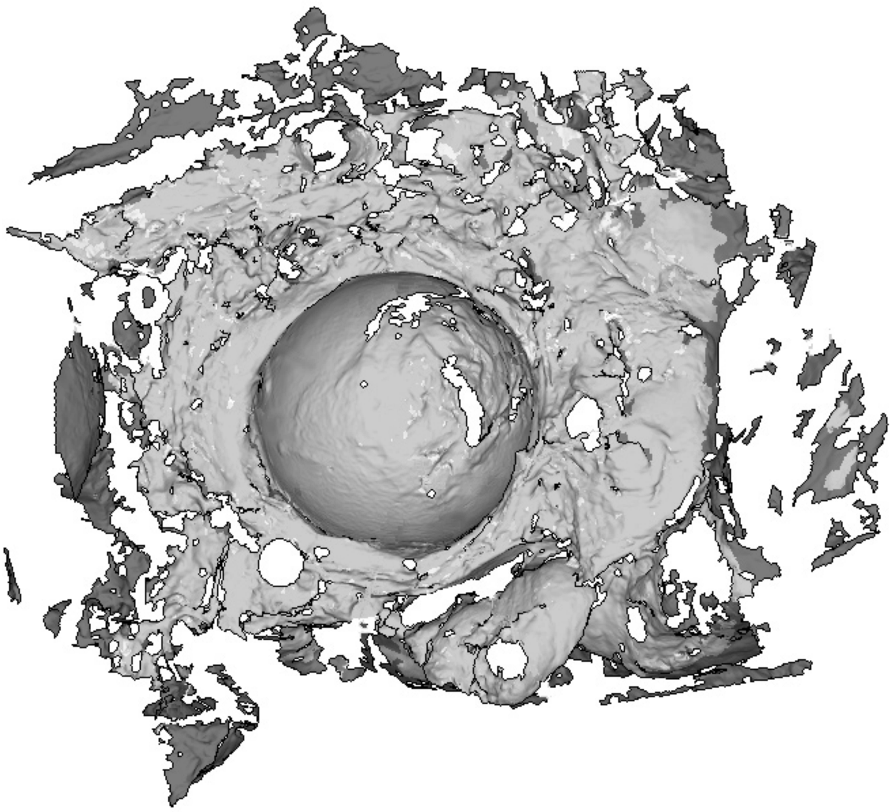
Reaming procedure and migration of the uncemented acetabular component in total hip replacement.

PhD thesis



Thomas Baad-Hansen

Faculty of Health Sciences
University of Aarhus
2006

From the Department of Orthopedics,
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Original papers

This thesis is based on the following papers, which will be referred to in the text by their roman numerals (I-IV)

I Baad-Hansen T, Kold S, Fledelius W, Nielsen, P T, Søballe K.
Comparison of reamer performance between conventional and minimally invasive surgery acetabular reamers.
Clin Orthop Relat Res. 2006 Jul;448:173-9

II Baad-Hansen T, Kold S, Fledelius W, Nielsen P T, Søballe K.
Alteration of hip joint center during acetabular reaming
Hip International 2007; In Press

III Baad-Hansen T, Bart L. Kaptein, Kold S, Søballe K.
Model based RSA applied to a cementless acetabular component
Acta Orthopaedica 2007; In Press

IV Baad-Hansen T, Kold S, Christensen P H, Laursen M B, Nielsen, P T, Søballe K.
Preliminary results of:
Trabecular Metal vs. Titanium fiber mesh acetabular component in total hip arthroplasty - a randomized RSA study of 50 hips
Manuscript 2006.

Preface

This thesis is submitted to the Faculty of Health Sciences at the University of Aarhus as part of the requirements for the Ph.D.-degree in Medical Sciences.
The thesis documents parts of my scientific studies carried out during my employment as research fellow at the Orthopedic Center, Aarhus University Hospital.

I am truly grateful for the enthusiasm and patience of my main supervisor Professor Kjeld Søballe MD., D.M.Sc. His great creativity and visionary mind have been very inspiring.

Special mention deserves my other supervisor Søren Kold, MD., Ph.D., for his excellent counselling, insight, and encouragement.

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Bart L. Kaptein MSc., Ph.D. is thanked for technical advice in matters of RSA.
I also thank Walther Fledelius MSc for developing the software applied in the experimental studies.

Niels Trolle Andersen, Lic.scient, Department of Biostatistics is thanked for superb statistical advice and assistance in study designing.

I am thankful to Poul Torben Nielsen, MD. , Mogens Berg Laursen, M.D., Ph.D. and Poul Hedevang Christensen, MD. who performed the surgical part of the clinical trial at the Orthopedic Surgery Department, Northern Orthopedic Division, Aalborg, Denmark.

Radiostereometric investigations and DEXA scans were, and still are, carried out at Farsø Sygehus.
The experimental studies were performed at the Institute of Anatomy, Aarhus University, Denmark and at the Department of Radiology, Aarhus University Hospital, Denmark.

Thanks to all my fellow Ph.D students, for broad-ranging discussions and sharing the joys and worries of orthopedic research.
Lone Løvgren Andersen, Birgit Dyhre and Gitte Broholm are thanked for helping with RSA analysis and patient logistics

Finally, I would like to express my loving thanks to my family - my wife, Lene Baad-Hansen, DDS, Ph.D. and my two daughters Eline and Andrea who has encouraged and helped me so much over the last three years. Many people told us that having two Ph.D. students in the same house was a recipe for disaster. Instead it has been incredibly stimulating.

Acknowledgements
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Instruments were kindly provided by Zimmer Scandinavia, Denmark
Financial support to the clinical trial was donated by Zimmer Inc., Warsaw, USA and The Danish Rheumatism Association.

Contents

Abbreviations

3D	Three-dimensional
AP	Anterior-posterior
BMD	Bone mineral density
CAD	Computer aided design
CCD	Charge coupled device
CR	Coefficient of Repeatability
CT	Computed tomography
CV	Coefficient of variation
DEXA	Dual energy x-ray absorptiometry
FEA	Finite Element Analysis
HA	Hydroxyapatite
HHS	Harris Hip Score
MANOVA	Multivariate Analysis of Variance
MbRSA	Model based RSA
MIREDIF	Minimal relevant difference
MIS	Minimally invasive surgery
MMA	Methylmetacrylate
NSAID	Non-steroidal anti-inflammatory drugs
RCT	Randomized controlled trial
PE	Polyethylene
POSE	Position and orientation
RE	Reverse engineering
RSA	Radiostereometric analysis
SEM	Scanning electron microscopy
SD	Standard deviation
THR	Total hip replacement

Definitions

Accuracy – A measure of reliability. The difference between the true value of a measured quantity and the most probable value, which has been derived from a series of measures.

Aseptic loosening – Mechanical loosening of a joint replacement implant without infection.

Condition number – A mathematical expression of how the markers in an object of interest, i.e., a "rigid body", relate to an arbitrary straight line passing through that rigid body.

Femoral offset –the perpendicular distance from the center of rotation of the femoral head to a line dividing the long axis of the femur.

Implant – A medical device made from one or more biomaterials that is intentionally placed within the body, either totally or partially buried beneath an epithelial surface.

Precision – A measure of repeatability. The degree of an agreement between individual measurements of a set of measurements, all of the same quantity.

Press-fit – Insertion of an implant into an under-sized cavity.

Revision – Replacement of one or both prosthetic component.

Stress-shielding – Bone loss due to by-passing of stresses in the surrounding bone as the weight-load and stresses are distributed through the implant.

Resolution –The smallest interval measurable by an instrument.

Reverse engineering –The process of analyzing an existing object to identify its components and create representations of the system in another form.

Abstract

The objectives of this Ph.D. thesis fall in two main categories.

- Evaluation of a newly designed minimally invasive surgery acetabular reamer and a

- A randomized controlled study using Radiostereometric analysis (RSA) to compare migration and rotation of two different acetabular cups.

The introduction of minimally invasive surgery (MIS) has opened new possibilities in orthopedic surgery. Reported benefits of less invasive hip replacement include less pain, more cosmetic incisions, less muscle damage, and maybe faster rehabilitation.
However, there is no standard method available for evaluation of the surgical instruments intended for MIS surgery. A new method was developed to evaluate a MIS reamer in a cadaver model and is described in study I and II.

In Study I the acetabular geometry was compared in 9 pairs of cadaver acetabuli. MIS reaming was performed in one acetabulum of each pair, and conventional reaming was performed

on the contra-lateral side. A new digitizing technique, optical three-dimensional (3D) scanning, was applied to the reamed acetabuli to determine the performance of the two reamers. Best-fit spheres were calculated for the reamed cavities.
The deviation between the diameter of the final reamer and the reamed cavity was small for both the MIS and conventional reamers, and no significant differences could be detected between MIS and conventional reaming.

In Study II the focus was on the change of the hip joint center location during preparation of the acetabular cavity for the acetabular component.
The two 3D images were merged into a single 3D image and displacements in all 3 dimensions were calculated.
The results showed no significant difference between MIS and conventional reaming with regard to transition vector length.

CE (Conformité Européene) marking of hip prosthesis is legally required in Denmark. However, the Danish Orthopedic Society recommends further clinical evaluation of new implant materials and designs before implementation in the daily clinic. Prospective studies require long observation periods, if the effect parameter is prosthesis replacement since the average prosthesis survival is 90% at 10 years. To obtain knowledge of a new orthopedic implant in a short observation period, pseudo endpoints such as implant migration has to be utilized.

Study III In a phantom study, conventional RSA utilizing tantalum markers was compared with an RSA system utilizing a hemispherical cup algorithm and a novel model based RSA system.
The precision of the migration was calculated based on double examinations of migration results of a hemispherical and a non hemispherical acetabular component.
Conventional RSA (hemispherical component) and model based RSA (hemispherical and non-hemispherical component) were significantly more

precise than the system based on the hemispherical cup algorithm.
No significant difference in precision between the conventional marker system and model based RSA could be detected.

Study IV
The results of study IV were based on a RCT where a newly designed non hemispherical acetabular cup made of trabecular metal was compared with a hemispherical titanium fiber mesh cup. Both cup types underwent migration analysis using model based RSA. At 3 month follow up no significant difference between the two cup types could be revealed, neither in terms of migration nor in rotation of the cups.

Conclusion
Study I and II
We conclude that even though the acetabular reamer-design has been greatly modified, no significant differences in the acetabular geometry were found after MIS reaming compared with conventional reaming technique.
The alteration of the hip center location is not influenced by the changes made to the MIS reamer domes in comparison with conventional reamer domes. However, in comparison with earlier studies the drift of the hip center caused by the acetabular reaming is reduced due to new reaming techniques and prosthesis designs.

Study III
The model based RSA software combines the advantages of the conventional RSA software with regard to precision and the convenience of the contour system’s software. Based on the results of the present study, we believe this new analyzing tools is a major step forward in measurement of acetabular component migration

Study IV
The preliminary results of study IV demonstrate an excellent fixation of both cup types at three month follow up. However, inclusion of additional patients is needed to provide a sufficient sample size. Furthermore a longer follow up period is required to describe adequately the migration pattern of the tantalum cup.

Introduction

The first modern hip prosthesis was implanted in 1962 by Sir Charnley, who developed the concept of low friction arthroplasty: a cemented stem with a 22 mm stainless steel head combined with a cup made of polyethylene, the cemented total hip replacement, as we know it today.
The increased rate of aseptic loosening of the acetabular component in long-term studies, especially in younger patients and patients with poor bone quality gave rise to a growing concern of the cement fixating principles [24, 29, 57, 86, 108].
To provide lasting fixation and bypass the problems linked to the cemented prosthesis a number of new cementless designs emerged in the mid 1980s. A variety of different textured surfaces were applied to the implants, such as grit blasting, plasma spraying, beads, fiber-mesh or trabecular metal [15, 69, 92, 126]. Bioactive materials have also been used to promote direct attachment of the bone to the implant in order to provide an even better fixation [38, 118].

Improvements of implant technology have paved the way for better results, but also new surgical techniques have been developed. One such technique is the minimally invasive surgery hip technique (MIS) featuring a smaller incision, thus preserving vital muscle and tendon groups. This may offer potential benefits to patients, including less pain, less scarring, less blood loss, and increased function immediately after surgery[82, 136]. However, this technique is still in its infancy and adequate testing is needed before it may possibly be labeled as the new gold standard [67].

Every year, more than 7000 primary hip endoprostheses are implanted in Denmark, and the incidence is rising with the increasingly aging population [73]. For older patients the incidence of a later revision of hip implantation is low. Unfortunately, as mentioned earlier long-term results have shown an increased rate of mechanical loosening in younger active patients with cemented prostheses [24]. Approximately 20% of patients below 55 years of age at the time of surgery need a new hip implant within 10 years [77, 78]. Therefore, it is necessary to explore the potentials of new materials and techniques in extending the long-term success of hip replacement in young patients.

Aim and Hypotheses

The aim of the present thesis was:

Studies I and II
To compare the performance of a new-designed acetabular reamer intended for minimal invasive hip surgery with a conventional acetabular reamer.

Study III
To validate a new marker free radiostereometric analysis method for metal backed acetabular components.

Study IV
To investigate migration and rotation of a new non-hemispherical acetabular component made of tantalum in comparison to a hemispherical acetabular component made of titanium. Pseudo endpoint is migration and rotation of the implant evaluated by RSA

Hypotheses:

Studies I and II
The newly designed MIS reamer will compared to a conventional reamer, create less optimal preparation of the acetabular host bone and larger displacements of the rotational hip center due to the chamfered design.

Study III
The Model based RSA system can be applied to a hemispherical cup as well as a non hemispherical cup with the same precision as conventional RSA software.

Study IV
The Monoblock® cup will migrate less than the Trilogy® cup due to

- a higher friction coefficient should improving primary fixation to the host bone.
- a highly interconnecting porous surface
- an elastic modulus more similar to the acetabular host bone.

Aseptic loosening of orthopedic implants

Aseptic loosening and osteolysis are considered as the major causes of failure in total hip replacement[89] and is the reason for more than 80% of revisions[77]. Hugh effort is put in this research area to identify the factors limiting the longevity of total hip replacements (THR). The pathogenesis of aseptic loosening is multifactorial and still remains unclear. Known risk factors of aseptic loosening are listed in table 1

Risk factors	
Age and physical activity	Young age and a high activity level increases the risk of later revision [9, 73, 77]
Body weight	Patients with a body weight less than 75 kg have a better outcome than patients weighing more than 75 kg (uncemented THR) [109]
Smoking	Cigarette smoking has shown to interfere with bone metabolism [7, 30]. However, previous studies have produced conflicting evidence to the relationship between smoking habits and aseptic loosening. Except for a single study [81] showing a 4.5 times greater risk of implant loosening in smokers, smoking had no overall negative effect on implant loosening [56, 79], one paper showed that former heavy smokers had and an increased risk of 2.8 of loosening compared with never-smokers [41]
Gender	According to Morscher[85] women are at higher risk of cup revision, whereas stem loosening is more frequent among men. Survival analysis from the Swedish hip register indicate an all over higher risk for aseptic loosening in male patients [85]. Male gender are highly associated with aseptic loosening of cemented cups with a relative risk of 2,7 [9]
Bone pathology	Despite lower activity level and usually lower body weight it is well documented that patients with rheumatoid arthritis have a poorer outcome due to aseptic loosening [29, 77, 122]. An animal study by Søballe et al [117] suggested that osteopenic bone due to disuse, rheumatoid arthritis or osteoporosis can be a limiting factor for implant fixation and in the long term cause aseptic loosening.
NSAID	In a retrospective review by Malik et al. [79] no significant relationship with regards to NSAID usages and early aseptic loosening in cemented THRs could be found. Likewise in a prospective 5 year follow-up study using indomethacin no inhibiting effect of NSAID were found in uncemented THRs [130] in contrast to a Swedish study showing a significant higher risk in a group of patients treated with ibuprofen [93]. Similarly a retrospective study by Kjærsgaard et al. [65] has indicated a significant increased risk for revision due to aseptic loosening in uncemented THRs patients treated with NSAIDs.

Table 1. Known risk factors of aseptic loosening

Two factors are primarily believed to cause aseptic loosening:

- Lack of initial stability or insufficient fixation of the implanted component [21, 94]
  and

- Wear debris-induced inflammation from polymethylmethacrylate (PMMA) bone cement or/and from the polyethylene (P.E)-metal interface leading to osteoclastogenesis [139].

Obtaining initial stability of orthopedic implants is of crucial importance, especially when dealing with uncemented prosthesis. Initial stability is an essential requirement to promote bone ingrowth and prevent micromotion of the implant. Micromotion less than 0.2 to 1 mm are tolerated [21, 94]. If this level is exceeded mechanical loosening can be initiated. Numerous amounts of acetabular implants has been developed with varying degrees of long-term results, and some even with devastating outcome in attempt to improve the initial implant fixation [62, 115].

As a result of micromotion, a fibrous membrane is created around the implant [116]. The motion-induced fibrous membrane differs from surrounding bone in such a way that it fails to provide a stable foundation for the prosthesis. This results in further increased micromotion. Furthermore, it has been suggested that a relative movement between the prosthesis and the bone influences bone ingrowth and remodeling greatly [20]. If this development is continuous, it will cause bone resorption, and the prosthesis will start to migrate and a vicious circle is started.

At present, this process of prosthetic loosening and bone resorption can only be stopped by removal of the prosthesis. Knowledge of early implant instability is important, as it could predict future loosening [46, 84]. RSA studies have shown a predictive power of 85 percent to identify implants at risk of loosening at 2 year follow up [105], and a strong correlation between implant revision at ten years follow up and large micromotion of the implant as early as 6 month postoperatively [61].

Retrieval analyses of cementless acetabular implants combined with histological, radiographic and clinical data have given important knowledge about the reason for implant loosening. In one study by Sumner et al. [120], 25 porous-coated cups with a titanium fiber mesh coating similar to the Trilogy® cup was retrieved from patients due to dysfunction (none were removed because of failure of fixation). Interestingly, the study showed that only 18 of the 25 cups had signs of bone ingrowth into the porous surface. Of the 18 cups an average of one third of the available pore structure was occupied by bone.
However, the results should be treated with a considerable measure of reserve because the implants had only been in place for a period of 30 weeks in average. Nevertheless, a similar estimate of the area of bone ingrowth was also found in a human postmortem retrieval study with a mean in situ period of five months [39].
A microradiograph analysis of retrieved postmortem porous acetabular components (Intermedics Orthopaedics) [13] showed an average direct apposition to the periprosthetic bone of 84% and a 12% occupation of bone in the porous coating.

In contrast to early revisions , late revisions of orthopedic implants is

among other factors, a result of an unintended inflammatory response [100].
The articulating surfaces of the artificial joints generate continuously sub microscopic wear particles and the polyethylene wear has been accepted as a major cause of osteolysis in total hip arthroplasty.
Submicron particles, which are secondary to abrasive wear, migrate into the effective joint space and stimulate a foreign-body response resulting in bone loss which is mainly mediated by macrophages and interleukins (IL-1, IL-6 and TNFα) [23, 34].

Early implant loosening often occurs as a result of poor surgical technique or due to infections (1 to 5% of primary arthroplasty [6]).
Recent research has brought attention to the fact that the number of patients diagnosed with aseptic loosened prostheses may be overestimated [49, 88].
These studies have suggested that, bacteria can persist for long periods around the implants in a quiescent state that limits their ability to be detected using standard microbiologic techniques due to small colony variants or intracellular *Staphylococcus* aureus " residing" in osteoblasts [88].
Clinical findings support the hypothesis, since bacterial biofilms can be detected on many implants removed from patients with aseptic loosening [11]. Moreover both Gram-negative and Gram-positive bacteria produce endotoxins (e.g. teichoic acid, peptidoglycans) capable of activating similar signal transduction and increasing production of cytokines as wear particles [95].

Materials and Patients

Acetabular reamers (studies I and II)

The reaming procedure is mandatory to prepare the acetabular bone for a prosthesis implantation. The acetabular reamer is designed to remove arthrotic bone and cartilage from the hip socket. The affected acetabular part of the hip joint must be converted to a hemisphere. This is done with a handheld dome-shaped acetabular reamer on which cutting edges are mounted in spiral-like configuration. The uncemented acetabular component is normally designed as portions of spheres (figure 3) so that spherical reaming will optimize contact between bone and implant.

Figure 1. Conventional reamer.

In studies I and II, two types of acetabular reamers were used: Zimmer®Conventional (figure 1) and Zimmer®Low Profile used for MIS (figure 2), both reamers produced by Precimed®, Switzerland.

With the introduction of minimally invasive techniques in hip surgery, demands for new-designed surgical instruments have risen [8]. The need for repeated access through smaller skin incisions, minimal opening of the capsula of the hip joint, and dissection in/between soft tissue has made development of new acetabular reamers necessary in order to avoid abrasion of the soft tissues. Such undesirable abrasions may hamper wound healing and cause infections [54].

In the MIS reamer both sides have been chamfered resulting in two sharp edges leading to a narrow reamer in comparison with conventional reamers. The MIS reamers are in average narrowed 27% in size and the number of cutting edges is reduced with approximately 34% compared with the conventional reamers.

In studies I and II only unused acetabular reamers were used.

Figure 2. Minimally invasive surgery acetabular reamer

Acetabular specimen (studies I and II)

With approval from the local Ethics Committee, 9 human specimen (pelvis, abdominal content, and spine) were

investigated in studies I and II. A total number of 18 acetabuli were reamed.
Mean age of the cadavers was 81 years (range 69–95 years). The specimens were embalmed with alcohol, glycerin, glutaraldehyde and formaldehyde, and the acetabuli were cleared of the capsula and surrounding soft tissues before the reaming procedure was initiated.

Hip prosthesis (studies III and IV)

The two acetabular components investigated in study III and IV was both uncemented metal-backed implants. The femoral component (uncemented Versys®femoral stem, provided by Zimmer®, Warsaw, USA) used in study IV was combined with either a Trilogy® or a Monoblock®cup.

The Trilogy®cup (Zimmer®, Warsaw, USA) (figure 3) is a modular hemispherical metal-backed cup consisting of a polyethylene liner and a metal shell.

Figure 3. Trilogy® cup

The modularity allows exchange of the liner if extensive wear or breakages of the liner should occur, and a total cup revision can be avoided.

The liner used is a 10° elevated rim liner made of GUR (granulated ultrahigh molecular weight polyethylene resin) 1050 resin and sterilized by gamma irradiation in a nitrogen environment. The liner articulates against a 28 mm femoral head made of chromium-cobalt. The metal shell is a non-holed shell made of a titanium-aluminum-vanadium alloy core upon which a 250μm thick sintered wire (fiber metal porous surface) of pure titanium is fastened.
An animal study [99] compared the fiber metal surface with a porosity of 62% with a closed pore alloy porous surface and revealed a superior performance with regard to bone on growth.
The Trilogy® cup is designed to be inserted in a slightly smaller (2mm) reamed acetabular cavity than the size of the implanted cup. This over-sizing or under-reaming technique is used to provide implant stability without additional screw or peg fixation, however, fractures have been reported with this type of underreaming[63].

The Monoblock®cup (Zimmer®, Warsaw, USA) (figure 4) has a hemi elliptic design

Figure 4. Monoblock®cup

In contrast to the Trilogy® cup, the Monoblock®cup has a built-in extension of 2 mm in the periphery to enhance

rim fixation and is therefore not a perfect hemisphere. The Monoblock®cup is inserted using the so-called line-to-line technique, which refers to a similar size of the reamed acetabular cavity and the base of the implanted cup.
The cup is a non-modular system, where the 10° liner is compression molded directly into the metal shell. The Monoblock®design eliminates the need for a locking mechanism and the fretting that may occur.
The risk of backside wear (articulation between liner and metalshell) is eliminated [111]; however, the non-modular system excludes the possibility only to revise the liner in case of breakage. Liner material consists of GUR 1050 resin and is with the rest of the metal shell sterilized by gamma irradiations. This liner also articulates against a 28 mm femoral head made of chromium-cobalt.
The metal backed shell, deposited upon a titanium alloy ring, is made of trabecular metal, which consists of interconnecting pores resulting in a structural biomaterial that is 75% to 80% porous, which allows a higher rate of bone ingrowth compared to conventional porous coatings and increased interface shear strength [15, 16]. In addition, due to a bone-matched elastic modulus of the trabecular metal a decrease in stress shielding should be obtained[15]; and a higher friction coefficient should improve primary implant fixation [27].

A recent canine study has shown a superior bone ongrowth in trabecular metal implants compared with glass bead blasted titanium alloy surface [98].
A pore size range of approximately 50 to 400 microns has been determined to provide optimum bone ingrowth [14].
The two acetabular components studied are both intended to provide ideal pore-size and thereby improve osseointegration of the implants.
A scanning electron microscopy (SEM) in backscatter mode of the two different surfaces is visualized in figure 5.

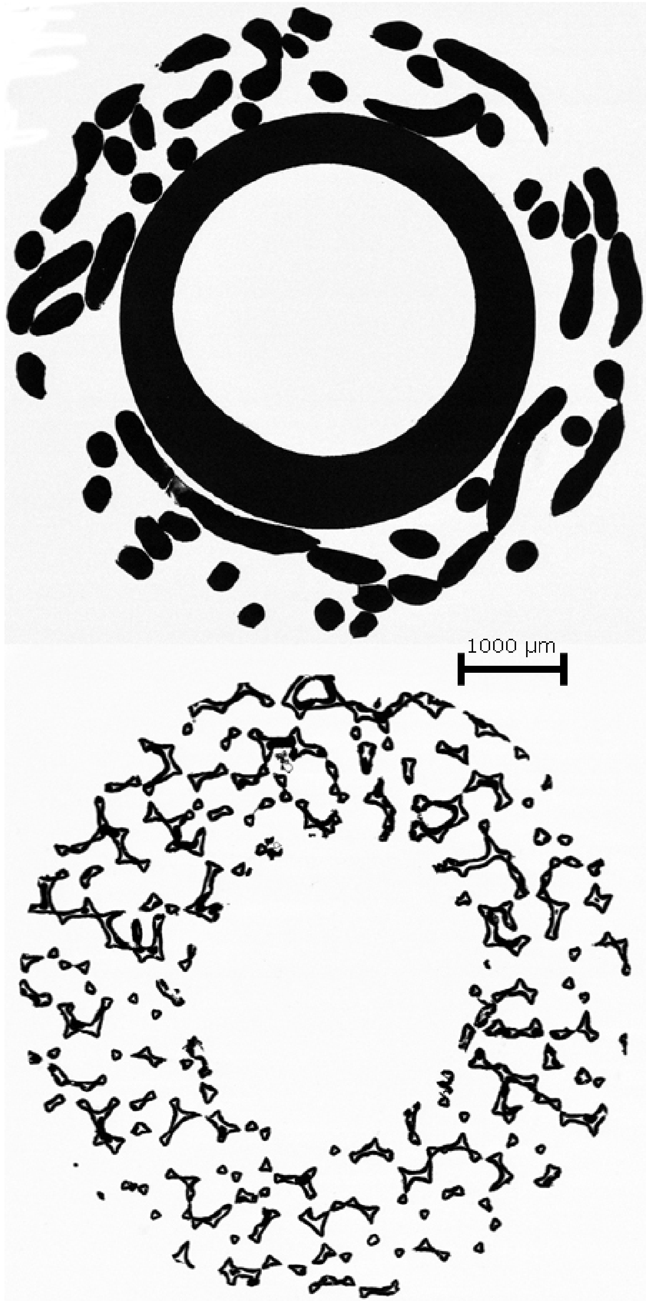

Figure 5. SEM of a fiber metal surface (upper photo) and a trabecular metal surface (lower photo).
Photos by courtesy of Ole Rahbek, MD., Ph.D.

Patients (study IV)

The design and conduct of the clinical trial was approved by the local Ethics Committee prior to inclusion of patients.
Additional approval was given to carry out double examination on ten patients.

The study was reported and approved by The Danish Data Protection Agency.

The study was performed in accordance with the Helsinki Declaration II[1]. Written informed patient consent was obtained from all patients.

The trial was registered before September 13, 2005 in an openly available database in accordance with the directions of the Committee of Medical Journal Editors (ICMJE)[31].

Patient inclusion criteria:

1. Patients with primary osteoarthritis in the hip.
2. Patients with sufficient bone density to allow uncemented implantation of an acetabular component.
3. Age > 50 years.
4. Age < 71 years.

Patient exclusion criteria:

1. Patients with neuromuscular or vascular disease in the affected leg.
2. Patients found upon operation to be unsuited for uncemented acetabulum component.
3. Regularly use of non-steroid anti-inflammatory drugs (NSAID). Patients were not allowed to use NSAIDs in the postoperative phase.
4. Patients with fracture sequelae.
5. Female patients of childbearing capacity.
6. Hip joint dysplasia.
7. Sequelae from childhood hip joint disorders.

Methodological considerations

Optical 3D scanning (studies I and II)

Previous studies concerned with the morphology of the reamed acetabular cavity have applied a variety of different measuring techniques to identify the correct shape and size of the reamed cavity. Casting techniques using dental alginate, impression stone [74], and artists' plaster [76] produce positive replicas which are measured with different types of 3D computer coordinate methods. In other studies 3D surface scanners [129] and profilometers [35] have been used to describe the acetabular surface. Even though the replica material has a high physical precision property, it may still influence parts of the acetabulum that has a relative low rigidity, which can change the shape of the replica. Furthermore shrinkage and adhesion of the replica material to the original surface may introduce artifacts.
In study I and II an optical 3D digitizing system (ATOS II SO - Advanced TOpometric Sensor II Small Objects, GOM®, (Gesellschaft für Optische Messtechnik) Germany, provided by Zebicon A/S Billund, Denmark) was used to measure cavity geometry.

So far surface 3D-scanning has only been utilized few time in orthopedic research [5, 107, 129]. However, surface 3D scanning has previously been used to assess clinical outcome after maxillofacial - and plastic surgery [42, 119], in growth and aging of facial soft tissues studies[43], and in forensic medicine for identification and 3D reconstructing of patterned injures [22, 124, 124, 125].
A recent study [28] compared MRI, CT and a 3D surface scanner of a plastic model and revealed a minimal difference in measurement accuracy .
The optical system captures a maximum scanning volume of 1 m^3 with accuracies of 0.02 mm [17], however the accuracy depends on the object size and increases with reduction of the size of the scanned item.

The Danish Technological Institute, an independent institution approved by the Danish authorities made an unprejudiced rapport of the ATOS II SO system detecting a measurement accuracy of 0.00049 mm (SD) of a 25 mm large object, where 20 individual measurements were made [128].
The optical 3D digitizing system is based on a triangulation principle[51], different light patterns are projected onto the acetabular cavity and are observed with a dual charge coupled device (CCD) camera [48]. (Figure 6).

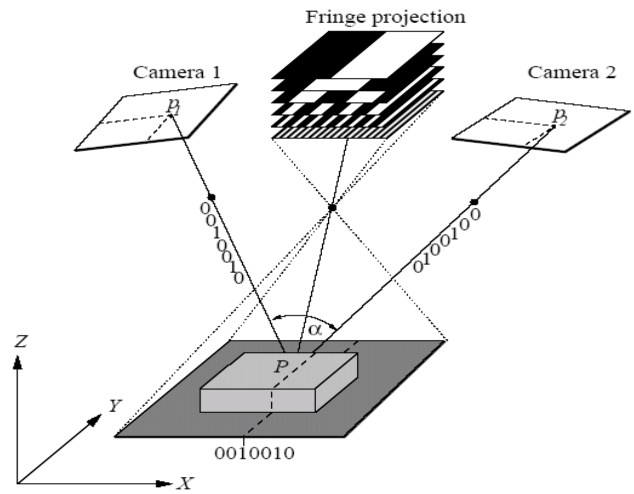

Figure 6. Fringe patterns projection. Photo by courtesy of Zebicon a/s.

The dual CCD camera and projector were mounted on a tripod (figure 7) and could easily be positioned relative to the specimen in order to obtain scans from different viewpoints. In average we needed 5 individual views to document the complete visible acetabular cavity. For measurement of the acetabulum, self-adhesive markers were attached in a non specific pattern to the nearby structures outside the area we wished to scan.

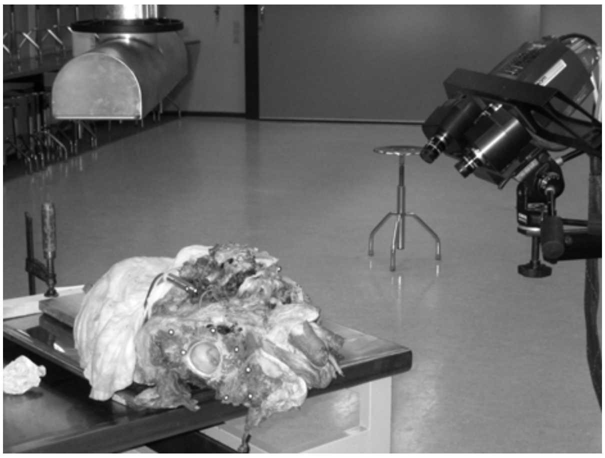

Figure 7. Optical 3D scanning set-up. To the left the acetabular specimen. To the right the dual CCD camera mounted on a tripod

The reference targets are needed for the ATOS software to recognize similar patterns on every scan and afterwards be able to merge the scans into a single dataset. The data set consists of a "point cloud" and at the end of the digitizing process each single scan is combined to a high-resolution 3-D polygon mesh and the 3D surface model is created (figure 8).

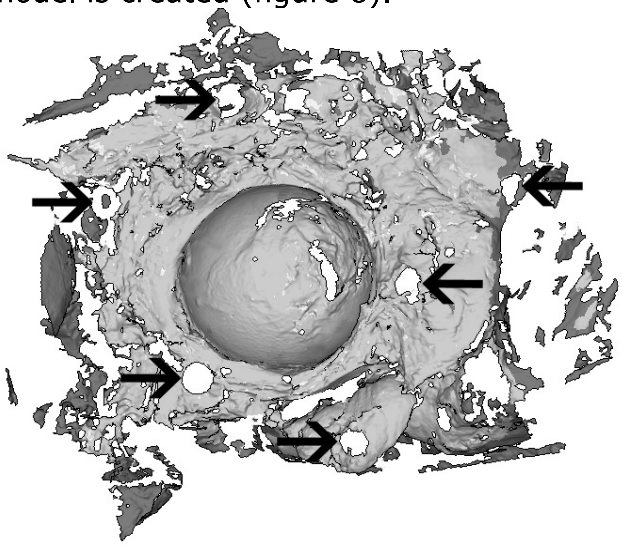

Figure 8. Optical 3D scanning of the acetabular cavity.

In average 70,000 coordinates were produced in a 3-D optical session varying from the smallest cavity (46mm) with 62,642 data points to the largest (60mm) using 110,124 data points.

Best-fit sphere

The "point cloud" consisting of single data points was uploaded into the workstation computer as an ASCII (American Standard Code for Information Interchange) file and all dataset were rotated to a predefined standard position (x,y,z). As the surface of the reamed acetabuli did not 100% resemble a perfect geometrical hemisphere an ideal virtual hemisphere was used to estimate the deviation from the scanned acetabuli with regard to size and shape (figure 9).

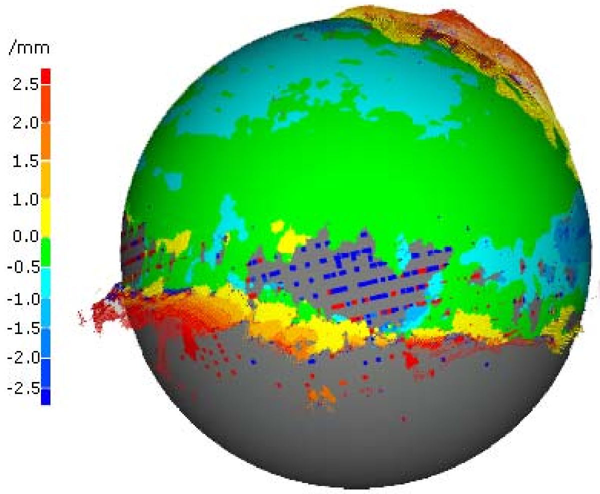

Figure 9. A virtual sphere is fitted to a scanned acetabulum. On the top of the sphere the fossa can be seen.

If the center of the sphere is at (xc,yc,zc) and the position of a point is (x,y,z) then, from the theorem of Pythagoras, the distance from the center to the point is

$$\sqrt{(x - xc)^2 + (y - yc)^2 + (z - zc)^2}$$

The squared distances from the points to the surface of the sphere were used to minimize the sum of the distance for every single point. The dataset was initially fitted with a sphere, having center and radius as free variables. After this first fit the dataset was iteratively fitted four times including only points above the center found in previous fit.

This was done to reduce the influence of the rim and data points below the fitted hemisphere. Marquardt-Levenberg implementation of non-linear least squares was used in Gnuplot®software (open source software).

Finally all sphere fits were visually checked for local divergence. Afterwards the discrepancy was calculated between the size of the final acetabular reamer and the best-fit sphere.

Measuring the reamer domes

In a similar way the final reamer domes used in the reaming procedure underwent optical 3D scanning (figure 10) and a virtual sphere was fitted using the same technique as referred to above in order to gain knowledge about the diameter of the reamers.

Figure 10 Optical 3D scanning of a minimally invasive surgery acetabular reamer dome size 46

Alteration of the rotational hip center

To determine the drift of the rotational hip center in the x,y and z direction optical 3D scans of the acetabuli were carried out before and after the reaming procedure. The fitted spheres from the pre- and post optical 3D scans were merged in a single image and the change in hip center could be calculated in medial - lateral, caudal-cranial and frontal-dorsal direction as well as the transition vector length, representing a displacement in 3D space, going from the origin - the preoperative calculated sphere center $< x_0,y_0,z_0 >$ to the postoperative calculated sphere center $<x_{reamed},y_{reamed},z_{reamed}>$.

Radiostereometric analysis (studies III and IV)

The main purpose of study IV was to assess the migration of the two different acetabular components.

The simplest way to evaluate migration of acetabular implants is to make a direct measurement with pencil and ruler on anterior-posterior (AP) radiographs of the pelvis. However, detection of migration of less than a few mm is not possible with regular radiographs and the method is inadequate for determination of prosthetic loosening at an early stage [45]. A variety of reference lines have been introduced to improve accuracy and feasibility. Using the teardrop line and Köhler's line, has been proposed to improve migration measurement accuracy by different authors [90, 121]. The accuracy of these techniques was calculated to be between ± 2.5 mm and ± 3 mm respectively.

The Ein Bild Röntgen Analyse (EBRA) developed by Russe and Krismer et al (1988) is a method for migration measurement of total hip replacement (THR) using standard pelvic AP-

radiographs. The system applies a grid of horizontal and vertical lines referring to bony landmarks on the pelvis.
Implant migration can be assessed with an accuracy of 1.0 mm for longitudinal and 0.8 mm for transverse migration (95% confidence limits) for the EBRA method dealing with acetabular implants [68].
RSA is a widely accepted clinical method for micro-motion evaluation of orthopedic implants. Selvik developed this method in the beginning of the 1970s [112] and since then the system has been further evolved and commercialized, and is today considered the most precise method for measuring implant micro-motion [60].
Clinical studies with double examinations have reported precision measurement ranging from 0.2 mm to 0.3 mm in the transverse direction (x-axis) 0.1 to 0.2 mm in the longitudinal direction (y-axis), and 0.3 to 1.0 mm in the saggital direction (z-axis) (all 95% confidence interval) using tantalum markers [61, 64, 83, 127].
Due to its high accuracy, RSA is able to provide sufficient statistical power to relatively small-numbered randomized clinical trials [132]. In addition RSA can also be utilized in clinical trials concerned with wear [32], spinal fusion [72], fracture healing [96, 97] and joint kinematics [40, 47].

Bone-and prosthesis markers

For the purpose of RSA, all patients were marked intraoperatively with tantalum beads with a diameter of 1.0mm located in the periacetabular bone (ilium and ischium) (figure 11).
The tantalum markers are radio-opaque due to a high atomic number (element number 73), are highly biocompatible [2, 3] and are corrosion resistant [142]. They are used to obtain well-defined measurement points, because bony landmarks are not sufficiently unique

In the periphery of the PE Monoblock®-liner, tantalum markers with diameters of 1.0mm and 0.8mm respectively were inserted in a specific pattern, while the Trilogy® component had 5 mm tantalum-spikes mounted by the manufacture (See figure 3 and 4).

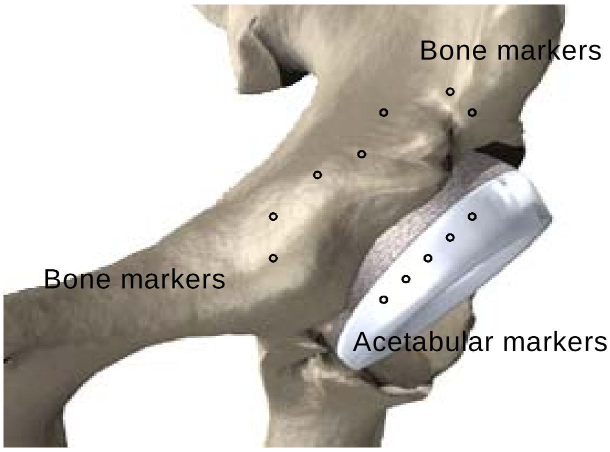

Figure 11. Placement of the tantalum beads

The accuracy of the RSA trial depends among other on the position in 3D space (condition number) and number of beads inserted. The beads must be in a position achievable for the surgeon, form a rigid body as large as possible, and be visible on both radiographs. A cut off level of the condition number was set to 150 in the cup migration study IV.

Radiostereometric x-rays examination

RSA examinations were done with the patient in a supine position. A calibration box (type 41, UmRSA® Calibration Cage Uniplanar) placed beneath the patient created a 3D coordinate system of the tantalum markers. Two roentgen tubes with a 40° angle between each other were positioned above the patient. The patient was exposed to the two simultaneously firing roentgen tubes (exposure 150kV and 3,2 mAs) (figure 12)

The reference examination was done within the first week after surgery and the follow-up examinations were done at 3 month, and ongoing at 1 and 2 years. The precision of the RSA measurements was determined by double examinations of 10 randomized patients.

Figure 12. RSA setup.

Identifying and marking tantalum markers

Until the late 1990's the marking and identifying of the tantalum beads was a slow and time-consuming process[55], because all steps in the analysis were done manually. In order to accelerate the procedure, special designed software-systems were developed for RSA studies (RSA-CMS®, Medis, medical imaging systems, Leiden, The Netherlands, UmRSA® ,RSA Biomedical, Umeå, Sweden and WinRSA®, Tilly Medical Products AB, Lund, Sweden).
With the introduction of these software packages the markers were automatically identified, sequentially numbered and their positions were measured with high precision without jeopardizing the accuracy of the measurement [134].

Calculation of cup movement

When all bone- and prosthesis markers were correctly identified and numbered, the two groups of markers were interconnected forming rigid bodies between which the relative motion was calculated. The rigid body formed by the bone markers was defined as a reference area.
Even though efforts are made to position the patient identically in the postoperative and in the following radiographs the reference markers are required to compare the radiographs.

The results of the RSA system are expressed as movements along 3 axes which gives 6 degrees of freedom. Corresponding to all 3 axes a rotational movement is also possible All potential movements are shown in figure 13.

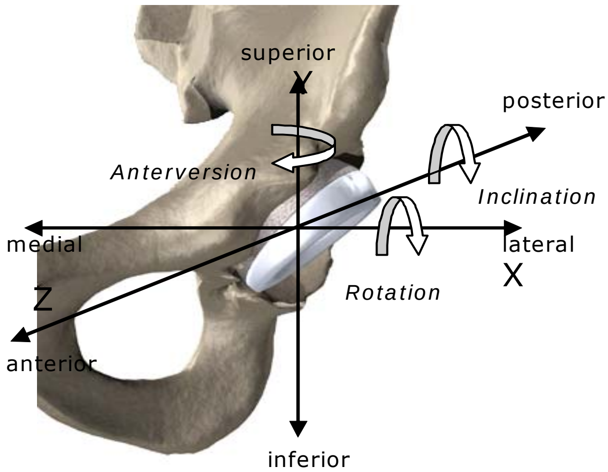

Figure 13. Orientation of the acetabular component.

RSA without prosthesis markers

Applying the RSA system to a clinical trial dealing with micro-motion of a femoral component is fairly easy. However, when it comes to judging the same parameters in a metal-backed cup it can be quite complicated if not impossible.

The major reasons are:

- Affixing the tantalum markers to the cup can be very troublesome and time consuming. In a size 52 cup at least 8-9 tantalum beads must be inserted in the polyethylene liner as peripherally as possible. These markers are inserted intraoperatively and therefore lengthens the operation time.

- Identification of the tantalum beads on the radiographs is often impossible, due to shadows of the metal-backed cup.

- Even if it is feasible to free-project the occluded tantalum beads, it is difficult to combine the corresponding markers on the two radiographs. At least three tantalum beads are required to characterize a rigid body, a job that often must be given up and the patient must be excluded.

Second generation RSA

Valstar et al. developed a second generation RSA method to overcome the above mentioned problems by identifying the micro-motion of hemispherical metal-backed cups without attaching markers [133].
A hemispherical cup algorithm calculates the cup position and the orientation (pose) of the base of the cup based upon the assumption that the implant has a hemispherical spherical geometric structure
This is done by manually applying a sufficient number of points on the edge of the cup base- and back. (figure 14)
However, in the study III and IV only one of the two cups is perfectly hemispherical

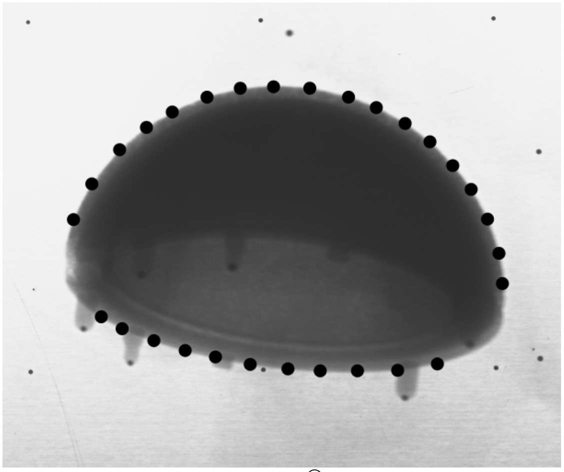

Figure 14. Trilogy® cup using the contour of the cup

Figure 15. Sectioned model of a Trilogy® cup

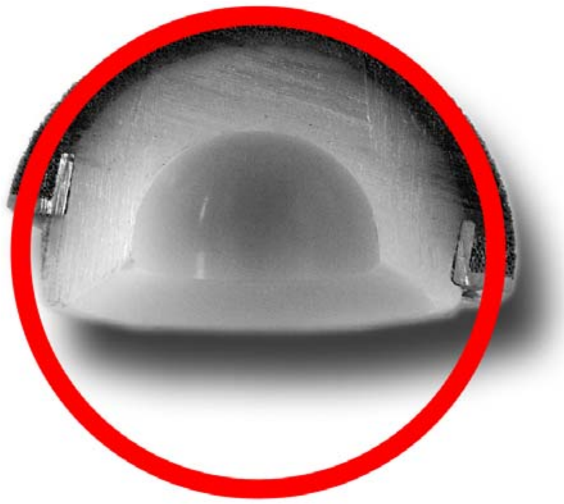

Figure 16. Sectioned model of a Monoblock®cup

Looking at the two cups in a sectioned view it is easy to see the difference in shape.
The Trilogy® cup, which is seen in figure 15, precisely follows the red circle illustrating a perfect geometric shape whereas the Monoblock®(figure 16) differs from the circle at the rim of the cup. Only about 50 % of the back of the Monoblock®cup is covered by the red circle.

Third generation RSA

Recently a new model based RSA system (MbRSA) was described in two papers by Kaptein et al. [58, 59] and previously by Valstar et al. [131]. In contrast to the contour system, Mb-RSA is based on 3D models either obtained from CAD drawing from the manufacture or by optical 3D scanning of the physical prosthesis as described in a previous section.

The 3D model is implemented into a software system (figure 17) and is matched with the RSA radiographs.
Subsequently the pose of the implant can be estimated by minimizing the difference between the contour of the 3D model and the contour of actual prosthesis as it appears on the RSA radiographs using mathematical algorithms.

The advantage of the MbRSA system is that the number of tantalum markers or towers can be left out of consideration even though the implant is not hemispherical.
In double examinations, the precision of the MbRSA has showed promising results [59]. However, until now the MbRSA has not been tested against traditional RSA system in a phantom study or a trial clinical.

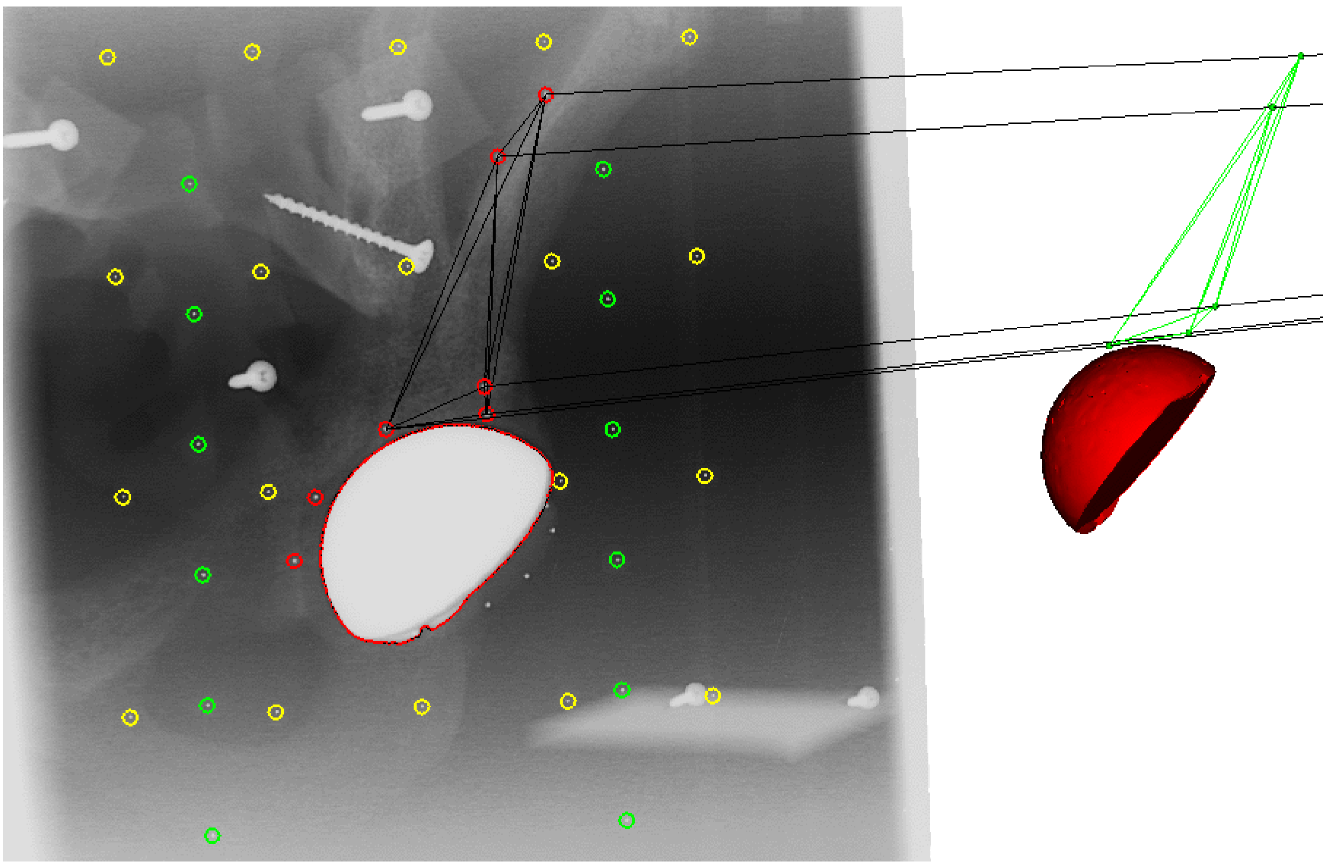

Figure 17. Model based RSA, on the left, a stereo roentgen image. Marked with red, the contour of the cup. On the right, the 3D model of the acetabular component

In study III, an acetabular phantom model was constructed to compare the conventional marker RSA system with

1. the hemispherical cup algorithm and
2. the MbRSA system

The acetabular cups applied to the different RSA systems in the phantom study were of the same 2 types as implanted in the clinical trial. For both cup types, 10 RSA radiographs were obtained. Between each exposure, either the position of the prosthesis with respect to the phantom bone or the pelvic tilt of the phantom was altered. In the present study, all radiographs were fully digitized and saved in a standard dicom file format (200 DPI, 10 grey level resolutions) and uploaded to a workstation.
During the analysis of the Trilogy® cup, the conventional RSA software automatically detected and combined all six tantalum cup-markers correctly in all 10 pairs of radiographs. The result of the migration was therefore based on all six markers.
On average, 30 dots were manually placed to mark the shape of the acetabular component in the hemispherical cup algorithm software. The dots creating the contour of the cup were possible to apply to all radiographs.
The evaluation of the radiographs of the Trilogy® cup was based on repeated stereoradiographic in different positions of the cup-pelvis phantom complex.
Each radiograph was analyzed to obtain a migration result (the first serving as reference and the second as a pretended follow-up). Ideally, the migration/rotation between the first and second analysis is zero since migration has not occurred. Deviations from zero reflect the measurement error of the system. Afterwards we calculated the means and standard deviations of the differences in migration results of all ten radiographs. The same procedure was applied to the radiographs of the Monoblock®cup; however, it was not possible to perform conventional RSA because of too few visible prosthesis markers.

Study limitations

Study I and II
Optical 3D scanning technology has some limitations and during our experimental setup we encountered limitations of the optical measuring system. Since there is a critical influence of stability and illumination, the preferable location for optical scanning is a room with a solid floor and possibilities for light reduction to optimize the light pattern projections. If the object to be scanned is glossy or is of high transparency (e.g. fatty-tissue) the projected fringe patterns may not be correctly identified by the digital cameras due to surface reflectivity.
In order to avoid misinterpretation it was in two cases necessary to apply a thin layer of titaniumoxyd in the range of 5-10µm to eliminate the artifacts produced due to surface reflectivity. With application of titaniumoxyd on basis of eliminating surface reflectivity a known confounder was introduced. However, the changes of 5-10µm seems insignificant in the clinical situation.
The two studies are conducted on embalmed cadavers which are known to alter the bone quality [138] and there may be a risk that embalmed bone is softer that physiological bone. Furthermore, Linde et al. have demonstrated that changes in biomechanical properties of cancellous bone occur immediately post mortem [71]. They found a ten percent decrease in compression stiffness of

cancellous bone during the first 24 hours. It may well be that a longer transition vector will be produced using pelvic specimen than in a in vivo setup.

In addition, using specimens with exarticulated lower limbs allowed us to overview the region of interest with regard to reamer depth and orientation of the reamer direction in relation to the specimen.
Osteopenic bone stock quality must be expected, due to the relative high mean age (81 years) of the chosen specimens and this does not fully correspond to a clinical situation where patients having uncemented THA's usually are younger. A paired design however, takes these considerations into account because the same bone quality is identical in both groups.

Study III and IV
Conventional RSA is an internationally recognized technology and the technique has been described in several published papers [60, 132]. With introduction of MbRSA, it may be that some restrictions linked to conventional RSA have been eliminated however, new limitations have developed.
A close co-operation with the implant manufacture is obligatory. Even though it is not necessary to attach markers to the prosthesis, 3D models of the prosthesis are needed for MbRSA. These can be obtained from CAD drawings from the manufacturer. Unfortunately CAD drawings can vary from the final product due to postproduction alterations (e.g. polishing). As an alternative, optical 3D scans of completed implants can be used. A previous study [58] compared the reversed engineered models and the manufacturers CAD models of a knee prosthesis. The results demonstrate that the reversed engineered models provide more accurate results than the CAD models.

It is reasonable to assume that a 3D surface scan of single implant can cover the requirements for MbRSA. However, a scale-up or down enlargement of an implant is not straightforward due to loss of accurate proportion of the prosthesis. This entails surface 3D scans of all implant sizes used in a clinical trial, but still, it is significantly less expensive than attaching all implants with tantalum markers. In addition the implants are left without modifications and can be utilized at some other time.
A specific subject related to cup MbRSA studies needs to be mentioned. In contrast to all other orthopedic implants the acetabular components have a symmetric design along its longitudinal axis. This result in lack of ability for the MbRSA software to detect potential rotation along that specific axis, however most cups have small deviation from the design e.g. liner locking mechanisms or grooves intended for the cup inserter that breaks the symmetry and allow measurement of the cups longitudinal axis.
The set-up of the phantom model described in study III was used to compare the different RSA systems under idealized conditions.
There is no reasonable doubt that a direct comparison between the results from the phantom study and similar results obtained from double examinations done in clinical trials on patients would be in favor of the phantom study. Interference from soft tissue and positioning of the patient is not taken into account in the phantom study.
A disadvantage of the MbRSA and the conventional RSA system is that the technique requires intraoperatively implantation of tantalum beads to define bony landmarks.

A study by Lawrie et al [70] observed a reduction of tantalum beads over time due to non-intended extra-osseous beads placement leading to an impairment of the RSA radiograph. Eldridge et al. found that in 64 patients having tantalum beads implanted intraoperatively, 40% of cases had one or more tantalum beads outside the postoperative radiograph [37], which in worst case will exclude the patient to participate in the study.
Even though, histological studies have demonstrated the bioinertness of tantalum markers [2, 3], the same authors have emphasized the risk of third body wear and recommend that tantalum markers only are used in small series of patients. In addition Alberius stated that the position of the markers relative to bone can change with time, which is especially import in studies with long term follow up.

MbRSA or conventional RSA can not be applied on retrospective studies due to its need for 2 simultaneously exposed radiographs. In this case the scientist has to resort to other measuring methods such as the EBRA technique

Repeatability

Repeated measurements on a series of subjects were used to evaluate the repeatability of the different methods utilized in the present thesis.

The Coefficient of Repeatability (CR) was calculated as 1.96 times the standard deviations of the differences (d) between the two measurements [12] as measurement of the precision of the systems.

$$CR = 1{,}96 \times \sqrt{\frac{\Sigma(d_2 - d_1)^2}{n-1}},$$

n=number of test subjects

Optical 3D scanning. Eight randomly selected acetabuli were 3D optical measured twice on one day, prior to the acetabular reaming procedure. Between the two investigations the equipment was removed from the location and repositioned before the second session. From these measurements two best-fit spheres were calculated for each acetabulum undergoing double examination. From this the CR was calculated to 0.05 mm.

RSA measurement comparison
To visualize the repeatability of the analyzing methods, Bland & Altman plots (difference of measurements against average of the two measurements) were drawn [12].

RSA cup migration
Double examinations in study IV were based on two consecutive x-ray exposures within a time interval of 10-15 minutes of ten randomly chosen patients at the 3 month follow up. The patients were asked to step down from the patient table and x-ray tubes, calibration box and patient table were repositioned. In this short time interval no movement of the prosthesis should occur with respect to the host bone. The precision was calculated from double examinations as described in the guidelines by Valstar et al. [132] and expressed as 99% confidence intervals (table 2).

	Cup migration
Migration	
Medial-lateral (X)	0.11 mm
Proximal-distal (Y)	0.19 mm
Anterior-posterior (Z)	0.15 mm
Rotation	
Transverse axis (X)	0.33°
Longitudinal axis (Y)	0.35°
Sagittal axis (Z)	0.45°

Table 2. Double examination of 10 patients. The precision presented as mean±2.7 SD of the error from the double examinations (99% confidence limits for significant migration/rotation).

Statistics

Statistical analyses were performed with STATA Special Edition (Stata Corporation 4905 Lakeway Drive College Station, Texas 77845 USA) software package.
P-values (two tailed) below 0.05 were considered significant in all studies

Studies I and II:
Assumptions of normally distributed data were tested using probability plots. As the parameters in the best-fit analysis and hip rotational center data were determined to be normally distributed, a paired t test was used. Data are presented as mean values with standard deviations.

Study III
To quantify the measurement precision, the CR was calculated.
Migrations and rotational values were assumed to be normally distributed based on probability plots.
One-way analyses of variance (ANOVAs) and Bartlett's test were used in the analyses of the CR of migration and rotation of the Trilogy® cup. A significant result of a Bartlett's test allowed us to perform a variance ratio test (f-test) between the applied methods.
The CR between measurements of the Monoblock®cup was assessed using a variance ratio test (f-test).

Study IV
In this study , data were not normally distributed. Therefore statistical evaluation was done using Mann-Whitney U test. Repeated measurement analysis of variance will be applied to the longitudinal data.

Sample size

The number of patients or specimens needed to enter the studies was based on the following calculation[10, 52].

$N = (C_{2\alpha}+C_{\beta})^2 \times SD^2/\Delta^2$
where

N=	Total number of patients
$C_{2\alpha}$=	Error of the first kind was set to 0,05
C_{β}=	Error of the second kind was chosen to 0,20 (erroneous conclusion that there is no difference in groups if in fact there is. (false negative result) corresponding to a study power of 0,80
SD=	Standard deviation
Δ=	Minimal relevant difference. (MIREDIF)

Optical 3D scan (Study I and II).
Sample size calculations showed that 9 pairs of acetabuli would enable this difference in best-fit spheres to be detected with 80% power at a P value of 0.05, SD = 0.1 mm [17, 128] and a minimal relevant difference of 0.11 mm (figure 17)

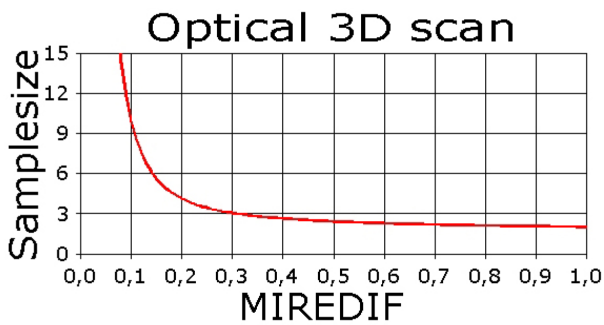

Figure 17. Relation between MIREDIF and sample size in the Optical 3D scan study

Clinical RSA stud (Study IV)

The following was estimated at study start:
Δ: 0.6 mm
SD: 0.7 mm [104]
2α: 0.05
Power: 0,8

A minimum of 22 patients in each group was needed. Due to the risk of loss of patients during the study, 25 patients in each group were included (figure 18)

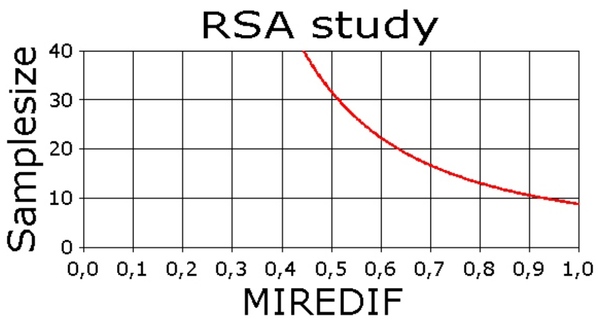

Figure 18. Relation between MIREDIF and sample size in the RSA study.

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Results

Acetabular geometry (study I)

Table 3 presents the divergence between the diameter of the final sized reamer (labeled on the reamers) and the measured diameter of the optical scanned cavity. Negative values indicate that the cavity has been measured to be smaller than the final acetabular reamer used. Figure 19 illustrates in pairs the deviation from final reamer and the measured diameter of the optical scanned cavity measured in mm.

For both reamer types, the deviations were consistently small; however half of the reamed cavities were measured to be smaller than the final reamer used. The acetabuli cavities produced by the Zimmer®conventional reamer had a mean deviation from the best-fit sphere of 0.3mm (SD 0.4mm) whereas the Zimmer®MIS reamer showed a mean deviation of 0.2mm (SD 0.5mm) (p=0.6).

Specimen number	Zimmer® standard	Zimmer® MIS	3D scan of reamed cavity with Zimmer®standard	3D scan of reamed cavity with Zimmer®MIS	dif Zimmer®standard	dif Zimmer®MIS
1	60	58	59.629	58.336	-0.371	0.336
2	46	48	46.108	47.516	0.108	-0.484
3	52	52	51.991	52.078	-0.009	0.078
4	48	48	48.033	48.104	0.033	0.104
5	52	46	52.037	45.511	0.036	-0.489
6	54	52	53.384	51.618	-0.616	-0.382
7	52	52	51.579	52.265	-0.421	0.265
8	52	50	51.767	49.545	-0.233	-0.455
9	52	50	52.081	50.407	0.081	0.407

Table 3. Deviation from final reamer size measured in mm

Hip joint center displacement (study II)

Table 4 gives the results of the hip center displacement. No significant difference between MIS and conventional reaming was found with regard to resulting vector length (P=0.9). The individual displacements (medial, cranial and dorsal) were not found to be significantly different between the two reamer types (p> 0.38).

	Medial displacement	Cranial displacement	Dorsal displacement	Length of resulting vector
Mean	2,9	1,8	0,8	3,6
SD	2,2	1,2	0,4	2,4
Range	0,4 - 7,7	0,1 - 1,8	0,3 - 4,8	0,6 - 9,2

Table 4. Displacement of hip center in all three dimensions and length of the resulting vector in mm.

RSA measurement comparison (study III)

The migration results of all three software systems are shown in table 5.

Hemispherical cup. Comparison of the different measurement techniques applied on the hemispherical shaped Trilogy® cup showed that the most precise measurement occurred, when the conventional marker system or MbRSA were used. No significant difference in CR between the conventional marker system and MbRSA with regard to translation P>0.26, or migration P>0.21 was observed.

Non-hemispherical cup. Comparison of the hemispherical cup based RSA system with MbRSA revealed a highly significant difference in precision with regard to migration along all three axes (P<0.007), but also with respect to rotation along all three axes (P< 0.01)
The precision of the hemispherical cup RSA system with regard to migration along the x-axis was half that of the conventional RSA and MbRSA. The same tendency, even to a higher extent, was seen along the other two axes (for all directions a significant difference in precision between the two systems was found, P<0.01).
A significant difference (P<0.001) in precision was also seen in rotations along all axes of the acetabular cup, most pronounced along the saggital axis comparing MbRSA and conventional RSA with the hemispherical cup RSA system The reproducibility of the x-axis migration of the all software systems are visualized in figure 19-23.

Trilogy® cup						
	X	Y	Z	X ROT	Y ROT	Z ROT
Marker based RSA						
Mean	-0.01	0	-0.02	-0.01	-0.07	-0.01
CR	0.05	0.04	0.11	0.12	0.24	0.15
Hemispherical cup based RSA						
Mean	0.01	0.04	0.04	0.53	-0.09	-0.37
CR	0.13	0.36	0.44	1.36	0.91	3.95
Model-based RSA						
Mean	-0.01	0	0	0.02	-0.02	0
CR	0.05	0.05	0.11	0.07	0.12	0.19
Monoblock® cup						
Hemispherical cup based RSA						
Mean	0.01	-0.02	-0.08	0.09	0.02	-0.08
CR	0.24	0.28	0.78	0.82	0.54	1.19
Model-based RSA						
Mean	0	-0.01	0.01	0.01	0.01	0.01
CR	0.02	0.03	0.09	0.06	0.08	0.06

Table 5. Precision of the marker, hemispherical cup and MbRSA system applied to the Trilogy® and Monoblock® cup. (Migration in mm and rotation in degrees)

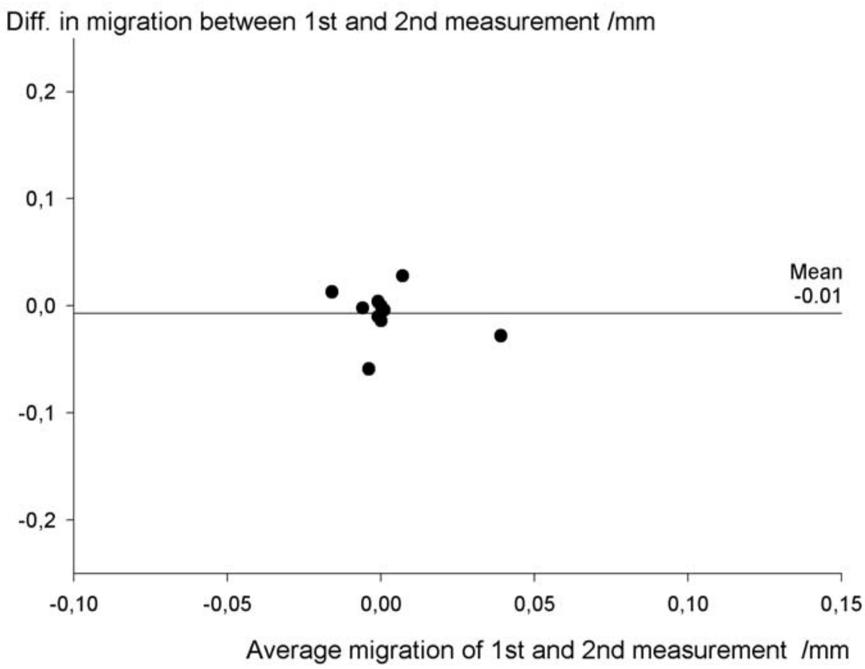

Fig.19 Repeatability of the Trilogy® cup migration - x axis (marker-based)

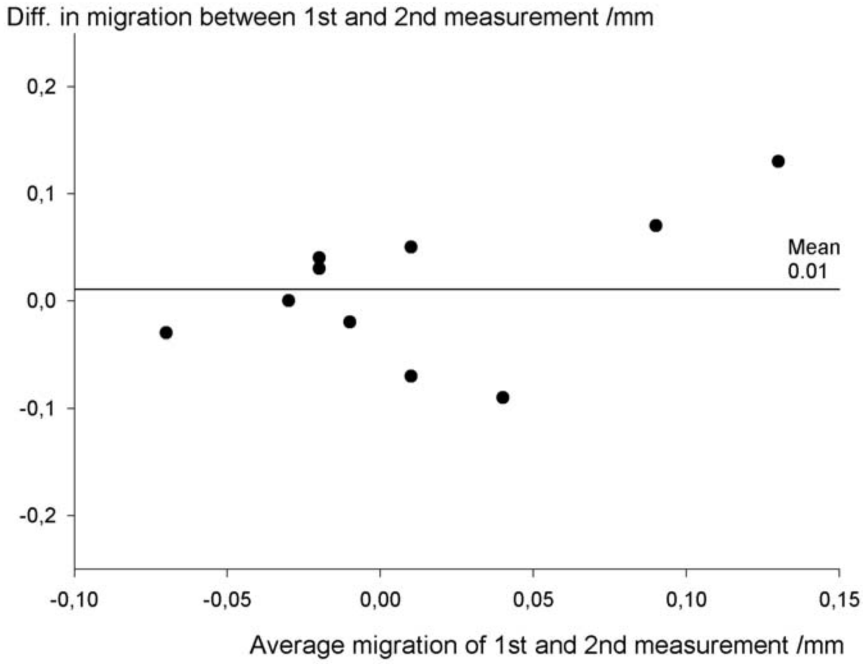

Fig.20 Repeatability of the Trilogy® cup migration - x axis (hemispherical cup algorithm)

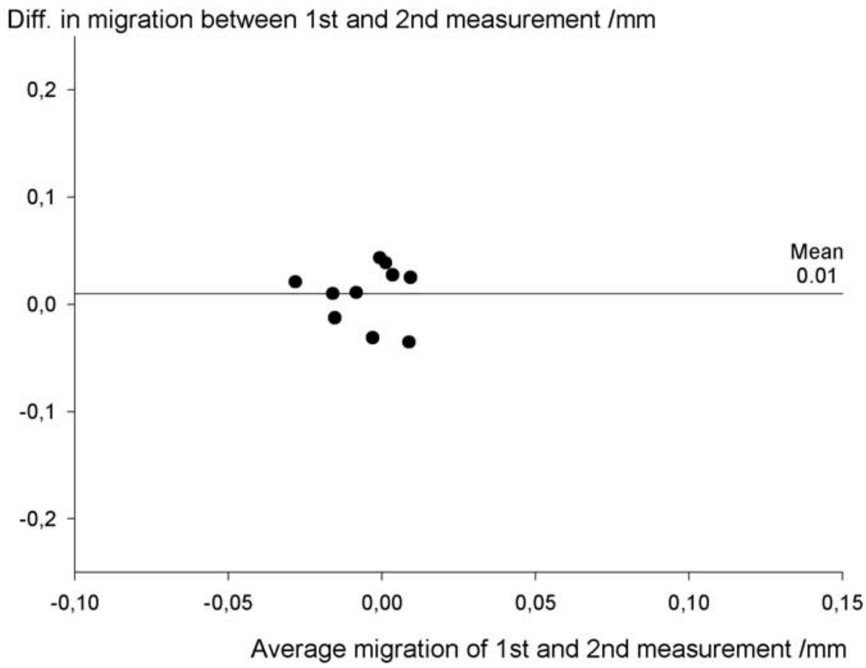

Fig.21 Repeatability of the Trilogy® cup migration - x axis (Mb-RSA)

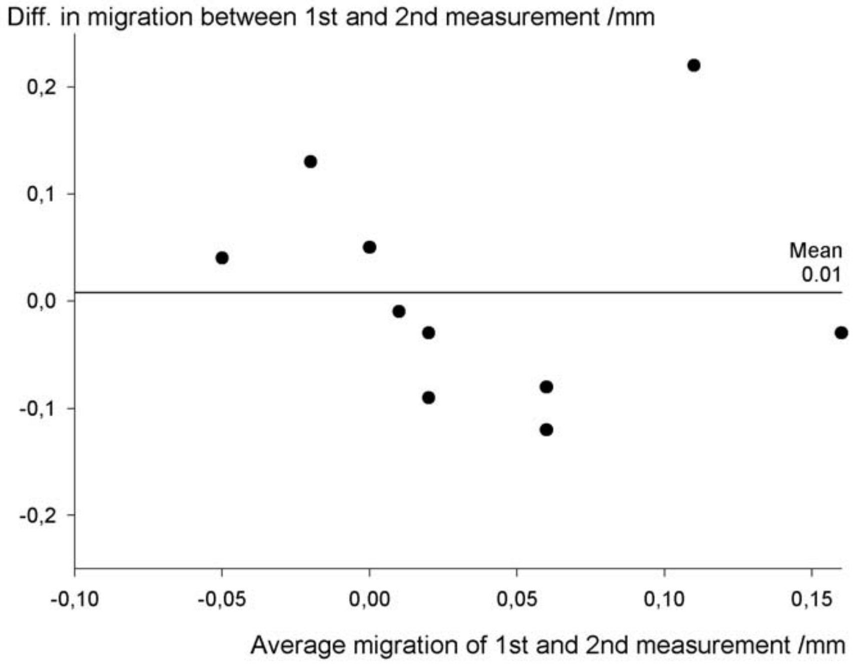

Fig.22 Repeatability of the Monoblock®cup migration - x axis (hemispherical cup algorithm)

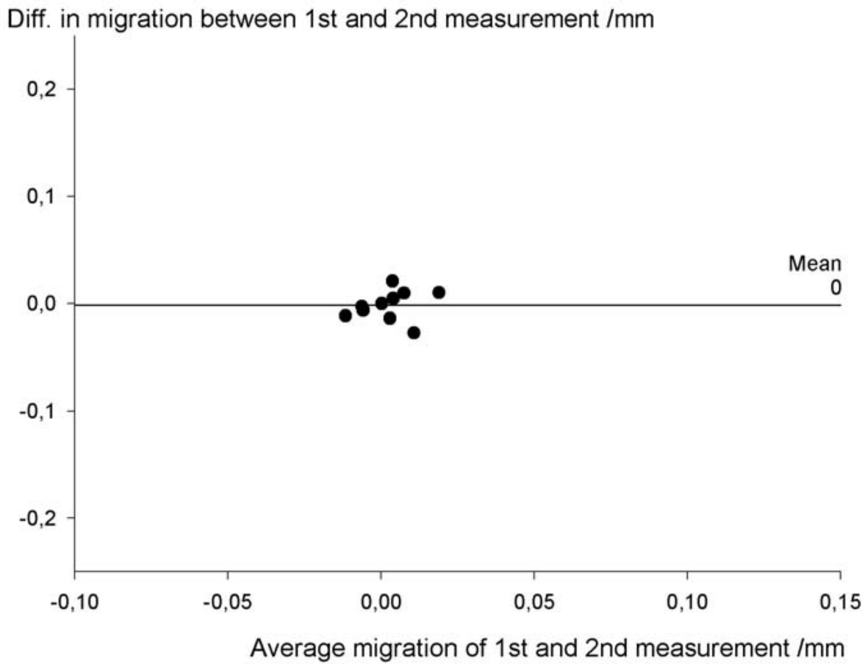

Fig. 23 Repeatability of the Monoblock®cup migration - x axis (Mb-RSA) migration along the X-axis

Cup migration (study IV)

The cup migrations in terms of median translation and rotation were small. No significant difference between the two cup types at 3 month follow up was observed neither in migration nor in rotation of the cups.
The most pronounced median migration was seen along the y axis in proximal direction for both cup types.

	Monoblock®(n=20)		Trilogy® (n=17)		
	Median	Range	Median	Range	p-value*
Cup translation/mm					
Medial-lateral (X)	0.01	-0.29 - 0.52	0.1	-0.17 - 0.60	0.16
Proximal-distal (Y)	0.15	-0.09 - 0.65	0.17	-0.24 - 0.74	0.39
Anterior-posterior (Z)	0.03	-0.93 - 1.33	0.14	-0.75 - 0.43	0.29
Cup rotation/ degree					
Transverse axis (X)	-0.1	-0.95 - 0.57	-0.28	-1.45- 0.86	0.28
Longitudinel axis (Y)	-0.07	-0.97 - 0.69	-0.01	-0.85 - 0.29	0.59
Sagittal axis (Z)	-0.36	-2.02 - 1.39	0.06	-1.05 - 1.07	0.6

Table 6. Migration and rotation of the two cup types at three month follow-up.
*Mann-Whitney U test.

Discussion

Acetabular geometry (study I)

Many factors exert influence on the final reamed surface [76]. Schwartz et al. [110] proposed three non-prosthesis related factors limiting implant-bone contact: Bony anatomy, asymmetric reaming and retention of the subchondrale plate.
Dense sclerotic bone in one region of the acetabulum may result in an eccentric reaming and a less ideal reamed hemisphere, which eventually leads to an eccentric cup placement and reduced initial apposition. In addition a drift towards softer cancellous bone can be expected, since the human acetabulum is of a heterogeneous bone density. Especially the MIS reamer was thought to have higher tendency to drift due to the chamfered sides than the conventional reamer. The speed of the revolving MIS reaming is of decisive importance since a too slow rotation of the MIS reamer will improperly engage the acetabular bone and not generate a true hemispherical geometry.
It is essential to perform the acetabular reaming deep enough to obtain rim fit of the acetabular component in order to obtain good apposition and fixation of the implant. As described in the surgical procedure it is necessary to remove the cartilage and ream until bleeding subsclerotic bone is exposed, but even then it is not always possible to create a perfect hemisphere due to the deeper-sited acetabular fossa.

The comparison of the left and the right side acetabulum on each specimen demonstrates a difference in the final size of the reamed acetabular cavities of up to 2 mm, and in specimen number 5 an even larger difference. This difference is believed to be due to anatomical variation since the choise of acetabular reamer and specimen number were blinded to the orthopedic surgeon.
Best-fit spheres were in 9 out of 18 cases measured to be smaller than the size of the final reamer. The measurement of the final reamer domes explains this finding, since the reamers intended for MIS as well as the conventional reamers were all measured to be nearly 2.5 mm smaller than the size labeled by the manufacturer. One could argue that comparison should have made between the measured reamer domes and the acetabular cavities but we believe, that the size labeled on the reamer domes are intended to inform the orthopedic surgeon that the current reamer dome is able to create a cavity approximately the size stated on the reamer. It is important to bear this discrepancy in mind when preparing the acetabular host bone for the orthopedic implant. Reaming with under reaming technique with usually 1mm the contact between bone and prosthesis will be underestimated and optimal initial stability of the implant will not be achieved.

Hip joint center displacement (study II)

A number of studies have pointed out the value of careful and exact preoperative templating of the hip as an important factor in restoring normal biomechanics [26, 36, 66]. Despite meticulous templating and carefully conducted hip surgery, displacement of the centre of rotation is reported in several studies [66, 103, 114, 140]. This may be due to alteration of the hip joint center during the acetabular reaming.

The results of the medial displacement are in agreement with the study by Knight and Atwater [66] and Silva et. al [114] who reported an average medial displacement of the hip centre of 5 mm and 1.8 mm respectively. The same tendency is also seen in studies by Russotti and Harris [103] and Yoder et. al. [140]. However, the extent of medialization in these studies [103, 140] is measured up to 9mm. An explanation for this discrepancy in medialization between the studies may be that in the late 60s and early 70s (in which the studies were performed) the common reaming procedure was to aim for a cranial and medial direction without taking the placement of the original hip joint centre into account. Furthermore retention of the subchondrale plate was not attempted. In addition, the cemented acetabular prosthesis implanted at that time period had a smaller inner and outer diameter leading to an even greater medial displacement. Likewise, the femoral component had a smaller articulation head, which had lead to the proposal, that ideal placement for the smaller head size differs from the larger head size [87].

Relocation of the hip centre in medial direction has to be compensated by an increased femoral offset component [137]. The majority of commercial femoral stems available come with different offsets, mostly obtained by alternation of the CCD angle (caput-collum-diaphysis angle).

In this thesis, the femoral offset is defined as by Charles et al [25] as the measured perpendicular distance between the center of rotation of the femoral head and a line drawn down the axis of the femoral shaft (figure 24) However, a recent study clarifies the close relation between cup inclination and the CCD angle of the stem [137]. An extended femoral offset will require a larger cup inclination to obtain optimum range of motion. Increased femoral offset has been documented to significantly increase femoral micromotion as it increases the non-saggital moment [33] and is particularly important in patients with elevated weight load [53] It has been shown that increasing femoral offset is positively correlated with the range and strength of abduction [4, 80] and furthermore, lateralization of the femoral component is beneficial with regard to reduction in polyethylene wear of the acetabular socket.

This can be accomplished by using femoral components with larger femoral offset thus improving soft tissue tension [106].

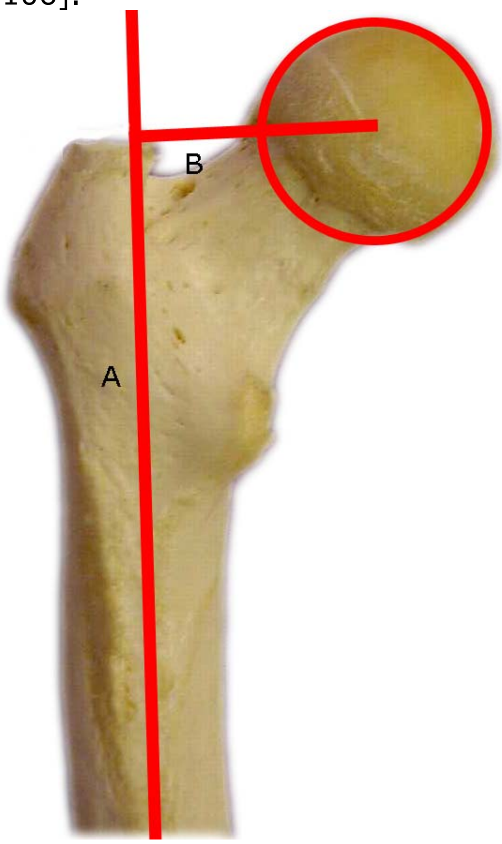

Figure 24 Femoral offset

An extensive medialization is thought to improve the contact between the acetabular component and the pelvic bone in terms of enhanced socket coverage. However, a medial drift of the hip joint centre can give rise to femoro-acetabular impingement, if the femoral component does not maintain the distance between the proximal femur and the socket as prior to surgery [102]. Even though the cause of hip dislocation in THA patients is not fully understood, amongst many factors impingement is described to play an important role in hip dislocations and damage to the acetabular liner [113].

The hip centre of rotation was moved superiorly in both groups of reamers and do not support the results reported by Russotti and Harris [103] or Yoder et. al [140]. A difference of 6mm in cranial displacement between our study and the above mentioned studies emphasizes the different goals and traditions in preparing the acetabular cavity with regard to re-establish the anatomical hip centre. The more recent study by Knight and Atwater [66] elucidates this, since they report similar values as the present study in terms of cranial displacement. In addition, with the introduction of total hip resurfacing arthroplasty Silva et al.[114] drew attention to the fact, that the orthopedic surgeon intentionally should aim for a more inferior hip centre location because of the limited ability to gain limb length compared to traditional femoral components.

In study II, the transition vector did not significantly differ between the modified MIS reamer and the conventional reamer. When the MIS reamer is revolving at an appropriate speed it imitates a hemisphere like the conventional reamer. The MIS reamer only differs in shape from the conventional reamer on the sides, while the top of the reamer dome is left unchanged. The force applied by the surgeon to the reamer is mainly directed to the reamer top engaging the acetabular bone and not to the chamfered sides. We believe that, this observable fact explains the lack of difference in displacement of the hip centre between the two reamer-types. In addition, the revolving direction (clockwise) of the reamer demonstrated a tendency towards a lateral drift on the left sided reamed cavities and a medial drift on the right sided reamed acetabuli, however this was not significant. These findings however, shall be taken with reservations since reaming an arthritic acetabular cavity consisting of heterogeneous bone quality will influence the drift of the reamer. Areas of the acetabulum with subchondral sclerosis will force the reamer towards a softer area and cause an unwanted drift, which even might be more pronounced utilizing the MIS reamer.

The study represents a new accurate approach facing alterations of the rotational hip centre. In contrast to previous studies, we did not use radiographs to determine the drift of the hip centre. Also, we did not have to deal with magnification ratio of the radiographs, variation in patient position between x-ray exposures and metering hip centre from bony landmarks, which kept sources of error at a minimum

RSA measurement comparison (study III)

The marker-free method is convenient for the orthopedic surgeon conducting clinical trials on migration of acetabular components. The prosthesis can be evaluated without alteration of the original design. Alterations may potentially influence the cup migration. In addition, it can be difficult to obtain trial approval by national authorities in some countries, if the orthopedic implant has been subject to even small modifications.

The aim of study III was alone to compare the RSA software systems. We did not wish to take the hardware setup into account since the primary object was to quantify the precision of the software systems. A direct comparison between precision values from clinical studies and the results from the present study is not possible, and can only give an indication of the magnitude of the migration variation. The results from double examinations done in clinical trials are usually based on two consecutive x-ray exposures and will be influenced by confounders arising from the clinical setup.

In table 7, precision in a number of clinical RSA studies are presented. The first study by Flivik et al. [44] reveal the precision with a cemented cup, and the following studies conducted by Thanner et al. [127], Önsten et al. [91], and Valstar et al. [133] describe the precision with uncemented acetabular components. All studies are performed with the use of tantalum markers, with the exception of the study by Valstar et al. used the hemispherical cup RSA system. Note the different standard deviations expressing the precision. To facilitate a comparison between the studies, the author has taken the liberty to convert the standard deviations to 99% tolerance limits.

The calculated CR from study III indicates that the highest precision of a cup migration analysis will be obtained using MbRSA or tantalum markers. Unfortunately, the conventional RSA system has limitations when applied to a metal backed cup.

The location of the tantalum markers on the acetabular cup has previously been discussed[19]. Bragdon et al. found no significant difference in accuracy and precision of the RSA system, whether the markers were positioned on the back of the cup protruding into the acetabular cavity or inserted into the rim of the acetabular liner[19]. Based on that study, it is reasonable to attach the markers on the convexity of the cup since free projection of tantalum markers is achieved. However, protrusion of several pegs into an acetabular cavity will affect the apposition of the uncemented cup and potentially bias the migration analysis.

Attachment of the markers to the base of the cup is preferable, since it will not interfere with the cup-bone interface.

This technique was used by cup studies performed by Thanner et al. [126, 127]and Önsten et al. [91]. On the other hand, insertion of tantalum markers into the periphery of the polyethylene liner can be complicated and caution must be taken, if the cup is of a modular design like the Trilogy® cup. A relative motion between the metal shell and the inserted liner may introduce a source of error to the migration analysis. If titanium towers are affixed to the shell, the length of the titanium towers must also be taken into consideration. High towers will increase the numbers of visible markers; however it is a trade-off between the number of markers and risk of femoro-acetabular impingement, and potential tower damage.

Study	Calculations	X-axis/mm	Y-axis/mm	Z-axis/mm
Flivik et al., 2005 [44]	2,7xSD	0.19 (0.19)	0.12 (0.12)	0.22 (0.22)
Önsten et al. 1994[91]	2,7xSD	0.2 (0.2)	0.2 (0.2)	0.3 (0.3)
Thanner et al. 2000[127]	2,7xSD	0.22 (0.16)	0.15 (0.11)	0.37 (0.27)
Valstar et al. 1997 [133]	2xSD	0.09 (0.12)	0.07 (0.09)	0.34 (0.41)
Baad-Hansen et al. (IV)	2,7xSD	0.11 (0.11)	0.19 (0.19)	0.15 (0.15)

Table 7. Calculated precision in a number of clinical RSA studies, the 99% confidence limits is shown in parentheses. Values represent mean ± 2,7 SD of the error.

Moreover, in study III we encountered severe problems with prosthesis marker occlusion and therefore we had to give up the migration analysis of the Monoblock® cup using conventional RSA. The tantalum markers in the work by Thanner et al. 2000 and Önsten et al. 1994 were easily identified because both papers were based on either the Trilogy® cup or the Harris-Galante® cup,sharing the low radio density of the titanium-alloy shell as the Trilogy® cup. In contrast the Monoblock®cup used in the present study consisted of the highly radiopaque tatalum metal. Flivik et al., 2005 used all-polyethylene cup, Opticup®, where all markers easily could be identified. If the hemispherical cup RSA software was applied to the hemispherical cup, the CR of the translation along all axes was significantly higher than with conventional RSA system or the MbRSA system. If the hemispherical cup RSA system was applied on a non-hemispherical cup, a larger magnitude of the CR of the translations was observed on the x – and z axes the than with the hemispherical cup.

An important difference between the hemispherical cup algorithm software and the MbRSA software is that in the MbRSA software, the contour detection is automatically, while in hemispherical cup algorithm, the contour detection was done manually by placing points on the contour of the cup. A previous RSA studies have demonstrated substantial difference between automated and the manually measurements in favour of the automated [18, 135]. This might have caused a larger variation in the results of the hemispherical cup system.

In a recent review (Valstar et al., 2005), the authors suggest that as little as 15-25 patients in a randomised trial in each group are sufficient to achieve valid results, due to high accuracy of the RSA method. However, even if a marker free-RSA system as the hemispherical cup RSA system will eliminate concerns with regard to marker location and application of titanium towers, it is reasonable to assume that the hemispherical cup RSA system due to a lower precision will require a higher number of patients to demonstrate a significant difference. The utilized cups in the study III have been subject to optical 3D measurement determining the exact dimension. We did not use the CAD models supplied by the manufacturer. Inaccuracies in size and shape of the cups as a result of the manufacturing process are therefore known for these two specific cups. In a clinical study, this procedure cannot be applied due to optical 3D measuring technique leading to non-sterilized implants. In such situation, one has to rely on CAD models of the implants. Alternatively reversed engineered cup models similar to the implanted cups can be used. Intolerances between the implanted cup and the 3D model may therefore alter the data.

Cup migration (study IV)

The preliminary results of the clinical study demonstrate an excellent fixation of both cup types at three months follow up. We detected no significant difference in translation or rotation between the cups measured by MbRSA.
At the time of writing, 46 patients have been included in the study. A number of patients were excluded as a result of technical shortcomings.
Three patients were excluded because of over-projection of acetabular bone markers and two patients due to poor

quality of the postoperative radiograph; in two cases the bone markers became loose, and finally two patients did not attend the follow-up examination. In total, nine patients were excluded.

Earlier, three RSA studies have described the migration pattern of the Trilogy® cup and a cup with a similar geometry and surface material, the Harris-Galante® cup. One randomized study compared two types of coated Trilogy® cups, one with and one without screw fixation [127]. Another study compared the Harris-Galante® cup with and without ceramic coating [126]. The results from these two studies could not display any effects of the application of screws to enhance early fixation with regard to migration or rotation at two years follow up. Likewise, no difference in migration between the coated and uncoated Harris-Galante® cup was shown. However, a significant reduction in rotation along the X axis of the coated cup was shown at 2 years follow up.

In comparison, our 3 months follow up-results are much like the results from Thanner et al. for the Trilogy® cup and also for the Monoblock® cup. A minimal migration along x- and z - axis and slightly larger migration along the y-axis was seen. Similar cup rotation along all three axes was also reported.

A long term study with 12 years of follow up of uncoated Harris-Galante® cups (type I and II) showed a minimum of translation in medial and proximal direction (mean 0.14 mm and 0.07 mm respectively). In addition, cup translation did not increase over time [101]. However, pronounced rotation of a number of liners suggested rotation of the liner (where the tantalum markers were inserted) within the metal shell leading to less precise results. The locking mechanism has been improved in the metal shell of the Trilogy® cup so this source of error may be eliminated if conventional RSA is used to assess micro motion of the Trilogy® cup.

Until now, only a limited number of studies have described the clinical outcome of trabecular metal cups and no RSA studies have been published. However, the few clinical studies available support the encouraging experimental results. A large multi center study of 414 Monoblock® cups has recently been published. At two years follow up, no cup revisions or evidence of lysis was reported based on radiographic evaluation [50]. The same tendency was observed in another study of 86 implanted cups revealing strong ostereoconditive properties of trabecular metal [75].

Schwartz et al. [110] proposed two prosthesis-related factors limiting implant-bone contact: cup design and incorrect version of applied cup (holes, spikes)

It has been hypothesized that the advantage of the Monoblock®cup is not only in the tantalum surface material but also in cup design [111].

Theoretically, the hemi-elliptic design of the Monoblock® cup should increase the initial stability of the acetabular component especially in the rim area (zone I and III). However, the interfacial friction coefficient of trabecular metal against bone is also reported to be increased in comparison to other porous material [141]

In contrast to the Trilogy® cup, the Monoblock®cup is inserted using the so-called line-to-line technique, which refers to matching size of the reamed acetabular cavity and the base of the implanted cup.

In an experimental study, line-to-line fit has revealed bone-implant gaps to be smaller than over-sizing cups with 2 or 4mm, respectively. In addition, fractures have been reported with this type of cup over-sizing [63].

In a study by Macheras et.al [75] a subgroup of 25 THR's with clear gaps between the acetabular host bone and the implant underwent migration analysis using the Einzel-Bild-Roentgen Analyse (EBRA) technique during the 2 first years after surgery. Even with large gaps of up to 5mm, no migration of the Monoblock® cup occurred. However, it must be remembered that the precision of the EBRA measuring systems is limited to 1mm.

In the Macheras et al. study, 29 percent revealed gaps, predominantly between the polar area (zone II) of the cup and acetabular host bone. This was also true for 19 percent in the multi center study by Gruen et al. [50]. Almost no gaps were present in zones I and III (rim area).
In contrast, the totals of postoperative gaps present in AP radiographs in the dome area of the non-coated Harris Galante cup were found to be approx. 7 percent[126]. This may be due to the hemispherical design.

Conclusions

Study I and II

A new model was created to compare different acetabular reamers with regard to preparation of the acetabular bone for the uncemented cup.

The results of our experiments demonstrated that a moderate alteration to an acetabular reamer as the Zimmer® MIS reamer did not influence the precision of the reamed surface with regard to obtaining an optimal sphere configuration. Likewise, no difference in change of the position of the hip center was observed between the two reamer types.

Although the benefits of minimally invasive hip surgery techniques have yet to be proven, it seems that the performance of the MIS reamer mentioned in the current thesis is fully acceptable for a clinical application

Study III

In conclusion, RSA is an excellent instrument to detect micro motion of orthopedic implants.

However, until now current methods available to determine the migration of metal backed cups have been technically demanding for the orthopedic surgeon, which may lead to exclusion of otherwise relevant patient material. Study III study demonstrates that a new RSA system, the MbRSA can bypass the technical challenges without compromising the precision that can be achieved using the conventional methods.

Study IV

Preliminary RSA results show small migrations in terms of translation and rotation at 3 month follow up and no difference between the cups could be observed. However, continuing inclusion of patients is mandatory to obtain a sufficient power of the migration results. Furthermore, long term RSA follow ups will be carried out to determine the migration pattern of the investigated cups.

Future studies and perspectives

The directions for future work from this thesis fall in two main categories.
First are directions for further improving of the experimental setup to describe the impact of the reaming procedure and implantation of the acetabular cup in the human pelvis.

Secondly proposals to further research in the area of clinical RSA studies using the newly developed mb-RSA system.

In the present studies the existing optical 3D scanning system has given a detailed knowledge of the reamer performance and its impact on the hip joint center. However, the information is based on static parameters.
A recent paper by Thali et al. describes a method – Virtopsy, where optical 3D surface scanning can be combined with radiological modalities (CT/MRI) to map injuries in traffic accidents [123].

A combination of Finite Element Analysis (FEA) or Computed tomography (CT) scans and optical 3D scanning will make it possible to add a dynamic dimension to the existing experimental setup. It would be of interest to quantify the deformation of the acetabular cavity after insertion of the acetabular socket and give an idea of the initial stability of the implant.

With the MbRSA a convenient and useful instrument to predict micromotion of orthopedic implants has been developed.
At the present time tantalum markers are still needed to define the bony landmarks of the patient. However, a combination of mb-RSA and other radiological modalities will be able to eliminate the use of tantalum markers.

Dansk resumé (Danish summary)

Ph.d.-afhandlingen er udformet som fire original artikler og en sammenfattende oversigt. De eksperimentelle studier er gennemført under min ansættelse på hoftesektoren Ortopædkirurgisk Center, Århus Universitetshospital. Det kliniske studie er gennemført i samarbejde med Ortopædkirurgi Nordjylland på Farsø sygehus.
Minimal invasiv hoftekirurgi (MIS) er en relativ ny kirurgisk teknik i Danmark. Metoden påfører patienten et mindre kirurgisk traume idet skader på muskel –og bløddelsvæv reduceres. Færre smerter, mindre ar og måske hurtigere rehabilitering er indtil nu beskrevet. Imidlertid fordrer MIS nye instrumenter som kan indfri de krav teknikken stiller.
Alle ortopædkirurgiske implantater som anvendes i Danmark kræver som alt andet medicinsk udstyr en EU godkendelse. Denne godkendelse indebærer kun præklinisk afprøvning. Dansk Ortopædkirurgisk Selskab anbefaler derfor yderligere klinisk afprøvning inden et nyt implantat anvendes som rutine i klinikken.

Det overordnede formål med ph.d. afhandlingen var at:

- Validere en ny acetabular reamer beregnet til MIS hoftekirurgi samt
- Stereorøntgenfotometrisk analyse af en ny acetabular cup baseret på et nyt protesemateriale - trabecular tantalum metal.

I artikel 1 blev acetabulums geometri på i alt 9 par af kadaver acetabuli sammenlignet. En MIS reamer blev anvendt på den ene side og en konventionel reamer på den kontralaterale side. Optisk 3D scanning blev anvendt. De opmålte kaviteter viste høj grad af sfærisitet og der blev ikke fundet nogen signifikant forskel på de to reamer typers evne til at præparere acetabulum.

Artikel 2 undersøgte og sammenholdte de to reamers effekt på hofteleddets centrum i forbindelse med reaming proceduren.
Beregningerne bygger på optisk 3D scanning præ- og postoperativt.
Den samlede forflytning blev beregnet til 3,6 mm. Sammenlignet med tidligere studier blev der fundet en markant mindre forflytning.
Der blev ikke fundet nogen signifikant forskel mellem de to reamer typer.

Artikel 3 beskriver et metodestudie som sammenligner tre forskellige RSA systemer til bestemmelse af cup migration. En konventionel metode beregner migrationen vha. monterede tantalum kugler, hvorimod et andet system anvender protesens omrids og endeligt et tredje system der gør brug af 3D modeller af proteserne som er implementeret i software systemet. En signifikant bedring i præcision af protesemigrationen blev vist ved brug af monterede tantalum kugler samt af det system som gør brug af 3D modeller i forhold til det system der anvender cuppens omrids.

Artikel 4 beskriver en RCT hvor to forskellige acetabulum komponenter (i form af geometri samt overfladebelægning) sammenlignes mht. migration bestemt vha. 3D-model baseret røntgenstereofotometri. Ved 3 måneders follow-up kunne påvises minimal displacering af begge acetabular komponenter. Mest udtalt migration blev observeret i proksimal retning andragende 0,17 henholdsvis 0,15 mm. Der blev ikke fundet nogen signifikant forskel mellem de to cup typer hverken mht. migration eller rotation.

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