Influence of postoperative treatment, surface treatment and stem design on the outcome of primary total hip arthroplasty

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To my parents Bart and Marijke

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”Har du dina ”jobbleksaker” i din väska?
Ska du jobba var din dator brukar stå?”

Noortje, December 2008

ABSTRACT

Aims

The aim of this study was to investigate the influence of postoperative treatment, surface treatment and stem design on the outcome of primary Total Hip Arthroplasty. The main intention was to study anteverted femoral stems.

Material and methods

Study 1: 43 patients who received an uncemented and hydroxyapatite coated prosthesis with an anteverted stem were randomized to partial or full weight bearing and followed for 1 year with radiostereometry (RSA). The patients in the partial weight bearing group were equipped with a pressure sensitive insole signalling when the patients load exceeded the prescribed weight limit. *Study II:* 80 patients (84 hips) randomly received a cemented anteverted cobalt-chromium stem (Lubinus SP 2) with matte, polymethylmetacrylate coating or a polished surface (uncollared) and were followed for 5 years with RSA, DXA and conventional radiography. *Study III:* 38 patients (40 hips) were randomized to receive either an uncemented stem with reduced stiffness or a solid metal stem. Patients were followed for 7 years using RSA, DXA, conventional radiography, Harris Hip Score and a pain questionnaire. *Study IV:* 72,991 primary cemented femoral stem implants (21,246 Exeter polished stems, 44,605 Lubinus SPII stems and 7,140 Spectron EF Primary) from the Swedish Total Hip Arthroplasty were studied. Design-specific characteristics were analyzed using separate Cox regression models that were adjusted for gender, age, diagnosis, incision and number of operation (1^{st} or 2^{nd}).

Results

Study I: The median migration in the two groups was equal and neither did the stem rotations differ. The cup translations, rotations and femoral head penetration were unaffected of postoperative partial weight-bearing or full weight-bearing. *Study II:* The polished stems subsided more than the matte and precoated versions ($p< 0.0001$) and mainly inside the cement mantle. After 1 and 2 years the polished stems had lost significantly less bone mineral in Gruen zones 1, 2, 6 and 7 ($p = 0.004$ to 0.03), but this difference had disappeared after 5 years. *Study III:* There were no differences in migration, wear or clinical results between the two groups At 2 years loss of bone mineral density was less in Gruen regions 1, 2, 6 and 7 for the Epoch stems ($p<0.04$) but at 7 years only region 7 had significantly denser bone in the Epoch group. No stem was radiographically loose. *Study IV:* In the selected groups the crude revision rate varied between 0.8 (Lubinus SPII) and 1.4% (Spectron Primary). Decreasing stem size and increasing neck length or offset negatively influenced the risk for non-infectious revision for both the Lubinus and the Spectron stem design. Also male gender negatively influenced the risk for revision for these two stem

designs. The risk for revision for the Exeter stem design was only influenced by patient- and surgery-related parameters and not by implant- related parameters. For all the three stem designs studied the use of an anterolateral incision had a protective effect against revision

Conclusions

Study I: Immediate weight bearing after the implantation of an anteverted uncemented and hydroxyapatite coated stem did not have any adverse effect. Immediate full weight bearing – as much as can be tolerated- after uncemented THA of the ABG-type is justified, provided that primary stability of the implant can be achieved. *Study II:* Polished anteverted cemented femoral stems without a collar subsided more and mainly inside the cement mantle during the first 2 postoperative years compared to matte or PMMA coated collared femoral stems of the same design. During the period of increased subsidence improved bone remodelling was seen around the polished version probably due to a more favourable loading of the proximal femur. No advantages or specific shortcomings were found with the use of a PMMA-coating. *Study III:* The uncemented fully porous-coated composite Epoch stem showed excellent fixation and good clinical results at medium term. This stem with increased flexibility had positive effects on early proximal bone remodelling compared to a solid uncemented stem during the first 2 postoperative years, but this effect decreased with time, suggesting that the load bearing area of the stem moved distally with time. *Study IV:* Overall, the survival rate for the three most frequently used cemented stem designs in the Swedish Hip Arthroplasty Register was high. Variations within each stem design influenced the risk for non-infectious revision for 2 of the implants studied. Our findings underline previous experiences form other implant designs, where relatively modest changes of the stem shape not delivered the expected clinical results

Key words

Primary total hip arthroplasty, anteverted stem, stem design, cemented and cementless fixation, radiostereometry, bone mineral density, clinical outcome

CONTENTS

LIST OF PAPERS

This thesis is based on the following papers:

1. Immediate weight bearing after uncemented total hip arthroplasty with an anteverted stem. A prospective randomized comparison using radiostereometry.
   Truike M. Thien, Lennart Ahnfelt, Mikael Eriksson, Christer Strömberg, Johan Kärrholm. Acta Orthop 2007 Dec;78(6):730-8.

2. Randomized comparison between 3 surface treatments of a single anteverted stem design: 84 hips followed for 5 years.
   Truike M. Thien, Jonas Thanner, Johan Kärrholm
   In press, J Arthroplasty 2009 Feb [Epub ahead of print].

3. Fixation and bone remodelling around a low modulus stem. 7-year follow-up of a randomized study with use of radiostereometry and DXA.
   Truike M. Thien, Jonas Thanner, Johan Kärrholm
   Submitted, J Bone Joint Surg *Am* 2009.

4. Design related risk factors for revision of primary cemented stems. Analysis of 3 frequent stems in the Swedish Hip Arthroplasty Register.
   Truike M.Thien, Johan Kärrholm
   Submitted, J Bone Joint Surg *Br* 2009.

ABBREVIATIONS

AP	Anterior Posterior
BMD	Bone Mineral Density
CI	Confidence Interval
CPP	Cost per Patient
DXA	Dual-energy X-ray Absorptiometry
F	Full Weight-bearing Group (study 1)
HA	Hydroxyapatite
HHS	Harris Hip Score
HMWPE	High Molecular Weight Polyethylene
M	Matte (study 2)
OA	Osteoarthritis
P	Partial Weight-bearing Group (study 1)
P	Polished (study 2)
PC	Polymethylmetacrylate Coated
PMMA	Polymethylmetacrylate
R_a	Root Mean Square Roughness
RR	Risk Ratio
RSA	Radiostereometry
ROI	Regions of Interest
SD	Standard Deviation
TCP	Tricalcium Phosphate
THA	Total Hip Arthroplasty
THR	Total Hip Replacement

PREFACE

This thesis aims to get more knowledge about femoral implants and their behaviour in total hip arthroplasty. However, at the same time as knowledge about any procedure increases, its limitations become more apparent. A certain implant or surgical technique may be the best available alternative in a specific patient population and therefore the medical profession may have reached consensus about a specific implant or surgical technique as first choice "the gold standard" in just that patient population. Newer implants, modifications of implants or in surgical technique can then be compared with this gold standard. However, no gold standard is the best standard in the world and the gold standard in total hip arthroplasty at this moment inevitable has to be replaced by another, someday in the future when the efficacy of new implants, modifications of implants or surgical procedures are evaluated and there is enough evidence for the new implant or surgical technique to perform better in the long-term.

"*It is the absolute truth that is never reached; gold standards are constantly challenged and superseded when appropriate"*.
Versi E, BMJ 1992;305:187

INTRODUCTION

Total hip arthroplasty (THA) has proved to be an effective treatment for degenerative hip diseases and one of the most cost-effective surgical procedures available[118]. The quality of life in many patients has radically improved by this operation when conservative treatment has failed[41]. In Sweden, about 14,000 THA's are performed annually and the number is increasing for every year.

Worldwide, more than one million patients receive a THA every year[44]. Most arthroplasties in Sweden are performed with cement, but since 2002 the percentage of uncemented arthroplasties is increasing and reached up to more than 20% of the total amount of total hip arthroplasties performed in 2007.

Tapered or straight stem designs are most frequently used outside Scandinavia, but in Sweden the most frequent used femoral stem is a cemented stem with an anteverted design. The survival rate for this anteverted cemented stem, reported by the Swedish Hip Arthroplasty Register, is excellent with a 15-year survival of about 95% in a population with an average age of 70 years[75].

Because of widening of indications for THA and because of an aging population, the conditions for the procedure such as bone quality and femoral anatomy are not always ideal. Moreover, the expectations of the procedure and the demands on the implant, especially in younger more active individuals, have increased. Although excellent results are achieved with the procedure in general, aseptic loosening still remains a problem; in Sweden over 60 percent of the total amount of revisions between 2005 and 2007 was performed because of aseptic loosening or osteolysis. The aetiology of aseptic loosening is generally accepted to be multi-factorial, involving both mechanical and biological processes. Poor initial stability as well as release of particles due to abrasive wear, with subsequent inflammatory response resulting in micro motion of the implant, are commonly accepted to initiate the failure process and lead to debonding, eventually cement fracture, when the THA is of cemented concept, and subsequently loosening. To address these problems, an increasing number of new implant materials, fixation principles, surface treatments, surgical procedures and rehabilitation programmes have been developed and were introduced

during the last decades. Despite extensive laboratory experiments and study of theoretical models and preclinical trials, many of the most successful hip implants are developed on an empirical basis and the reasons for the success of those specific implants are not completely understood. However, the clinical performance of new implants or new surgical techniques that, based on preclinical testing, have expected superior performance compared to contemporary standards can only be adequately evaluated in prospective randomized studies in comparison with established concepts and the studied patient groups have to be small to minimise the amount of patients at risk. High-resolution methods are necessary to early detect micro motion and small changes in the amount of wear and bone mineral density, important information for the prediction of later failure. Radiostereometry (RSA) and dual energy X-ray absorptiometry (DXA) are suitable methods with enough resolution for the proper evaluation of new implants in small patient populations.

Despite the overwhelming amount of research done in the field of THA for many decades, there are still many questions to be answered. It has become generally accepted that the clinical outcome in THA has to be related to stem shape and surface, but the optimum roughness of the surface treatment, especially for cemented stems, is still not clear. Furthermore, few studies on the bone remodelling around cemented and uncemented stem implants have been performed in a randomized way with longer follow up and with high-resolution methods. Clear evidence to support the recommendation of full weight-bearing immediately after implantation of uncemented THA is still lacking although this regimen is frequently practised.

Much effort has also been made to understand the mechanisms of stress shielding and to counteract the loss of proximal bone- mineral density (BMD) and osteolysis to reduce the need for revision. Uncemented femoral stems with reduced stiffness were introduced to improve bone remodelling and to reduce the development of distal sclerosis, but poor fixation and unacceptably high revision rates due to aseptic loosening turned out to be a major problem. To address this problem of fixation a new composite stem with reduced structural stiffness was developed, but the outcome of this stem has so far only been evaluated in a randomized way in the short term. The present study emphasized on the femoral component in THA with anteverted stem designs. The purpose was to evaluate the effects of postoperative weight bearing, surface treatment and the use of an isoelastic stem on the clinical outcome, fixation and bone remodelling in three prospective randomized studies using RSA,

DXA, conventional radiography and clinical instruments: All well established clinical methods for the evaluation of THA.

We also investigated in a fourth study whether design related factors play any role in the risk of non-infectious revision of the femoral component in primary cemented THA using extensive material from the Swedish Hip Arthroplasty Register. A pilot study on the effect of surface treatment of femoral stem prostheses in a laboratory animal model is also included.

Fixation: cemented THA

The modern concept of cemented THA as performed today with high molecular weight polyethylene (HMWPE) cups and polymethyl-metacrylate (PMMA) cement was introduced in 1962 by Sir John Charnley (1911-1982). Others had developed less successful and uncemented concepts since the late 1800s. During the last decades, Charnley's low friction total hip prosthesis system has been further developed and modified. It has enabled a normal life with long-term pain relief and improved function in vast numbers of patients with hip joint diseases[38].

Better cementing techniques, from finger packing (first generation) to the use of a femoral plug and retrograde filling of the femoral canal (second generation) and the use of pulsative lavage, vacuum mixing, proximal seal and compression of the cement (third generation) has notably improved the fixation of the femoral and the acetabular component resulting in reduction of the loosening rate. Under ideal circumstances, the femoral prosthesis is cemented in a neutral position[47,108] surrounded by an at least 2 mm thick and homogenous cement mantle without any defects and voids. PMMA cement is a filling material and do not act as an adhesive. It is often mixed with barium sulphate or zirconium oxide to become visible on radiographies and commonly antibiotics (usually Gentamicin) are added to the powder. Its elastic modulus is equal to bone and much lower than metal and when loaded, the cement will creep[48,116]. Although cement has been successfully used during the last decades, the curing (polymerisation) process of the cement with release of heat[123] and toxic effect of the monomer itself[117] has been regarded to be a problem due to impairment of bone regeneration at the bone-cement interface. To address this problem, several cement types were developed that have been tried in clinical situations with various, sometimes disastrous outcomes e.g. the Boneloc [52,109].

Several other prosthesis designs than that of Charnley with different shapes and made of other alloys, but still fixed with cement, have achieved similar and sometimes

even better long-term outcome, but in general comparatively limited progress has been achieved by development of new implants during the last decades. In Sweden the most frequently used cemented stem designs are the Lubinus SPII, the collared Spectron EF Primary and the tapered, polished Exeter prosthesis[75].

Fixation: uncemented THA

Uncemented THA is frequently used, especially in younger patients outside Scandinavia, although the number of uncemented arthroplasties is increasing also in Sweden. The outcome of uncemented THA depends on the same factors of cemented THA, related to the patient, the surgical procedure and the implant. Most implant designs currently used rely on a press-fit principle, which means that the femoral canal is under-reamed to provide as much initial bone contact as possible. The surface of the uncemented stem is roughened or coated to improve bone ingrowth and stable long term fixation. Thigh pain is more frequently reported by patients with uncemented THA than in those with cemented THA. It has been associated with micro motions or loosening of the implant. However, thigh pain has also been reported in patients with stable and fixed uncemented stems, probably due to the use of stem implants with excessive stiffness[16,21,34,70].

Excellent long-term outcome has been reported for several designs of modern uncemented THA, indicating that they can achieve fixation in a reproducible way[3,43,17]. However, proximal loss of bone (osteopenia) and osteolysis, partly due to a more distal load transfer from the stem to the bone with time as well as inflammatory processes caused by wear particles from the articulation are remaining problems in uncemented THA.

Stem material

Since the early days of orthopaedic surgery, cemented femoral stems in THA have often been made of stainless steel (e.g. the Exeter and the Charnley stems). However, cobalt-chromium alloys are preferred by most manufacturers today, due to the higher strength and hardness of this material compared to stainless steel.

In uncemented THA, titanium and titanium alloys are often first choice for femoral stem implants, due to their high biocompatibility, high strength, fatigue resistance and corrosion resistance. The elastic modulus of titanium is half compared that of cobalt-chromium. Therefore stress shielding and the amount of bone resorption are expected to be smaller. To even further decrease the elastic modulus and preserve the periprosthetic bone, other materials have been tried for uncemented stems. However, these

stem implants with reduced stiffness showed poor fixation and unacceptably high revision rates due to aseptic loosening with long-term follow-up[6]. In finite element studies, flexible stem designs produced greater micro movements and higher interface stresses than did stiffer stem designs[20,58]. Therefore micro motions at the implant- bone interface, also caused by inferior surface characteristics might have inhibited biological fixation of these stems[6]. One exception is the Epoch stem used in study III in this thesis, in which a polymer called polyaryletherketone (Ultrapek KR4177) is used as an injected-molded layer on a central core of cobalt-chromium alloy. The reliability of this stem for up to two years follow-up was established in earlier clinical studies[45,74] and more recently, an intermediate-term non randomized follow-up of hips treated with the Epoch stem indicated excellent clinical success[2].

Stem shape

There are two main principles to obtain durable fixation of a cemented stem[56,59]. The first is the shape-closed stem design, which is normally collared and supposed to become immediately and firmly fixed to the cement mantle which reduces cement stresses (e.g. Lubinus SPII, Spectron EF Primary). The second is the sliding taper stem design, a double tapered uncollared stem design (e.g. the Exeter) made to subside into the cement mantle to achieve secondary stability from compression forces in the cement mantle.

In uncemented THA the stem designs most commonly used can be divided in anatomic, straight and tapered shaped (wedged) stems. The anatomically shaped stems, e.g. the ABG, the Anatomic and the Epoch are supposed to fill and exactly fit the proximal femur to achieve primary stability, close bone contact and proximal bone ingrowth. The tapered uncemented stem is supposed to subside in the femoral bone to achieve secondary stable fixation. Initially the area of bone contact with this design is smaller.

Overall anteverted stems have been less frequently used than straight stem types both in cemented and uncemented THA. One exception is the cemented and matte Lubinus SP2 stem (Waldemar Link, Germany), which is frequently used in some countries and especially in Sweden[75].

Stem surface & coating

Surface treatment may have significant influence on the clinical outcome of uncemented and cemented stems. Any change in surface treatment may alter the clinical performance of a stem sometimes in an unpredictable way [99,89,90]. The matte surface previously used on the Exeter design e.g. could

probably not counteract subsidence inside the mantle. This resulted in abrasive wear, particle production, third body wear, osteolysis and loosening. Another change in surface treatment, precoating with polymethylmetacrylate (PMMA) used e.g. on the Iowa Hip, led to a dramatic change in the durability of the implant. It was believed that the proximal PMMA coating on the femoral stem would increase the long-time survival of the prosthesis, but instead an increase in the prevalence of loosening was seen[90,104].

The choice of surface treatment depends on the shape of the stem and mode of fixation. Cemented stems designed to achieve secondary stable fixation through subsidence e.g. tapered stem designs should most certainly be polished, especially when they are made of material with low resistance to abrasive wear. Anatomically shaped stem designs with a more complex and "locked" cement-stem interface (e.g. ABG, Lubinus, and Spectron) might be better stabilized by a matte, rough or precoated surface.

In many cemented THA designs, however, stem subsidence inside the cement mantle may occur according to previous RSA studies[94,33,109], regardless presence of a rough surface finish. Prosthetic subsidence caused by volume reduction of the cement during curing and subsequent creep of the cement has been calculated to be about 50 µm[115], and may explain why debonding can occur despite of surface treatments such as PMMA-coating or grit-blasting[91].

Several finite- element studies and preclinical studies have been performed comparing polished and rough cemented stems[8,37,79]. A number of clinical studies have shown tapered polished cemented stems to have better performance than some designs of rough cemented stems[23,24,55]. However excellent results have been reported with other types of tapers and shapes of cemented stems with a matte surface finish also in the Swedish Hip Arthroplasty Register[75]. Previous clinical studies on surface finish[23 31] did not have prospective and randomized study designs and have been based on studies of straight stems. Therefore, there is still not enough evidence for one stem surface to be superior to another when used on cemented stems with an anteverted design.

In uncemented THA, many coatings used to enhance bone ingrowth are well-documented with excellent outcome. The quality of ceramic coatings may vary depending on their crystallinity, purity, density and thickness. The coatings have to be thin partly to avoid fracture and if applied to a porous surface to preserve the porosity of the implant surface. If these coatings are too thin they will disappear too quickly jeopardising the bone ingrowth. Calcium phosphate ceramics such as

hydroxyapatite (HA) and tricalciumphosphate (TCP) are the most frequently used coating materials in uncemented THA. Hydroxyapatite, naturally present in bone mineral, has shown to be osteoinductive, which means that it enhances bone ingrowth across gaps between the implant and bone, even in unstable conditions[101,102]. The osteoinductive properties of HA have been confirmed by retrieval studies[10-12]. TCP is more bio-resorbable than HA and is therefore added to some HA-coatings to stimulate early ingrowth of bone. The ceramic coatings are often plasma-sprayed on implants with a porous mesh made of pure titanium e.g. the Epoch and proximally on the Anatomic stems used in this study. They may also be fixed to grit-blasted surface (e.g. the ABG or Omnifit stems).

Postoperative rehabilitation after uncemented THA

Although osseous ingrowth onto uncemented implants is enhanced by the use of HA[101,102] , it is definitely inhibited by excessive micro motion at the interface between implant and bone, but will occur when rigid initial stability of the implant in the bone is achieved[64,97]. Postoperative rehabilitation after uncemented THA including immediate weight bearing may cause micro movements at the interface between the implant and the bone, which might jeopardise the primary stability and ingrowth of the implant. Protected weight bearing for 6-12 weeks after insertion of uncemented implants has therefore been frequently recommended and practised at many orthopaedic centres[67,4,63], at our department as well, in order to prevent premature loading of the implant. However, some authors proposed that the patients' rehabilitation and functional recovery after THA-surgery could be promoted by early weight bearing with preservation of higher BMD of the periprosthetic bone[98,5,69]. Therefore, the opinion on weight bearing after uncemented THA successively changed and many orthopaedic centres started to allow immediate weight bearing as much as tolerated by the patient, although very little evidence was found in the literature to advocate this. More recently, some studies on weight bearing after uncemented THA have been published without showing any adverse effects of immediate weight bearing[22,13].

Outcome measurements of THA

The efficacy of THA surgery has been studied using a range of objective and subjective outcome instruments to obtain standardized evaluations[103]. These outcome measures focus on pain, function, range of movement and activity, quality of life of the patient and radiographic parameters, assessment of changes in BMD, evaluation of

migration and revision rate (survival analysis) of the prosthesis.
Validity, reliability, precision and accuracy are definitions that are frequently used to describe the properties of clinical outcome instruments. Validity means that the instrument measures what it is intend to measure. Reliability means that the instrument is able to repeat the measurement with consistent results. This repeatability of an instrument is called precision. Accuracy is the ability of the instrument to correctly detect the true changes of a parameter/measure.

Clinical evaluation

To evaluate the clinical outcome of THA, two main types of patient-based measures, disease-specific questionnaires e.g. WOMAC[28], and the MACTAR scale[110] and generic questionnaires such as the Short Form 12 and 36[113] the Nottingham Health Profile (NHP 66)[61] and the Sickness Impact Profile (SIP)[29] with varying validity and reliability[106], have been used. These methods are self-administered (subjective) or do need a clinical assessment with an independent and objective observer, which is more costly and less straightforward to organize. A combination of subjective and objective measures and disease-specific and generic measures is recommended to achieve a complete assessment of health-related quality of life and overall outcome in total joint arthroplasty[27,81]. During the last decade, cost-effectiveness analysis (the comparison of cost-utility between different surgical interventions) have become increasingly important, due to the limited health care budgets worldwide, and new generic measures specially emphasizing on this topic have been developed.
The Harris Hip Score is an example of an objective (not self-administered) disease-specific outcome measure. This score was originally introduced in 1969 to evaluate the outcome after acetabular fractures[50]. It is a standardized form on pain, function, activities of daily living, range of motion and deformity (leg length discrepancy).
Specific pain drawings and visual analogue scales[62] are two examples of subjective measures that only focus on pain.

Conventional radiography

Despite the development of more sophisticated methods, the standard method for the evaluation of hip implants worldwide still is conventional radiography, with radiographic examination with anterior-posterior (AP) and lateral views under standardized conditions (magnification, exposure rate and patient position) at regular time intervals. The radiographic evaluation is further standardized with division of the interface around

the acetabular and the femoral component into 7 regions for the stem[47] (figure 1) and three regions for the cup[30] both on the AP and lateral views. Regular follow-up of THA with conventional radiography is done to detect early signs of radiographic loosening for whatever reason. Signs of bone remodelling, radiolucent lines (zones), erosions, formation of granuloma and presence of osteolytic lesions are defined and described in the different regions on the acetabular and femoral side. The quality of the cement mantle is commonly graded according to Barrack around the femoral stem[9] and a modified but quite similar grading is used for the evaluation of the cement mantle around the acetabular cup[105]. Eventual formation of heterotopic bone is graded according to Brooker[19].

The presence of radiolucent lines and/or osteolytic lesions indicates bone resorption and is of prognostic value for mechanical loosening[71]. However, the most important prognostic factor for implant loosening is early migration[78], which is difficult to measure with enough precision on plain radiographs.

During the last decade, the development of various computer software programmes has notably facilitated the evaluation of conventional radiographs; large series of radiographs can now be digitized and assessed in relatively short time. However, the procedure is still subjective with considerable inter- and intra-observer variability[18,87] and the amount of reported changes on radiographs are underestimated as compared with findings from retrieval studies[40]. Another problem is that there is no consensus about the definition of radiographic signs: radiolucent lines and osteolytic lesions e.g. have been defined in many different ways.

Bone remodelling & DXA

After the insertion of a femoral prosthesis, the loading of the proximal femoral bone will be reduced, which results in decreased BMD due to adaptive bone remodelling with redistribution of the bone adjacent to the prosthesis until a new equilibrium has been established (Wolff's law)[120]. The process of bone remodelling is most pronounced in the proximal part of the femur and during the first postoperative years[68,72] but continues at a slower rate thereafter[3,14]. If and when a steady state will be reached is depending on multiple mostly patient-related factors[92]. This phenomenon of skeletal response, stress shielding, probably occurs with the same magnitude around both cemented and uncemented stems[86] and increases the stiffer the femoral implant[56,80]. It is more likely to develop the lower the patient's preoperative BMD[85,39] and depends also on stem size and the mode of fixation. The amount of cortical

stress-shielding for uncemented stems e.g. is higher in fully coated implants compared to implants with coating on the proximal third only [39,57].

Dual energy x-ray absorptiometry (DXA) has frequently been used for the evaluation of bone mineral density after total hip arthroplasty [13,32,68,93]. It is a non-invasive clinical evaluation method that provides the accuracy and precision necessary to detect and quantify changes in bone mineral density (BMD), which means BMC (bone mineral content) divided by the area of the region of interest (ROI), in vivo. The precision of the DXA-method is most optimal when the variation in patient position between following examinations, especially the rotational position of the femoral bone in cemented stems, is minimized[46]. Change of bone mineral density is usually reported in percentages.

Radiostereometry

Radiostereometric analysis (RSA), initially called roentgen stereo-photogrammetric analysis has been increasingly used since its introduction in 1974 by Selvik[100]. Selvik modified and developed the original roentgen photogrammetry method by Hallert[49]. RSA with use of tantalum markers implanted in the skeletal bone, cement and onto the orthopaedic implant has been described in several articles and theses and has been continuously developed to improve its applicability in a number of fields in orthopaedic research[73,76,77,100,112,15,95,122]. The high precision of the method makes it possible to measure both migration and wear in three dimensions with higher resolution than conventional radiography (provided that at least three well-spaced, stable tantalum markers are present) which today is required for documentation of equivalent or better performance of new or modified implant designs.

Revision rate (survival analysis)

Survival analysis is a commonly used measure to evaluate the outcome of total hip arthroplasty. The probability for an implant to survive is calculated using revision as endpoint. The follow-up among the patients may vary and at any stage cases can be entered or withdrawn for whatever reason.

Observational studies such as the national hip arthroplasty registers in several countries apart from Sweden provide, due to large patient cohorts, valuable information on the performance of hip implants. In the Swedish Hip Arthroplasty Register, the estimation of survival is calculated using the Kaplan-Meier method[66] with revision (exchange of any or all of the prosthetic components or removal of the implant) and reoperations (revision or any further hip surgery) as endpoint. Thus the definition of

reoperations embraces a wider concept. Confidence intervals have to be reported, because the number of patients at risk in any survival analysis decreases with time.

Revision or reoperations as endpoint, however, are precise but blunt instruments and they do not provide information about the outcome from the patient's point of view. All patients who still have their prosthesis in situ do not have a good outcome. There are patients with pain and discomfort who are not revised and neither planned for any revisions. The cohort of unrevised patients with problems probably is as large as the revised cohort[103]. The number of revisions depends on the local operation capacity and the availability of a skilled surgeon to perform an often complicated revision operation. The revision rate is also dependent of the frequency and the way in which the patients are evaluated. Furthermore any "wait-and-see" approach i.e. avoiding operation for complications such as e.g. recurrent dislocation, results in underestimation of the number of revisions.

The Kaplan-Meier method cannot be used to assess the influence of design-specific characteristics, age, gender, diagnosis, incision and number of operation on the risk of revision of the prosthesis. When assessing such implant-, demographic- and surgery-related parameters, multivariate Cox proportional hazard regression models (Cox regression analysis) are often used.

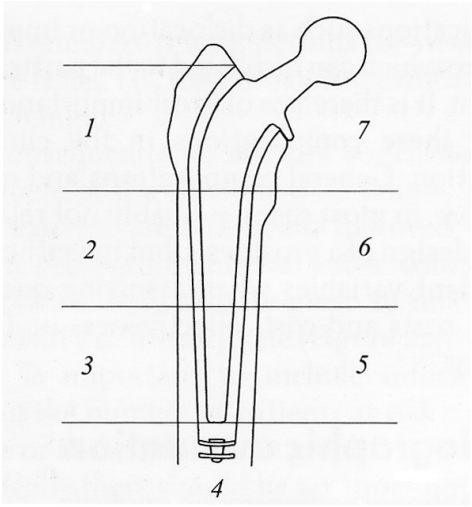
The Swedish Hip Arthroplasty Register

The Swedish Hip Arthroplasty Register was initiated by Herberts and Ahnfelt[1] thirty years ago to improve the outcome of total hip replacement surgery. Since then the Register has become well established and has proved to be an important tool for continuous monitoring of outcome after total hip replacement in Sweden[53,54,83].

The Register covers all operation units, although participation is voluntary, and is representative for a wide spectrum of orthopaedic surgeons with variable clinical experience. Since 1999, the data from the Register are available to the public on the internet (www.jru.orthop.gu.se). Since its start in 1979, the Register has mainly concentrated on results of different implants and surgical techniques and revision/reoperation of any of the implant components has been the failure endpoint in the survival analyses. Individual registration of primary arthroplasty was introduced in 1992 and demographic data from primary arthroplasty, such as age, gender and diagnosis were included. Since 1999 the Register has increased the data capture to also include the individual article number of each component in an individual THR, which makes the analysis of

implant-related parameters e.g. stem size, neck length, head size and material used in the individually assembled THR possible. Since 2002 the Register has been completed with a clinical follow-up tool (individually based health outcomes and measurements of health-related quality of life) and a radiological follow-up tool and also the term CPP (cost per patient) has been introduced. In ongoing projects non-operative treatment of hip and knee pain is evaluated. Data from the Register are also used to study health-economy and cost-effectiveness with relation to THR.

Figure 1: standardized division of the interface around the femoral component (here exemplified for the Lubinus SPII) into 7 regions according to Gruen et al.



AIMS OF THE STUDY

The aim of this study was to investigate the influence of postoperative treatment, surface treatment and stem design on the outcome of primary total hip arthroplasty. The main intention was to study femoral stems with an anteverted stem design.

The specific aims were:

Study I:

To evaluate the effects of a full vs. partial weight bearing during six weeks after uncemented primary total hip arthroplasty on femoral stem and cup migration/rotation and the penetration of the femoral head.

Study II:

To evaluate the effect of 3 different surface treatments (matte, polished or PMMA-coated) on an anteverted femoral stem fixed with cement on stem and cup migration, penetration of the femoral head, radiographic appearance and bone remodelling of the proximal femur.

Study III:

To evaluate the medium term results of an uncemented anteverted stem with reduced stiffness using a solid stem as reference. Outcomes were stem migration, bone remodelling, radiographic appearance, Harris Hip Score and pain drawings.

Study IV:

To evaluate if design related factors play any role for the risk of non-infectious revision of the femoral component in primary cemented total hip replacement. Data from the Swedish Hip Arthroplasty Register were used and adjusted for bias caused by demographic and surgery related factors.

PATIENTS

The demographic data for Study I-III are presented in table 1.

Study I:

Between February 1996 and February 2000, 21 men and 22 women with a mean age of 53 (41-63) years, mean weight of 79 (59-140) kg and mean preoperative Harris score of 46 (23-57) entered the study after informed consent. All the patients were planned for primary uncemented THA at Norra Älvsborg/Uddevalla Hospital and at Kungälvs Hospital. Thirty-six patients had primary OA, 3 had secondary OA due to dysplasia and 4 had secondary OA due to various reasons.

Before the operation, the patients were stratified on the basis of sex and weight (<75 kg, ≥ 75 kg and more) and randomly allocated (using envelopes) to post-operative rehabilitation programmes either allowing partial (Group P) or full weight bearing (Group F) for the first 6 weeks after operation. The clinical parameters did not differ preoperatively between the two groups. Patients were evaluated using clinical outcomes/measures and RSA 5-7 days postoperatively, at 3 months and at 1 year after the operation. In one patient, a 60-year old male, who was randomized to full weight bearing a fracture in the femoral cortex occurred peroperatively. The postoperative regimen was therefore changed and the patient had to be excluded from the study but continued participating in the clinical and radiological follow up. In further one, a 56-year-old female, a fracture was suspected first on follow up at 3 months. This patient was randomized to partial weight bearing and continued her mobilization according to the protocol. No examinations were missing but not all radiostereometric calculations could be done, primarily due to insufficient visualization of the tantalum markers in the peri-acetabular bone on the postoperative radiographs. In 4 patients (all F) insufficient numbers of tantalum markers in the proximal femur were seen on the immediately postoperative or the 1-year follow up. Thus 38 femoral stems (19 P, 19 F) could be evaluated using RSA. There were no reoperations during the first year and none of the patients were planned for revision at 1 year follow up. Neither were there any other patients lost to follow up for other reasons than mentioned above.

Study II:

Between April 1998 and April 2000, 80 consecutive patients (31 male, 49 female, 68 *46-78* years, 84 hips) with non-inflammatory osteoarthritis of the hip, who were planned for cemented primary THA at the

Sahlgrenska University Hospital, Göteborg, entered the study after informed consent. Patients with multiple joint diseases were excluded. Before the operation, the patients were stratified on the basis of age, sex, and weight and randomly allocated using sealed envelopes to receive either stem type of the Lubinus SP II anatomic cemented stem design combined with a whole cemented polyethylene cup. Twenty-eight hips received a PMMA coated stem (Ra 1.5 µm), 27 hips a matte stem (Ra 1.5 µm) and 29 hips a polished femoral stem (Ra < 0.05 µm). The clinical parameters did not differ preoperatively between the three groups. All the patients were evaluated 5-7 days postoperatively and at 6 months, 1, 2 and 5 years after the operation. Clinical evaluation was performed using the Harris Hip Score. Component fixation and wear were evaluated using RSA and conventional radiography. In additionally 40 of the 84 hips, the BMD around the stem was measured at every follow-up occasion. There were no reoperations during the 5-year follow-up and no patients were revised. At the 5-year follow-up, there were eleven missing RSA observations and conventional radiographs were missing in 6 cases. One patient died between the one and 2-year follow-up and three patients (1 P, 1 PC, and 1 M) died between the two and 5-year follow-up of causes not related to the hip operation. One patient (PC) was excluded from the study immediately postoperatively because of co-morbidity (rheumatoid arthritis) and another patient (M) did not want to continue participating in the study after the 2-year follow-up, although she was satisfied with her THA. In one patient (M) the postoperative RSA examinations were missing. The patients with "missing or poor quality RSA examinations" attended the clinical and conventional radiographic follow-up.

Study III:

38 consecutive patients (28 males, 10 females, mean age 57, *41-74,* 40 hips) with non-inflammatory osteoarthritis of the hip and a femoral canal that was at least 14 mm in diameter entered the study after informed consent. All the patients were planned for uncemented primary THA at the Sahlgrenska University Hospital, Göteborg and were operated on between June 1994 and October 1998. Before the operation, the patients were randomly allocated using a software program that stratified the groups on the basis of age, gender, and the presence of primary or secondary OA to receive either a stem with reduced stiffness (Epoch) or a stem made of solid metal (Anatomic). Clinical evaluation, conventional radio-graphy, RSA examinations and measurements of the BMD around

the femoral stem were done postoperatively (5-7 days), after 3 months, 6 months, 1, 2, 5 and 7 years. One patient (male, bilateral Epoch and Anatomic) died after two years and two patients (male, anatomic) died between the 5 and the 7 years follow-up from reasons not related to the hip surgery. At 7 years 1 stem had been revised (Anatomic) due to late infection probably related to a chronic paronychia on his right hand. Multiple cultures from the hip did not show any specific agent. There were no other revisions at 7 years and no patient was planned for revision at the time of writing.

Study IV:

The three most frequently used stem designs in the Swedish Hip Arthroplasty between January 1st 1999 and December 31st 2006 Register were studied using revision of the femoral component with or without any simultaneous revision of the acetabular component as endpoint. Specially designed implants (e.g. some dysplasia or extra long stems) were excluded as well as femoral components or implants used in small numbers (n<50). All THR revised due to infection and those performed because of local malignant tumour were excluded. 72,991 cemented femoral stem implants (21,246 Exeter polished stems, 44,605 Lubinus SPII stems and 7,140 Spectron EF Primary) were analyzed at an average follow-up period of 3.5 ± 2.2 years.

Table 1: Demographic data of all patients in study I-III.

	Study I[1]		**Study II**[2]			**Study III**[2]	
Groups	Partial	Full	Polished	Matte	PMMA	Epoch	Anatomic
Male/female	10/9	11/13	14/15	11/16	8/20	14/8	16/2
Age	54(41-63)	53(46-60)	70(46-77)	69(52-77)	67(52-78)	57(42-69)	61(64-111)
Weight (kg)	76(59-30)	82(60-140	78(53-115)	80(57-100)	70(57-90)	75(53-100)	87(64-111)
Harris Hip Score Preop	46(23-57)	45(30-57)	44(21-72)	44(23-66)	42(25-76)	53(19-70)	48(30-62)

[1] Mean (range)
[2] Median (range)

IMPLANTS

Implants Study I-III

All patients in Study I received an uncemented total hip prosthesis of the ABG I type (Stryker-Howmedica®) (figure 2a). The hemispheric acetabular cup made of titanium alloy is coated with pure hydroxyapatite (HA) with a coating thickness of 60 µm (chemical purity of 99.99%, crystallinity of 98% to 99%) and fitted with a polyethylene insert. Initial mechanical stability is achieved by press fit. The titanium femoral stem is anteverted and tapered proximally but straightened distally. It is designed to provide anchoring only at the metaphyseal portion of the stem which is coated with HA. The ABG stems used in Study I were supplied with 3 titanium towers each with a tantalum marker attached to its tip. In all cases, a modular 28 mm cobalt-chrome head was used.

The Lubinus SP II anatomic cemented stem design (Waldemar Link, Hamburg, Germany, figure 2c) and two modifications of this stem design, a PMMA coated femoral stem and a polished femoral stem (figure 2b), were used in Study II, combined with a whole cemented polyethylene cup (Lubinus eccentric, Waldemar Link, Hamburg, Germany) in all patients. 28 hips received the PMMA coated stem (Ra 1.5 µm), 27 hips the standard matte stem (Ra 1.5 µm) and 29 hips a polished femoral stem (Ra < 0.05 µm). All stems were anteverted and made of Cobalt-Chromium alloy. They were double curved with anterior and posterior ridges and had an anatomic shape corresponding to the shape of the femoral bone. The PMMA coated and the matte stems were equipped with a collar, the polished stem had no collar. All prostheses were produced by the same manufacturer (Waldemar Link, Hamburg, Germany) and they were supplied with titanium towers each with a tantalum marker attached to its tip. A modular 28 mm cobalt-chrome head was used in all combinations.

In Study III the Epoch and the Anatomic stem designs (Epoch® and Anatomic®; Zimmer, Warsaw, Indiana, USA) were used (figure 2d and e). Both have an anteverted neck.

The Epoch stem has a central core made of forged cobalt-chromium alloy with an injected-molded layer of polyaryletherketone (Ultrapek KR4177) onto it. The polymer completely covers the metallic core up to the shoulder of the stem. It is supplied with an additional surface layer, which consists of a porous fiber-metal mesh made of commercially pure titanium. This mesh has an effective thickness of

0.83 mm and an average pore size of approximately 300 µm. It is anchored to the polymer at the time of injection moulding. A ceramic coating consisting of approximately 65% HA and 35% Tricalcium-phosphate (TCP) was plasma-sprayed on the proximal two-thirds of the mesh to achieve an approximate thickness of 70 µm (minimum 51µm). The Epoch stems used in Study III were additionally supplied by the manufacturer with tantalum markers in the polymer and at the tip of 2 titanium towers at the tip and the shoulder of the stem. Today the Epoch stem is available down to size 13 and the anteverted version has been replaced by a straight design. However, the design used in Study III corresponds to the original anteverted stem design and was available from 14 mm to 18 mm.

The anatomic stem is made of surgical-grade titanium alloy (Ti-6Al-4V). The proximal porous coating is circumferential and of the same quality as the coating used on the Epoch stem. The porous surface of the Anatomic stem is supplied with a HA-TCP coating. In addition a pure HA coating was supplied from the porous area down to the polished distal third of the stem. The Anatomic stems used in Study III had been supplied by the manufacturer with 3 titanium towers, mounted with a tantalum marker, at its shoulder and its tip.

In one hip a Harris-Galante® –II cup (Zimmer Inc, USA) was used. In the other 39 hips Trilogy® cups (Zimmer Inc, USA) were used. Screws were used in seventeen of those Trilogy cups for supplementary fixation. All cups had a porous titanium fiber mesh with a HA-TCP coating onto it and polyethylene liners gamma-sterilized with 2.5 Mrad in inert nitrogen gas. A modular 28 mm head was used in all cases. Thirty-four hips received a cobalt-chrome head and six hips (4 Epoch, 2 Anatomic) received a head made of aluminium oxide.

All cups in Study I-III had tantalum markers in the liner or the polyethylene respectively for radio-stereometric measurements.

Implants Study IV

In Study IV the three most frequently used (cemented) stem designs in the Swedish Hip Arthroplasty Register were analyzed. The Exeter® prosthesis (Stryker/ Howmedica/ Osteonics, Allendale, NJ, USA) is highly polished, tapered and made of low corrosion stainless steel (Orthinox). It does not have a collar and is equipped with a hollow centralizer made of pre-polymerized acrylic cement that is applied to the tip of the stem to allow subsidence of the stem in to the centralizer. The Ra of the Exeter® stem is about 0.1-0.3µm. The Exeter® stem designs used in Sweden between 1999 and

2006 have consisted of two slightly different prosthesis systems, one older version and the newer Exeter V40™ with a spigot at the head-neck junction to allow the use of a ceramic bearing combination. The shape of the part of the stem in contact with the cement is equal for both stem designs. The stem is available in 7 sizes with 6 increasing offsets and further offset options are provided by different neck lengths with the modular heads.

The Lubinus SPII stem prosthesis (Lubinus eccentric, Waldemar Link, Hamburg, Germany) used in Study IV is made of cobalt-chromium alloy. The stem has an anatomic shape corresponding to the shape of the femur and does not have a centralizer. It is double curved with ridges on the anterior and the posterior side. The stem has a matte surface with a surface roughness (R_a) of 1.5 µm and is available in 7 increasing sizes, each with a standard or extended neck length, and with three different neck angles (117º, 126º and 135º). The length of all Lubinus stems analyzed in Study IV is 150mm.

The Spectron EF primary prosthesis (Spectron primary, Smith and Nephew, Memphis, TN, USA) is straight and also made of cobalt-chromium alloy (CoCr). The proximal 1/3 of the stem is grit-blasted (R_a = 2.8 µm) and the distal part is smoother (R_a = 0.7 µm). A centralizer is applied on the tip of the stem. The Spectron EF Primary is available in five sizes with increasing length and thickness. Each stem size is available with normal or high offset. All sizes have the same neck angle (131º). In the high offset design the neck length of the stem is extended relatively to each stem size.

The pressure-sensitive insole

The pressure-sensitive insole used in Study I (Pedi-sense) is developed in Göteborg by Aggero Produkt & Affärsutveckling (figure 3 © Acta Orthopaedica) and has been used in several clinical studies earlier [13,111]. It is a battery-operated pressure-sensitive auditory device incorporated in the insole of the shoe. The auditory device is applied with three pressure-sensitive sensors, two in the forefoot and one in the heel that can be calibrated to a certain weight limit. When the load on the sensors exceeds this calibrated weight limit, the device gives an auditory signal.

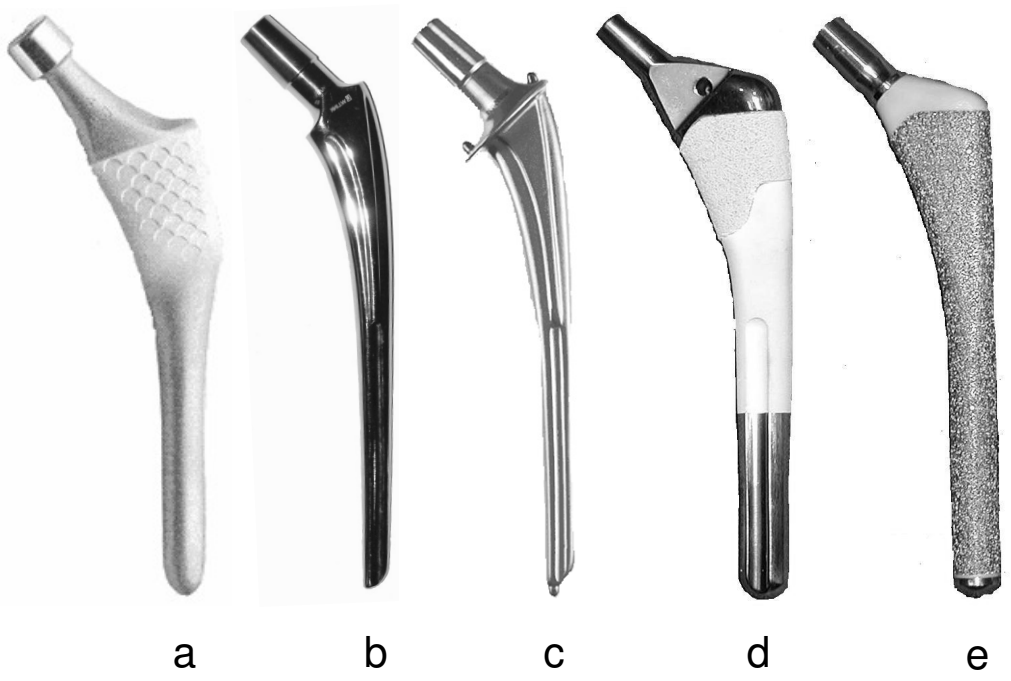


Figure 2: The uncemented ABG stem (a), the collarless polished Lubinus SPII stem (b), the standard Lubinus SPII stem (here supplied with titanium towers to facilitate RSA) (c), the solid Anatomic (d) and the Epoch stem with reduced stiffness (d). All stems with an anteverted design.

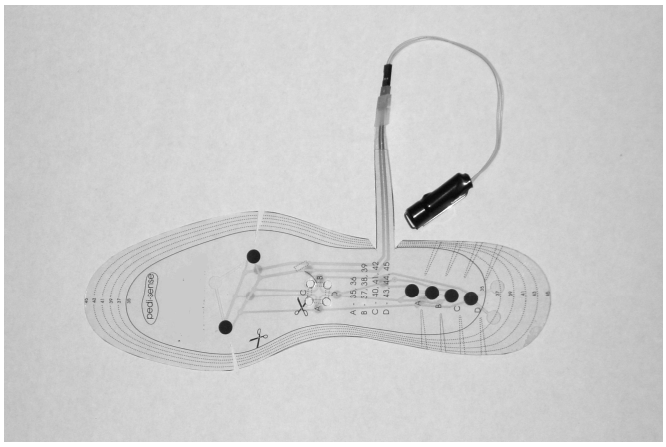


Figure 3: The battery-operated pressure sensitive auditory device (Pedi-sense, Aggero Produkt & Affärsutveckling, Sweden).

METHODS

Surgical technique

All the operations in study I-III were performed in an environment with laminar airflow by experienced surgeons with use of an anterolateral approach with the patient on the side and instruments made for the specific implant design. All patients received prophylactic antibiotics. In study I and III, the rotational stability of the stem was intraoperatively checked using a torque wrench[51] and if the largest rasp used resisted a torque of 13.6 N-m, the implant was considered to be stable. In study II, third generation cementing technique was used including prechilled vacuum mixed Palacos® cement with gentamicin (Schering Plough), cement restrictor, cement gun and continuous pressurisation with a proximal seal. The Lubinus SPII stem has no centralizer. Modular 28 mm heads were used in study I-III. In study I and II only cobalt-chrome heads were used, whereas in study III, six out of 34 hips received a head made of aluminium oxide.

Radiostereometry

Radiostereometric examinations in study I-III were done with the patient supine postoperatively (5-7 days, all studies), after 3 months (study I and III), 6 months (study II and III), 1 year (study I-III), 2 and 5 years (study II and III) and after 7 years (study III). Uniplanar technique with the calibration cage positioned under the examination table was applied[73,77,100,112]. At each examination, two radiographs were exposed simultaneously with the x-ray tubes angled 35 to 40º in relation to each other. The two dimensional position of the calibration cage and patient markers were recorded to be able to calculate the three-dimensional co-ordinates of the markers in the patient. All markers in the same segment, the bone, the implant and the cement were modelled as rigid bodies. In order to maintain the precision (repeatability) of the measurements the RSA evaluations were only done if the marker scatter corresponded to a condition number < 120 and their stability to 0.3 mm (mean error of rigid body fitting[100]). If less than 3 markers were available in the implant, only the translation (point motion) of each individual marker could be calculated and not the translations or rotations of any segment. This type of evaluation was only done when one medial and one lateral marker could be seen. The mean value of these markers represented translation.

The rotations of the stem were measured in relation to the 3 cardinal axes. Subsidence of the gravitational centre of the stem markers and the centre of the femoral head were

calculated. Migration of the femoral stem in relation to the bone was only studied in terms of subsidence. The migration of the cup was measured as rotations around the three axes and translations of the cup centre. The translations of the femoral head centre using the cup markers as fixed reference segment were evaluated to measure the femoral head penetration, here called wear. For all measurements and calculations used the UmRSA system (RSA Biomedical, Umeå, Sweden) was used. In study I and partly in study III, the old manual method to measure RSA radiographs on a digitizing table with servomotors and a joystick was used. This method was substituted during study III with a semi automated digital method, with higher speed and proven increased accuracy, decreased mean error of rigid body fitting and increased precision[15]. In study II, all RSA measurements were done with the digitized method. To assess the precision (repeatability) of the RSA measurements, double examinations of the cup and stem were performed in study II and III with a time interval of 10-15 minutes the same day. The precision data from study II are presented in table 2. All migration data in study I-III are presented as signed values.

Table 2: Precision based on 42 double examinations of the Lubinus cup and 40 Double examinations of the Lubinus stem.

	Cup migration	**Wear**	**Stem migration**	**Cement mantle migration**[1]
Translations (mm)				
Transverse axis	0.10	0.11	-	-
Longitudinal axis	0.11	0.09	0.22	0.35
Sagittal axis	0.18	0.29	-	-
Rotations (degrees)				
Transverse axis	0.47	-	0.47	-
Longitudinal axis	0.51	-	0.94	-
Sagittal axis	0.22	-	0.26	-

[1] *n= 33*

The data corresponds to significant motions in the individual case at the 99% confidence interval (absolute mean difference between repeated examinations + 2.7 SD).

Conventional radiography

The radiographic evaluation in study II and III was based on AP, lateral and pelvic views exposed immediately postoperatively and at the 5-year and 7-year follow-up, respectively. All measurements were performed using a computer software program M-desk™ (RSA Biomedical). One observer, not involved in the surgical procedures of the patients, studied all the radiographs.

In study II, the cementing of the stem was graded according to Barrack[9] and a modification of this classification[60] was used to assess the cementing of the cup. Heterotopic bone formation was classified according to Brooker et al[19]. The interface around the acetabular component was analyzed in 6 regions corresponding to 3 equal regions on each view, a modification of the original regions described by Delee and Charnley[30]. The femoral stem interface was analyzed in 7 regions on the AP view and the lateral views according to Gruen[47] (figure 1). Radiolucent lines around the cemented implant components in the different regions were recorded and classified into four grades: no lucency, < 50%, 50-99% and 100%. Radiolucencies greater than 2 mm were defined as *osteolytic lesions*.

In study III heterotopic bone formation was classified according to Brooker et al[19]. The femoral stem interface was analyzed in 7 regions on the AP view according to Gruen[47]. Radiolucent lines around the uncemented stem implant with a minimum width of 0.3 mm in the different regions were recorded and classified into four grades: no lucency, < 50%, 50-99% and 100%. Any increase of cortical hypertrophy compared to postoperative radiographs was recorded. Changes in radiographic density in the calcar region (calcar resorption) and the area of intramedullary sclerosis distal to start of narrowing of the tip of the prosthesis (tip sclerosis) were, if present, defined and recorded in square cm.

DXA

Dual-energy X-ray absorptiometry (DPX-IQ; Lunar Co, Madison, Wisconsin, USA) was used in study II (40 patients) and in study III (all patients) to measure the bone-mineral density (BMD) of the periprosthetic femoral bone. The measurements were done within 7 days from the operation and after 6 months, 1 year, 2 years, 5 years and 7 years (study III only). The patients were measured in a supine position by one of two experienced technicians. Foot brace and knee supports were used during scanning to obtain standardized positions. The BMD was analyzed in 7 regions of interest (ROIs) according to Gruen[47](figure 1) and expressed as

areal BMD, g/cm^2. Region 1 and 7 were modified depending on the patient's anatomy to include the tip of the greater trochanter and to exclude any of the pelvic bone, respectively. For each patient we aimed to maintain the same size of the regions of interest throughout the entire follow up period. The BMD changes over time were calculated in percentages with the postoperatively recorded BMD values as reference.

Clinical evaluation

The Harris Hip Score[50] was used for clinical evaluation in study I-III. In study II, the patients were also asked to grade their pain on a visual analogue scale (0-100 mm)[62]. In study III, the clinical evaluation was expanded with a more specific questionnaire about pain and discomfort (appendix)**,** in which the patients were asked whether they had any pain or discomfort in the region of the hip and, if so, to indicate the location of the symptoms (groin, greater trochanter, buttock, thigh or a combination of this). They were also asked to rate the frequency of the pain or discomfort (rarely, now and then, often, or always).

Statistical methods

Study I

Signed values were used in the statistical calculations for stem and cup migration. The study was designed to detect a difference in stem subsidence after 3 months of 0.2 mm based on the presumption of a SD of 0.2 between the two groups (> 80% probability). Binary logistic regression was performed for including the stratification criteria age, sex and weight as covariates. Statistical evaluation was performed with non-parametric tests (Mann-Whitney) because all the measurements of the primary parameters were not normally distributed at three months. Any difference was considered to be statistically significant when $p< 0.05$. Data are presented as mean with SE in figures and as mean with ranges and 95% Confidence Intervals in tables.

Study II:

Signed values were used in the statistical calculations for stem migration. Statistical evaluation was performed with non-parametric tests, because most of the parameters analyzed were not normally distributed. Comparisons between the 3 stem types were based on Kruskal-Wallis tests to reduce the number of computations. Further analysis was performed using the Mann-Whitney U-test if a difference was regarded as established in the Kruskal-Wallis Test ($p<0.05$). A p-value of less than 0.05 was considered to be statistically significant. To reduce the number of statistical tests evaluation of RSA data was only done at 6 months and

at 5 years. Data are presented as mean and range for migration and wear or as median and range for patient data and changes in BMD.

Study III:

Signed values were used in the statistical calculations of stem migration. The study was designed to detect a difference in stem subsidence of 0.2 mm based on the presumption of a SD of 0.1 between the two groups (> 80% probability). The power of the present study was 99 % on the basis of observed scatter of the data with an observed population mean for stem subsidence of 0.20 mm and an observed SD of 0.10 mm and a difference in BMD change of 10-20% could be detected with at least 80% probability depending on the Gruen region analyzed.

The measurements of the primary parameters were not normally distributed (Saprio-Wilk's: W= 0.3-0.99) and therefore statistical evaluation was performed with non-parametric tests (Mann-Whitney). Any difference was considered to be statistically significant when $p< 0.05$. To restrict the number of calculations, statistical analyses were performed on the RSA data obtained at the 2, 5 and 7-year follow-up only. A linear regression analysis was used to study additional factors (gender, age, weight, postoperative BMD, stem size and proximal wear at 7 years) with a possible influence on the change in BMD between the postoperative and 7-year follow-up examinations. Data are presented as mean and range for migration and rotations and as median and range for patient data, wear and changes in BMD. In the radiographic analysis median values are reported including 95% confidence intervals.

Study IV:

Design-specific characteristics of the femoral implant were analyzed using separate Cox regression models that were adjusted for gender, age, diagnosis, incision and number of operation (1^{st} or 2^{nd}). Stem size, neck length, and a constructed offset variable including presence of offset version (Lubinus SPII and Spectron EF Primary) and neck length were given sequential numbers and were analyzed both as continuous and classified variables. Stem type (Exeter), CCD angle (Lubinus SPII), use of extra offset version (Lubinus SPII, Spectron EF Primary) and head material and size that were analyzed as classified variables Adjusted risk ratios, 95% confidence intervals (CI) and p-values are reported. A p-value < 0.05 was considered to be significant. Statistically significant relative risks of stem revision and 95% confidence intervals for implant-related, patient-related and surgery-related parameters are reported for each stem type.

Ethics

Studies I-III were approved by the Ethics Committee of Gothenburg University and were conducted according to the Helsinki Declaration of 1975.

Figure 4: One specimen before mounting in the MTS-machine

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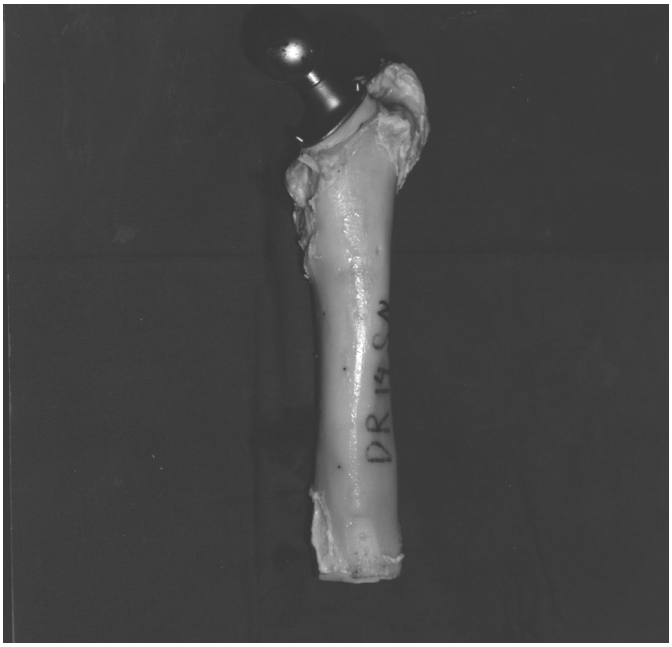
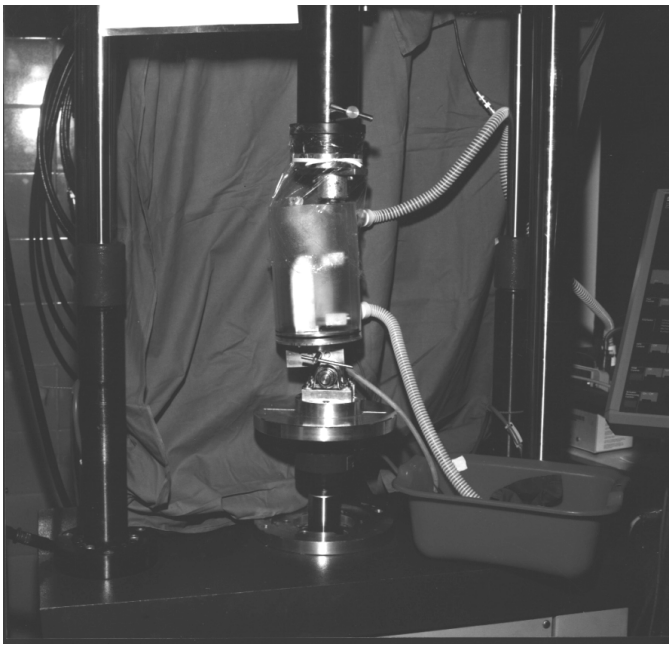


Figure 5: The MTS-machine loaded



FIXATION OF ANTEVERTED POLISHED, MATTE AND FEMORAL STEMS IN A LABORATORY MODEL (*performed autumn 1997*)

Introduction

Femoral stem design and surface treatment play a significant role for fixation and ultimate clinical performance[89,90,99]. So far the influence of these factors is not completely understood. Before starting a prospective randomized clinical study (study II in this thesis), we designed a laboratory model as a pilot study. We evaluated the fixation of matte (M), polymethyl-metacrylate-coated (PC) and polished (P) stems of the Lubinus SPII design when cemented into femora of adult sows.

Material & methods

Eighteen fresh frozen cadaver sow femora were retrieved from a slaughterhouse and prepared after thawing. Soft tissue was removed and after side identification weight and dimensions of the bone were determined (table 3). The femoral head and the femoral condyles were removed and the femoral canal was prepared by reaming and brushing and distally closed with bone cement to obtain a stable distal end. Six prostheses of either stem type were cemented in the prepared sow femora using the third generation cementing technique with use of Palacos ® cement (Scheringh-Plough) (figure 4). The matte and precoated stems were supplied with a collar and had the same surface finish (R_a=l.5 μm). The polished stem had no collar. All stems were made of cobalt-chromium alloy. All prostheses were produced by the same manufacturer (Waldemar Link, Hamburg, Germany). Tantalum markers (Ø 0.8mm) were placed in the bone and at the collar and tip of the prostheses. Additional spherical tantalum markers (Ø 1.0 mm) were inserted in the cement. Each preparation was mounted in an MTS-machine and the heads of the prostheses were loaded (figure 5). Dynamic load was applied under four hours with a frequency of 5 HZ with 500-3000 N (72,000 cycles).
Radiostereometric measurements were done twice, before and after loading, with uniplanar technique with the calibration cage positioned under the examination table. After the second radiostereometric measurements, two preparations from each group were subjected to maximum load or displacement possible with the MTS-machine before additional radiostereometric measurements were done. For all measurements and calculations the

UmRSA system was used (RSA Biomedical, Umeå, Sweden). In one specimen of each design thin transversal slices of bone and cement layer were examined with Scanning Electron Microscopy (SEM) to study the interface between the cement and the prostheses. These examinations were done in collaboration with the Department of Chemical engineering at Lund University.

Statistics

Statistical evaluation (SPSS for windows (SPSS Inc Chicago, IL, USA) was performed with non-parametric tests. Comparisons between the 3 stem types were based on Kruskal-Wallis tests. A difference was regarded as established when $p<0.05$.

Results

Loading in the MTS-machine resulted in minimum proximal (+)/distal (-) migration. In all 3 groups (P: -0.01 mm-0.77 to 0.11; PC: -0.05 mm, -0.09 to 0.05; M: 0.01 -0.18 to 0.07, $p>0.6$). (table 4). In the total material there was a slight median distal (-0.06 mm) displacement in relation to the cement, whereas the cement mantle displaced slightly proximally (0.03 mm, $p=0.006$). Maximum load resulted in distal migration inside the cement mantle of -0.5 to -0.6 mm (P), -0.2 to -0.1 mm (PC) and -0.3 to -0.1 mm (M). Both polished stems "failed" before maximum load (18-20.000 N) was reached and in one of them there was an obvious fracture of the cement. In 2 stems (1 P, 1 N) the cement mantle also displaced distally (-0.2 mm). Electron microscopy showed a smoother surface structure of the cured cement with the polished design (figure 6).

Conclusion & discussion

When present, subsidence mainly occurred inside the cement mantle regardless of surface treatment. The polished design subsided at the same amount as the precoated and matte stems when subjected to moderate cyclic loads, but had reduced tolerance to high constantly increasing load. The bench test was performed with only one hip force using a cadaver bone model, which does not have the same adaptability and endurance as living bone. This study suggests that in clinical practice the short term behaviour of the three surface treatments could be similar. When subjected to high loads above those normally expected in the human hip joint polished SP II stems may be more likely to fail by cement mantle fracture.

Table 3: Data of the 18 specimen.

Specimen	Side	Weight (kg)	Diameter frontal/sagittal (cm)	Storage period (hrs)
Polished				
1	Right	0.66	3.30/ 3.40	24
2	Right	0.60	3.31/ 3.40	24
3	Left	0.64	3.53/ 2.71	48
4	Left	0.48	2.64/ 2.73	24
5	Right	0.56	2.80/ 2.84	24
6	Right	0.70	3.28/ 3.47	48
Matte				
1	Right	0.66	3.08/ 3.17	48
2	Right	0.60	3.05/ 3.17	24
3	Left	0.64	3.38/ 3.24	24
4	Left	0.46	3.03/ 2.86	48
5	Left	0.56	3.20/ 3.14	24
6	Right	0.72	3.36/ 3.41	24
PMMA-coated				
1	Right	0.62	3.22/ 3.25	48
2	Left	0.64	3.42/ 3.09	24
3	Left	0.54	3.03/ 3.01	24
4	Right	0.64	3.01/ 2.96	24
5	Right	0.62	3.22/ 3.25	48
6	Right	0.74	3.34/ 3.53	24

Table 4: Stem and cement mantle migrations after loading before maximum loading for all specimens. Signed values. Median and *range.*

	Median value *range*		**p-value**[1]
Stem rotations (degrees)			
Anterior +/ Posterior -			0.7
Polished	0.04	*-0.10 to 0.16*	
Matte	0.00	*-0.05 to 0.04*	
PMMA coated	-0.02	*-0.14 to 0.14*	
Ante -/ Retroversion +			0.5
Polished	-0.00	*-0.48 to 0.65*	
Matte	-0.00	*-0.58 to 0.12*	
PMMA coated	-0.17	*-0.22 to 0.28*	
Valgus +/ Varus -			0.5
Polished	0.02	*-0.14 to 0.14*	
Matte	-0.12	*-0.05 to 0.01*	
PMMA coated	-0.04	*-0.06 to 0.03*	
Stem subsidence in femur(mm)			
Proximal +/ distal -			0.8
Polished	-0.01	*-0.11 to 0.11*	
Matte	-0.03	*-0.18 to 0.07*	
PMMA coated	-0.05	*-0.09 to 0.05*	
All stems	-0.05	*-0.18 to 0.11*	
Stem subsidence in cement(mm)			
Proximal +/ distal -			0.6
Polished	-0.05	*-0.14 to 0.08*	
Matte	-0.09	*-0.29 to 0.08*	
PMMA coated	-0.07	*-0.17 to -0.005*	
All stems	-0.06	*-0.29 to 0.09*	
Cement subsidence (mm)			
Proximal +/ distal -			0.7
Polished	0.03	*0.01 to 0.07*	
Matte	0.03	*-0.03 to 0.12*	
PMMA coated	0.05	*-0.04 to 0.11*	
All stems	0.03	*-0.04 to 0.12*	

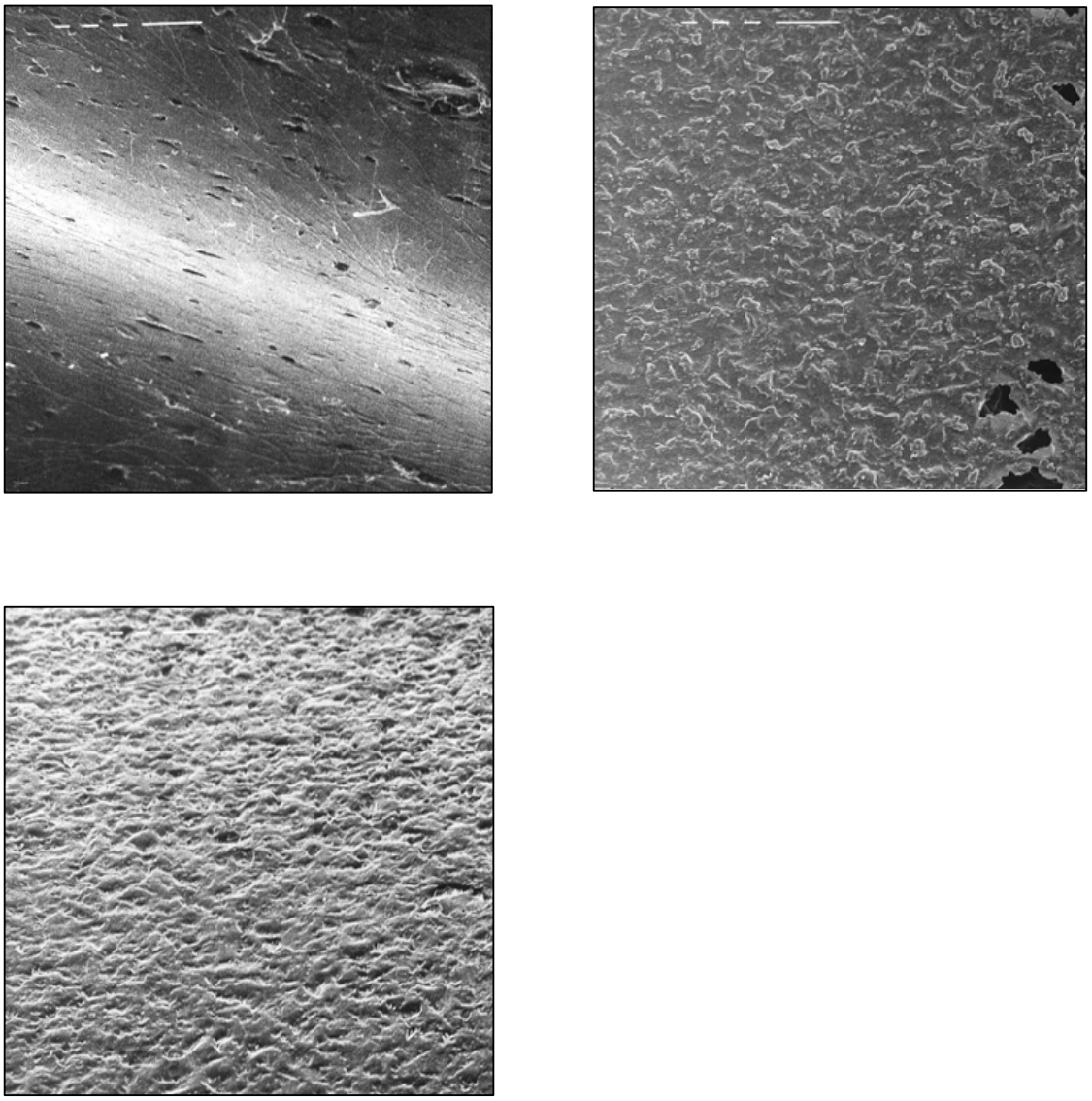


Figure 6: There were no fractures in any of the samples based on the SEM analyses. There were slightly more pores at the interface with the standard matte stem (down left) and the PMMA-coated stem (top right). The cement facing the polished stem (top left) appeared to have a smoother surface (150x and 180x)

SUMMARY OF PAPERS

Study I: Immediate weight bearing after uncemented total hip arthroplasty with an anteverted stem. A prospective randomized comparison using radiostereometry.

Early weight bearing is frequently practiced in uncemented total hip arthroplasty, but there is still not much evidence to support this recommendation. In order to evaluate the effects of full weight bearing after uncemented total hip arthroplasty a prospective randomized study was designed. Primary outcome parameters were migration of the stem and cup and penetration of the femoral head. Patients were randomized to full or partial weight bearing. Our hypothesis was that immediate weight bearing after uncemented total hip arthroplasty would lead to increased motion during the first 3 months.

Patients & methods

43 consecutive patients (21 men, 22 women, mean age 53, 41-63) with primary OA of their hip were operated with an uncemented and hydroxyapatite coated prosthesis (ABG, Stryker-Howmedica) with an anteverted stem. The patients were randomized to the partial (P) or full weight bearing (F) group during the first 6 weeks after operation. The patients in the partial weight bearing group were equipped with a pressure sensitive insole signalling when the patients load exceeded the prescribed weight limit.

RSA was used to measure wear and migration and rotations of the acetabular component and migration and rotations of the femoral stem at 3 months and after 1 year. Statistical evaluation was performed with non-parametric tests (Mann-Whitney). Means and *SE* are presented.

Results

At 3 months follow-up the mean proximal (+)/ distal (-) migration of the stem was -0.14 mm (-1.93- 0.11) in group P and -0.31 mm (-4.30- 0.16) in group F (p= 0.6) (table 5). At 1-year follow-up the mean migration was -0.17 mm (-2.18- 0.21) and -0.28 mm (-4.31- 0.11), respectively (p= 0.9) (figure 7). Neither did the stem rotations differ (p>0.2) (table 6). The cup translations, rotations and femoral head penetration were similar in the two groups (p>0.1) (table 7 and 8). There were no reoperations during the first year.

Conclusions

We found no adverse effect of immediate weight bearing up till one year after the implantation of an uncemented and hydroxyapatite coated prosthesis with an anteverted stem design. The overall wear rate measured was, however, high. Immediate full weight bearing – as much as can be tolerated- after uncemented total hip arthroplasty of the ABG type is justified, provided that primary stability of the implant can be achieved. Because initial stability is a factor influenced by prosthesis design and surgical technique, the results of this study may not be applicable to all uncemented designs.

Table 5: Stem migration and rotations at 3 months follow-up. All hips.

		n[1]	Mean value *(signed)*	95% confidence limits of the mean	Range	p-value[2]
Stem translations (mm)						
Proximal +/Distal -						
	Partial	19	-0.14	-0.33 – 0.67	-1.93 - 0.11	0.6
	Full	19	-0.31	-0.34 – 0.67	-4.30- 0.16	
Stem rotations (degrees)						
Anterior +/Posterior - tilt						
	Partial	19	0.02	-0.55 – 0.13	-0.38 – 0.32	0.3
	Full	19	0.23	-0.56 – 0.14	-0.25 – 3.13	
Ante- -/Retroversion +						
	Partial	19	0.18	-1.37 – 1.15	-0.87 – 1.22	0.2
	Full	19	0.29	-1.41 – 1.18	-3.75 – 10.54	
Increase +/Decrease - of the inclination						
	Partial	19	-0.09	-0.23 – 0.48	-0.50 – 0.36	0.9
	Full	19	-0.21	-0.24 – 0.49	-3.18 – 0.23	

[1] Calculations not possible primarily due to poor visualization of the tantalum markers
[2] Mann Whitney test between the two groups of patients.

Table 6: Stem migration and rotations at 1-year follow-up. All hips.

		n[1]	Mean value *(signed)*	95% confidence limits of the mean	Range	p-value[2]
Stem translations (mm)						
Proximal +/Distal -						
	Partial	19	-0.17	-0.38- 0.59	-2.18- 0.21	0.9
	Full	19	-0.28	-0.37- 0.58	-4.31- 0.11	
Stem rotations (degrees)						
Anterior +/Posterior - tilt						
	Partial	19	0.11	-0.42- 0.14	-0.47- 0.67	0.8
	Full	21	0.25	-0.41- 0.14	-0.11- 2.58	
Anteversion -/Retroversion +						
	Partial	19	0.16	-1.28- 1.04	-0.71- 1.51	0.2
	Full	21	0.28	-1.25- 1.01	-3.58- 9.87	
Increase +/Decrease - of the inclination						
	Partial	19	-0.09	-0.27- 0.40	-0.56- 0.19	0.6
	Full	21	-0.14	-0.26- 0.39	-3.11-0.33	

[1] Calculations not possible primarily due to poor visualization of the tantalum markers.
[2] Mann Whitney test between the two groups of patients.

Figure 7: Subsidence of the stem in mm in relation to bone in 38 cases (19 P, 19 F). Mean stem subsidence with SE at 3 months and at 1 year follow up.

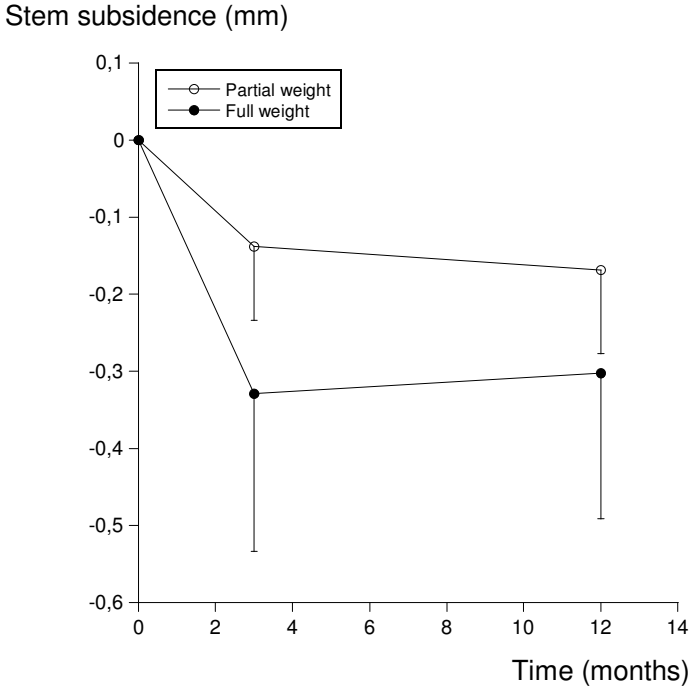


Table 7a: Cup migration at 3 months follow-up. All hips.

		n[1]	Mean value *(signed)*	95% confidence limits of the mean	Range	p-value[2]
Cup translations (mm)						
Medial +/Lateral -						
	Partial	17	-0.003	-0.12- 0.11	-0.26- 0.20	0.8
	Full	21	0.007	-0.12- 0.10	-0.36- 0.52	
Proximal +/Distal -						
	Partial	17	0.12	-0.02- 0.16	-0.03- 0.54	0.3
	Full	21	0.06	-0.02- 0.16	-0.21- 0.28	
Anterior +/Posterior -						
	Partial	17	0.02	-0.16- 0.17	-0.30- 0.61	0.5
	Full	21	0.02	-0.17- 0.17	-0.41- 0.49	
Cup rotations (degrees)						
Anterior +/Posterior - tilt						
	Partial	13	0.04	-0.49- 0.38	-1.78- 0.85	0.5
	Full	18	0.10	-0.51- 0.38	-0.47- 1.45	
Anteversion -/Retroversion +						
	Partial	13	0.03	-0.25- 0.59	-0.73- 1.53	0.8
	Full	18	-0.14	-0.27- 0.61	-1.41- 0.31	
Increase +/Decrease - of the inclination						
	Partial	13	0.008	-0.21- 0.34	-0.43- 0.46	0.7
	Full	18	-0.06	-0.19- 0.32	-0.88- 0.86	

[1] Calculations not possible primarily due to poor visualization of the tantalum markers.
[2] Mann Whitney test between the two groups of patients.

Table 7b: Cup migration at 12 months follow-up. All hips.

		n[1]	Mean value *(signed)*	95% confidence limits of the mean	Range	p-value[2]
Cup translations (mm)						
Medial +/Lateral -						
	Partial	17	-0.01	-0.31- 0.12	-0.26- 0.23	0.7
	Full	23	0.08	-0.29- 0.11	-0.28- 1.73	
Proximal +/Distal -						
	Partial	17	0.14	-0.06- 0.16	-0.10- 0.51	0.7
	Full	23	0.09	-0.06- 0.16	-0.33- 0.46	
Anterior +/Posterior -						
	Partial	17	-0.02	-0.29- 0.50	-0.93- 0.49	0.8
	Full	23	-0.13	-0.26- 0.47	-3.15- 0.39	
Cup rotations (degrees)						
Anterior +/Posterior - tilt						
	Partial	12	0.40	-0.40- 0.82	-0.47- 1.63	0.2
	Full	19	0.31	-0.56- 0.74	-1.08- 4.10	
Anteversion -/Retroversion +						
	Partial	12	0.17	-0.07- 0.84	-0.35- 1.40	0.2
	Full	19	-0.20	-0.06- 0.82	-2.19- 0.45	
Increase +/Decrease - of the inclination						
	Partial	12	-0.13	-0.75- 0.24	-0.62- 0.51	0.3
	Full	19	0.12	-0.70- 0.19	-0.61- 2.76	

[1] Calculations not possible primarily due to poor visualization of the tantalum markers
[2] Mann Whitney test between the two groups of patients.

Table 8: Penetration at 1-year follow-up (signed values. mm).

		N[1]	Mean	95% confidence limit of the mean	Range	p-value[2]
Medial+/lateral-						
	Partial	13	-0.06	-0.05- 0.01	-0.18- 0.04	0.7
	Full	19	-0.07	-0.04- 0.09	-0.34- 0.08	
Proximal+/Distal-						
	Partial	13	0.22	-0.04- 0.17	0.03- 0.55	0.4
	Full	19	0.17	-0.04- 0.17	-0.12- 0.45	
Anterior+/Posterior-						
	Partial	13	-0.15	-0.39- 0.02	-0.72- 0.53	0.6
	Full	19	0.03	-0.40- 0.03	-0.35- 0.56	
Total Translation [3]						
	Partial	13	0.37	-0.07- 0.21	0.17- 0.92	0.7
	Full	19	0.30	-0.09- 0.23	0.05- 0.79	

[1] Calculations not possible primarily due to poor visualization of the tantalum markers.
[2] Mann Whitney test
[3] Three dimensional translation

Study II: Randomized comparison between 3 surface treatments of one single anteverted stem design: 84 hips followed for 5 years.

Previous studies have shown that the surface treatment of the cemented stems may have significant influence on the clinical outcome but the optimum roughness of cemented femoral stems is still not clear. Polished femoral stems have been compared with femoral stem designs with different shapes and surfaces in clinical situations, but the influence of surface finish on clinical performance of cemented stems have often been studied only for straight stem designs and not for anteverted stems. In this prospective randomized clinical study the influence of stem surface was studied using modifications of only one anteverted stem design. Our hypothesis was that polished stems would subside more than both the matte and the precoated stems. We also had the hypothesis that polished stems would preserve a higher amount of BMD in the proximal region of the femur due to a more favourable load distribution.

Patients & methods

80 patients (31 male, 49 female, 68 (*46-78* years), 84 hips) with non-inflammatory OA randomly received either stem type: cemented matte

with collar (M, standard design), polymethylmetacrylate-coated with collar (PC) or polished without collar (P, collarless). Component fixation and wear were studied with radiostereometric analysis (RSA) and the bone mineral density was measured with DXA around the stem in 40 patients at 6 months, 1, 2 and 5 years. The radiographic appearance was studied on AP, lateral and pelvic views exposed postoperatively and at the 5-year follow-up. Non-parametric tests were used for statistical evaluation.

Results

The polished design showed increased distal migration at 6 months (Mean and *range)* P: -0.21mm *-0.52 to 0.09*, M: -0.07mm *-0.34 to 0.26*, PC: -0.03 *-0.18 to 0.18* and at 5 years P:-0.49mm *-1.46 to 0.16*, M: -0.18mm *-0.80 to 0.33*, PC: -0.12mm *-1.40 to 0.12* ($p < 0.0001$) (Figure 8, table 9a). This increased subsidence occurred inside the cement mantle (table 10). The rotations of the stem did not differ ($p>0.4$) (table 9a). Neither did the migration of the cemented cup and the wear differ between the 3 groups ($p>0.1$) (table 11).

After 1 and 2 years the polished stems had lost significantly less bone mineral in Gruen zones 1, 2, 6 and 7 (p 0.004 to 0.03). After 5 years this difference had disappeared (table 12). The conventional radiographic follow-up did not differ between the three groups. None of the cups had a complete radiolucent line on either view and 5 stems had incomplete lines (3P, 1M, 1PC) (table 13). The Harris Hip Scores at 5 years improved during the postoperative year for all hips and did not differ between the three groups (table 1).

Conclusions

A polished surface without collar on the anteverted Lubinus SPII stem design resulted in increased subsidence of the stem inside the cement mantle up to 2 years. Between 3 and 5 years the sub-sidence equalized (table 9b). The period of improved bone remodelling around the polished version coincided with the early period of increased subsidence suggesting that stem motions inside the mantle resulted in a favourable loading of the proximal femur. Based on our observations in this study, future polished femoral stem designs could have alternative shapes than tapered. However, further follow- up in larger materials is needed to be sure that such changes not are associated with any adverse effects as new or modified hip implant designs must be regarded as experimental as long as long-term documentation is not available.

Table 9a: Stem and cement mantle migrations at 6 months and at 5 years for all hips. Signed values. Mean and *range.*

	n 6 mths	Mean value *range* 6 mths	n 5 yrs	Mean value *Range 5 yrs*	p-value[1] 6 mths	p-value[1] 5 yrs
Stem rotations (degrees)						
Anterior +/ Posterior -					0.6	0.04
Polished	25	-0.04 *-0.47 to 0.41*	27	-0.24 *-0.76 to 0.36*		
Matte	24	0.11 *-0.42 to 2.00*	23	0.05 *-0.62 to 1.25*		
PMMA coated	25	-0.01 *-0.35 to 0.41*	25	-0.19 *-0.75 to 0.48*		
Ante -/ Retroversion +					0.9	0.9
Polished	25	0.27 *-0.84 to 2.97*	27	0.62 *-0.66 to 5.08*		
Matte	24	0.13 *-0.65 to 0.79*	23	0.34 *-0.78 to 1.73*		
PMMA coated	25	0.20 *-0.40 to 0.95*	25	0.01 *-6.50 to 0.94*		
Valgus +/ Varus -					0.1	0.1
Polished	25	0.06 *-0.22 to 0.53*	27	0.07 *-0.70 to 0.47*		
Matte	24	-0.03 *-0.54 to 0.25*	23	-0.06 *-1.10 to 0.58*		
PMMA coated	25	-0.02 *-0.59 to 0.25*	25	0.00 *-0.80 to 0.16*		
Stem subsidence in femur(mm)						
Proximal +/ distal -					<0.0005	<0.0005
Polished	25	-0.21 *-0.52 to 0.09*	27	-0.49 *-1.46 to 0.16*		
Matte	24	-0.07 *-0.34 to 0.26*	23	-0.18 *-0.80 to 0.33*		
PMMA coated	25	-0.03 *-0.18 to 0.18*	25	-0.12 *-1.40 to 0.12*		
Stem subsidence in cement(mm)						
Proximal +/ distal -					<0.0005	<0.0005
Polished	17	-0.23 *-0.56 to -0.06*	12	-0.55 *-1.77 to -0.08*		
Matte	15	-0.05 *-0.16 to 0.06*	12	-0.05 *-0.24 to 0.15*		
PMMA coated	13	-0.03 *-0.17 to 0.07*	13	-0.14 *-1.03 to 0.06*		
Cement subsidence (mm)						
Proximal +/ distal -					0.9	0.1
Polished	17	0.03 *0.27 to 0.28*	12	0.06 *-0.21 to 0.46*		
Matte	15	0.01 *-0.27 to 0.26*	12	-0.12 *-0.74 to 0.18*		
PMMA coated	13	0.02 *-0.14 to 0.25*	13	-0.06 *-0.38 to 0.16*		

[1]Kruskal Wallis test between the three groups of patients

Table 9b: Stem subsidence between 2 and 5 years (all hips).

	n	Mean value (signed)	95% Confidence limits of the mean	Range	p-value[a]
Stem subsidence in femur(mm)					
Proximal+/ distal –					0.04
Polished	24	-0.11	-0.19 to -0.03	-0.52 to 0.42	
Matte	23	-0.11	-0.26 to 0.04	-1.62 to 0.23	
PMMA coated	25	-0.09	-0.21 to 0.02	-1.15 to 0.20	

[a]Kruskal Wallis Test between the three groups of patients

Table 10: Evaluation at 5 years in 4 classes <50%. 50-75%. 76-99%, 100% of stem subsidence in cement as part of total stem subsidence in femur.

	Polished		**Matte**		**PMMA coated**	
	n	%	N	%	n	%
< 50 %	1	8.3	8	66.7	6	46.2
50% - 75%	0	0	2	16.7	2	15.4
76% - 99%	4	33.3	0	0	2	15.4
100%	7	58.3	2	16.7	3	23.1
Total	12	100	12	100	13	100

Table 11: Wear (penetration) of the acetabulum at 5-years for all hips. Signed values. Mean and *range.*

	Polished (n=27)		**Matte (n=23)**		**PMMA coated n=25)**		**p[a]**
Wear (mm)							
Medial +/ Lateral -	-0.07	*-0.47- 0.33*	-0.10	*-0.35- 0.18*	-0.07	*-0.26- 0.36*	0.9
Proximal +/ Distal -	0.59	*0.18 - 1.17*	0.54	*0.06- 1.31*	0.56	*0.23- 1.24*	0.9
Anterior +/ Posterior -	-0.10	*-0.41- 0.26*	-0.14	*-0.55- 0.17*	-0.09	*-0.34- 0.26*	0.9
Total Wear (Three dimensional)	0.65	*0.24- 1.19*	0.63	*0.19- 1.31*	0.61	*0.23- 1.24*	0.8

[a]Kruskal-Wallis Test

Table 12: Changes in BMD (%) in the 7 Gruen regions around the femoral stems at 1 year and at 5 years in 40 patients (11P, 12M and 17PC)
(a= Mann Whitney Test, b= Kruskal Wallis Test). Median and *range.*

	n 1 yr	Median value *range* 1 yr		n 5 yrs	Median value *Range* 5 yrs		p-value 1 yr	p-value 5 yrs
Region 1							0.003[a]	0.3[b]
Polished	11	-0.9	*-18 to 9*	10	-6	*-25 to 63*		
Matte	12	-2	*-30 to 9*	10	-3	*-21 to 10*		
PMMA coated	16	-9	*-24 to 4*	17	-8	*-24 to 1*		
Region 2							0.001[a]	0.3[b]
Polished	11	-2	*-11 to 2*	10	-10	*-31 to 2*		
Matte	12	-8	*-33 to 3*	10	-11	*-42 to -2*		
PMMA coated	16	-10	*-17 to 4*	17	-12	*-27 to -4*		
Region 3							0.2[b]	0.4[b]
Polished	11	-3	*-11 to 7*	10	-8	*-15 to -2*		
Matte	12	-5	*-21 to 8*	10	-4	*-28 to 6*		
PMMA coated	16	-6	*-14 to 2*	17	-9	*-25 to 1*		
Region 4							0.3[b]	0.4[b]
Polished	11	-1	*-10 to 10*	10	0	*-10 to 6*		
Matte	12	-5	*-13 to 30*	10	-0.4	*-17 to 23*		
PMMA coated	16	-5	*-99 to 19*	17	-4	*-99 to 16*		
Region 5							0.8[b]	1.0[b]
Polished	11	-2	*-11 to 15*	10	-5	*-13 to 5*		
Matte	12	-3	*-17 to 2*	10	-5	*-34 to 8*		
PMMA coated	16	-4	*-15 to 5*	17	-6	*-19 to 2*		
Region 6							0.003[a]	0.6[b]
Polished	11	-4	*-16 to 4*	10	-12	*-38 to -1*		
Matte	12	-15	*-44 to 3*	10	-13	*-59 to 6*		
PMMA coated	16	-4	*-22 to -4*	17	-12	*-35 to -3*		
Region 7							< 0.0005[a]	1.0[b]
Polished	11	-3	*-25 to 11*	10	-23	*-43 to 1*		
Matte	12	-3	*-42 to 7*	10	-18	*-49 to 6*		
PMMA coated	16	-10	*-38 to 9*	17	-20	*-41 to -4*		

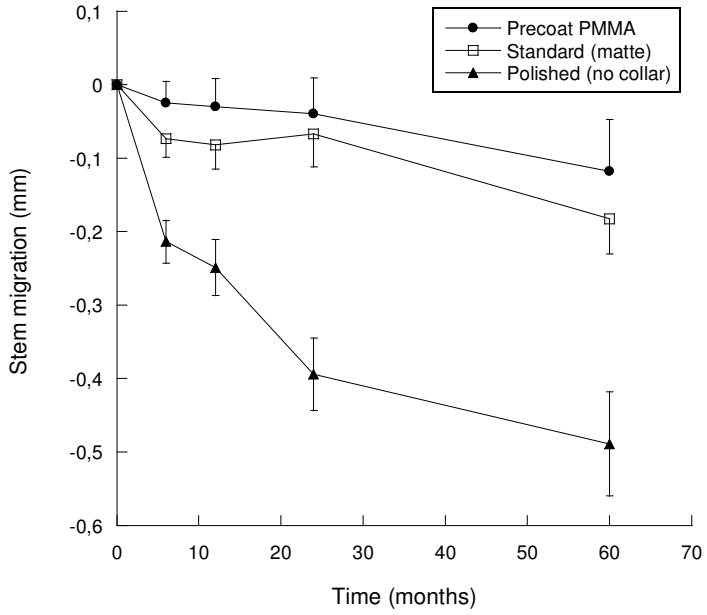
[a] P< PC: Mann Whitney Test between two groups
[b] Kruskal Wallis Test between the three groups

Table 13: Distribution of Radiolucent lines in the Different Regions of the Cup in four grades: no lucency, < 50%, 50-99% and 100% of the region.

Radiolucent lines	n (missing)	1	2	3	4	5	6
Polished	28 (1)	21/6/0/1	24/4/0/0	22/4/2/0	26/0/2/0	28/0/0/0	22/4/2/0
Matte	25 (2)	20/4/1/0	21/2/2/0	15/6/4/0	20/5/0/0	24/1/0/0	13/7/4/1
PMMA-coated	25 (3)	16/8/1/0	23/1/1/0	19/4/2/0	22/3/0/0	23/2/0/0	16/4/5/0
p value[a]		0.46	0.68	0.27	0.45	0.32	0.12

[a] Kruskal Wallis Test between the three groups

Figure 8: This graph shows the proximal (+)/distal (-) migration of all three stem types versus the femoral bone in all cases. Mean and SEM.



Study III: Fixation and bone remodelling around a low modulus stem. 7-year follow-up of a randomized study with use of radiostereometry and DXA.

Femoral stems with reduced stiffness were introduced in total hip arthroplasty to prevent periprosthetic bone loss due to stress shielding. Poor fixation and unacceptably high revision rates due to aseptic loosening turned out to be a major problem with these prostheses. To address the problem of fixation a fully porous-coated, composite stem with reduced structural stiffness was developed that achieved excellent primary fixation with less decrease of proximal bone-mineral density. However, randomized evaluations with longer follow-up than two years have not been performed. In this prospective randomized study two anteverted stems, one uncemented fully porous-coated composite stem and one uncemented proximally porous coated solid stem were compared up to 7 years after implantation. Our hypothesis was that the stems with reduced stiffness would function well clinically even at the 7-year follow-up with more preservation of the proximal bone density compared to the stiffer control stems.

Patients & methods

Thirty-eight consecutive patients (28 men, 10 women, mean age 57, *41-74,* 40 hips) with non-inflammatory osteo-arthritis were randomized to receive either an uncemented fully porous-coated composite stem (Epoch) or an uncemented proximally porous coated solid stem (Anatomic), both with and anteverted neck and additional ceramic coating on their proximal two thirds. Partial weight bearing during the first 6 weeks after operation was practiced. Patients were followed for 7 years with repeated evaluations using RSA, DXA, conventional radiography, Harris Hip Score and a detailed questionnaire about pain and discomfort (appendix).

Results

Subsidence and stem rotations were close to zero without any difference between the two groups ($p > 0.12$) (figure 9, table 14). Median wear rates were lower than expected (0.45 mm up to 7 years) in both groups (figure 10, table 15). At 2 years loss of bone mineral density was less in Gruen regions 1, 2, 6 and 7 for the Epoch stems ($p<0.04$), but this difference tended to disappear with time (table 16). At 7 years only the calcar region (Gruen region 7) had

significantly denser bone in the Epoch group ($p<0.001$) and in region 3 a small gain of bone density was found for the Anatomic stem ($p=0.01$). After 7 years and in region 1, increased proximal wear was associated with increased loss of BMD (adjusted $r^2 =0.21$, $p=0.021$). In region 2, female gender and use of a stiffer stem were negatively associated with the change in BMD (adjusted $r^2 =0.40$, $p=0.004$). In region 5, the amount of bone loss at 7 years was greater the less dense the bone was at the postoperative examination and the change in BMD was positively associated with increasing weight and decreasing stem size (adjusted $r^2 =0.65$, $p<0.000$). In region 7, the use of the Epoch stem was associated with less bone loss at the 7-year follow-up than for the Anatomic stem. In addition, female gender was associated with significantly more bone loss compared to male gender (adjusted $r^2 =0.46$, $p=0.002$). In region 3, 4 and 6 none of the variables entered into the regression analysis showed any influence on the change of BMD. No stem was radiographically loose on the postoperative radiographs, although fewer sclerotic lines surrounding the stem and less sclerosis at the tip of the prosthesis were found for the Epoch stems compared to the Anatomic stems (0.00 cm^2, *0.00 – 0.00*) compared to the Anatomic stems (0.25 cm^2 *0.00-0.75*) ($p\leq$ 0.002) (table 17). There were no complications directly related to the operation. The Harris Hip Score scores did not differ (table 1) and at the 7-year follow-up some pain or discomfort was reported by 12 patients without any difference between the two groups.

Conclusion

The uncemented fully porous-coated composite Epoch stem with reduced stiffness had positive effects on early proximal bone remodelling compared to a solid metallic stem inserted without cement, but this effect decreased with time. It might be that stress shielding is inevitable for any stem design in the long-term.

Table 14: Stem rotations and migration in proximal (+) and distal (-) direction at 2 years and at 7 years for all hips. Signed values. Mean and *range.* Mann Whitney test.

	n 2 yrs	Mean *range* 2 yrs	n 7 yrs	Mean *range* 7 yrs	p-value 2 yrs	p-value 7 yrs
Stem rotations (degrees)						
Anterior +/ Posterior -					0.3	0.3
Epoch	22	0.02 *-0.28 to 0.30*	16	-0.15 *-1.28 to 0.24*		
Anatomic	16	-0.04 *-0.56 to 0.56*	11	-0.01 *-0.28 to 0.40*		
Ante-/ Retroversion +					0.4	0.2
Epoch	22	0.02 *-0.68 to 1.49*	16	-0.16 *-1.27 to 0.96*		
Anatomic	16	0.08 *-0.88 to 1.09*	11	0.45 *-0.94 to 3.19*		
Valgus +/ Varus -					0.5	0.1
Epoch	22	0.03 *-0.21 to 0.30*	16	0.07 *-0.14 to 0.36*		
Anatomic	16	0.07 *-0.06 to 0.45*	11	-0.07 *-0.34 to 0.22*		
Stem subsidence in femur(mm)						
Proximal +/ distal -					0.6	0.1
Epoch	22	-0.01 *-0.16 to 0.15*	16	-0.03 *-0.23 to 0.27*		
Anatomic	16	0.02 *-0.21 to 0.31*	11	-0.09 *-0.21 to 0.06*		

Table 15: Migration, rotations and wear (penetration) of the acetabular cup at 2 years and at 7 years for the two groups.
Mean and *range.* Median and *range.* Mann Whitney Test.

	n 2 yrs	Mean *range* 2 yrs	n 7 yrs	Mean *range* 7 years	p-value[1] 2 yrs	p-value[1] 7 yrs
Cup translations (mm)						
Medial +/Lateral -					0.9	0.4
Epoch	16	0.04 *-0.45 to 0.94*	17	0.00 *-0.71 to 0.64*		
Anatomic	13	0.02 *-0.45 to 0.49*	10	-0.13 *-0.57 to 0.25*		
Proximal +/Distal -					0.2	0.4
Epoch	16	0.10 *-0.08 to 0.79*	17	0.03 *-0.18 to 0.56*		
Anatomic	13	0.00 *-0.18 to 0.20*	8	-0.01 *-0.15 to 0.27*		
Anterior +/Posterior -					0.1	0.8
Epoch	16	-0.06 *-0.80 to 0.54*	17	0.07 *-0.32 to 0.56*		
Anatomic	13	0.18 *-0.37 to 1.02*	8	0.07 *-0.14 to 0.36*		
Cup rotations (degrees)						
Anterior +/ Posterior - tilt					0.05	0.7
Epoch	15	-0.01 *-2.85 to 1.31*	17	0.22 *-2.44 to 4.09*		
Anatomic	13	-0.22 *-1.07 to 0.27*	8	0.19 *-0.23 to 0.70*		
Ante -/Retroversion +					0.5	0.7
Epoch	15	-0.39 *-4.55 to 0.22*	17	-0.14 *-4.46 to 4.11*		
Anatomic	13	0.03 *-0.49 to 1.31*	10	-0.14 *-1.47 to 0.58*		
Increase +/Decrease - of the inclination					0.9	0.7
Epoch	15	0.15 *-0.54 to 1.95*	17	-0.14 *-2.70 to 0.99*		
Anatomic	13	0.06 *-0.50 to 0.89*	8	-0.14 *-0.29 to -0.27*		

	n 2 yrs	Median *range* 2 yrs	n 7 yrs	Median *range* 7 yrs	p-value[1] 2 yrs	p-value[1] 7 yrs
Wear (mm)						
Medial +/Lateral -					0.6	0.7
Epoch	12	0.01 *-0.16 to 0.13*	18	-0.07 *-0.48 to 0.57*		
Anatomic	13	0.04 *-0.28 to 0.37*	8	-0.02 *-0.35 to 0.16*		
Proximal +/Distal -					0.2	0.2
Epoch	12	0.26 *0.09 to 0.75*	18	0.45 *-0.35 to 1.69*		
Anatomic	13	0.18 *-0.50 to 0.59*	8	0.30 *-0.40 to 0.97*		
Anterior +/Posterior -					0.4	0.7
Epoch	12	0.05 *-0.67 to 0.75*	18	-0.04 *-0.47 to 0.55*		
Anatomic	13	-0.08 *-1.21 to 1.18*	8	-0.03 *-0.88 to 2.30*		
Total Wear (three dimensional)					0.9	0.6
Epoch	12	0.29 *0.17 to 1.04*	18	0.50 *0.15 to 1.78*		
Anatomic	13	0.30 *0.13 to 1.39*	8	0.50 *0.27 to 2.36*		

[1]Mann Whitney Test

Table 16: Changes in BMD (%) in the 7 Gruen regions around the femoral stems at 2 years and at 7 years. Mann Whitney Test, Median and *range.*

	n 2 yrs	Median *range* 2 yrs	n 7 yrs	Median *range* 7 yrs	p-value[1] 2 yrs	p-value[1] 7 yrs
Region 1					0.04	0.7
Epoch	20	-6 *-3 to 4*	17	-14 *-35 to 25*		
Anatomic	14	-23 *-54 to 12*	13	-18 *-35 to 12*		
Region 2					0.01	0.4
Epoch	20	-12 *-24 to 2*	17	-10 *-31 to 12*		
Anatomic	14	-19 *-52 to -4*	13	-15 *-70 to 13*		
Region 3					0.4	0.01
Epoch	20	-6 *-13 to 6*	17	-5 *-19 to 4*		
Anatomic	14	0 *-55 to 15*	13	3 *-36 to 48*		
Region 4					0.4	0.2
Epoch	20	-8 *-17 to 0*	17	-9 *-25 to 8*		
Anatomic	14	-6 *-30 to 28*	13	-4 *-37 to 40*		
Region 5					0.04	0.1
Epoch	20	-5 *-45 to 3*	17	-5 *-14 to 24*		
Anatomic	14	0 *-16 to 16*	13	3 *-26 to 15*		
Region 6					0.02	0.97
Epoch	20	-10 *-19 to 16*	17	-7 *-26 to 16*		
Anatomic	14	-22 *-43 to 3*	13	-10 -40 *to 15*		
Region 7					<0.001	<0.001
Epoch	20	-15 *-33 to 5*	17	-18 *-41 to -3*		
Anatomic	14	-38 *-54 to -4*	13	-31 *-45 to -18*		

[1] Mann Whitney Test between two groups

Table 17: Radiographic results at 7 years for all hips. Mann Whitney Test.

	Epoch (n= 20)				Anatomic (n=15)				P[1]
Radiolucent lines[2]:									
Gruen region 1	20/0/0/0				15/0/0/0				1.00
Gruen region 2	20/0/0/0				15/0/0/0				1.00
Gruen region 3	20/0/0/0				14/1/0/0				0.76
Gruen region 4	20/0/0/0				13/0/1/1				0.52
Gruen region 5	20/0/0/0				14/0/1/0				0.76
Gruen region 6	20/0/0/0				15/0/0/0				1.00
Gruen region 7	20/0/0/0				15/0/0/0				1.00
	Median	**Min**	**Max**	**95 % CI**	**Median**	**Min**	**Max**	**95% CI**	**P[1]**
Tip sclerosis (cm^2)	0.00	0.00	0.00	0.00 to 0.00	0.27	0.00	0.75	0.11 to 0.39	0.002
Calcar resorption (cm^2)	0.06	0.00	1.00	0.04 to 0.28	0.00	0.00	0.75	0.02 to 0.29	0.93
Cortical hypertrophy[3]	0.00	0.00	0.00	-0.13to0.53	0.00	0.00	0.00	0.03 to 1.04	0.42
Heterotopic bone formation[4]	11/6/2/2/0				4/9/1/1/0				0.32

[1] Mann Whitney Test between both groups
[2] Radiolucent line ≥ 2mm, 4 classes: 0/ <50%/ 50-99%/ 100%
[3] Increase of cortical hypertrophy compared to postoperative radiographs
[4] Grades 0/1/2/3/4

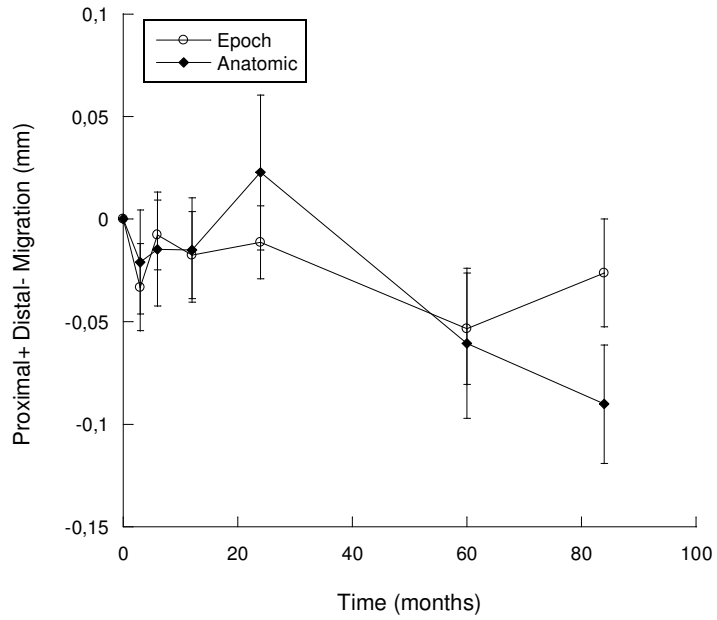


Figure 9: This graph shows the proximal (+)/distal (-) migration of both stem types versus the femoral bone in all cases. Mean and SEM.

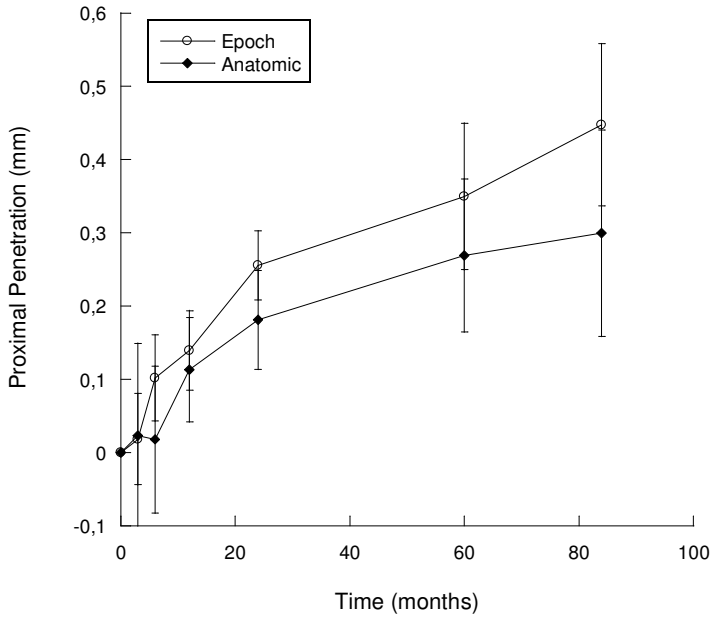


Figure 10: This graph shows the proximal penetration (wear) of all sockets over time. Median values and SE.

Study IV: Design related risk factors for revision of primary cemented stems. Analysis of 3 frequent stems in the Swedish Hip Arthroplasty Register.

Small changes in femoral stem design and variations in standard stem designs such as stem size, neck angle and offset may influence the behaviour of stems in total hip replacement and have an influence on the risk for failure. The aim of this study was to investigate whether design related factors play any role in the risk of non-infectious revision of the femoral component in primary cemented total hip replacement, when adjusted for bias caused by demographic and surgery related factors recorded in the Swedish Hip Arthroplasty Register. The analysis was restricted to the three most frequently used stem designs between 1999 and 2006 (table 18). Design-specific characteristics (table 19) of 72,991 cemented femoral stem implants (21,246 Exeter polished stems, 44,605 Lubinus SPII stems and 7,140 Spectron EF Primary stems) were analyzed using separate Cox regression models that were adjusted for gender, age, diagnosis, incision and number of operation (1^{st} or 2^{nd}). The Exeter polished stem consisted of two slightly different prosthesis systems, the older Exeter and the newer Exeter V40™, and both designs were analyzed both individually and as one group.

Results

The overall revision rates were low and varied between 0.8 (Lubinus SPII) and 1.4% (Spectron Primary) (table 20). The adjusted risk ratios, 95% confidence intervals (CI) and significant p-values ($p< 0.05$) are presented in table 21.

For the Exeter stem only patient and surgery-related parameters influenced the outcome. A higher risk for revision was found when the indication for the THR was a fracture or the patient had been operated on earlier with a THR on the contra lateral side.

The risk for revision increased significantly for the Exeter stem with the presence of idiopathic necrosis of the femoral head and the risk for revision was lower when a lateral or anterolateral incision was used compared to a posterior incision. Further analysis of the two subgroups of this stem revealed that the older stem version was more frequently revised because of aseptic loosening and the newer version more commonly due to dislocation. The reasons for revision of both Exeter designs are shown in table 22.

For the Lubinus stem, we found that stem size, but only the smallest stem size, and a stem with extended neck length combined with a femoral head with increasing neck length or the use of cobalt-chromium head negatively influenced the outcome (table 21). The risk for revision for the Lubinus stem was nearly doubled

for male patients and also when the patients were operated because of fracture. A decreasing risk for revision was also seen with increasing age and in patients with primary osteoarthritis. The risk for revision was lower when an anterolateral incision was used compared to posterior or lateral incisions.

For the Spectron stem the risk for revision increased not only with decreasing stem size, but also with increasing offset calculated as the combined effect of high offset design and increasing neck length (table 21). Patients operated with a Spectron stem due to fracture were at higher risk for revision. Male gender alone was also a risk factor.

Conclusions

For the Exeter stem the risk for revision was influenced only by patient and surgery-related parameters and not by implant related variables. Insertion of a THR due to fracture doubled or almost doubled the risk of revision for all three designs and males who were operated on with Lubinus or Spectron stems were at higher risk for revision. A protective effect against revision with all designs was seen for anterolateral incisions compared to a posterior incision. Overall revision rates were low, but design characteristics such as size and neck length or offset influenced the risk for non-infectious revision for two of the stem designs studied.

Table 18: Number of femoral stems selected for the analysis related to year of operation.

	Year								
	1999	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**total**
Spectron EF primary	734	846	945	966	1077	1041	928	824	**7361**
Exeter Polished	1830	2238	2493	2956	3360	3300	3218	3182	**22577**
Lubinus SPII	3824	4227	4977	5815	6086	6688	6820	6467	**44904**

Table 19: Design characteristics divided in stem and femoral head variables used in the analysis for each stem type.

Stem Type		Variable		
Exeter	Stem	Offset	4 classes	Continuous/classified
		Size	4 sizes	Continuous/classified
		Type	V40 or not	Classified
	Head	Material	Standard Aluminium oxide Orthinox	Classified
		Size	4 sizes	Classified
		Neck length	4 classes	Continuous/classified
Lubinus	Stem	Offset	normal extended	Classified
		Size	6 sizes	Continuous/classified
		CCD	117 126 135	Classified
	Head	Material	Cobalt chrome Aluminium oxide	Classified
		Neck length	4 classes	Continuous/classified
		Stem offset + neck length head		Continuous/classified
Spectron Stem		Offset	normal extended	Classified
		Size	5 sizes	Continuous/classified
	Head	Neck length	6 classes	Continuous/classified
		Stem offset + neck length head		Continuous/classified

Table 20: Revisions (%) for all the analyzed femoral stems (infections excluded)

	Exeter Polished (All)	Exeter (old)	Exeter V40	Lubinus SPII	Spectron EF Primary
	% (n)	% (n)	% (n)	% (n)	% (n)
Aseptic Loosening	0.4 (96)	1.1 (71)	0.2 (25)	0.3 (114)	0.8 (57)
Dislocation	0.5 (116)	0.6 (3)	0.5 (77)	0.5 (244)	0.5 (35)
Fracture	0.2 (43)	0.3 (18)	0.2 (25)	0.0 (17)	0.0 (3)
Implant failure	0.0 (3)	0.0 (0)	0.0 (3)	0.0 (8)	0.0 (0)
Technical reason	0.1 (12)	0.1 (7)	0.0 (5)	0.0 (12)	0.1 (4)
Only pain	0.0 (6)	0.0 (0)	0.0 (3)	0.0 (5)	0.0 (2)
Total	**1.2 (276)**	**2.1 (99)**	**1.1 (138)**	**0.8 (400)**	**1.4 (101)**

Table 21: Statistically significant relative risks of stem revision and 95% Confidence interval for implant-related, patient-related and surgery-related parameters for each stem type.

	Relative Risk [Exp. (B)]	95 % confidence interval		p-value
		lower	upper	
Exeter polished *(n=21,246)*				
Operation number (1st vs. 2nd)	**0.71**	0.52	0.97	0.032
Diagnosis: fracture (y/n)	**1.92**	1.36	2.77	0.000
Diagnosis: idiop. fem. head necrosis (y/n)	**3.24**	2.05	5.10	0.000
Lateral incision, patient on back (y/n)	**0.62**	0.40	0.94	0.025
Anterolateral incision, patient on side (y/n)	**0.52**	0.36	0.75	0.000
Lubinus SPII *(n= 44,605)*				
Head material (Cocr/ Aluminium oxide)	**1.94**	1.34	2.82	0.000
Smallest stem size	**1.72**	1.26	2.36	0.001
Combined offset (0 -1) and neck length head (1-4)	**1.26**	1.10	1.43	0.001
Gender (male/female)	**1.60**	1.28	2.00	0.000
Increasing age	**0.99**	0.98	1.00	0.019
Diagnosis: fracture (y/n)	**1.90**	1.25	2.91	0.003
Diagnosis: primary osteoarthritis (y/n)	**0.55**	0.38	0.80	0.002
Anterolateral incision (with posterior incision as reference)	**0.69**	0.55	0.90	0.005
Spectron EF Primary *(n=7,140)*				
Increasing stem size	**0.59**	0.45	0.77	0.000
Increasing neck length	**1.34**	1.09	1.64	0.005
Combined offset (0 -1) and neck length head (1-6)	**1.33**	1.11	1.59	0.002
Gender (male/female)	**1.90**	1.23	2.92	0.003
Diagnosis: fracture (y/n)	**2.21**	1.35	3.60	0.002
Anterolateral incision (y/n)	**0.52**	0.34	0.79	0.002

Table 22: Revisions (%) for all the analyzed femoral stems (infections excluded).

	Exeter Polished (All)	**Exeter (old)**	**Exeter V40**	**Lubinus SPII**	**Spectron EF Primary**
	% (n)	% (n)	% (n)	% (n)	% (n)
Aseptic Loosening	0.4 (96)	1.1 (71)	0.2 (25)	0.3 (114)	0.8 (57)
Dislocation	0.5 (116)	0.6 (3)	0.5 (77)	0.5 (244)	0.5 (35)
Fracture	0.2 (43)	0.3 (18)	0.2 (25)	0.0 (17)	0.0 (3)
Implant failure	0.0 (3)	0.0 (0)	0.0 (3)	0.0 (8)	0.0 (0)
Technical reason	0.1 (12)	0.1 (7)	0.0 (5)	0.0 (12)	0.1 (4)
Only pain	0.0 (6)	0.0 (0)	0.0 (3)	0.0 (5)	0.0 (2)
Total	**1.2 (276)**	**2.1 (99)**	**1.1 (138)**	**0.8 (400)**	**1.4 (101)**

DISCUSSION

This thesis aimed to investigate the influence of postoperative treatment, surface treatment and stem design on the outcome of primary THA, with the main emphasis on femoral stem implants with an anteverted stem design.

We did not found any adverse effect of full weight bearing immediately after primary uncemented THA (Study I). This is promising because the compliance to prescribed limited weight bearing is low[111]. The ability of healthy volunteers to weight bear partially was found to be better than that of patients who had sustained either a fracture of the lower limb or surgery[25]. This comprised ability of patients was thought to be due to the pain they experienced compared to the healthy volunteers. Also other factors such as muscle power and mental state influence the ability to perform the prescribed weight bearing. Some form of concurrent feedback, like the auditory device in the present study, is essential to improve the patients ability to weight bear partially[119]. Immediate full weight bearing then, as much as tolerated by the patient, would be much easier to perform. However, although no adverse effects of immediate weight bearing were found by us as well as by others[13], a full weight bearing regime cannot simply be exerted in all uncemented THA and in all patients. There are clinical situations, in which partial weight bearing still is advised e.g. when implant components are undersized or in the event of unexpected complications during surgery such as a fractures or the need of an osteotomy[121].

The clinical outcome in THA can be substantially deteriorated due to small changes in femoral stem design e.g. the matte surface on the Exeter design[89,99] and the rough surface on the VerSys femoral stem[31] and the Iowa hip[90,104]. This study has shown that changes in surface treatment or flexibility of the femoral stem influences the amount of stress shielding around the implant during the first postoperative years. The amount of bone loss was decreased during the first postoperative years for a polished anteverted stem compared to a standard matte anteverted stem (Study II) as well as for a stem with increased flexibility compared to a stem with standard stiffness (Study III). However, this preservative effect on bone remodelling with those two modifications disappeared with time. Our results point in the direction of an ongoing balance between fixation and bone turnover around cemented as well as uncemented stems designs. This phenomenon results in transfer of the load distally after a certain amount

of time. During the first two postoperative years, the cemented polished Lubinus stem without a collar was allowed to subside inside the cement mantle. Based on the migration data, the polished stem probably achieved secondary stability, resulting in shift of the maximum load from the proximal to the more distal parts of the stem. Between 2 and 5 years the polished Lubinus stem subsided equally to the standard matte stem (figure 8). Also for the Epoch as compared to the Anatomic stem, the bone preserving effect of the former stem with increased flexibility only existed during the first postoperative years. It might be that a new equilibrium in bone turnover was established as soon as the implant reached a fixed position as interpreted from the migration data. Based on our observations, it seems that proximal stress shielding is inevitable in the long term despite design adjustments of the stem component made to counteract this problem.

We also showed that small modifications of thoroughly evaluated stem designs with successful performance did not reach the same results as their predecessors or those standard sizes previously used (Study IV). The smallest size of the Lubinus SPII stem e.g. was introduced as a compliment several years after the initial launching of this design on the Swedish market. The Spectron Primary replaced the preceding Spectron EF design, which had a constant stem length and fewer sizes. Careful preclinical research and stepwise introduction of new concepts in THA is necessary to detect such unexpected properties of well established implant designs in an early stage and to avoid unacceptable patient suffering[84]. New concepts or modifications of standard stem designs must at least result in the same performance as the commonly used "gold standard" implants. Although the use of evaluation techniques with high resolution has increased the possibility to identify promising new implant concepts, there must be enough evidence for long term performance before those new implants may be used on a larger scale. The behaviour of the stems evaluated in study IV was also found to be influenced by other variations in standard stem designs such as neck angle and offset, which was found to have an influence on the risk for failure. Exact restoration of the normal anatomical offset during THA theoretically is advantageous[26,88], but difficult to achieve, despite accurate planning and surgical technique. Offset can of course be changed in several ways not only by changing implant-related parameters, but also by stem positioning and level of neck resection[96], two surgery-related parameters that govern the selection of parts that constitute the final implant, but are not known by us.

The true offset of a THA in situ is therefore difficult to determine and in study IV we had no information if the normal anatomy was restored or not.

We found that one stem design can show significant different risks for non-infectious revision depending on its size and the final combination of offset and neck length (Study IV). However, moderate differences in survival between well-performing stems should be interpreted with caution since the observed differences may at least partly be caused by factors other than the stem itself. It is not possible to determine if the increased risk for revision for small stem sizes of both the Lubinus and the Spectron design in this study is solely due to the chosen implant or due to selection bias. Small stem sizes are not only used in short and light weighting patients with thin femoral bones, but also in patients with inferior bone quality and especially in males with a thick femoral cortex and consequently narrow femoral canal. Such patients are probably more active and subject their implants to higher loads. It might be that alternative implants such as uncemented or cemented polished femoral stems are favourable when small stem sizes are required, but further studies are needed to confirm this.

As expected the preoperative diagnosis, such as a fracture of the femoral neck or the presence of idiopathic femoral head necrosis, negatively influenced the outcome in terms of early revision. On the other hand, patients were at lower risk for revision when they had got their THA inserted due to primary osteoarthritis. Difficulties with restoration of the anatomical offset in combination with reduced bone mineral density for patients with a femoral neck fracture or idiopathic femoral head necrosis may possibly explain this increased incidence of revision in these groups.

We found that the use of a posterior incision increased the risk for early revision (Study IV). This is interesting since the optimal approach for THA is still under debate[7,114,35]. According to a Cochrane review there is not enough evidence to recommend either a posterior or a lateral approach in cases with primary osteoarthritis[65]. These authors identified 44 studies, 11 of them proved to be relevant but only 4 met the eligibility criteria and could be included. Conclusions were made that the quality and quantity of information to date was insufficient to make any firm conclusion on the optimum choice of surgical approach in adult patients undergoing THA for osteoarthritis. Our study speaks in favour for anterolateral incision to avoid early non-septic revisions. To become more generalized this information needs to be supplemented with studies of other implant designs and patient related

outcomes such as pain and overall satisfaction and long-term follow up. It has been reported that changes in bone density can produce more than three-fold changes in femoral modulus[82] and the less dense the bone is before THA surgery, the greater the extent of bone loss after THA regardless of the fixation type (cemented or uncemented)[86]. Accelerated bone loss has also been seen for women who had lower BMD than men and it has been suggested by Sychertz et al[107] that those differences in BMD and geometry between femurs may result in differences in stiffness that varied as much as the stiffness of the implants. These authors did not found any other clinical factor including stem size to be a significant predictor of bone loss after THA.

Strengths and limitations of this study

The follow-up in all the four studies is still short. Long-term follow-up is necessary to identify substantial changes in survival outcome of new implants or implants that have undergone more or less pronounced changes. However, the use of prospective randomized study designs and the use of high precision clinical measures in combination with few dropouts may partly compensate for the comparatively short follow-up periods so far.

In Studies I-III we used the Harris Hip Score for the assessment of the clinical outcome of all implants. However, it has become increasingly clear that clinical assessment of pain, physical function and range of motion by using objective outcome instruments often is inaccurate and not reproducible[36]. Other more subjective scores are not only easier to organize, but have also been shown to have larger repeatability. It would therefore have been preferable to use both a disease-specific and a generic measure also in the present studies as recommended[81].

RSA is, due to its high accuracy, a suitable method to evaluate the motion of orthopaedic implants in three-dimensional direction and in a relatively small patient cohort, provided that the standardized recommendations for this method are followed[112]. Consequently, the number of patients “at risk” will be minimized. However, RSA is a labour intensive and invasive method that can only be used in a specially designed laboratory setting and therefore, it will probably never been used in the daily clinic.

Although DXA is a clinical measure with high resolution, it is sensitive for differences in femur rotation between two examinations, especially in cemented stems. Therefore, patient positions have to be standardized. By reporting median values, we tried to compensate for the large scatter as

found in the examinations of BMD around the cemented stems. Another limitation of the DXA-method is that it only can measure the presence of bone mineral. Complete resorption of bone in any part of the periprosthetic bone will consequently not be detected. In the case scenario of complete bone resorption, conventional radiography, despite its lower resolution is of value to assess the amount of bone loss.

We did not assess the patient activity in study I-III, but we believe that we, at least partly, compensated for this by the use of a randomized study design and exclusion of patients with multiple joint diseases. In study I, however, it would have been desirable to also include registrations of the load actually performed over time. However, at the time of the study, the dimensions of the computer equipment were far from compact and bearing of the equipment by the patient would have been incompatible with normal daily life. Furthermore, we did not evaluate the effect of weight bearing on the BMD during the first year after surgery, although it should have been interesting and has been done by others[13]. Neither did we report an evaluation of the conventional radiographs, because early changes of loosening after uncemented THA rarely can be detected earlier than 2 years after the operation.

It might have been suitable in study II to include also a polished anteverted stem with a collar. However, the inclusion of a polished stem with a collar to prevent the stem from subsiding would have been contradictory to our hypothesis. Moreover, a higher incidence of distal femoral osteolysis in collared polished stems compared to collarless polished femoral implants was recently found by others[42], suggesting that polished stems preferably should be collarless making subsidence possible in order to achieve "secondary stability" and prevent stress shielding.

In study III, only patients with a femoral diameter of at least 14 mm were included due to the fact that the Epoch stem implant only was available from that size. It would have been interesting to evaluate the behaviour and outcome of smaller stem sizes of the Epoch design. However, the elastic modulus of smaller stem components is more like that of the bone and therefore stress shielding in general is expected to be less pronounced around smaller compared to larger sized stem components.

As explained in the introduction part of this thesis, the survival of every implant in the Swedish Hip Arthroplasty Register is directly correlated to the revision rate. However, implants are not revised due to implant related factors only: many other environmental factors do play a role for the survival of every

implant combination. The initiation of detailed recordings of all assembled implant parts in 1999 warranted a short to intermediate term evaluation to identify any new problems that could be related to an increasing modularity or range of sizes associated with the majority of the hip implants on the market. To reduce the effect of bias we restricted the analysis to the three most commonly used cemented femoral implants.

Summary and future recommendations

The results have improved over time as reflected by a relative decrease of clinical failures requiring reoperation. This is partly an effect of improvements in surgical technique, implant and patient selection. In Sweden the long history of a National Register is probably the most important factor for this improvement. Between 1992-2007 the 16-year survival based on revision due to any cause was 84.8% for all ages and all stem implants (cemented and uncemented) for all diagnoses and reasons for revision and 90.6% for all cemented stem implants inserted because of primary osteoarthritis and with aseptic loosening as only cause for revision[75]. The best performing cemented stem implants have a survival of nearly 95% after 16 years. The possibilities for any further improvement of well-functioning hip implants in general is limited as older implant designs still show good outcome.

In this study, we have shown that modifications of stem surface and material did not have the expected preservative effect on the bone mineral density at the 5- and 7- year follow-up, respectively, despite promising results two years after implantation. In the young patient with a long life expectancy and in revision surgery further development in this area may be of interest. Based on the findings in this thesis, it seems as further technologic development may become very difficult and might be supplemented with pharmacological interfere of the bone metabolism to have any effect in the long term. If this is possible without introduction of any adverse effects still remains to be studied. For the older patients it might be that further development of new implant is of limited value. Instead it seems more eligible to concentrate on choosing the appropriate implant for the individual patient and further development of optimum patient information, care, preoperative planning, surgical technique and rehabilitation. Stress shielding with loss of BMD may be inevitable around any femoral stem and makes any future revision more complicated.

However, the impact of stress shielding and its clinical effects are still not completely clear. Prevention

of osteolysis and stress shielding in other ways than experimenting with modifications of stem design includes also use of new articulations with less wear and reduced production of particles with potential to induce an inflammatory response leading to bone resorption. In addition drugs which inhibit osteoclastic resorption may be valuable at least in some situations. If one or several of these treatments alone or in combination can reduce stress-shielding without causing any adverse effects and to a low price, the number of future revision and the morbidity associated with this type of surgery might be reduced.

In future (and ongoing) studies any effect of highly cross-linked polymers on the bone remodelling around the joint is of particular interest. As concerns implant design and modularity, further studies of large cohorts also of uncemented stems and newly developed acetabular components with increased elasticity may be of interest. More detailed studies of the importance to restore anatomical offset and use of larger femoral heads on hip function and implant survival should be done. Further evaluation of small polished and cemented stems used in populations with a narrow femoral canal or a small femur such as in the Asian population and patients with dysplastic hip disease is also eligible.

CONCLUSIONS

I Immediate weight bearing after the implantation of an anteverted uncemented and hydroxyapatite coated stem did not have any adverse effect. Immediate full weight bearing – as much as can be tolerated- after uncemented THA of the ABG-type is justified, provided that primary stability of the implant can be achieved.

II Polished anteverted cemented femoral stems without a collar subsided more and mainly inside the cement mantle during the first 2 postoperative years compared to matte or PMMA coated collared femoral stems of the same design. During the period of increased subsidence improved bone remodelling was seen around the polished version probably due to a more favourable loading of the proximal femur. No advantages or specific shortcomings were found with the use of a PMMA-coating.

III The uncemented fully porous-coated composite Epoch stem showed excellent fixation and good clinical results at medium term. This stem with increased flexibility had positive effects on early proximal bone remodelling compared to a solid uncemented stem during the first 2 postoperative years, but this effect decreased with time, suggesting that the load bearing area of the stem moved distally with time.

IV Overall the survival rate for the three most frequently used cemented stem designs in the Swedish Hip Arthroplasty Register was high. Variations within each stem design such as size and neck length or offset influenced the risk for non-infectious revision for 2 of the implants studied. Our findings underline previous experiences form other implant designs, where relatively modest changes of the stem shape not delivered the expected clinical results.

SVENSK SAMMANFATTNING
(Summary in Swedish)

Total höftledsartroplastik är en effektiv behandling med låg frekvens av komplikationer för patienter med höftsjukdom, när alternativa metoder inte längre ger tillräcklig symptomlindring. Operationen är en av de mest kostnadseffektiva kirurgiska ingreppen. För de flesta patienter återställs livskvaliteten till för åldern normal nivå. Risken för omoperation (revision) är låg, cirka 3 till 5 % under en 10-årsperiod. Den vanligaste orsaken till revision är icke-infektiös proteslossning. Omfattande forskning har bedrivits för att kartlägga och förebygga lossnings-processen. Såväl mekaniska som biologiska faktorer kan ligga bakom men det kvarstår fortfarande flera oklarheter beträffande genesen till proteslossning.

Avhandlingens mål är att utvärdera betydelsen av postoperativ avlastning samt stammens ytbehandling och form för risken att utveckla proteslossning. Eftersom det ofta tar lång tid att utveckla kliniska tecken på lossning användes radiostereometri (RSA) för att mäta protesrörelser och därmed få en tidig information om protesens stabilitet samt mätning av bentäthet för att tidigt registrera hur benvävnaden påverkades av implan-tatet. Totalt ingår 3 prospektiva randomiserade kliniska studier och en analys baserat på det Svenska Höftprotesregistret. I de 3 kliniska och randomiserade studierna använ-des radiostereometri och bendensitometri (DXA). I register-studien utvärderades om före-kommande variationer av en specifik protesdesign påverkar utfallet i form av revision.

I den första kliniska studien (delarbete 1) har 43 patienter opererats med en anteverterad ocementerad stam med proximal hydroxyapatit beläggning (ABG). Patienterna randomiserades till omedelbar full belastning eller stegmarkering under 6 veckor. De patienter som stegmarkerat fick ett inlägg som ger ifrån sig en ljudsignal när belastningen har överstigit ca 30 % av kroppsvikten. Protesdelarnas fixation och plastslitaget mättes med RSA. Kliniskt utfall utvärderades enligt Harris (Harris Hip Score). Vi fann inte några säkra fördelar med att låta patienten stegmarkera efter operation med en ocementerad höftprotes och rekommenderar därför belastning till smärtgräns i standardfallet när ABG protesen används.

I delarbete 2 jämfördes tre variationer av cementerade Lubinus-proteser, en med PMMA-täckning (polymetylmetakrylat), en med blästrad yta samt en polerad stam utan krage. 80 patienter (84 höfter)

ingick. Samtliga följdes kliniskt enligt Harris (Harris Hip Score), med RSA och med konventionell röntgen. 40 patienter utvärderades med bentät-hetsmätning (DXA). Vi fann att den polerade protesstammen sjönk betydligt mer och framförallt in i cementmanteln. De kliniska resultaten skiljde sig inte. Analys av bentätheten visade mindre benmineralförlust kring den polerade stammen under de första 2 postoperativa år men efter 5 års uppföljning hade denna effekt försvunnit.

I delarbete 3 randomiserades 38 patienter antingen till en special-utvecklad ocementerad stam med minskad styvhet (Epoch) eller en ocementerad solid metallstam (Anatomic). Uppföljning utfördes med samma metoder som i delarbete 2. Stammarna i båda grupperna visade låga migrationsvärden utan någon skillnad mellan grupperna. Även plastslitaget var lägre än förväntat. Under de första 2 åren efter operation var bentätheten högre runt den mer flexibla stammen men liksom i delarbete 2 avtog denna effekt med tiden.

Resultaten i studie 2 och 3 talar emot att man genom modifikation av stammens elasticitet eller sätt att fixera kan påverka förlusten av benmineral ur ett längre perspektiv.

I delarbett 4 studerades de vanligaste stamproteserna i Sverige (Exeter Polished, Lubinus SPII och Spectron EF Primary) använda under perioden 1999 – 2006 och i det Svenska Höftprotesregistret (sam-manlagt 72,991 höftproteser). Från artikelnummer för respektive implantat har protesens storlek, offset, halslängd samt andra implantatspecifika egenskaper identifierats. Efter omkodning av databasen har utfallet utvärderats i olika regressionsmodeller som är korrigerade för kön, ålder, preoperativ diagnos, operationssnitt och sida (operationsnummer). Vi fann en revisionsfrekvens av dessa protesstammar på 0.8% (SPII) till 1.4% (Spectron EF Primary). Variationer av en specifik protes-design såsom stamstorlek, halslängd och offset påverkade utfallet i form av revision för 2 av de proteserna (Lubinus SPII och Spectron EF Primary). Beträffande Spectron EF Primary ökade risken för revision med minskande storlek, medan endast den allra minsta storleken av Lubinus SP II stammen var associerad med en ökad risk. Använding av den längsta halsen (SPII och Spectron EF Primary) och ökat offset (endast Spectron EF Primary) innebar också ökad risk för revision. Ledhuvud av aluminiumkeramik minskade risken för revision av SPII stammen.

Våra fynd tyder på att förhållandevis små förändringar av en specifik protes stam kan påverka utfallet och att denna känslighet varierar beroende på protesens grundläggande utformning.

NEDERLANDSE SAMENVATTING
(Summary in Dutch)

Operatieve totale heupvervanging door plaatsing van een totale heupprothese (THP) is een effectieve behandeling voor patiënten met arthrose van het heupgewricht bij wie een conservatieve behandeling niet langer het gewenste effect heeft. Functioneel beperkte patiënten bereiken na de operatie over het algemeen een uitstekend resultaat met een toename in kwaliteit van leven naar een voor hun leeftijd normaal niveau. Het risico op complicaties tijdens en na de operatie is laag en het risico op een re-operatie (revisie) ligt tussen de 3 en 5 % gezien over een periode van 10 jaar. De meest voorkomende reden voor een revisie is niet-infectieuze (aseptische) loslating van de prothese. Ondanks dat er de laatste decennia enorm veel onderzoek is verricht naar de mechanisch en biologische factoren, die de aseptische loslating mogelijk zou kunnen verklaren,is nog niet in alle gevallen duidelijk waardoor aseptische loslating plaats vindt.

Het doel van de studies in dit proefschrift was te onderzoeken welke invloed postoperatieve belasting, oppervlakte behandeling en de vorm van de prothesesteel hebben op het risico op een revisie.

Omdat het vaak lang duurt voordat loslatings-symptomen voor de patiënt merkbaar worden, hebben we gebruik gemaakt van Radiostereometrie (RSA) zodat in een vroeg stadium eventuele migratie en instabiliteit van de prothese ontdekt kunnen worden. Tevens hebben we met Dual energy x-ray absorptiometrie (DXA) de botdichtheid rond de prothesesteel bepaald om te kijken wat voor invloed de steel heeft op het omliggende botweefsel.

Totaal bestaat de studie uit 4 deelstudies: 3 klinische studies en 1 analyse gebaseerd op data van het Zweedse Nationale Heup Register.

In de eerste klinische deelstudie zijn 43 patiënten met een ongecementeerde steel gerandomiseerd voor het al dan niet maximaal belasten van hun geopereerde been gedurende de eerste 6 weken na de operatie. De patiënten die hun been niet maximaal mochten belasten werden voorzien van een inlegzooltje in hun schoen dat een geluidssignaal gaf als de patiënten hun been belastten met meer dan 30 % van hun lichaams-gewicht. We vonden dat partïeel belasten geen duidelijke voordelen had ten opzichte van maximaal belasten voor de gebruikte prothese. We raden daarom aan dat standaardpatiënten direkt na de operatie deze prothese tot de pijngrens mogen belasten.

In de tweede klinische studie werden 84 gecementeerde Lubinus-prothese-

stelen met 3 verschillende oppervlaktes (gepolijst, gematteerd of voorgecoat) met elkaar vergeleken met behulp van RSA en klinische parameters. Bij 40 prothesen werd rondom het prothesemateriaal de botdichtheid onderzocht.
De klinische resultaten waren gelijk voor de 3 varianten. Het bleek dat de gepolijste prothesesteel, vergeleken met de 2 andere varianten, meer naar beneden zonk in de cementmantel de eerste 2 jaar na de operatie met minder botdichtheidsverlies. Na 5 jaar was dit effect verdwenen.
In de derde klinische studie ontvingen 38 patiënten (40 heupen) een speciaal ontwikkelde flexibele ongecementeerde steel (Epoch) of een ongecementeerde solide metalen steel (Anatomic). Dezelfde methoden als in studie 2 werden gebruikt om de resultaten voor beide protheses te kunnen vergelijken. Het bleek dat beide protheses weinig migreerden met minder slijtage van de kunstof cup dan verwacht. Tijdens de eerste 2 jaar was het botdichtheidsverlies minder rond de meer flexibele Epoch steel, maar evenals in studie 2 verdween dit effect mettertijd.
In de vierde analyse studie werden de 3 in het Zweedse Nationale Heup Register meest voorkomende prothesestelen (Exeter Polished, Lubinus SPII, Spectron EF Primary) in detail bestudeerd. Met behulp van het artikelnummer van elk implantaat werden de prothesemaat, de offset, de halslengte, het gebruikte kopmateriaal en andere kenmerken van iedere steel geïdentificeerd. Vervolgens werden regressiemodellen toegepast die gecorrigeerd waren naar geslacht, leeftijd, diagnose voor de operatie, type operatie-incisie en de geopereerde zijde. We vonden dat de revisiefrequentie varieerde van 0.8 % (Lubinus) tot 1.4 % (Spectron). Voor sommige protheses (Lubinus en Spectron) was er een duidelijk verband tussen bepaalde steelvariaties zoals de maat van de steel, de halslengte en de offset. Voor de Spectron prothese was het risico op revisie groter hoe kleiner de maat van de steel. Voor de Lubinus prothese was er een duidelijk groter risico voor de allerkleinste prothesemaat. Het bleek ook dat de prothesehals met de grootste lengte van negatieve invloed was op het revisierisico voor zowel de Lubinus als de Spectronsteel. Voor de Lubinusprothese was het risico op revisie daarentegen in combinatie met een kop van aluminiumkeramiek minder groot.
Onze resultaten duiden erop dat in verhouding kleine veranderingen van een specifieke prothesesteel van grote invloed kunnen zijn op het klinische resultaat. De gevoeligheid voor deze veranderingen varieert afhankelijk van de grondvorm van de prothese.

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APPENDIX

Enkät angående smärta-obehag efter operation

1. Vilken sida som opererats eller om du har protes på båda sidor vilken av dem som avses

Vänster
Höger

2. Hur har operationen påverkat dina höftsmärtor?
   a. Jag har inga smärtor eller obehag
   b. Jag har inga smärtor men känner obehag (t ex muskelvärk) sällan, ibland eller ofta
   c. Jag känner smärtor åtminstone vid enstaka tillfällen.

3. Om du har smärtor obehag eller muskelvärk, var lokaliserar du besvären. Du kan kryssa för flera alternativ
   a. ljumske
   b. baksidan av höften
   c. utsidan av höften
   d. låret
   e. annan lokal…

4. När känner du dessa besvär?
   a. vid aktivitet
   b. vid vila
   c. både vid vila och vid aktivitet

5. Hur ofta har du smärtor eller obehag?
   a. alltid
   b. ofta
   c. ibland
   d. sällan