this analysis age, gender, type of stem, visit (factor variable), and the interaction of stem-type by visit as fixed effects were entered. In an additional model we also included choice of incision as a fixed effect. Patient was a random factor. An unstructured covariance pattern was used. The absolute migration values were log-transformed to obtain normally distributed data. The obtained results were anti-logarithmized and are presented as geometric means and ratios of geometric means and 95% confidence limits.

All statistical analyses were performed using the IBM SPSS v. 24 (IBM, Armonk, New York, USA) and SAS/STAT (SAS institute, Solna, Sweden).

4.3.6 ETHICS AND FUNDING

All patients gave consent in accordance with the Helsinki guidelines. The study underwent ethical review by the Gothenburg ethical committee (nr 140-15) and was registered in the National Clinical Trials database (NCT04599582)

4.4   PAPER II

4.4.1   GENERAL CHARACTERISTICS

Study II was a prospective RCT comparing the CFP stem (Waldemar LINK, Hamburg, Germany) with the Corail stem (DePuy Synthes, Raynham, MA, USA). Due to its long-term follow-up and excellent results in national registries, the Corail stem was used as the reference stem. The 5-year results were presented in this study.

Use of the direct lateral approach was determined for all patients in accordance with the study protocol. Full weight bearing was encouraged postoperatively.

4.4.2   PATIENT SELECTION

Patients eligible for THA with clinical and radiological signs of osteoarthritis were selected from the outpatient clinic at Sahlgrenska University Hospital, Mölndal, Sweden, between May 2012 and May 2014. In total, 458 patients eligible for uncemented fixation were examined at the outpatient clinic. Exclusion criteria were previous treatment with corticosteroids and low activity due to comorbidities or generalized joint disease. The randomization process was managed by a study nurse, using envelopes. No stratification was used. Neither patients nor surgeons were blinded. All patients had an anatomy suitable for both implant design and were aged between 35 and 75 years at inclusion. A total of 82 patients (40 CFP, 42 Corail) entered the study. At 5 years, a total of 71 patients (35 CFP, 36 Corail) remained in the study **(Figure 16).**

In two cases, the study protocol was violated – one patient was operated with a posterior approach and one patient received a Trilogy cup (ZimmerBiomet, Warzaw, IN, USA) due to a lack of sterile instruments. Both patients remained in the study.
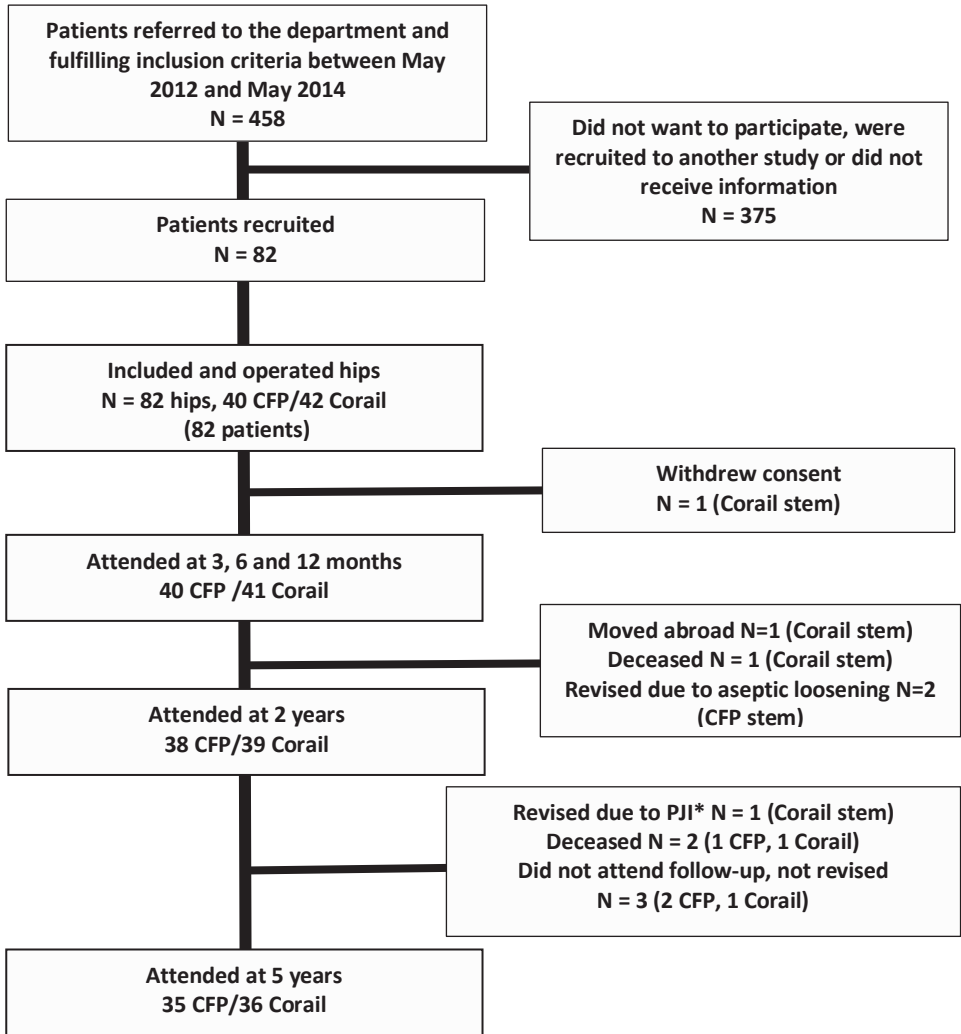
Figure 16. *Flowchart Study II. *Periprosthetic Joint Infection*

4.4.3 IMPLANTS

4.4.3.1 CFP

The CFP stem is available in 6 different sizes, with two types of curvature and two different CCD angles (117 and 126 degrees, respectively). It is straight in the sagittal plane. The stem is categorized as a short, collum-sparing stem. The rationale behind the design is to preserve proximal bone and to mimic the femoral anatomy. The entire stem is coated with calcium phosphate **(Figure 17)**.

Figure 17. The CFP stem © Waldemar Link.

4.4.3.2   CORAIL

See information for Paper I.

4.4.3.3   ACETABULAR COMPONENT

All patients (except one) received a Delta TT-cup (Trabecular Titanium, Lima Corporate, Milan, Italy). Highly crosslinked polyethylene liners (X-lima) were used in both groups. A Longevity liner was used for the single Trilogy cup.

4.4.4   FOLLOW-UP PROTOCOL

4.4.4.1   CLINICAL EVALUATION

Patients filled out the questionnaires preoperatively, at 3 months and at 1, 2 and 5 years. The HHS was filled out by physicians at patient visits at the outpatient clinic. The numbers of patients participating in clinical evaluations are presented in **Table 3**.

Table 3. Numbers of examinations at follow-up. CFP/Corail.

Score	Preop	3 m.	1 y.	2 y.	5 y.
OHS	39/41		36/41	37/38	34/36
EQ-5D	38/40	37/40	36/40	37/39	34/36
EQ-VAS	38/40	37/41	37/40	37/39	33/36
Pain-VAS	38/40	37/41	37/41	37/39	34/36
Satisfaction-VAS		37/41	37/40	37/39	34/36
HHS	22/22		37/40	34/38	33/34
UCLA act.	38/41	37/41	35/40	37/38	33/34

4.4.4.2 RADIOLOGICAL EVALUATION

The numbers of patients attending the radiographic and DXA examinations are presented in **Table 4**.

Table 4. Numbers of examinations at follow-up. CFP/Corail.

Examination	Post op	3 m.	6 m.	1 y.	2 y.	5 y.
RSA	40/41	39/40	39/40	39/40	38/38	35/36
DXA	37/38	39/41	40/40	39/40	36/39	26/33
Radiographs	40/41			40/41	38/39	35/36

At 5 years, the median error of mean body fitting was 0.18 (IQR 0.01–0.34) and median condition number was 33 (IQR 16–116). The median number of markers used in the reference segment was 7 (IQR 3–9). The precision of RSA examinations was presented in the 2-year follow-up study by Klein et al. 2019. (173) The medial (+) or lateral (-), proximal (+) or distal (-), and anterior (+) or posterior (-) translation of the femoral head centre could be measured with a precision of 0.18, 0.18, and 0.45 mm, respectively. All but two of the attending patients had complete RSA follow-ups. Those two patients had missing examinations at 3 or 6 months. These data were extrapolated and included in the analysis. All RSA examinations fulfilled the RSA guidelines for mean errors of body fitting and condition number. RSA examinations were carried out at a median of 2 days (range 1–20) postoperatively. An explanation to why one patient did not undergo RSA examination until day 20 cannot easily be found.

At 5 years 15 patients (10 CFP and 5 Corail) did not undergo DXA, this due to a lack of capacity and logistical problems. Another four patients lacked examinations at earlier times. Thus, 53 patients had complete follow-up data.

Conventional radiographs were analysed for tip sclerosis, welding and radiolucent lines. The amount of neck length resorption was measured for all

CFP stems and for those Corail stems supplied with a collar. The results are presented as the quotient between remaining neck (A in **Figure 18**) and length from lesser trochanter to stem collar on postoperative radiographs (B).
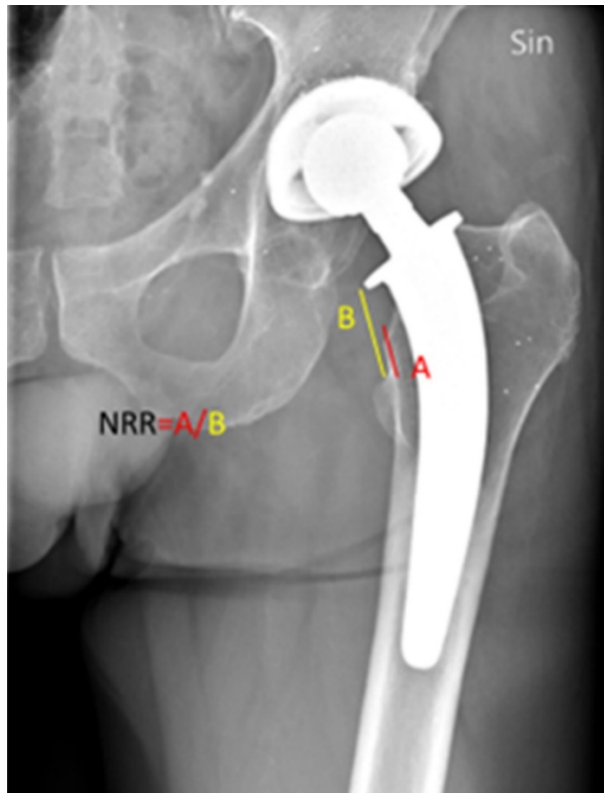
Figure 18. *Neck resorption ratio calculated for the CFP stem.*

4.4.5 STATISTICS

The OHS was used as the primary outcome. Secondary outcomes were subsidence, BMD changes and additional PROM data.

Determination of sample size was based on the assumption that a group difference of 5 points in the OHS could be detected, provided a standard deviation of 7. A total of 32 patients in each group was needed to reach 80% power. The actual power at 5 years was 86%.

Most parameters had non-normal distribution. Thus, the Mann-Whitney U test was used for comparisons between groups. The BMD data had a nearly normal distribution, and a T-test was used for analysis. All tests were 2-sided and a p value < 0.05 was considered significant. Repeated measure analysis (linear mixed models) was used to evaluate migration and change of BMD over the 5 follow up occasions up to 5 years. In both models type of stem (CFP or Corail), age, sex, visit and stem by visit were explanatory variables. Patient was a random factor. An unstructured covariance pattern was applied. The overall treatment effects on femoral head migration and BMD changes over time are presented as differences in estimated means with 95% confidence limits.

All statistical analyses were performed using the IBM SPSS v. 24 (IBM, Armonk, New York, USA) and SAS/STAT (SAS institute, Solna, Sweden).

4.4.6 ETHICS AND FUNDING

The study complied with the Helsinki guidelines and all patients gave written consent. Ethical approval was retrieved from the Gothenburg ethical board (Nr 234-12). The study was registered in the National Clinical Trials (NCY02983526).

4.5 PAPER III

4.5.1 GENERAL CHARACTERISTICS

The study was a prospective RCT comparing the Fitmore (ZimmerBiomet, Warsaw, IN, USA) stem with the CLS Spotorno stem (ZimmerBiomet, Warsaw, IN, USA). Patients underwent one-stage bilateral THA. This study design was used to minimize the risk of bias of individual differences in BMD and migration patterns.

4.5.2 PATIENT SELECTION

Patients assessed at the outpatient clinic at Sahlgrenska University Hospital, Mölndal, Sweden, with bilateral arthrosis eligible for THA, were screened for participation. A total of 44 patients (88 hips) were enrolled in the study between 2011 and 2016. Inclusion criteria were anatomy suitable for both implants, general health compatible with bilateral one-stage surgery, and age between 35 and 75 years. Exclusion criteria were treatment with corticosteroids, inability to understand or speak the Swedish language, short life expectancy, osteopenia or osteomalacia, or ongoing oncologic treatment. The hip causing most pain was randomized to either implant. The second hip was operated with the type of stem not used for the first one. The randomization process was conducted by a study nurse using envelopes. No stratification was used. At 5 years, 35 patients remained in the study **(Figure 19)**.

All operations were performed by one of four surgeons using a direct lateral approach. Immediate weight bearing was encouraged postoperatively. The study protocol was breached in one case. The patient developed blisters on the contralateral side during the first operation, and the second hip surgery was postponed. The patient remained in the study, but the results were not included in the analysis.
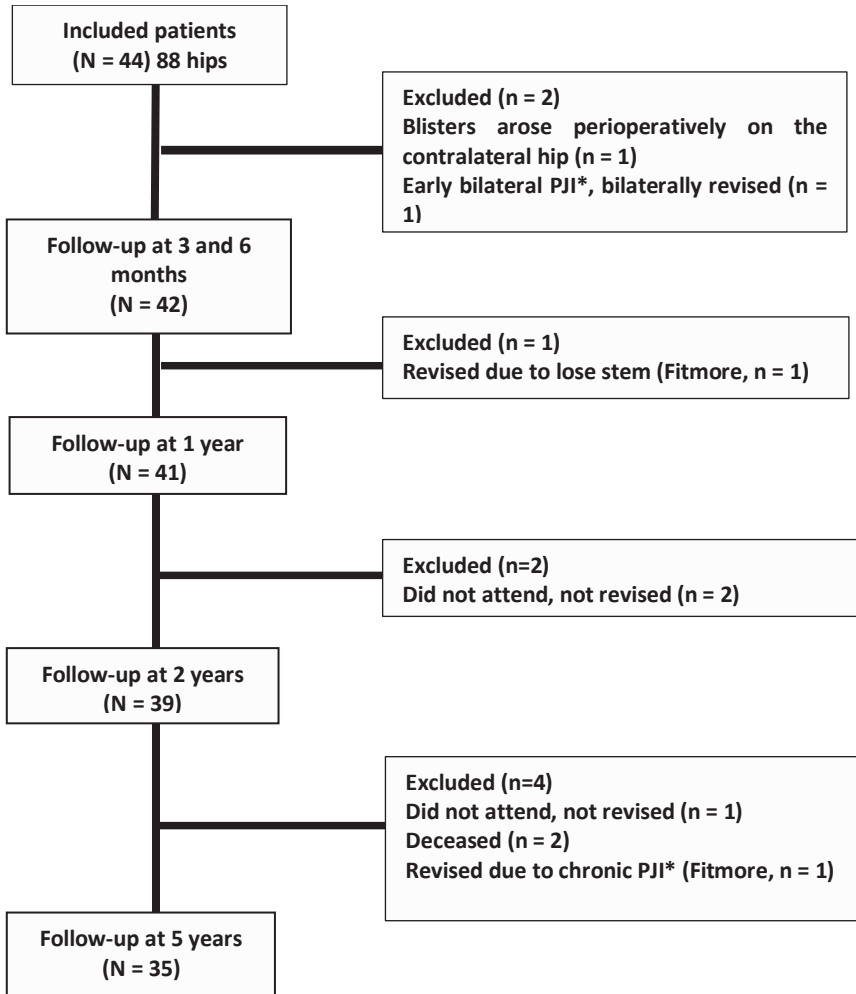
Figure 19. *Flowchart Study III. *PJI = periprostethic joint infection.*

4.5.3 IMPLANTS

4.5.3.1 FITMORE

The Fitmore stem is categorized as a short stem with mainly metaphyseal fixation. It is slightly curved in the frontal plane and has a trapezoid cross-section. The stem is made of a titanium alloy that is plasma spray-coated with titanium alloy proximally and grit-blasted distally. The system includes the component families (A, B and C) where family B has two different offsets to restore anatomy in a wide spectrum of femoral morphologies **(Figure 20)**.

Figure 20. *The Fitmore stem ©*
Zimmer Biomet.

4.5.3.2   CLS SPOTORNO

The CLS Spotorno stem is a straight stem, trapezoidal in both the frontal and the lateral view. The trapezoidal shape promotes stability even if the stem settles. It is made of a titanium alloy and has proximal grooves to enhance bone in-growth. The implant is available with three different CCD angles; in this study, only 125° and 135° stems were used. The stem has been on the market in its current design since the 1990s and has excellent results in arthroplasty registries. In this study, the CLS stem was used as the reference stem **(Figure 21)**.

Figure 21. The CLS stem © Zimmer Biomet.

4.5.3.3   ACETABULAR COMPONENT

All patients received a Trilogy cup (Zimmer Biomet, Warsaw, IN, USA). A highly cross-linked polyethylene insert (Longevity) was used in all patients.

4.5.4 FOLLOW-UP PROTOCOL

4.5.4.1 CLINICAL EVALUATION

Patients were evaluated using both hip-specific and general health assessment tools. There is no validated PROM for bilateral operations, so an unvalidated score was used for hip-specific evaluation. PROMs were filled out preoperatively and at 3 months and 1, 2 and 5 years postoperatively. VAS-pain and VAS-satisfaction were recorded separately for the two hips, though no bilateral recording was made preoperatively. At 5 years, bilateral assessment of VAS-pain and VAS-satisfaction was missing in 10 patients. Only 25 patients were evaluated bilaterally and included in the analysis. The numbers of patients clinically evaluated on each occasion are presented in **Table 5**.

Table 5. Numbers of examinations at each follow-up.

Score	Preop	3 m	1 y	2 y	5 y
EQ-5D	40	40	38	39	33
EQ-VAS	40	43	38	38	32
VAS-pain **Bilateral assessment**	40 0	40	35	37	25
VAS-satisfaction **Bilateral assessment**		40	35	37	25
SF-36	37	39	39	39	33
My hip	40			37	33
HHS **Bilateral assessment**	42		39	36	33
UCLA act. Score	39	39	37	36	32

4.5.4.2 RADIOLOGICAL EVALUATION

Data on patients with bilateral radiographic and DXA examination are presented in **Table 6**.

Table 6. Numbers of bilateral examinations.

Examination	Post op	3 m.	6 m.	1 y.	2 y.	5 y.
RSA	41	40	40	40	38	33
DXA	39	40	40	39	39	33
Radiographs	41	41		42	40	34

Patients were followed up until revision, regardless of reason for revision.

At 5 years, the median value of the mean error of body fitting was 0.18 (IQR 0.15–0.22), the median condition number 31 (IQR 26–42), and the median number of markers in the reference segment 7 (IQR 5–8). In one patient, the examinations did not fulfil the RSA guidelines for condition number (> 150). In this case, both hips were excluded from analysis. One patient had missing data at 6 months; these data were extrapolated and included in the analysis. All other patients had complete RSA follow-up to 5 years. The first RSA examination was performed on a median of 4 days (range 0–7) after the operation.

Precision analysis of the RSA examinations was carried out through double examinations in 85 hips. Translation of the femoral head centre could be measured with a precision of 0.28 mm medial (+) or lateral (-), 0.22 mm proximal (+) or-distal (-), and 0.7 mm anterior (+) or-posterior (-).

4.5.5 STATISTICS

My hip was used as the primary outcome at 2 years. The results were cross-tabulated, and Fisher's exact test was used for analysis. RSA and PROM data were non-normally distributed and paired assessment using Wilcoxon's signed rank test was carried out. BMD data had a normal or nearly normal distribution, and the paired T-test was used for assessment. Distribution of data was assessed using plotting and tests (Shapiro-Wilk, Kolmogorov-Smirnov). All tests were two-sided, and the significance level was set to 5%. Sample size calculation was based on the assumption that there would be 35 patients remaining in the study at 2 years. Provided that 26 of them preferred one of the implants, a power exceeding 80% would be reached. All statistical analyses were carried out using SPSS v. 24.0.00 (IBM, Armonk, New York, USA).

4.5.6 ETHICS AND FUNDING

This study was performed in accordance with the Helsinki Declaration (Ethical approval 617-10, Regional Ethical Committee Gothenburg, Sweden). Written informed consent was obtained from all patients. The study was registered in ClinicalTrials.gov (reg. nr. NCT03112785).

4.6   PAPER IV

4.6.1   GENERAL CHARACTERISTICS

The study was a register-based study on short stems. Patients who had received a short stem were selected from the Australian (AOANJRR), Dutch (LROI) and Swedish (SAR) arthroplasty registries. A matched cohort with patients who had undergone surgery with a standard stem was used for comparison. The overall cumulative revision rate (CRR) for short stems were calculated and compared to that for the matched standard stems. First-time stem revisions were identified and analysed with respect to the type of stem used. The stem used in the revision was categorized as either a standard-length stem (< 160 mm) or a revision stem (≥ 160 mm or modular stem). This was used as a proxy to classify revisions as 'easy' and 'bone-sparing', without invasion of the distal femur. The overall CRR for second revisions was also calculated.

4.6.2   NATIONAL ARTHROPLASTY REGISTERS

4.6.2.1   AUSTRALIAN ORTHOPAEDIC ASSOCIATION NATIONAL JOINT REPLACEMENT REGISTER (AOANJRR)

The Australian arthroplasty register was started in 1999, becoming national in 2002, and a total of 642,704 total hip replacements had been reported to the register by 31 December 2022. The data are validated in multiple steps, comparing the reported procedures with health department data. The validation process identifies procedures not reported to the register; sufficient data are then retrieved from the state unit records to request data from hospitals. According to calculations performed, the completeness of the register is approximately 99.2% for hip, knee and shoulder replacements. The AOANJRR is the only register globally that reports short stems separately.

4.6.2.2 THE DUTCH ARTHROPLASTY REGISTER (LANDELIJKE REGISTRATIE ORTHOPEDISCHE INTERVENTIES - LROI)

The Dutch national register contains data on arthroplasties since 2007. It is a population-based register established by the Dutch Orthopaedic Association. In total, 550,227 primary THAs were reported to the register between 2007 and 2022. The register is validated in multiple steps, comparing the reported data with data in the hospital information system. The completeness for primary THA is high, approximately 99%; for revisions, the corresponding figure is 97%. Data on both patient and implant characteristics are collected. Prosthesis characteristics are derived from an implant library with information provided from the manufacturers.

4.6.2.3 SWEDISH ARTHROPLASTY REGISTER (SAR)

The SAR is a merger of the former Swedish Hip Arthroplasty Register and the Swedish Knee Arthroplasty Register. In 2021, they were merged into the SAR. The Swedish Hip Arthroplasty Register was founded in 1979, making it one of the oldest hip arthroplasty registries globally. Between 1979 and 2022, 541,078 primary hip arthroplasties were reported to the register. The data are validated through a multi-step process where the reported data are compared to data in the patient register managed by the Swedish National Board of Health and Welfare. The completeness of the register was approximately 98% in 2022. The register contains data on patients as well as implant characteristics. Information on implants is derived from information given by the manufacturers.

4.6.3 PATIENTS AND IMPLANTS

4.6.3.1 DEFINITION OF SHORT STEM

The Australian definition of short stems was used to select implants from the AOANJRR and the SAR. This states that a short stem is designed as a short implant and has mainly metaphyseal fixation. This overlaps the Dutch definition, which was used for selection in the LROI. (5, 174)

4.6.3.2 STUDY POPULATION

Patients operated with a short stem THA between 2007 and 2022 were identified in each of the three registries. Patients operated with THA following malignancy and with metal-on-metal bearing were excluded. All other patients were included, and their primary surgery and any subsequent first and second revisions were retrieved from the registries. A matched cohort with patients operated with the three most common uncemented stems in each register was used as control. The matching was done separately in each of the three registries. A 1:2 propensity score matching using the nearest neighbour was performed based on age, sex, diagnosis, bearing material and surgical approach. Information on approach was first recorded in the AOANJRR in 2015; therefore, the Australian cohort was not matched on approach.

In total, 16,258 patients operated with short stems were identified. The matched cohort comprised 32,515 patients (**Figure 22**).

Reasons for revisions varies between registries, to harmonize six categories were used: aseptic loosening, periprosthetic fracture, periprosthetic joint infection, dislocation, other and missing. Reasons such as leg length discrepancy, implant failure including fracture, and pain without any other reason were cathegorized as "other".

In the LROI and the AOANJRR multiple reasons for revision can be recorded, while up to two reasons can be recorded in the SAR. Therefore, a hierarchical structure (infection, aseptic loosening, periprosthetic fracture, dislocation, other reasons and 'missing') was used for all registries.

Revision was defined as a new surgical intervention where any part of the implant was removed or exchanged. A total of 427 first revisions, of which 239 were revisions of the femoral component, were identified among the short stem THAs. The corresponding figures for the standard stem THAs were 756 and 352 (**Figure 17**). Implant used for first revision of the femoral component was identified and categorized as either standard implant or revision implant (see below for definitions). Further, second revisions (all revisions, all reasons) were also identified (short stem primary THA: 79, standard stem primary THA: 142) and reasons for second revisions were recorded.

Figure 22. *Flow chart study IV.*

Identified in registries:
16,258 Short stem THAs
32,515 Standard stem THAs

First revisions (All reasons/all revisions):
427 revision procedures short stem THAs

First revisions (All reasons/all revisions):
756 revision procedures standard stem THAs

Stem revisions:
239 stem revision procedures short stem THAs

Stem revisions:
352 stem revision procedures standard stem THAs

Excluded:
N = 8: only extraction
N = 9: no information on implants used in revision surgery

Excluded:
N = 5: only extraction
N = 4: no information on implants used in revision surgery

Included in analysis of stem used in first revision:
222 Short stem THAs

Included in analysis of stem used in first revision:
343 Standard stem THAs

Second revisions (any cause and procedure:
79 Short stem primary ....

Second revisions (any cause and procedure:
142 Standard stem primary THA

4.6.3.3   IMPLANTS USED IN PRIMARY THA

There are also differences in the implant used in primary THA. In the AOANJRR, Taperloc Microplasty, Optimys and Minihip were used in almost 88% of the short stem cases. In the LROI, Fitmore, Optimys and CFP were the three most commonly used short stems (comprising 95.5% of the cases). In the SAR, the CFP, Fitmore and Proxima stems comprised almost 94% of the short stems. In table 7 the total amount of each stem used is presented. With the standard-length stems, only Corail were used in all three countries **(Table 7).**

4.6.3.4   DEFINITION OF STEM USED IN FIRST REVISION

Implants used in first revisions were classified as standard stems (less than 160 mm in length) or revision stems (160 mm or longer). For modular stems, only the length of the proximal part was registered – the length of the distal part was not known. Hence, all modular stems were classified as revision stems due to distal fixation and the design of the stems.

Table 7. Stems used in primary surgery.

Short stems:	N (%)
CFP (Waldemar Link, Hamburg, Germany)	976 *(6)*
Collo-MIS (Lima Corporate, Milan, Italy)	15 *(0.1)*
Fitmore (Zimmer Biomet, Warzaw, IN, USA)	2,800 *(17.1)*
GTS (Zimmer Biomet, Warzaw, IN, USA)	96 *(0.6)*
Mayo (Zimmer Biomet, Warzaw, IN, USA)	43 *(0.3)*
M**etha** (B. Braun Aesculap, Tuttlingen, Germany)	123 *(0.8)*
MiniHip (Coringroup, Circencester, UK)	1,457 *(9.0)*
MiniMax (Medacta International, Castel San Pietro, Switzerland)	415 *(2.5)*
N**anos** (Smith and Nephew, London, UK)	704 *(4.3)*
Optimys (Mathys, Bettlach, Switzerland)	4,549 *(28.0)*
Proxima (Smith and Nephew, London, UK)	93 *(0.6)*
Pulchra System (Adler Orthro, Cormano, Italy)	63 *(0.4)*
Silent (Depuy Synthes, Warsaw, IN, USA)	54 *(0.3)*
Taperloc Microplasty (ZimmerBiomet, Warzaw, IN, USA)	4,870 *(30.0)*
Standard stems:	
Corail (Depuy Synthes, Warsaw, IN, USA)	15,753 *(48.4)*
Po**larstem** (Smith and Nephew, London, UK)	5,171 *(15.9)*
Quadra-H (Medacta, Castel San Pietro, Switzerland)	4,743 *(14.6)*
Alloclassic Zweymuller (ZimmerBiomet, Warzaw, IN, USA)	1,260 *(3.9)*
Taperloc Complete (ZimmerBiomet, Warzaw, IN, USA)	4,661 *(14.3)*
C**LS** (Zimmer Biomet, Warzaw, IN, USA)	609 *(1.9)*
Bi-Metric (ZimmerBiomet, Warzaw, IN, USA)	318 *(1.0)*

4.6.4 STATISTICS

A propensity score matching (1:2) using the nearest neighbour was performed based on the variables presented above. In the LROI and AOANJRR data the standardized mean differences of the matching balance were all <0.1. In the SAR data the standardized mean difference of the matching balance varied between <0.10 and 0.26.

Descriptive statistics were used to summarize patient, prosthesis and procedure characteristics. Kaplan-Meier analysis was performed to calculate the overall survival of primary and secondary surgery up to 12 and 5 years, respectively. Beyond that, the number of patients at risk (< 150) was judged to be too low for further analysis. The log-rank test was used for comparison of CRR between groups. The significance level was set at 5%.

The Australian register does not report the status at revision of individual components. Thus, despite that the number of stem revisions was known, the reason for their revision was not specified. Therefore, we had only access to revision rates based on the outcome "all types of revision due to any reason" concerning the Australian data.

Choice of stem (<160 mm, ≥160 mm or modular) was evaluated using the chi-squared test. Stratified analysis of choice of stem used in first revision was performed with stratification by age and sex. The age groups were younger than 63 years and 63 years or older (median age in population). Sub-analysis of aseptic femoral stem revisions was also performed. SPSS (IBM, Armonk, New York, USA) and R (The R Foundation for Statistical Computing, Vienna, Austria) were used.

4.6.5 ETHICS AND FUNDING

Ethical approval to share anonymous data from the SAR was granted from the National Ethical Board of Sweden (Nr: 2022-06130-02). For the LROI and the AOANJRR, no ethical approval was required – both registers use opt-out

systems to obtain informed consent from patients. All data included in the study were anonymized. The study was funded by the Dutch Arthroplasty register, the Gothenburg Medical Association and the Swedish state under the agreement between the Swedish government and the county councils, the ALF agreement (721791).

05

5 RESULTS

5.1   PAPER I

5.1.1 BASELINE DEMOGRAPHICS

Baseline demographics did not differ between groups. Notable is the difference in the distribution of incisions, with more SP-CL stems inserted with a posterior approach **(Table 8).**

Table 8. Baseline demographics.

Factor	SP-CL N = 37	Corail N = 38
Age, years (mean (95% CI)) **Median (IQR)**	58 (55–61) 56 (51–65)	62 (60–64) 62 (58–68)
Sex, male/female	17/20	14/24
Diagnosis, nr (%) Osteoarthritis, primary Osteoarthritis, secondary Missing	34 (92) 3 (8)	37 (97) 1 (3)
ASA class 1 2 3 > 4	16 20 1 0	10 27 1 0
BMI, kg/m² Median (IQR**)**	26.6 (25.5–30.0)	27 (23.5–29.0)
Charnley class A B C Missing	19 2 11 5	14 6 11 7
Surgical approach Posterior Direct lateral	32 5	19 19

5.1.2 CLINICAL RESULTS

During the first three months postoperatively, there was a steep improvement in clinical outcome. The OHS almost doubled during the first months postoperatively, after which the improvement slowed down **(Figure 23)**. Between 3 and 6 months, there was a statistically significant increase (p < 0.001) within both groups, but thereafter patients reported no increased quality of life, less pain or better function regardless of the implant chosen. In the linear mixed models on OHS the estimated mean difference up to 2 years was –0.70 (CI –4.3 to 2.9) and after adjustment for incision 0.04 (CI –4.0 to 4.0), hence no difference could be observed between groups.
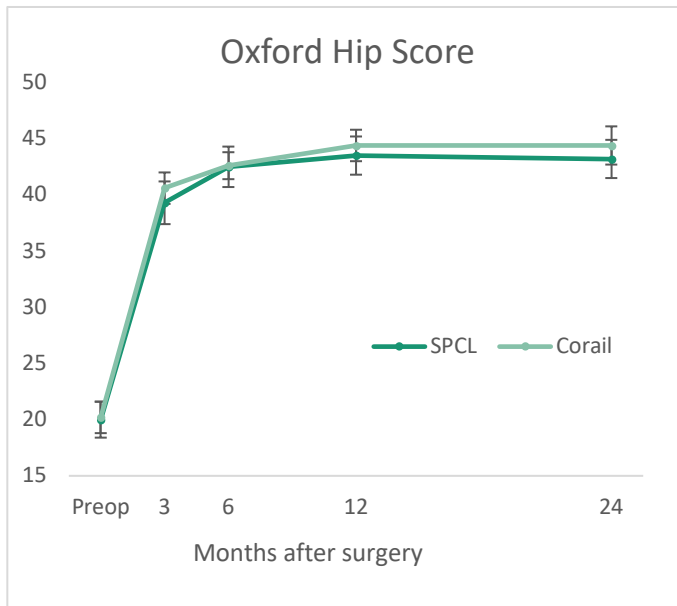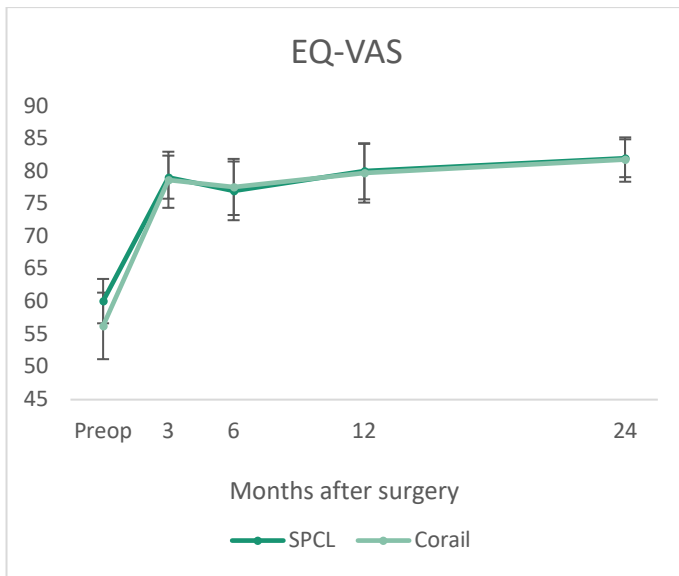
Figure 23. *Mean OHS and EQ-VAS scores (+/- 2 standard error of the mean) preoperatively, at 3 and 6 months, and 1 and 2 years. All available patients (see Table 1) were included in the analysis.*

All other PROMs and the HHS followed the same pattern, with a steep improvement that then gradually slowed down. After 6 months, no further improvement within groups could be seen. At 2 years, no statistical difference could be seen in any PROM or the HHS between groups **(Table 9)**.

Table 9. Patient-reported outcome measures and Harris Hip Score. VAS pain and VAS satisfaction were reported on a scale 0–100 where 0 is the best result. EQ-VAS was reported on a scale 0–100 where 100 is the best result. * Mann-Whitney U-test

Instrument	Type of stem	Preoperative		2 years		P-value*
		N	Median *IQR*	N	Median *IQR*	2 years
Oxford Hip Score	SP-CL	36	20 *16–25*	33	46 *42–48*	0.9
	Corail	33	21 *16–26*	35	47 *42–48*	
Harris Hip Score	SP-CL	37	54 *45–65*	34	100 *95–100*	0.8
	Corail	38	56 *43–65*	34	100 *96–100*	
Forgotten Joint Score	SP-CL	35	6 *2–25*	34	74 *48–94*	0.7
	Corail	33	6 *1–15*	35	83 *46–98*	
EQ-5D	SP-CL	31	0.55 *0.23–0.60*	34	0.97 *0.90–0.97*	0.5
	Corail	31	0.41 *0.20–0.66*	36	0.93 *0.87–0.97*	
EQ-VAS	SP-CL	31	60 *30–80*	33	85 *75–95*	0.9
	Corail	32	60 *50–74*	36	84 *75–95*	
VAS Pain	SP-CL	36	64 *58–72*	34	5 *0–14*	0.3
	Corail	34	62 *57–75*	36	2 *0–11*	
VAS Satisfaction	SP-CL			34	2 *0–16*	0.4
	Corail			36	1 *0–7*	
UCLA	SP-CL	36	4 *3–5*	34	4 *3–5*	0.5
	Corail	34	4 *3–5*	36	4 *4–5*	

5.1.2.1 REVISION

Two patients (Corail) were revised due to periprosthetic joint infection (PJI); no patient was revised for non-infectious reasons.

5.1.3 RADIOLOGICAL RESULTS

5.1.3.1 RSA

The two types of stems displayed similar migration patterns, with early migration followed by stabilization. Both types of stems subsided, medialized and migrated posteriorly (corresponding to retroversion of the femoral head) during the first 3 months postoperatively. The SP-CL stem showed a slightly more scattered migration pattern, but no statistically significant difference could be seen between groups at 3 months. (Medial-lateral p=0.8; proximal-distal p=0.09; anterior-posterior p=0.5, Mann-Whitney U-test) Beyond 3 months little further migration was seen **(Figure 24)**.
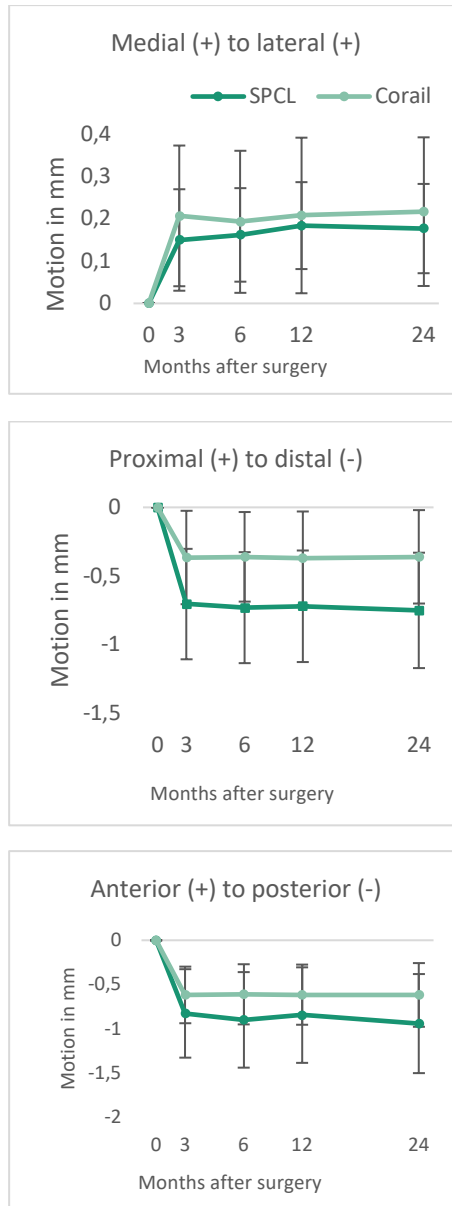
Figure 24. Mean migration (mm) ±2 standard error of the mean.

When analysed using linear mixed models, no difference could be seen between implants in the first model (including stem, age, sex, visit and stem by visit as explanatory variables). When incision was added the SP-CL stem showed a statistically significant greater subsidence than the Corail stem **(Table 10)**.

Table 10. Overall treatment effect SP-CL/Corail (3, 6, 12 and 24 months)

Direction or type of migration	Ratio of estimated mean (95% CI)
Model 1	
Medial or lateral	1.0 (0.6-1.6)
Proximal or distal	2.0 (0.95-4.0)
Anterior or posterior	0.9 (0.5-1.8)
Model 2 (+incision)	
Medial or lateral	0.9 (0.5-1.6)
Proximal or distal	2.7 (1.3-5.7)
Anterior or posterior	0.9 (0.5-1.9)

Migration between the two last examinations were calculated to assess individual late movements. Between 1 and 2 years the median migration along either of the three axes was less than 0.1 mm regardless of stem **(Table 11)**. During the second year, 5 SP-CL and 9 Corail showed migration above the 99% detection level along any of the 3 axes. In the SP-CL group, four stems only subsided and one stem showed migration in both the anterior-posterior and the medial-lateral direction. With the Corail stem, four stems migrated only in the anterior-posterior direction and three in only the medial-lateral direction. The Corail stem migrated in both the proximal-distal direction and medial-lateral direction in one case and in both the medial-lateral direction and the anterior-posterior direction in one case.

Table 11. Migration between 1 and 2 years. *Mann Whitney U-test

	Type of stem	Median (mm) *IQR*	p-value*
1–2 years			
Medial (+)-lateral (-)	SP-CL	0.04 *-0.05–0.11*	0.4
	Corail	0.007 *-0.06–0.07*	
Proximal (+)-distal (-)	SP-CL	-0.02 *-0.11–0.02*	0.2
	Corail	-0.01 *-0.07–0.07*	
Anterior (+)-posterior (-)	SP-CL	-0.07 *-0.19–0.05*	0.4
	Corail	-0.03 *-0.19-0.11*	

5.1.3.2 BMD

In the lateral zones (1–3), a decrease could be seen for both types of stems without any statistically significant difference between groups. In the distal zones (4, 5), there was no obvious change of BMD in either of the groups. Unlike Corail, SP-CL showed a slight decrease in zone 6. In zone 7, both types of stems showed a marked decrease in BMD, with a significantly larger decrease in the SP-CL than in the Corail group (p = 0.003) **(Table 12, Figure 25)**.

Table 12. Postoperative bone mineral density by Gruen zones and postoperative mean change at 6 months and 1 and 2 years. Only patients with complete follow-up are included in analysis (SP-CL 34, Corail 28) P-value calculation at 2 years includes all available examinations. *Ind. T-test

Gruen zone	Type of stem	6-month mean change in %. 95% CI	1-year mean change in % 95% CI	2-year mean change in % 95% CI	p-value* at 2 years
1	SP-CL	-7.5 -11.0– (-4.1)	-6.7 -10.2– (-3.1)	-7.6 -11.1– (-4.1)	0.4
	Corail	-7.5 -10.6– (-4.3)	-6.9 -10.1– (-3.7)	-5.9 -9.6– (-2.2)	
2	SP-CL	-6.9 -10.9– (-3.6)	-5.2 -8.0 – (-2.5)	-7.1 -10.5– (-3.7)	0.9
	Corail	-2.4 -5.5–0.7	-4.1 -7.1– (-1.1)	-7.1 -10.5– (-3.6)	
3	SP-CL	-0.7 -2.9–1.4	-1.3 -3.1–0.5	-1.9 -4.0–0.1	0.7
	Corail	-1.9 -4.7–0.7	-0.1 -2.6–2.4	-2.8 -4.9– (-0.6)	
4	SP-CL	0.8 -1.3–2.9	0.3 -1.3–1.9	-1.5 -3.2–0.1	0.6
	Corail	0.6 -1.2–2.3	0.2 -1.5–1.8	-2.0 -3.6– (-0.4)	
5	SP-CL	1.0 -1.3–3.4	1.6 -0.2–3.4	0.4 -1.8–2.6	0.9
	Corail	2.1 -0.5–4.7	1.4 -0.2–2.9	0.3 -2.2–2.9	
6	SP-CL	-5.8 -8.8– (-2.7)	-6.6 -10.4– (-2.7)	-9.1 -12.8– (-5.5)	0.05
	Corail	-4.5 -7.5– (-1.6)	-3.2 -5.8– (-0.7)	-3.7 -7.9–0.5	
7	SP-CL	-20.1 -25.5– (-14.6)	-18.9 -26.7– (-11.1)	-25.4 -30.8– (-19.9)	0.003
	Corail	-16.7 -20.3– (-13.1)	-15.1 -19.3– (-10.8)	-14.8 -20.0– (-9.7)	
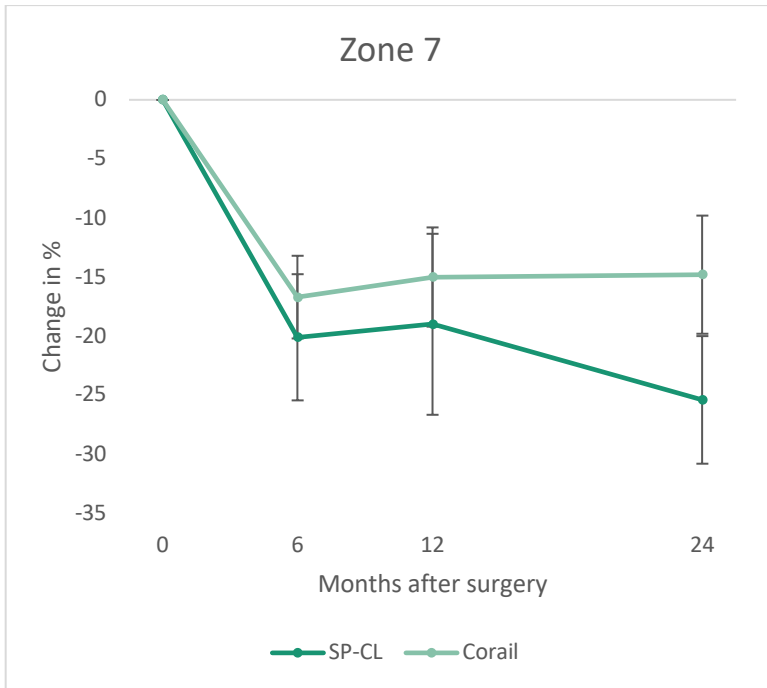
Figure 25. *Mean change in BMD ±2 standard error of the mean. Only patients with complete follow up were included in the analysis.*

5.1.3.3   CONVENTIONAL RADIOGRAPHS

No radiographs at any time showed tip sclerosis or welding. Postoperatively, no stem in any group showed any radiolucent lines in either view. At 2 years, 7 SP-CL and 9 Corail stems showed radiolucent lines in either the frontal or the lateral view. In the frontal view, one SP-CL stem showed radiolucent lines measuring 5% of the relative length. A total of 8 Corail stems showed radiolucent lines in the frontal view; the median (in cases with lines) was 7% (range 6–16). On the lateral view, the corresponding figures were 9.5% (range 7–13) among 6 SP-CL stems, and 9% (range 7–17) among 8 Corail stems.

5.2 PAPER II

5.2.1 BASELINE DEMOGRAPHICS

Baseline demographics did not differ between groups **(Table 13).**

Table 13. Baseline demographics.

Factor	CFP N = 40	Corail N = 42
Age, years (mean (95% CI))	61 (58–64)	60 (57–63)
Median (IQR)	64 (53–68)	60 (53–66)
Sex, male/female	25/15	27/15
Diagnosis, nr (%)		
Osteoarthritis, primary	38 (95)	40 (95)
Osteoarthritis, secondary		
Missing	2 (5)	2 (5)
ASA class		
1	21	16
2	16	20
3	1	4
>4	0	0
missing	2	2
BMI (kg/m²)		
Median (IQR)	26.3 (24.1–29.2)	28.8 (25.1–32.3)
Charnley class		
A	20	26
B	4	8
C	14	6
Missing	2	2

5.2.2   CLINICAL RESULTS

There was a steep improvement in hip function and general health during the first postoperative year, a pattern true for both implants. Thereafter little further improvement could be seen in any of the groups **(Figure 26)** .
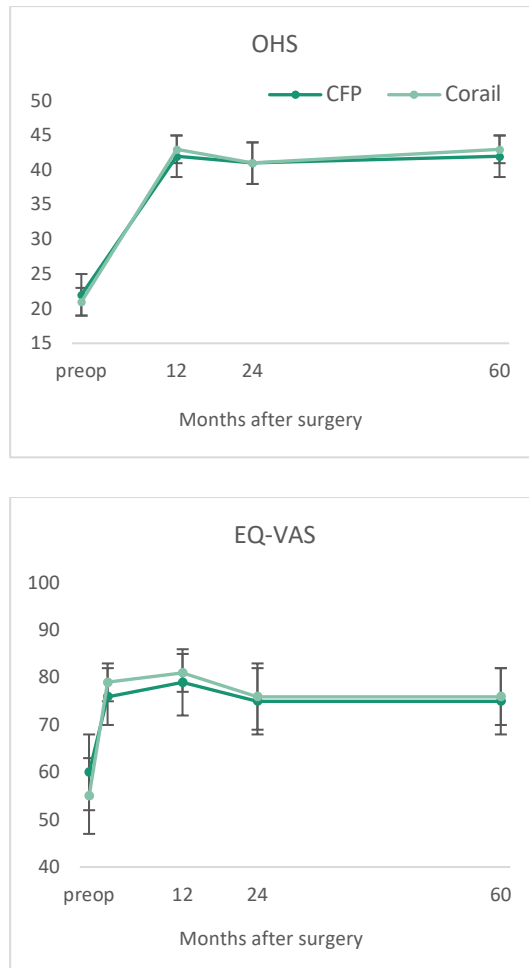

Figure 26. *Clinical results, mean ±2 standard error of the mean. All available patients included in the analysis*

At 5 years, neither the PROMs nor the HHS differed with statistical significance between the two groups studied, **Table 14**.

Table 14. Patient-reported outcome measures and Harris Hip Score. VAS pain and VAS satisfaction were reported on a scale 0–100 where 0 is the best result. EQ-VAS was reported on a scale 0–100 where 100 is the best result. *Mann-Whitney U-test

Instrument	Type of stem	Preoperative		5 years		p-value*
		N	Median IQR	N	Median IQR	5 years
Oxford Hip Score	CFP	39	21 *15–26*	34	45 *35–48*	0.7
	Corail	41	20 *14–26*	36	45 *40–48*	
Harris Hip Score	CFP	22	53.5 *42–63*	33	99 *92–100*	0.7
	Corail	22	51.5 *41–63*	34	99 *95–100*	
EQ5D	CFP	38	0.47 *0.12–0.73*	34	0.92 *0.87–0.97*	0.6
	Corail	40	0.23 *0.06–0.7*	32	0.93 *0.80–0.97*	
EQ-VAS	CFP	36	60 *33–84*	33	80 *63–90*	0.9
	Corail	40	60 *38–70*	36	80 *75–89*	
VAS Pain	CFP	38	70 *56–78*	34	4 *1–25*	0.8
	Corail	40	64 *54–78*	36	9 *1–21*	
VAS Satisfaction	CFP			34	91.5 *70–99*	0.15
	Corail			36	96.5 *90–100*	
UCLA	CFP	38	5 *4–6*	33	6 *5–6*	0.7
	Corail	41	5 *4–6*	34	6 *5.5–6*	

A statistically significant improvement of UCLA activity scores from median 4 to 6 was observed in both groups between 2 and 5 years (CFP p = 0.008; Corail p = 0.004, Wilcoxon's signed rank test). None of the other PROMs confirmed an improvement within this period.

5.2.2.1 REVISION

Two patients operated with the CFP stem were revised before the 2-year follow-up due to aseptic loosening. One Corail stem was revised due to chronic infection. No patient was revised due to loosening of the acetabular component.

5.2.3 RADIOLOGICAL RESULTS

5.2.3.1 RSA

In total, 35 CFP stems and 36 Corail stems had complete RSA follow-up at 5 years. During the first months postoperatively, medial, distal and posterior migration was seen in both groups. During the first 3 months, the Corail stems showed greater posterior migration (corresponding to retroversion of the femoral head) than the CFP stems did (p = 0.04). The magnitude of the migration in the other two directions did not differ during the same period (medial-lateral p = 0.5, proximal-distal p = 0.06; Mann Whitney U-test). The stems then stabilized and little further migration could be seen beyond 3 months postoperatively, **Figure 27**.
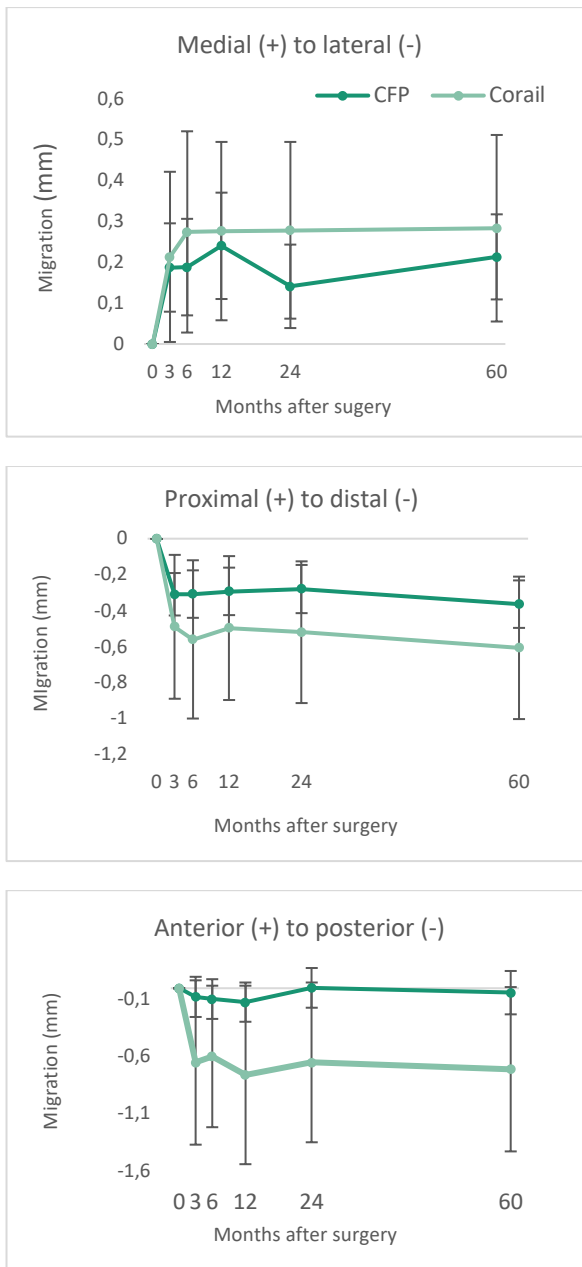
Figure 27. *Mean migration (mm) ±2 standard error of the mean.*

In linear mixed models up to 5 years no statistically significant difference could be seen **(Table 15)**.

Table 15. Overall treatment effect CFP/Corail up to 5 years.

Direction or type of migration	Ration of estimated mean (95% CI)
Medial or lateral	1.33 (0.79-2.23)
Proximal or distal	1.16 (0.67-1.99)
Anterior or posterior	0.72 (0.42-1.34)

Between 3 months and 2 years only small movements were detected. To analyse late migration in the individual stem, migration between 2 and 5 years was calculated. The findings are described in **Table 16**; no statistically significant difference could be seen between groups. In total, 7 CFP and 9 Corail stems migrated above the detection limit for RSA along any of the cardinal axes between 2 and 5 years. In the CFP group, 5 stems showed migration in either the medial-lateral or the proximal-distal direction and 2 stems migrated in two directions (medial-lateral and proximal-distal). In the Corail group, 6 stems migrated in the medial-lateral or proximal-distal direction, and 2 stems migrated in both the medial-lateral and proximal-distal direction. In one case, the stem showed migration in all three directions and had radiological signs of loosening. At 5 years, no revision surgery was planned for this patient.

Table 16. Migration 2–5 years. * Mann-Whitney U-test

	Type of stem	Median (mm) *interquartile range*	p-value*
2–5 years			
Medial(+)-lateral(-)	CFP	0.04 *-0.02–0.07*	0.42
	Corail	-0.01 *-0.09–0.08*	
Proximal(+)-distal(-)	CFP	-0.04 *-0.12–0.06*	0.14
	Corail	-0.09 *-0.16–0.03*	
Anterior(+)-posterior(-)	CFP	0.01 *-0.14–0.07*	0.13
	Corail	-0.08 *-0.18–0.08*	

5.2.3.2   BMD

At 3 to 6 months, proximal reduction of BMD was observed in both groups. However, the CFP stems showed more marked resorption in the proximal zones during the first months postoperatively. After 6 to 12 months, there was restitution of proximal BMD in both groups, but this started later and was less pronounced in the CFP group. At 5 years, there was a statistically significantly difference in BMD change in Gruen zones 1, 3 and 7, with less restitution in the CFP group (Gruen zone 1 p = 0.004, Gruen zone 3 p = 0.007, Gruen zone 7 p = 0.007, T-test) **(Table 17 and Figure 28**).

Table 17. Mean change in BMD, only patients with complete examinations (CFP 24, Corail 29) at all follow-up occasions are presented. Independent T-test. P-value calculations at 5 years included all available examinations. *Independent T-test

| Gruen zone	Type of stem	3-month mean change in % 95% CI	6-month mean change in % 95% CI	1-year mean change in % 95%CI	2-year mean change in % 95% CI	5-year mean change in % 95% CI	p-value* at 5 years
1	CFP	-11.6 -14.9-(-8.4)	-13.0 -16.2-(-9.8)	-13.4 -17.9-(-8.9)	-10.2 -14.4-(-6.0)	-9.1 -14.1-(-4.1)	0.004
	Corail	-3.5 -11.5-4.5	-6.5 -10.2-(-2.7)	-2.4 -7.8-3.0	2.2 -4.6-9.0	-0.2 -4.8-4.4	
2	CFP	-6.1 -8.8-(-3.4)	-6.2 -9.2-(-3.2)	-7.5 -11.1-(-3.9)	-6.8 -10.6-(-3.0)	-9.9 -15.4-(-4.4)	0.07
	Corail	-5.7 -9.5-(-2.0)	-3.4 -5.5-(-1.3)	-2.4 -5.1-0.3	-2.4 -6.0-1.3	-4.0 -8.0-(-0.4)	
3	CFP	-6.4 -10.7-(-2.1)	-3.1 -6.8-0.6	-6.2 -12.1-(-0.1)	-1.7 -6.7-3.3	-5.3 -8.8-(-1.7)	0.007
	Corail	3.9 -5.6-(-2.2)	-1.9 -3.7-(-0.1)	-0.2 -2.5-2.0	0.7 -1.6-3.1	1.4 -2.2-5.0	
4	CFP	1.4 -5.7-8.6	2.6 -4.4-9.6	2.6 -4.7-9.9	2.3 -5.7-10.3	0.2 -7.7-8.0	0.6
	Corail	-1.9 -3.2-(-0.7)	-1.0 -2.0-0.0	0.15 -1.1-1.4	1.1 -0.7-2.8	-1.7 -4.5-1.1	
5	CFP	-3.7 -7.0-(-0.4)	-4.1 -8.3-0.12	-0.2 -3.7-3.7	-0.9 -4.9-3.0	0.6 -2.4-3.6	0.6
	Corail	-1.2 -3.3-0.9	0.2 -1.6-1.1	0.8 -1.1-2.7	2.2 1.4-6.4	2.1 -3.3-7.5	
6	CFP	-5.2 -10.1-(-0.2)	-2.4 -7.6-2.8	-2.3 -8.0-3.4	-7.2 -13.5-(-0.9)	-8.2 -17.1-0.6	0.1
	Corail	-2.2 -5.8-1.4	-1.6 -5.0-1.8	1.0 -2.3-4.3	1.3 -2.8-5.4	-1.1 -7.4-5.2	
7	CFP	-14.3 -19.1-(-9.5)	-19.3 -24.3-(-14.3)	-23.0 -29.6-(-16.3)	-25.7 -33.3-(-18.2)	-22.9 -29.8-(-16.1)	0.007
	Corail	-11.8 -17.5-(-6.2)	-12.2 -17.5-(-7.0)	-12.7 -18.1-(-7.4)	-11.1 -16.8-(-5.5)	-9.8 -16.7-(-2.9)	
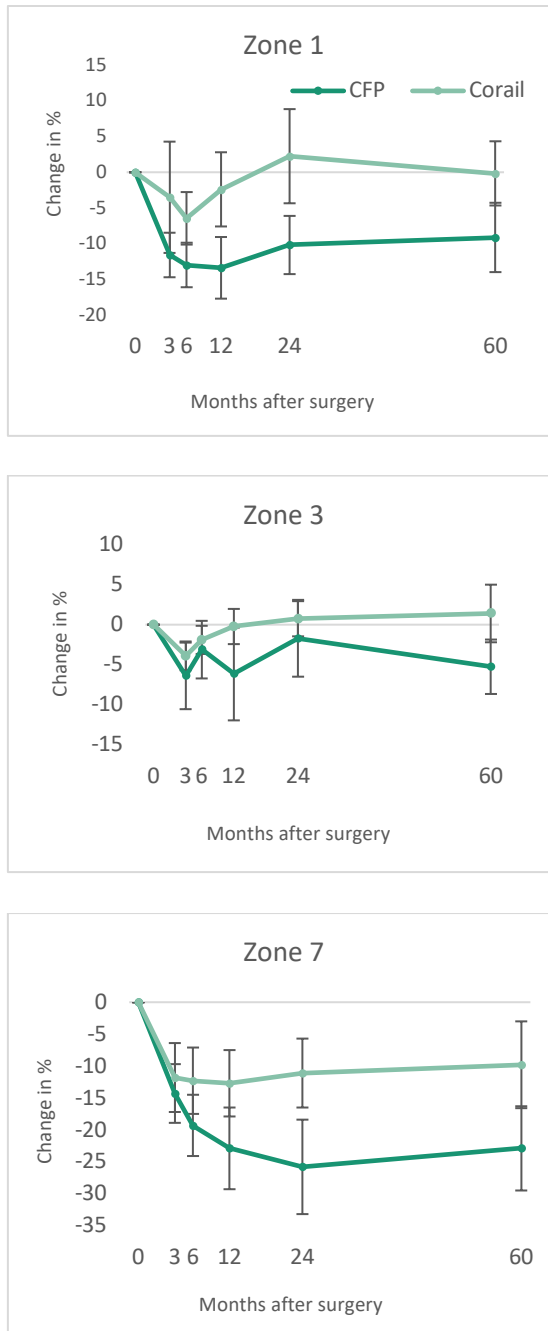
Figure 28*. Zones with significant differences in BMD.*
Mean change % ±2 standard errors of the mean.

In the linear mixed models, CFP showed significantly increased reduction in zone 1 (p = 0.002), 2 (p = 0.046), 3 (p = 0.027), 6 (p = 0.041), and 7 (p = 0.004) **(Table 18)**.

Table 18. Difference of mean BMD loss in % based on all available observation up to 5 years

Gruen Zone	Difference, % (95% CI)
1	-9.4 (-14.3 – (-4.6))
2	-3.4 (-6.7 – (-0.1))
3	-3.2 (-6.1 – (-0.4))
4	1.8 (-2.9 –6.5)
5	-1.8 (-4.5 – 0.9)
6	-5.4 (-10.6 – (-0.2))
7	-9.6 (-15.9 – (-3.2))

5.2.3.3 CONVENTIONAL RADIOGRAPHS

Partial resorption of the remaining proximal femoral neck was observed in six patients (all CFP). In four of the six patients the process of resorption began in the first postoperative year, in the remaining cases it started after 1 and 2 years, respectively **(Figure 29)**. None of the Corail stems had any radiographically visible proximal resorption.

There was no difference in clinical outcome between patients with neck resorption and those without. The median OHS in patients with neck resorption at 5 years was 47 (range 36–48).

The Corail stems were more prone to developing proximal radiolucent lines than the CFP stems. At 5 years, none of the CFP stems showed radiolucent lines on the anteroposterior view, whereas two had lines on the lateral view (two in Gruen zones 8 and 14 and one in zone 9 as well). In these cases, the radiolucent lines occupied less than 15% of the stem-bone interface. Fourteen Corail stems showed radiolucent lines on the anteroposterior view

in zones 1 and 7. Nine hips had lines on the lateral view corresponding to zones 8, 9 and 14. In two hips, the total lengths of the lines were 19% and 15% on the anteroposterior view and 21% and 19% on the lateral view, respectively. The remaining stems had radiolucent lines < 15% on either view.

CFP stems more often showed spot welding, cortical hypertrophy and tip sclerosis. In total, 37% of the CFP stems had any of these radiological findings or a combination of them. Only one Corail stem showed any of these findings.
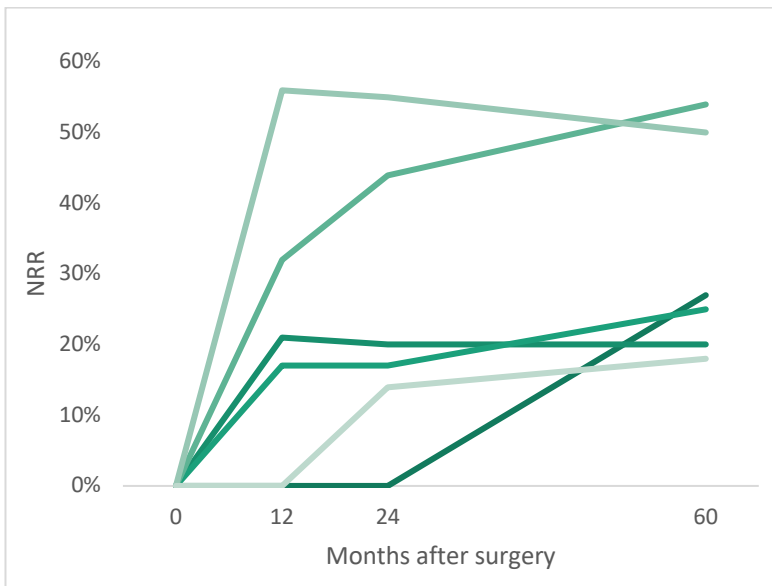
Figure 29. *Neck resorption ratio (NRR) in 6 CFP stems. Neck resorption at different follow-up occasions calculated as a percentage: remaining neck length divided by postoperative length*

5.3 PAPER III

5.3.1 BASELINE DEMOGRAPHICS

The baseline demographics in the 44 patients with bilateral hip arthroplasties are presented in **Table 19**.

Table 19. Baseline demographics.

Factor	Patients N = 44
Age, years, mean (95% CI)	59 (56–61)
Median (IQR)	59 (55-65)
Sex, male/female	22/22
Diagnosis, nr (%)	
Osteoarthritis, primary	39 (88)
Osteoarthritis, secondary	2 (5)
Missing	3 (7)
ASA class	
1	12
2	26
3	3
>4	0
missing	3
BMI (kg/m²)	
Median (IQR)	26.5 (22.8–30.4)
Charnley class	
A	0
B	15
C	14
Missing	15

5.3.2 CLINICAL RESULTS

Each patient's opinion on which hip was best at the 2-year follow-up was used as primary outcome. This was evaluated with use of the My hip form. Patients tended to be more satisfied with the hip operated with the CLS stem, but without any statistically significant difference. This tendency was evident also at 5 years, but still without statistical significance, **Table 20**.

Table 20. My Hip scores. *Fisher's exact test.

	Implant	2 years		*P-value at 2 years**	5 years		*P-value at 5 years**
Question		*n*	Distribution of answers		*n*	Distribution of answers	
Which hip is strongest?	Similar Fitmore CLS	37	14 8 15	0.13	33	13 9 11	0.79
Do you have pain in or on the outside of your thigh?	Both Fitmore CLS Neither	37	3 6 3 25	0.79	33	2 6 4 21	0.76
Do you consider your hip to be unstable?	Both Fitmore CLS Neither	37	0 4 1 32	0.36	34	0 3 1 29	0.61
Which hip has the best overall function?	Both Fitmore CLS	37	18 7 12	0.14	34	18 5 10	0.24

The patients reported improved joint function, life quality and satisfaction during the first year postoperatively. Thereafter, no further improvement was observed **(Figure 30, Table 21).**
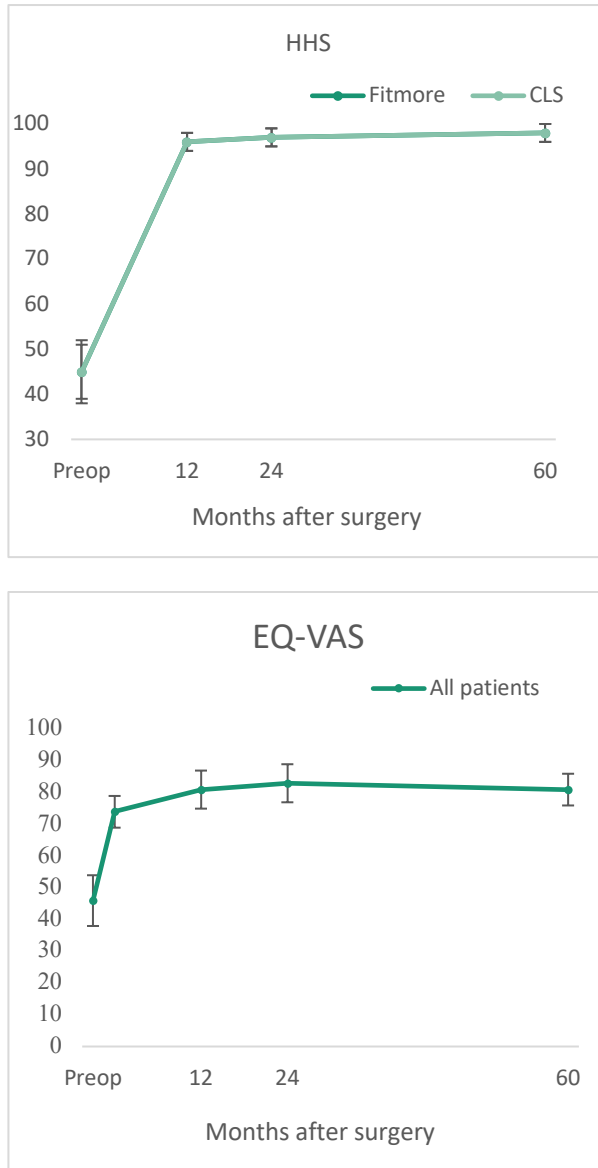
Figure 30. *Clinical outcome. Bilateral assessment of Harris Hip Score shows no difference between groups. EQ-VAS reflects an increase in general health.*

Table 21. Clinical outcome Study IV. Patient-reported outcome measures and Harris Hip Score. VAS pain and VAS satisfaction were reported on a scale 0–100 where 0 is the best result. EQ-VAS was reported on a scale 0–100 where 100 is the best result * Wilcoxon's signed rank test, # assessed bilaterally.

| Instrument | Preoperative | | 5 years | | *p-value** |
	n	Median IQR	*n*	Median IQR	5 years
General health					
SF-36	37		33		n/a
Mental		47 *38–54*		55 *48–57*	
Physical		23 *18–29*		50 *41–54*	
EQ5D	40	0.68 *0.59–0.76*	33	0.93 *0.87–0.97*	n/a
EQ-VAS	40	38 *30–64*	32	81 *75–90*	n/a
UCLA	39	3 *3–6*	32	6 *6.0–7.5*	n/a
Hip-specific					
VAS Pain #					
Fitmore	40	70 *60–77*	25	5 *0–27*	0.3
CLS	40	70 *60–77*	25	5 *0–17*	
VAS Satisfaction #					
Fitmore			25	3 *0–25*	0.3
CLS			25	3 *0–23*	
Harris Hip Score #					
Fitmore	21	43 *43–56*	33	99 *99–100*	0.7
CLS	21	42 *31–53*	33	99 *97–100*	

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5.3.2.1 REVISIONS

Three patients (4 hips) were revised before the 5-year follow-up. In one case, the patient suffered from an early PJI and was bilaterally revised. One Fitmore stem was revised due to aseptic loosening within the first year postoperatively. In the second year postoperatively, one hip (Fitmore) was revised due to chronic infection. In these cases, data were excluded from the date of revision.

5.3.3 RADIOLOGICAL RESULTS

5.3.3.1 RSA

Initial migration (first 3 months postoperatively) followed by stabilization was seen in both groups. After the initial migration, little further migration was seen in either group **(Figure 31)**. No statistically significant difference could be seen in any direction at 3 months. (Medial-lateral p=0.3; Proximal-distal p=0.7; Anterior-posterior p=0.9, Wilcoxon´s signed rank test)
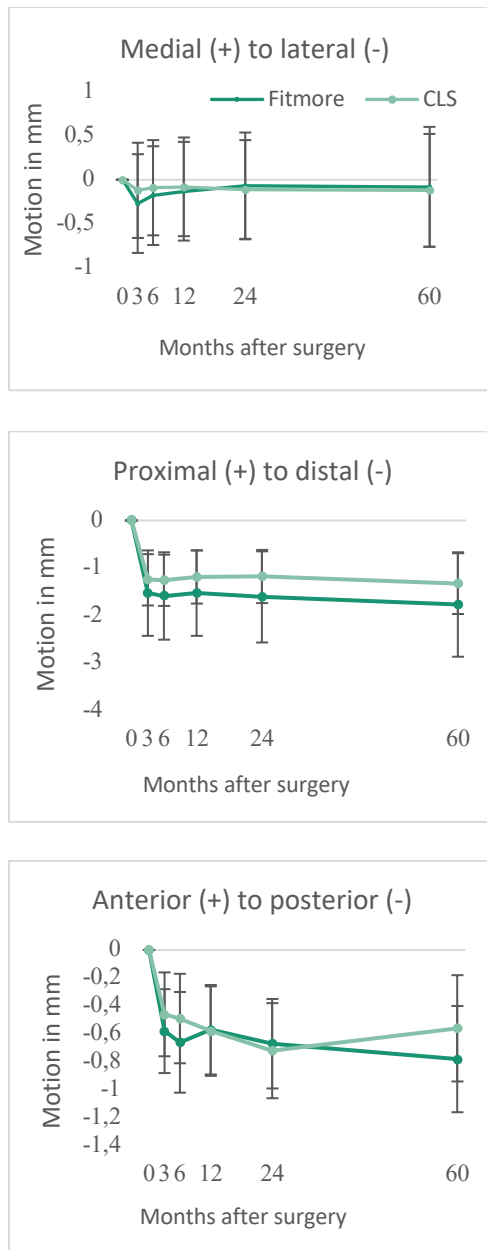
Figure 31. *Mean migrations in mm ±2 standard error of the mean.*

To evaluate individual late migration, change between 2 and 5 years were calculated. These calculations showed minor migration, nevertheless some stems showed migration above the detection limits. In total, 7 implants showed migration above the detection limit between 2 and 5 years. One Fitmore stem showed migration in both the proximal-distal and anterior-posterior directions and 6 hips (3 Fitmore and 3 CLS) showed migration only proximally or distally. The patient with migration in two directions on the side with a Fitmore stem showed no radiological signs of loosening and had excellent clinical results. Migration of the two types of stem between 2 and 5 years is shown in **Table 22**.

Table 22. Migration between 2-5 years. *Wilcoxon's signed rank test.

	Type of stem	Median (mm) *IQR* 2–5 years	*p-value**
Nr		**33**	
Medial(+)-lateral(-)	Fitmore	0.07 *-0.04–0.13*	0.68
	CLS	0.03 *-0.05–0.08*	
Proximal(+)-distal(-)	Fitmore	-0.01 *-0.15–0.07*	0.70
	CLS	-0.02 *-0.09–0.06*	
Anterior(+)-posterior(-)	Fitmore	-0.07 *-0.21–0.13*	0.18
	CLS	-0.01 *-0.11–0.08*	

5.3.3.2 BMD

At 5 years, 27 patients (54 hips) had complete follow-up on all occasions. No statistically significant differences were found between implants at 5 years. Both sides showed an early loss of proximal BMD followed by restitution. In Gruen zone 1, the Fitmore had lost slightly more BMD at 2 years (p = 0.001),

but the difference had become statistically insignificant at 5 years (p = 0.09). A marked loss could be seen in Gruen zone 7. However, no statistically significant differences were observed at either 2 or 5 years (p = 0.44 and p = 0.39, respectively, paired T-tests) **(Figure 32, Table 23).** All other zones showed similar pattern of resorption or gain in BMD.
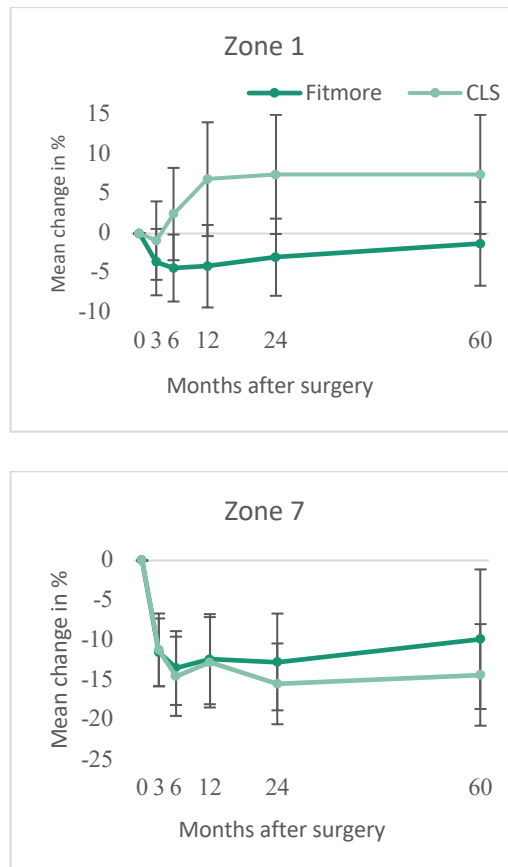

Figure 32. Mean change in percent ±2 standard error of the mean

Influence of Stem Design on Total Hip Arthroplasty

Table 23. Mean change in BMD in %. Only patients (n = 27) with complete follow-up at 5 years were included in the analysis. *Paired T-test.

Gruen zone	Type of stem	3-month mean change in % 95% CI	6-month mean change in % 95% CI	1-year mean change in % 95% CI	2-year mean change in % 95% CI	5-year mean change in % 95% CI	p-value* at 2-years	p-value* at 5-years
1	Fitmore	-3.8 -8.2- 0.7	-4.4 -8.9–0.1	-4.7 -10.2–0.8	-3.1 -8.3–2.0	-1.3 -6.9–4.4	0.001	0.09
	CLS	-0.9 -6.2- 4.4	2.1 -4.1–8.3	6.4 -1.2–14	7.1 -0.9–15.1	4.5 -3.3–12.3		0.71
2	Fitmore	-7.8 -11.2- -4.3	-6.1 -10.3–(-1.8)	-4.7 -8.8–(-0.5)	-5.5 -10.1–(-1.1)	-6.2 -12.0–(-0.5)	0.07	
	CLS	-2.0 -4.7- 0.7	-1.7 -5.5–2.1	1.3 -2.2–4.8	-1.7 -4.3–0.9	-5.4 -9.6–(-1.1)		0.12
3	Fitmore	-5.8 -8.0- -3.6	-3.8 -6.5–(-1.2)	-1.1 -4.1–1.9	-0.8 -3.7–2.0	0.8 -4.4–5.9	0.76	
	CLS	-3.2 -5.7- -0.6	-2.1 -4.5–0.3	-0.9 -3.4–1.5	-0.3 -2.8–2.3	4.4 -1.3–10.2		0.77
4	Fitmore	-2.4 -3.6- -1.1	-0.3 -1.9–1.3	1.4 -0.8–3.6	2.4 0.4–4.4	0.8 -2.4–4.0	0.36	
	CLS	-1.3 -2.3- -0.2	-0.6 -1.8–0.7	0.1 -1.2–1.5	1.4 -0.1–2.8	1.3 -0.8–3.3		0.15
5	Fitmore	-0.9 -2.3- 0.5	2.1 -0.1–4.2	3.6 0.9–6.3	5.1 2.6–7.7	5.2 2.6–7.9	0.12	
	CLS	-2.2 -3.8- -0.7	-1.1 -3.2–1.0	0.01 -2.3–2.4	2.9 0.5–5.3	2.6 -0.2–5.4		0.34
6	Fitmore	3.8 -1.9- 9.6	5.7 -2.3–13.7	9.9 2.1–17.7	7.7 -0.3–15.7	0.4 -7.0–7.8	0.48	
	CLS	0.6 -3.1- 4.4	2.0 -2.5–6.4	7.6 2.2–13.0	4.7 -0.1–9.5	3.5 -2.0–9.0		0.39
7	Fitmore	-12.0 -16.4- -7.6	-14.0 -18.8–(-9.2)	-12.4 -18.5–(-6.4)	-13.2 -19.5–(-6.8)	-10.0 -19.3–(-0.6)	0.44	
	CLS	-11.6 -16.4- -6.8	-14.8 -20.1–(-9.5)	-13.0 -19.0–(-6.9)	-15.6 -21.0–(-10.2)	-14.3 -21.1–(-7.6)		

5.3.3.3   CONVENTIONAL RADIOGRAPHS

In 9 cases (6 Fitmore, 3 CLS), there were radiolucent lines on either the anteroposterior or the lateral view. One Fitmore and one CLS showed radiolucent lines on both the anteroposterior and the lateral view. In the remaining cases (5 Fitmore, 2 CLS), there were radiolucent lines in one projection. The relative length of the lines did not exceed 20% of the implant-bone interface in any projection for any hip.

5.4   PAPER IV

5.4.1   BASELINE DEMOGRAPHICS

A total of 16,258 of short stems and 32,515 standard stems fulfilled inclusion criteria and were included. The baseline demographics are presented in **Table 24**. There are some differences in patient characteristics between the registries. In the Swedish population, the patients tended to be slightly younger. In the Netherlands, more women were operated with short stem THA and the matched cohort therefore included more women as well. In Australia, more patients were classed as ASA 3 or 4 and they tended to have a higher BMI. No patient in Sweden was operated using the DAA, whereas this was most common approach in Australia and the second most common in the Netherlands.

Table 24. Baseline demographics.

	Total	
	Short-stem primary THA	**Standard-stem primary THA**
Nr of patients	16,258	32,515
Age, years (mean, *SD*))	63 *(11.4)*	63 *(11.1)*
Sex		
Male *(%)*	7,791 *(48)*	15,231 *(47)*
Female *(%)*	8,467 *(52)*	17,284 *(53)*
BMI[1], kg/m² (mean *(SD)*)	28.4 *(5.4)*	29 *(5.5)*
ASA[2]		
I	3,169 *(19)*	4,999 *(15)*
II	8,649 *(54)*	17,266 *(53)*
III[3]	3,261 *(20)*	8,067 *(25)*
IV	161 *(1)*	377 *(1)*
Unknown	1,013 *(6)*	1,965 *(6)*
Diagnosis		
Osteoarthritis	15,089 *(93)*	30,516 *(94)*
Other	1,169 *(7)*	1,999 *(6)*
Surgical approach		
Direct anterior	9,118 *(56)*	14,975 *(46)*
Direct lateral, lateral	1,665 *(10)*	4,242 *(13)*
Posterior, lateral	3,707 *(23)*	9,878 *(30)*
Other	47 *(0.3)*	59 *(0.2)*
Unknown[4]	1,722 *(11)*	3,361 *(10)*

5.4.2 CUMULATIVE REVISION RATES OF PRIMARY THA

At 12 years, the CRRs did not differ between groups. The CRR was 4.7% (CI 4.1–5.5%, number at risk = 720) for short stems and 4.8% (CI 4.3–5.3%, number at risk = 1,463) for standard stems (log-rank test, p = 0.07) **(Figure 33)**. When data were separated by country, the CRRs differed slightly with the Netherlands having statistically significantly higher revision rates with short stems **(Table 25)**.

Cumulative overall revision rate
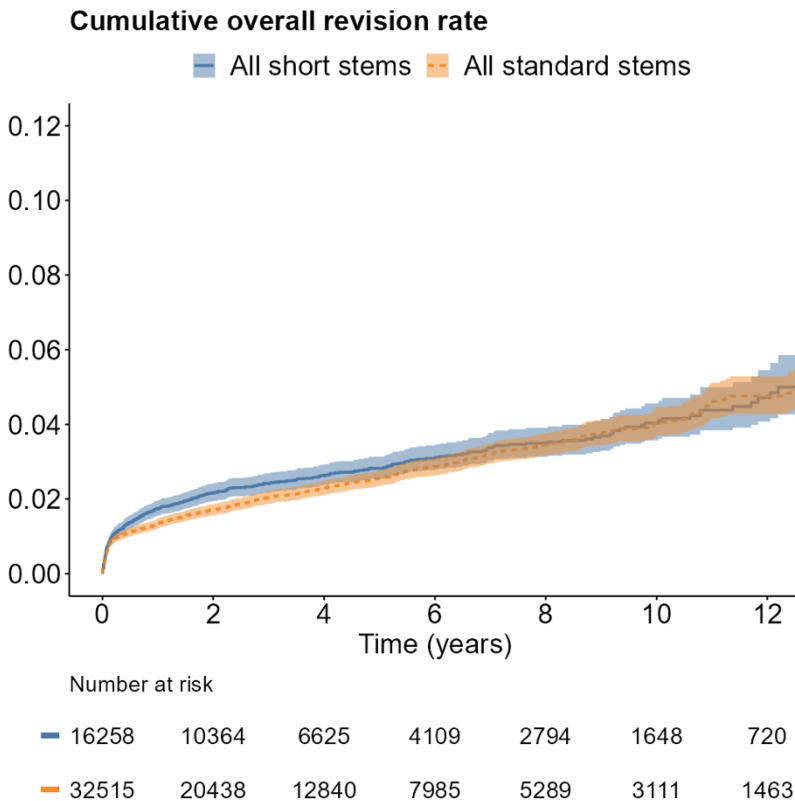
Figure 33. Overall revision rate, all revisions all reasons.

Table *25.* CRR at 12 years. *Log rank test.

	N at risk	Short[1] (95% CI)	N at risk	Standard[2] (95% CI)	P*
AOANJRR	167	3.2 (2.7–3.8)	298	5.2 (4.5–6.0)	0.09
LROI	326	5.6 (4.3–7.3)	614	2.5 (1.9–3.4)	< 0.001
SAR	227	7.6 (5.9–9.8)	551	6.0 (4.8–7.4)	0.08

[1]*Short stem primary THA*
[2]*Standard stem primary THA*

5.4.3 FIRST REVISION SURGERY

A total of 427 revisions were identified in the short stem group, of which 239 (56%) were registered as stem revisions. There was information on the stem used in first revision in 222 (93%) of those 239 cases. The corresponding figures for the standard group were 756 revisions, of which 352 (47%) were stem revisions, with information on the revision implant used available in 343 (93%) cases. Baseline demographics for all revisions and stem revisions are presented in **Table 26**.

Table 26. Baseline demographics stem revisions. N *(%)*

Baseline demographics	All reasons, all revisions		Femoral revisions	
Primary surgery	**Short[1]**	**Standard[2]**	**Short[1]**	**Standard[2]**
N of THAs	427	756	239	352
Age, years (mean, *SD)*	63 *(12.3)*	63 *(11.8)*	64.4 *(11.6)*	64.6 *(11.8)*
Sex				
Male *(%)*	219 *(51)*	358 *(47)*	137 *(57)*	179 *(51)*
BMI, kg/m^2 *(SD)*[3]	29 *(6)*	30.2 *(6.1)*	28.9 *(6)*	29.5 *(5.8)*
ASA classification[4]				
I	67 *(16)*	80 *(11)*	41 *(17)*	37 *(11)*
II	189 *(44)*	343 *(45)*	105 *(44)*	159 *(45)*
III[5]	130 *(30)*	275 *(37)*	71 *(30)*	130 *(37)*
IV	7 *(2)*	18 *(2)*	5 *(2)*	7 *(2)*
Missing	34 *(8)*	40 *(5)*	17 *(7)*	19 *(5)*

[1]*Short stem primary THA*
[2]*Standard stem primary THA*
[3]*Since 2014 in the LROI and since 2015 in AOANJRR.*
[4]*Since 2012 in the AOANJRR.*
[5]*ASA III and ASA IV are merged in the LROI.*

No difference could be seen between groups as regards reason for revision. (chi-square test, p = 0.3), **Table 27.**

Table 27. Reasons for revisions N *(%)*.

Reason for revision	All revisions		Femoral revisions	
Primary surgery	Short[1]	Standard[2]	Short[1]	Standard[2]
N of THAs	427	756	239	352
PJI	75 *(17.7)*	193 *(25.5)*	30 *(12.6)*	55 *(15.6)*
Aseptic loosening	142 *(33.4)*	214 *(28.3)*	88 *(36.8)*	140 *(39.8)*
Periprosthetic fracture	88 *(20.7)*	124 *(16.4)*	79 *(33)*	107 *(30.3)*
Dislocation	52 *(12.3)*	124 *(16.4)*	9 *(3.8)*	20 *(5.7)*
Other	64 *(15)*	95 *(12.6)*	31 *(13.0)*	28 *(8)*
Missing	6 *(0.9)*	6	2 *(0.8)*	2 *(0.6)*

[1]*Short stem primary THA* [2]*Standard stem primary THA*

It was more common to revise a short stem with a stem of standard length; this was seen in 58% of the cases. The corresponding share in the standard stem group was 48% (p = 0.02, **Table 28**). In the Australian cohort: two standard stems were revised using a short stem (MiniMax) possibly representing a registration error. Exclusion of these stems did not alter the results (p = 0.01) Sub-analysis of only aseptic stem revisions did not alter the results either (p = 0.01).

Table 28. Stems used in first revision surgery N (%). *Chi-squared test.

	Stem inserted		
Stem extracted length	Total < 160 mm	≥ 160 mm	p*
Short[1]	129 (58)	93 (42)	
Standard[2]	165 (48)	178 (52)	0.02

[1]*Short stem primary THA*
[2]*Standard stem primary THA*

When sensitivity analysis was performed by sex and age, no difference in choice of stem used in revision was seen in the female group (p = 0.7). In the male group, on the other hand, short stems were significantly more often (63%) revised using a stem with a length of less than 160 mm (p = 0.005) **(Table 29).**

Age older than the median (63 years) was correlated with using a longer stem in revision surgery (60%) when a standard stem was used for the primary surgery (p = 0.001). In the younger age group, there was a tendency to use a stem less than 160 mm when a short stem was revised (63%), but the difference was not statistically significant (p = 0.3) **(Table 30)**.

Table 29. Choice of stem in first revision stratified by sex N *(%).* *Chi-square test**.**

	Stem inserted		
Stem extracted *length*	Total		*p**
	< 160 mm	≥ 160 mm	
Female			
Short[1]	49 *(52)*	46 *(48)*	*0.7*
Standard[2]	82 *(49)*	85 (*51*)	
Male			
Short[1]	80 *(65)*	47 *(35)*	*0.005*
Standard[2]	82 *(47)*	94 *(53)*	

[1]*Short stem primary THA*
[2]*Standard stem primary THA*

Table 30. Choice of stem used in first revision, stratified by age N *(%)*.
*Chi-square test.

	Stem inserted		
Stem extracted	Total		p*
length	< 160mm	< 160mm	
≤ 63 years			
Short[1]	57 (63)	33 (37)	0.3
Standard[2]	91 (56)	70 (44)	
> 63 years			
Short[1]	72 (55)	60 (45)	0.01
Standard[2]	73 (40)	109 (60)	

[1]*Short stem primary THA*
[2]*Standard stem primary THA*

5.4.4 SECOND REVISION SURGERY

In total, 79 second revisions (18.5% of all first revisions) could be identified in the short stem group. The corresponding figure for the standard-length group was 142 (18.7%). All second revisions were included in the analysis, regardless of type and reason for revision. The reasons for second revisions differed slightly from the reasons for first revisions, **Table 31**. Periprosthetic infections were the reason for more than 50% of the second revisions. Reasons for second revisions were equally distributed between groups (chi-squared test 0.6).

Table 31. Reasons for second revisions. N *(%)*.

	Total	
Type of stem[1]	Short	Standard
N of 2nd revisions	79	142
Reason for 2nd revision		
PJI	41 *(52)*	81 *(57)*
Aseptic loosening	15 *(19)*	25 *(17.6)*
Periprosthetic fracture	4 *(5)*	3 *(2.1)*
Dislocation	11 *(14)*	23 *(16)*
Other	7 *(0.09)*	10 *(7)*
Missing	1 *(1.3)*	0

[1] stem used at primary THA

At 5 years, the cumulative rate of second revisions was 19.7% (95% CI 15.8–24.3) in the short stem group. In the standard-length group, the corresponding rate of second revisions was 21.1% (95% CI 18–24.8, log rank test p = 0.7**) (Figure 34).**
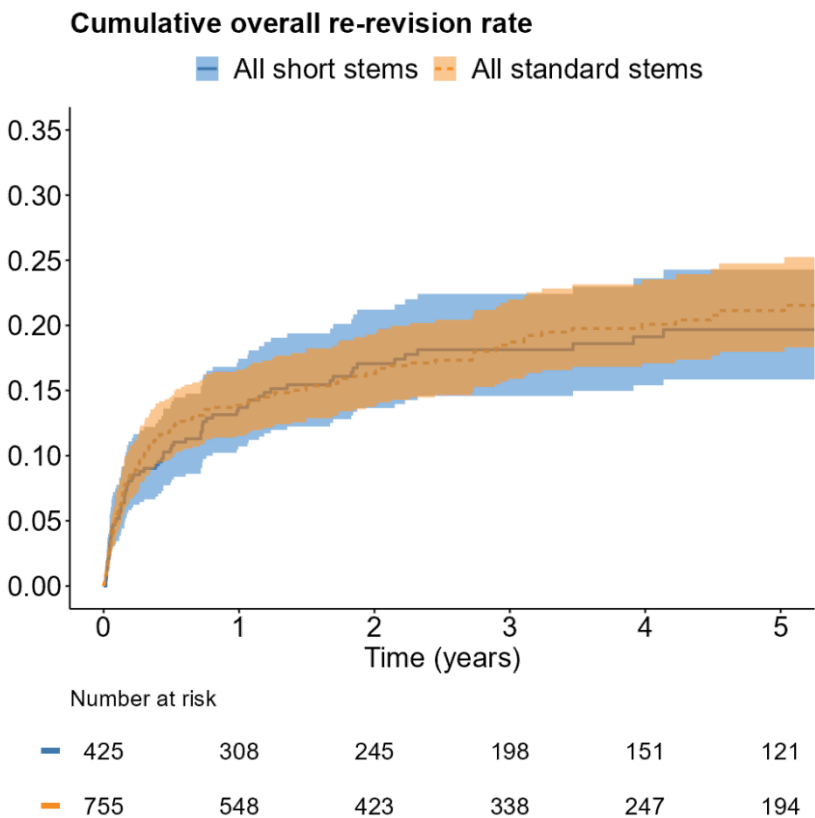
Cumulative overall re-revision rate

Figure 34. Overall rate of second revisions

06

6 DISCUSSION

6.1 STUDIES I, II AND III

6.1.1 PROMS

6.1.1.1 HIP-SPECIFIC PROMS

No significant differences could be seen between implants in any of the studies included in this thesis. All three studied implants performed as well as the reference. No studies on PROM results for the SP-CL stem have been published previously. As regards the CFP and Fitmore stems, our findings are supported by earlier studies, although clinical results for the CFP have not been evaluated in RCTs. (34, 175-180) The Fitmore has been evaluated in comparison to the CLS stem in one earlier study, results being similar to ours. (181)

Patients, as a group, tended to be satisfied with the operation. However, both the OHS and the HHS suffer from ceiling effects. (110, 111) Patients nowadays have high expectations on physical function and might not be satisfied with their hip function even if they have high scores on the OHS or the HHS. In the OHS, the highest score on physical function is described as being able to walk for 30 minutes or more, getting dressed independently and doing housework without pain. Many patients have higher demands on hip function today. Patients, especially younger ones, want to be able to go back to the same physical activity levels as before the onset of arthritis. This includes sporting activity. There is little evidence that even high impact sports lead to greater wear than more indolent lifestyles. (148) However, various studies show that returning to sports does not depend on the implant received during surgery, but rather on the activity level before surgery. (147, 182, 183)

The inability to differentiate between a good and an excellent result is a general problem when assessing THA, this applies also to the studies included in this thesis. New PROMs need to be developed to enable identification of implants with inferior or superior clinical results. The recently introduced but rarely used FJS might enable such differentiation. (110, 184)

6.1.1.2   GENERAL HEALTH

Pain and low physical function impact the general perception of health for most patients. Several earlier studies have shown that hip arthritis affects general health and that THA on correct indications improves general health. (82, 185)

This conclusion could also be drawn from the studies included in this thesis. Patients reported an increase in general health during the first year postoperatively, with values levelling out without further improvement after that. The same pattern was seen for all generic PROMs used in this thesis. The improvement did not differ between implants. In all three studies, patients report an EQ-VAS at approximately 80 points at 2 years, regardless of the implant used. EQ-VAS and EQ-5D tend to decrease with age, especially at ages over 70 years. (186) Given the mean age in our studies (approximately 65 years) a comparison with the normative population in Sweden yields roughly the same scores in the EQ-VAS and EQ-5D. (187) In conclusion, the patients included in our studies reported approximately the same general health as the population at large.

It is known that preoperative low general health, especially worse mental health, influences the outcome of THA. (83, 84, 87, 188) Patients with low general health report improvements following surgery but usually do not reach the same postoperative level as patients who score higher preoperatively in mental health PROMs. There is also a correlation between opioid use and clinical outcomes. (90, 92) It is not known whether this depends on the opioids or is rather a proxy for worse mental health and poor coping strategies for pain, indicating psychological issues.

6.1.1.3 REVISION AS OUTCOME

The implants in our studies showed the expected revision rates, not exceeding those in earlier studies on the specific implants or the revision rates of uncemented stems reported in national registries. (3, 5, 175, 177-180)

Revision rate is a robust outcome parameter after THA but has several shortcomings. Patients with failed implants might not be revised for many reasons, such as frailty, low activity level and poor general health. It could thus be argued that revision is a crude measure and a rare event preceded by a period of varying length with deteriorating function, with or without pain. For the individual surgeon, it may be difficult to detect inferior results for a specific implant. Due to a limited number of observations and the overall low revision rates of modern implants, each surgeon will struggle to see that an implant has increased incidence of mechanical failures such as loosening. A large cohort of patients must be followed for a long period of time, and resources for such projects are not regularly available. Therefore, the national registries collecting large amounts of data play an important role in detecting implants with inferior results.

6.1.2 RADIOLOGICAL OUTCOMES

6.1.2.1 RSA

All five implants included in our studies showed the same migration pattern. Initial subsidence, retroversion and medialization were followed by stabilization. At the group level, the stems showed stable migration patterns after 3 months, with little further movement in any direction.

The evidence is mounting that an initial migration followed by stabilization is acceptable for uncemented stems. (34, 119-124, 189) Even a large initial migration can be followed by stabilization. (118) The role of RSA in predicting aseptic loosening with uncemented implants is debated. For cemented

closed-shaped designs, there is a consensus that migration exceeding 0.15 mm during the first 2 years postoperatively indicates higher risk of future revision. There is still no evidence that this applies to uncemented stems as well. (190) Although there are no clearly defined limits on the magnitude of acceptable initial migration compatible with good long-term results for uncemented stems, stabilization should most probably occur early, with no or minimum migration occurring past 6 to 12 months after the operation. Fixation of uncemented stems relies on on-growth of bone, which cannot be achieved if there is continuous migration. (19)

In our studies, there were also patients with migration above the precision limits of RSA between the final two examinations. The movements recorded were small and often in only one or two directions. None of these patients was planned for revision surgery. It was also notable that patients operated with the Corail and CLS stems showed migration between the two last RSA examinations. Both these stems are known for their good long-term results in registries. Drawing firm conclusions on whether this late, small but detectable migration affects long-term fixation would require follow-up, preferably with RSA and as large cohorts as possible. It might also be that these small movements, at least in some of the cases, are an expression of bone remodelling around the stem, but this hypothesis requires further study.

6.1.2.2 BMD

Loss of proximal BMD may jeopardize any future femoral revision surgery, but there are no studies in which this potential problem has been quantified. In our studies, all implants exhibited the same resorption pattern with an initial decrease followed by stabilization and even an increase of BMD in some Gruen zones. The pattern of bone remodelling reflects postoperative load changes in accordance with Wolff's law and would be expected if any of the contemporary femoral components on the market was chosen. In our studies, all patients tended to lose proximal BMD. Both the SP-CL stems and the CFP

stems, which are designed for a better distribution of load, exhibited more proximal bone loss than the Corail stems.

One benefit of short stems that has been brought forward is that they save proximal bone. The CFP stem and the Fitmore stem, which are both short stems, also showed a pattern of unloading of the proximal femur. We found that the CFP stems led to pronounced loss of BMD in proximal Gruen zones and, in many cases, some resorption of the remaining medial part of femoral neck. This has been reported in earlier studies on the CFP stems. However, the resorption does not seem to affect clinical results. (34, 191) There is little and somewhat conflicting evidence supporting the idea that short stems reduce proximal bone loss. (181, 192-195) A systematic review states that more research needs to be conducted and that the short stem designs have a large spectrum of shapes altering the load of the femur in different ways. (33) Neither of the short stems in this study seemed to have a more favourable pattern of BMD alterations compared with the reference stem.

In conclusion, although one of the main reasons to use a short stem is to save proximal femoral bone, none of the studied stem designs could be shown to do so.

6.1.2.3   RADIOGRAPHS

Radiographic changes surrounding stems are partly a result of the changed loading pattern inevitably occurring after THA. Radiolucent lines may indicate failure of osseointegration, which tends to appear in areas with poor implant-bone contact and poor implant-bone load transfer. Generally, they occur in the proximal femur. Radiolucent lines involving more than 50% of the interface between implant and bone are regarded as associated with increased risk of clinical loosening. The clinical importance of proximal radiolucent lines smaller than 50% is not fully understood; earlier studies show no adverse clinical outcomes. (137, 138)

Welding spots and cortical hypertrophy are results of stress contact and increased load. These radiographic changes reflect a change in bone mineral density. Cortical hypertrophy does not seem to influence clinical outcome but is rather a sign of increased load in the distal femur. (141, 196) In our studies, such changes were mainly observed with CFP stems, suggesting proximal unloading combined with increased load in the distal femur.

6.1.3   INTRODUCTION OF IMPLANTS

Although all implants studied in the three RCTs presented in this thesis have been on the market for some years, there is scarce scientific evidence for their efficacy.

The SP-CL has been on the market since 2014 but few clinical studies have thus far been performed. (123, 197) The stem performed as well as the Corail stem in this thesis, but large-scale multicentre studies are needed to consolidate the results.

The CFP stem was first introduced in the 1980s and has had its current design since the 1990s. (198) It has been on the market for more than 30 years, but there are few studies which compare its performance with a standard stem. The studies published thus far report similar results to those for standard stems, but no reference group has been used in any of the studies. (34, 175-178, 199-201)

The Fitmore stem has been on the market since 2007. There are few studies that have documented its performance, especially in the longer term. (140, 179-181, 196) Despite this, it is one of the most commonly used short stems in the Netherlands.

All these implants have been introduced to the market with scarce scientific evidence, with none of them following the algorithm for safe introduction of implants. Our studies showed little differences when compared with a reference stem; no benefits were seen from using the studied implants.

Earlier studies on the CFP and Fitmore stem show revision rates in line with most contemporary stem designs, but questions regarding the long-term results remain.

6.1.4   LIMITATIONS STUDIES I-III

6.1.4.1   STUDIES I–III

In all our studies involving RSA, the femoral head was used as the reference for measurements. None of the implants was available with incorporated markers. This means that no data on stem rotations or translation of other parts of the stem was calculated. However, roughly medial-lateral femoral head translation could be interpreted as varus-valgus tilting and anteroposterior translations as anteversion or retroversion. A more comprehensive evaluation would probably not have influenced the overall results. Using the femoral head centre is a well-evaluated method, documented in several studies. (114, 126, 127)

6.1.4.2   STUDY I

When Study I, was started the SP-CL was available only in 126° CCD. Only patients with an anatomy suitable for this stem design were recruited, resulting in a loss of external validity.

6.1.4.3   STUDY III

The primary outcome used in Study III was not a validated PROM. However, to the best of our knowledge, there is no validated PROM designed for bilateral assessment. None of the other PROMs with bilateral assessment used in the study showed any difference between implants. Thus, one can assume that the results for the primary outcome are valid.

6.2   STUDY IV

6.2.1   REVISION RATES

In this study, the overall revision rate of short stem THAs did not differ from that of standard stem THAs. Earlier register-based studies and systematic reviews on revision of short stems support these findings. (202-208)

In the last few years, there have been some register-based studies on short stems. (202, 203, 205, 208) The reported mid-term revision rates (all reasons) in the studies are approximately 3% at 5 years, which is similar to those of standard stems, when adjusted for differences in population. No long-term results have been published, despite the increasing popularity of short stems. In the German register, they make up approximately 10% of the primary THAs. (202)

In our study as well as in earlier register-based studies, we found an abundance of stems used. This makes evaluation of revision rates difficult, as some implants have been used in very limited numbers. In the study based on data from the German register, only stems used in more than 2,000 cases were included in the analysis as an attempt to circumvent these difficulties. (202) Van Veghel et al. did a sub-analysis of the most common stems (Optimys and Fitmore), finding them to yield better survival rates than that for the cohort as a whole. (203) This is a common problem, when analysing survival rates of short stems: there is an abundance of designs, some of which might not be in use anymore. Survival rates of short stems as a group are difficult to interpret as the findings are highly dependent on what stems are included. This could also be regarded as problematic in our study, in which 14 stem design were included, some of which had been used in fewer than 100 cases. Further studies are needed to establish the survival rates of individual stem designs as they can be both better or worse than conventional stems. An earlier study from the AOANJRR also showed that newly introduced implants might have inferior results compared with established implants. (50)

Although initial results are promising, long-term results are still lacking. Short stems are intended for proximal fixation in an area exposed to a high degree of BMD loss, as a result of both altered loading and natural decline due to age. This might affect the stability of the stems in an aging population and lead to higher demands on revision later in life when such procedures may be jeopardized by frailty and poor general health.

6.2.2 REVISION OF SHORT STEMS

Standard-length stems were more often used in revision of short stem THAs than in revision of standard stem THAs. The CRR of first revisions was similar between the two cohorts studied up to 5 years. Implants used in primary surgery did not influence the outcome of first-time revisions, although short stem THAs were more often revised using a stem of standard length.

There is little evidence that a short stem is in fact easier to revise than a stem of standard length. To the best of our knowledge, there was only one previous study focusing on this – a finite element analysis where the Metha stem was revised with a CLS stem in synthetic bone. Loading of the CLS stem showed little movement and the conclusion was that a short stem could be revised using a stem of standard length. (209) This was an in vitro study, and its clinical relevance is uncertain. Revision surgery is often complex and there are many factors to consider when deciding on which implant to use. Loss of proximal bone mass, osteolysis, age of patient and reason for revision are among the factors influencing the choice of implant. In our study, there was a statistically significantly difference in choice of stem depending on the stem used in primary surgery. Short stems were more often revised using a stem shorter than 160 mm. A sub-analysis of revisions for aseptic reasons showed no change in results. When patients were stratified by age and sex, results changed slightly. Males in the short stem group were often revised using a stem shorter than 160 mm, but in females, there was no correlation between the stem used in primary surgery and the length of stem used in revision

surgery. In the analysis stratified by age, patients older than 63 years were more often revised using a stem longer than 160 mm when operated with a standard stem primarily. In the younger age group, no correlation was seen. These findings might reflect fear of poorer proximal bone stock with elderly and female patients, which influences surgeons to choose a longer stem with a higher degree of distal fixation. However, the groups in the stratified analysis were small and the distribution of revisions stems used might be due to chance. Nonetheless, the similar distribution of revision stems with standard and extended length observed in the younger age group call the use of short stems in these patients into question. More studies – preferably including radiographic information about bone loss at revision, difficulties met during implant removal and details about surgical technique are needed to improve our knowledge. One could draw parallels to large metal-on-metal articulation used for hip resurface replacements. These were initially considered to be easy to revise, but revision procedures were found to often become extensive due to pseudo-tumours. Nor is there evidence that short stems have other characteristics, such as biomechanical properties or higher levels of return to sports, making them superior to stems of standard length. (144, 183, 210)

Notwithstanding that short stems seem to have limited benefits if any, the overall CRR of first revisions was not influenced by the choice of stem in primary THA. This indicates that a short stem can be safely revised using a stem of standard length. The number of second revisions was small. It is difficult to draw any firm conclusions, but the share of aseptic second revisions was not higher in the short stem group. This supports the theory that short stems are bone-sparing and easier to revise, given that using a standard stem for revision is considered bone-sparing and easy.

6.2.3 LIMITATIONS STUDY IV

There are many limitations to the register-based study. First, it was based on register data and there might be incorrect registrations and missing data influencing the results. The categorization of stems used in first revisions was also crude, as it was based only on length or whether the stem was modular or not. Individual aspects such as comorbidities, osteolysis or loss of proximal bone stock affecting choice of stem were not considered. However, this affected both groups and should therefore not skew the results.

Ideally, the endpoint in Study IV would have been the CRR of stem revision, but as the AOANJRR did not include information about reason for exchange of individual components, only the CRR for all types of revision procedures could be analysed. The AOANJRR makes up the greater part of the total dataset. It was not meaningful to do separate analyses with use of stem revision as the endpoint based on the remaining data from the LROI and the SAR.

Although data were pooled from three large national registries, only 222 short stems could be included in the analysis of stems used in revision. No power analysis was performed; results might be partly due to chance. Nevertheless, as there were no earlier clinical studies on revision of short stems, we found the results noteworthy.

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7 CONCLUSIONS

Overall conclusion:

No clinical differences were observed between study implants and controls. Most patients were satisfied with the result of the surgery and the implants regularly stabilized, usually within 3 months. Loss of proximal BMD was more pronounced with the CFP and SP-CL stem in contrast to the aim of the design. Short stems may have the advantage that they can be safely revised using a stem of standard length.

Specific conclusions:

- With the SP-CL stem no difference in clinical outcome could be detected and only minor differences in radiological changes was observed. The SP-CL had a more pronounced BMD loss in the proximal femur even though the aim of the design is a better distribution of load. (Paper I)
- The CFP performed as well as the Corail stem in the clinical evaluation. The implants showed small early migration patterns followed by stability. The CFP stem exhibited more pronounced BMD loss in the proximal femur opposed to the aim of its design. (Paper II)
- Patients undergoing one-stage bilateral THA with use of the Fitmore stem and the CLS stem reported equal clinical outcome on the two sides. No significant differences could be seen in the radiological assessment. (Paper III)
- In the register-based study, no difference could be seen in overall CRR in the short-stem group compared to the standard-stem group. If revised, short stems were more often revised using a stem of standard length (<160 mm) than did those standard stems that underwent revision. Despite this no difference could be seen in risk of a second revision between groups. These findings might support the theory of bone-sparing properties associated with use of short stems. (Paper IV)

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8 FUTURE PERSPECTIVES

- Long-term evaluation of the studied implants, preferably in multicentre prospective studies.
- Further evaluation of RSA to establish guidelines for acceptable migration patterns in uncemented stems.
- Register-based long-term surveillance of individual short stem designs to identify designs with better or worse outcomes.
- Evaluation of other advantages of the short stems, such as shorter operation times, less postoperative pain or better functional outcome in patients with high physical activity.
- Studies on revision of short stems with special focus on preservation of the proximal femur.

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APPENDIX

Frågeformulär – Min bedömning av mina höfter

1. Vilken höft känns starkast?

☐ Höger

☐ Vänster

☐ Höger och vänster är lika.

2. Har du smärta på höftens utsida eller i låret

Vänster:	☐ Ja	☐Nej
Höger:	☐ Ja	☐Nej

3. Känns det som om höftleden glappar eller är instabil

Vänster: ☐ Ja   ☐Nej

Höger: ☐ Ja   ☐Nej

4. Vilken höft fungerar bäst?

☐ Höger

☐ Vänster

☐ Höger och vänster är lika.