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ON FIXATION OF HIP RESURFACING IMPLANTS

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To the memory of my mother and father, whose hard work, unlimited love, care and support made me the person I am. The reminiscence of your words and advices had given me the strength to fulfil this work even though your lost is great.

ABSTRACT

Hip resurfacing became a recognized entity in hip replacement in the 1970's. This generation of resurfacing implants was abandoned due to loosening and debris. The interest in resurfacing was renewed due to the need of a bone conservative solution for young active patients with osteoarthritis, and a new generation metal on metal (MoM) resurfacing implants was introduced in the late 1990's using the same alloy as in earlier MoM total hip replacements (THR's). Although sharing similar resurfacing features, they could differ in aspects such as fixation method, design features and manufacturing process.

Radiostereometric analysis (RSA) is the golden standard method to study micromotion in hip and knee implants; early micromotion is a strong indicator for loosening and poor long term survival. No RSA studies had been performed on earlier MoM THR´s. This meant that it was important to perform RSA studies on the new MoM resurfacing implants. In Studies I-II, RSA examinations were performed on the Birmingham Hip Resurfacing Implant (BHR), to investigate whether translation and or rotation occurred early postoperatively (Study I) and at mid term (Study II). In Study III, a two year RSA follow - up was performed on the Birmingham Mid Head Resection (BMHR) implants. The results demonstrated stable implants during the periods studied, indicating that fixation and stability should not contribute to eventual failure.

One MoM resurfacing device, the Articular Surface Replacement (ASR) was recalled from clinical use in 2010 due to inferior outcome. Femoral head implant loosening and femoral neck fractures indicating instability of fixation were dominant causes at short term. The cementing technique for ASR fixation (high viscosity (HV), indirect) differed from the technique used for clinically successful resurfacing implants (low viscosity (LV), direct). Study IV was an investigation using a cadaver model, to clarify morphological differences between the HV and LV cementing techniques on ASR implants. The results demonstrated a superficial fixation with the HV technique, which in traditional hip and knee implants has been demonstrated to be favourable, but may in the ASR be insufficient to maintain adequate stable fixation.

The use of the resurfacing method has declined since the ASR withdrawal, although other issues concerning the long term effects of elevated ion levels also contributed to the decline. The ASR experience underlines the importance of thorough studies of factors such as migration and wear before general market introduction of new implants.

Sammanfattning

Ett nytt ytersättningsproteskoncept där en cementerad lårbenshuvudkomponent i krom-
koboltlegering ledade mot en ocementerad bäckendel i samma material lanserades i
slutet av1990 talet. Detta koncept ansågs attraktivt då det erbjöd ett bensparande
alternativ till konventionella höftproteser där lårbenshuvudet och halsen avlägsnas.
Ledens rörelsecentrum kunde bevaras vilket medförde en belastningsfördelning på
övrelårbensänden som mer påminner om normala förhållanden. Valet av metall-mot-
metallartikulation (MoM) gjordes till följd av tidigare erfarenheter från 1970-talet där
polyetylen-mot-metallartikulation användes och gav upphov till tidig implantatlossning
till följd av slitage.

RSA-tekniken anses som det mest precisa sättet att mäta protesmigration. Man har
kunnat visa en koppling mellan tidig protesmigration och lossning vilket gör metoden
till ett viktigt verktyg att använda inför lansering av nya protesimplantat. Inga tidigare
RSA studier har genomförts för att kvantifiera migration av äldre MoM total
höftproteser eller äldre generation ytersättningsproteser. Målsättningen i delarbetena (I-
III) är att kartlägga om fixationsprincipen fungerar genom kvantifiering av protesernas
rörelse relativt till benet över tid med hjälp av RSA.

I delarbeten I-II studerads Birmingham Hip Resurfacing (BHR) protesen. I delarbete I
uppmättes migration av protesens båda komponenter upp till två år efter operation,
medan i delarbete II uppmättes migration av lårbenshuvudkomponenten upp till fem år
efter operation. Resultaten visar på stabila förhållanden vilket framställer att
protesmigration avseende BHR under medellång observationstid inte är en förväntad
orsak till proteshaveri.

En förutsättning för att kunna utföra ytersättning är att det inte föreligger större
deformiteter och eller försvagat ben på lårbenshuvudet. Denna typ av problem
förekommer tex. hos patienter med olika former av dysplasier eller nekros i
lårbenshuvudsdelen efter tex. trauma. Detta har lett till utveckling av en ny
lårbenshuvudkomponent där man kan avlägsna en större del av lårbenshuvudet men
bibehålla övriga karakteristika för ytersättningskonceptet. Bäckendelen är densamma
som vid BHR. Det nya implantatet, Birmingham Mid Head Resektion (BMHR)
saknade en radiostereometrisk utvärdering för den nya lårbenshuvudsdelen varför en

protesmigrationsstudie (delarbete III) med RSA utfördes med en uppföljningstid på två år. Våra resultat visar på stabila förhållanden under observationstiden.

Den gängse tekniken för ytersättning innebär att ledkulan omformas till en cylinder. Man använder lågviskös cement (LV) som hälls i protesens ledhuvudkomponent som sedan trycks in över det preparerade benet. I Articular Surface Replacement (ASR) implantatet används istället högviskös cement (HV) som appliceras på det preparerade huvudet innan insättning av protesdelen för att teoretiskt möjliggöra en kontrollerad trycksättning. Protesen uppvisade sämre kliniska resultat med högre risk för tidig lossning och lårbenshalsfrakturer i jämförelse med implantat som använder sig av gängse cement teknik. ASR drogs ur marknaden 2010.

Informationen i litteraturen är bristfällig avseende hur cementpenetration ser ut vid användning av LV respektive HV cement i lårbenshuvudet vid ytersättning. I delarbete VI studerades effekten av cementtekniken på cementmantel och penetration in i lårbenshuvudet. Färskfrusna lårbenspar preparerades för ASR protes och cementerades med antigen LV eller HV teknik. Kvantitativ och kvalitativ analys utfördes genom datortomografisk kartläggning.

Den rekommenderade HV tekniken för ARS gav en tun cementmantel mellan implantat och lårbenshuvudet utan cement penetration i ben vilket indikerar ytlig cementering medan LV tekniken resulterade i en betydande cementpenetration i ben samt cement ansamling på ledhuvudets tak. Då kliniska resultat för ytersättningsimplantat som använder LV tekniken är överlägsna i förhållande till ASR, förefaller det att ytlig cementering uppnådd med HV tekniken är suboptimal ur fixation- och stabilitetssynpunkt.

LIST OF PUBLICATIONS

This thesis is based on the following original papers.

I. **Itayem R**, Arndt A, Nistor L, McMinn D, Lundberg A.

    Stability of the Birmingham Hip Resurfacing arthroplasty at two years. A radiostereophotogrammetric analysis study.
    J Bone Joint Surg Br. 2005 Feb;87(2):158-62.

II. **Itayem R**, Arndt A, McMinn DJ, Daniel J, Lundberg A.

    A five-year radiostereometric follow-up of the Birmingham Hip Resurfacing arthroplasty.
    J Bone Join Surg Br. 2007 Sep;89(9):1140-3.

III. **Itayem R**, Arndt A, Daniel J, McMinn DJW, Lundberg A.

    A two year radiostereometric follow-up of the Birmingham Mid Head Resection arthroplasty.
    Submission process

IV. **Itayem R**, Lundberg A, Arndt A.

    Cement mantle thickness and penetration in two different cementing techniques of hip resurfacing implants. An in vivo Computed Tomography analysis on human femoral heads.
    Submission process.

CONTENTS

LIST OF ABBREVIATIONS

ASR	Articular Surface Replacement arthroplasty
AVN	Avascular necrosis
BHR	Birmingham Hip Replacement arthroplasty
BMHR	Birmingham Mid Head Resection arthroplasty
CN	Condition number
CT	Computed Tomography
HA	Hydroxyapatite
HIP	Hot isostatic pressing
HV	High viscosity
IP	Insoluble particles
LV	Low viscosity
ME	Mean Error
MoM	Metal on metal articulation
OA	Osteoarthritis
ROI	Region of interest
SHT	Solution heat treatment
SM	Soluble metal ions
THR	Total hip replacement

1 INTRODUCTION

Early attempts at salvaging both hip function and anatomy of the hip in the presence of end stage osteoarthritis (OA) include interposition arthroplasty of fascia lata [1] as well as artificial implants. In the search for a more durable material than glass, Smith-Petersen introduced a cast cobalt chromium molybdenum alloy interposition cup in 1940 [2]. In the 1930's Wiles introduced a hip implant more similar to current hip resurfacing devices [3]. Charnley was early in using "double cups" made of teflon [4-6]. Due to excessive wear, he soon abandoned this method in favour of metal on polyethylene articulation, which he started using in 1962 [7]. Despite these early pioneers, implants introduced in the 1970's are usually referred to as first generation resurfacing devices, e.g. the Wagner polyethylene acetabular components articulating with metal femoral heads. Short term results were promising, but discouraging mid term clinical results and concerns regarding polyethylene wear debris made this method unpopular and it was abandoned [8-11].

The main alternatives for the Charnley metal-on-polyethylene articulation were cemented (McKee-Farrar) or cementless (Ring) total hip devices with metal-on-metal (MoM) articulations [12-14]. The high incidence of early loosening of the McKee-Farrar system combined with the theoretical advantage of low-frictional torque and the more consistent clinical performance of the Charnley hip device, led to a sharp decline in the clinical application of MoM bearings.

Metal-on-polyethylene total hip replacement (THR) is performed with satisfactory results in the main group of OA patients, who tend to be elderly with low activity demands. These implants often outlive their hosts and the risk for revision (reoperation) is relatively low.

Younger, more active patients with OA have traditionally been advised to wait for their hip to be replaced since the failure rate in this group of patients has been far higher than in the elderly group routinely receiving THR's. Young patients are more likely to outlive their implants, resulting in a potential need for several reoperations and less satisfactory clinical outcome. The Swedish Hip Arthroplasty Register reports 10 year survival rates of 65.8%, 66.6% and 64.0% with cemented, uncemented and hybrid THR implants respectively in male OA patients under the age of 55 years [15].

Polyethylene wear has become an issue in THR's since it has been recognised that debris from wear of polyethylene -on- metal articulations is correlated with particle induced osteolysis and aseptic loosening. New alternatives for bearings that could

decrease or eliminate polyethylene debris began to be investigated parallel with the high incidence of failure of conventional THR's in the younger population and the increased demand for better functional performance and higher activity levels in this group. The resurfacing method provided a bone conservative solution, however poor outcome from earlier experiences of polyethylene on metal articulations led to a renewed interest of MoM articulations in the early 1990's as this alternative eliminated polyethylene debris. Furthermore, later results indicated good long term performance for some MoM THR's [13].

Issues such as debris from the MoM articulation, malignancy from metal wear particles and hypersensitivity reactions were raised already in the 1970's [16, 17]. However, the primary reason for the decision to abandon MoM resurfacing in favour of the Charnley concept was the inferior short term outcome of the McKee Farrar prosthesis [18]. Studies on retrieved MoM implants revealed low wear and the loosening issue for the McKee-Farrar devices became more attributed to design, fixation and patient selection factors [19-22]. This information, together with advances in metallurgy and manufacturing technology, resulted in the birth of a new generation of MoM resurfacing devices. The need to use a metal alloy with a very hard articulating surface led to the use of the cobalt chromium molybdenum alloy.

The first MoM resurfacing device introduced by McMinn was inserted in 1991. It was a press-fit design. The disappointing rate of loosening, with a revision rate of 8.6% at 44-54 months [23], led to a change to cemented fixation of both the acetabular component and femoral head. Cement solved the femoral head loosening problem, but not that of acetabular component loosening. According to McMinn, 67% of inserted implants had complete radiolucent line at three years postoperatively [24]. The design of the acetabular component was altered back to uncemented fixation with a hydroxyapatite (HA) coating. Single heat treatment of hot isostatic pressing (HIP) or solution heat treatment (SHT) was performed in 1995, and double heat treatment of both HIP and SHT was introduced in 1996 in order to overcome porosity of metal casting and scraping when machined and polished. The modes of failure of the 1996 series were metallosis, osteolysis and acetabular component loosening. The ten year Kaplan- Meier survival analysis showed a failure rate of 4% and 14% for single heat-treated and double heat-treated implants respectively [24].

Ring and McKee prostheses were manufactured with a cast, instead of a heat treated metal structure. The McMinn group decided to continue with this cast structure and assumed that the porosity issue would be solved by vacuum casting in combination with waxes and metal feeds. Furthermore, a cast, HA-coated porous ingrowth surface was added to the cup. The clearance (distance between the two articulating surfaces) of

the Birmingham Hip Resurfacing implant (BHR) was chosen from the lower end of the range of clearance of the Ring and McKee - Farrar implants. The range of clearance in the BHR implants was from 200 μm for the 38 mm ∅ head up to 300 μm for the 60 mm ∅ head [25].

The BHR was introduced in 1997 with the abovementioned properties and it gained Federal Drug Agency (FDA) approval in 2009. The Conserve Plus, developed by Amstutz and manufactured by Wright Medical was introduced at the same time as the BHR [26]. Since then several further implants have become available, e.g. the Recap by Biomet and the Articular Surface Replacement (ASR) by DePuy. Despite some common resurfacing device features these differed in a number of aspects. The BHR and ASR resurfacing implants are discussed in this thesis. ASR was withdrawn from the market in 2010 while BHR is still the leading resurfacing device.

Several general mechanisms that may influence both short and long term survival rates have been proposed. Some of these factors are highlighted in Table 1.

Table 1. Points of interest and issues of concern in hip resurfacing arthroplasty.

	Points of interest	**Issues of concern**
Tribology [27-30]	Full fluid film lubrication. Clearance.	Malpositioned implants and/or implants with insufficient clearance generate excessive wear.
Metallurgy [31-40]	Wear produces soluble metal ions (SM) and insoluble particles (IP). SM are cleared into the blood stream and exerted in the urine. Some IP remain in the joint fluid and periarticular tissues. Some are ingested by macrophages and giant cells, while others are transported through the lymphatic system and are deposited in the regional lymph nodes, liver and spleen.	Hypersensitivity. Aseptic lymphocytic vasculitis. Pseudotumors. Malignancy. Placental transfer of metal ions.
Circulation [41, 42]	Intra- and postoperative circulation insult.	Fractures. Osteonecrosis. Femoral head loosening.
Fixation	Cementation techniques of the femoral head.	Implant-bone cement mantel. Excessive cement penetration into femoral head. Implant stability.

This thesis presents studies on the final factor of fixation, in particular the issues of implant stability and cementation technique.

1. 1 ANATOMIC CONSIDERATIONS AND PATIENT SELECTION

The ideal patient for hip resurfacing needs to have an acceptable femoral head bone quality and a regular anatomy of the acetabulum and femoral neck, in order to minimize the risk of femoral neck fractures.

Anatomic indications for hip resurfacing

- Patients with a large femoral offset (distance between the centre of the femoral head and a perpendicular line through the mid shaft of the femur). THR's have limited offset options for this patient group resulting in a narrow offset and subsequently weakened hip abductor muscles.
- Patients with a wide femoral canal or femoral shaft deformity making THR femoral stem implantation awkward.
- Patients with osteopetrosis (marble bone disease) which makes it very difficult to prepare the femoral canal with enough space to accommodate an adequate THR femoral stem.

Anatomic contraindications for hip resurfacing

- Advanced dysplasia in which the socket is hypotrophic and too poorly developed to host an implant cup large enough for resurfacing.
- Childhood hip disorders. Post-slipped capital femoral epiphysis and post-Perthes, where the presence of a short, wide femoral neck offers a challenge and poor foundation for implantation of the resurfacing femoral head.
- Severe leg length discrepancy, since resurfacing does not provide for large leg length corrections.
- Femoral head avascular necrosis (AVN).
- Coxa vara.

Short stemmed neck-retaining devices have been developed as an attempt to provide a less invasive hip arthroplasty procedure for cases with these contraindications or with poor bone quality which does not allow resurfacing. Most of these devices, whether short or long stemmed, employ a femoral resection level at or distal to the head-neck junction. The site of load bearing is distal to the neck which introduces the risk of proximal stress shielding [43-45].

The Birmingham Mid-Head Resection prosthesis (BMHR) shares the articulation characteristics of the BHR. The resection level on the femoral head is distal to the BHR resection line and runs through the middle of the femoral head. Theoretically this has the advantage that patients with poor bone quality in the proximal femoral

head or with challenging anatomy can have a device retaining some of the characteristics of resurfacing (head size and position, minimal femoral bone resection) if desired. The lower resection level in the femoral head provides a convergent conical internal profile below the resection, which offers a suitable geometry for robust stem fixation and a load pattern that would prevent stress shielding [46]. BMHR has recently been used on a limited scale with promising short-term results. A study investigating the migration patterns of the BMHR is presented in this thesis (Study III).

It has been said that the reason for surgical complications may be the wrong operation performed correctly, the right operation performed incorrectly or the wrong operation performed incorrectly. All of these can lead to failures with resurfacing. Therefore, a correct patient selection in terms of age, activity level and anatomy combined with good surgical technique and a well proven resurfacing implant is vital for success.

1. 2 RADIOSTEREOMETRIC ANALYSIS (RSA)

The main reason for revision surgery in hip replacements is aseptic mechanical loosening. It may be induced by wear particles, insufficient initial prosthesis fixation, high stresses on the bone-prosthesis interface or bone necrosis and resorption adjacent to the implant. Implant loosening produces micromotion and a fibrous layer forms around the interface. Radiolucent lines are seen in radiographs. The fibrous tissue can not retain the implant in place resulting in further migration. Measuring early migration on plain radiographs is very difficult, since implant and bone landmarks are difficult to locate in a reproducible manner and radiolucent areas may be obscured by the metal of the implant.

In 1974 Selvik [47] introduced Radiostereometric Analysis (RSA) as a clinical tool for precise measurement of skeletal kinematics. RSA has an accuracy between 0.05 and 0.5 mm for translations and 0.15^0 and 1.15^0 for rotations [48]. RSA has been used to study topics such as prosthesis fixation, joint stability and kinematics, skeletal growth and fracture stability.

Because of the high accuracy of RSA, small patient cohorts are in general sufficient. It is a valuable tool to study micromotion prior to the introduction of new implants to the market or when changes in design parameters or surface structure are made.

Other, technically simpler, methods proposed for the study of implant migration are the 2D methods of Matched Indicators for Radiographic Assessment (MIRA), with a subsidence accuracy level of 1 mm [49] and Ein-Bild-Röntgen-Analyse (EBRA) that measures vertical and transverse migrations with error levels exceeding those of RSA by 0.39 ± 0.32 mm for vertical migration and 0.26 ± 0.31 mm for transverse migration

[50]. However, three-dimensional RSA remains the golden standard for migration studies.

Early micromotion can predict long term clinical fixation for both knee and hip arthroplasty [48]. In THR's, subsidence of more than 1.2 mm of cemented femoral components during the first two postoperative years indicated a revision probability of more than 50%, while subsidence of more than 2.6 mm indicated a 95% probability for revision [51]. One should nevertheless be cautious drawing conclusions from short term results since some implants such as the cemented Exeter stem (Stryker, UK), which has a tapered design allowing it to migrate through the cement mantle, showed pronounced migration but good clinical outcome with a low rate of mechanical loosening [52]. Therefore, patients with newly introduced or modified implants showing larger micromotions, should be carefully monitored and implant introduction to the market be delayed until long term clinical results are obtained.

The BHR hip resurfacing device was introduced to the market in 1997. This thesis includes an early two year RSA follow - up (Study I) and the only five year study published to date (Study II). Furthermore, the only two year RSA follow - up of the BMHR is presented (Study III).

Tantalum (radiopaque) beads with a diameter of 0.8 mm were used. They were attached to the acetabular cup (Studies I, II) and to the femoral stem (Studies I-III) on titanium towers on the components. Tantalum markers were also implanted in the femur (Studies I-III) and the pelvis peroperatively (Studies I-II).

Migration and rotation of the cup (Studies I-II) and the femoral head (Studies I-III) were calculated along and about the three axes of the RSA coordinate system (the transverse axis (x), the longitudinal axis (y) and the antero-posterior, or sagittal axis (z)).
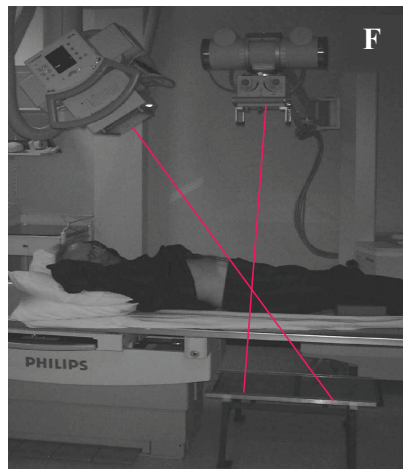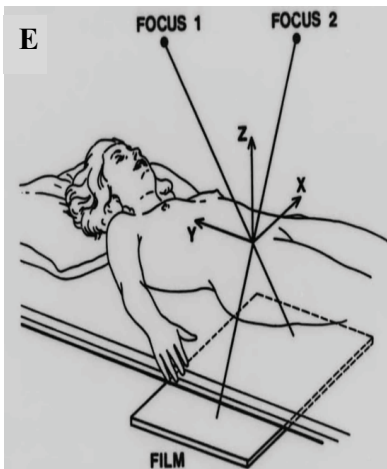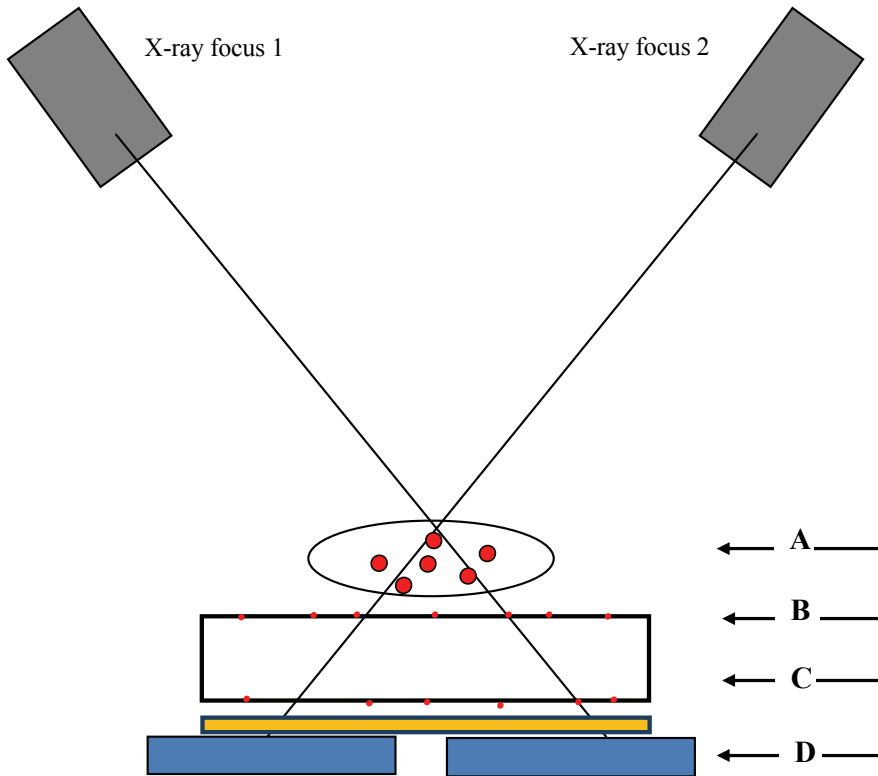
Figure 1: Illustration of an RSA set up. **A**: Object with markers. **B:** Calibration box with markers **C:** Reference plate with projection markers. **D:** X-ray film cassettes 1 and 2. **E**: The three axes of the global coordinate system. **F**: RSA performed on a BHR patient (photo taken with permission).

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RSA examinations were performed with simultaneous X-ray examinations from two oblique directions, a calibration cage, two film cassettes under the cage, a scanner and RSA software (UmRSA) from RSA Biomedical, Umeå, Sweden.

The calibration cage included tantalum markers, which defined the three dimensional global coordinate system. The first (reference) examination was performed without the implant, resulting in a film pair identifying the cage and reference markers. In the subsequent patient examination the calibration cage was removed, resulting in a film pair identifying the implant, bone and reference markers. The film pairs were scanned to a digital format, marker identification was performed and by mapping the reference markers in both examinations, the position of the calibration cage markers could be reconstructed and the three dimensional position of the implant and bone markers could be calculated. Motion can be quantified with six degrees of freedom, i.e. three translation and three rotation components.

The quality of the mapping of rigid body motion is expressed as the mean error (ME) of rigid-body fitting. Furthermore, it is important that tantalum markers are well distributed in the segment of interest in order to achieve an optimal segment configuration that is less sensitive for measurement error. This marker distribution is described in RSA by the condition number (CN). A high CN indicates a poor marker distribution and therefore less favourable configuration.

RSA includes several steps in which errors may occur. These include marker placement in the bone and on the implant, the radiographic set up, film scanning, identification of tantalum marker positions, calculation of object points and computation of the three-dimensional motions. The single most important factor for quality data is the insertion of an adequate number of well distributed stable markers in the segments under investigation.

1. 3 BONE CEMENT AND HIP RESURFACING

Acrylic bone cement has been widely used in THR's for many years. The bone-cement interface and cement penetration into bone are known to be important for the survival of the cemented implant since bone cement forms a mantle between the implant and bone, distributing loading forces and sealing interfaces. Several studies exist on cementing techniques and fixation of conventional THR and total knee arthroplasty [53-58]. Depth of penetration of cement into bone, total cement volume and the completeness of the cement mantle might influence the survival of a cemented implant. Two to five mm of cement penetration is suggested as optimal for component fixation [59-62]. Several aspects of the cementation process may result in bone damage and a decrease in failure load. These include the physical trauma to bone, a deeper cement

penetration (which is suggested to increase the risk of thermal tissue damage due to the high polymerization temperature of bone cement) and embolization of intraosseous blood vessels due to pressure exerted by cement penetration into the cancellous bone [63-65]. However, the risk of revision varies widely, illustrating that optimal cementing technique is still not fully understood even in conventional THR [66, 67].

All hip resurfacing implants available use uncemented fixation on the acetabular side, while the femoral component is cemented in all except for the Cormet by Corin, UK, which has a cemented femoral head option. The predominant use of cement for the femoral component is based upon the results of the studies by McMinn et al. as previously described [24].

The most common causes for revision in hip resurfacing are femoral head or neck fractures and aseptic loosening of the femoral component [68-70]. Neck fractures are most frequently observed in the first 3-4 months after surgery. The overall fracture rate has been found to be approximately 1-2%.[70, 71]. Several failure mechanisms have been attributed to poor surgical technique [72], especially concerning surgical approach, implant orientation and notching of the femoral neck cortex [41, 70, 73].

The assumption has generally been made that the same cementing principles that have been established for conventional THR would also apply to resurfacing. This has led to concerns regarding the consequences of cementation of the femoral head implant on the viability and integrity of the remaining femoral head as well as the risk of neck fracture or early aseptic loosening.

Little is known about the impact of cementing techniques on the clinical outcome in hip resurfacing, and retrieval analyses of failed resurfacings show large variations in cement mantle thickness and femoral head penetration. These may be influenced by factors controlled by the surgeon such as lavage, haemostasis, cementing method, cement viscosity, volume of cement instilled and the level of impaction force. Others, such as bone mineral density, bone quality of the femoral head and implant design cannot be controlled during the operation.

Resurfacing implants generally share common design features, but may differ in internal–external geometry, metallurgy and the design of the centering pin. Therefore, different cementing techniques and cement viscosities have been recommended by different manufacturers. Two cementing techniques have dominated. In the indirect technique, low viscosity (LV) cement is poured into the femoral component prior to the placement of the femoral implant. This technique is used with implants such as the BHR (Smith and Nephew, Warwick, UK), which provides a tighter femoral component fit with minimal or no cement. In the direct technique, high viscosity (HV) cement is pasted on the prepared bone surface prior to the placement of the femoral implant. This

is used for implants with prosthetic designs giving an intended cement mantle of about 0.5-1 mm, as recommended for the ASR system (Depuy, Leeds, UK) [74-76]. ASR was withdrawn from the market in 2010 due to inferior short and mid term clinical outcome. The implant was highly represented in retrieval studies of early failures due to femoral neck fractures. In the Study IV presented in this thesis, an in vitro experiment was performed on cement mantle parameters and penetration into ASR resurfaced cadaveric femoral heads using the direct HV technique recommended for the ASR and the indirect LV technique recommended for the BHR.

2 AIMS

The aim of the studies presented in Studies I-III was to study if translation and or rotation patterns existed early (two years postoperatively, Studies I (for the BHR) and III (BMHR)) and at mid term (five years postoperatively, Study II (BHR)), using RSA.

The aim of Study IV was to investigate whether differences in cementing technique could result in different cement morphology in bone and at the implant-bone interface.

3 METHODS

Studies I-III were RSA studies. Study IV was a cementing study using computed tomography (CT) for evaluation.

3. 1 STUDIES I AND II
Twenty hips from 19 physically active male patients (one bilateral) aged 34-63 years (mean 54 years) treated with BHR implants at the Birmingham Nuffield Hospital, UK, were included in Study I. One patient had died from unrelated cause at the five years follow - up and was not included in Study II, leaving 19 hips (18 patients) available for evaluation in in this study.
All operations were conducted by the same surgeon. The implants were equipped with 0.8 mm diameter tantalum markers on titanium towers. During surgery, six to eight tantalum markers were introduced into the pelvis and the femur segments respectively.
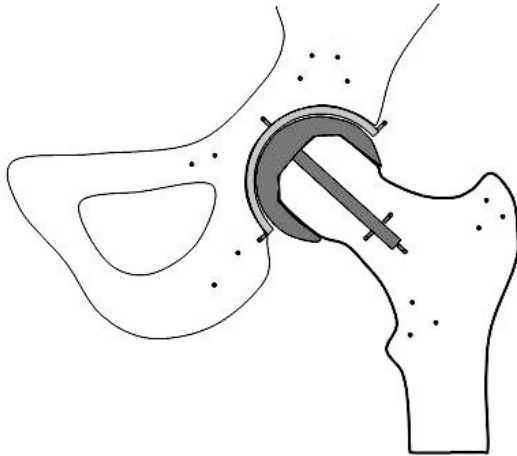
Figure 2: A schematic diagram of the Birmingham Hip Resurfacing implant with tantalum markers mounted on the femoral and acetabular implant components and implanted in the femur and pelvis.

Radiological examinations were performed postoperatively and after two months, six months, one year and two years for Study I and at five years post-operatively for Study II. The two-dimensional positions of implant and skeletal markers in each radiograph (two radiographs at each time point) were digitised and their three-dimensional coordinates were calculated using commercially available RSA software (RSA Biomedical, Umeå, Sweden). Migrations were calculated using the kinematics software, provided in the same package.
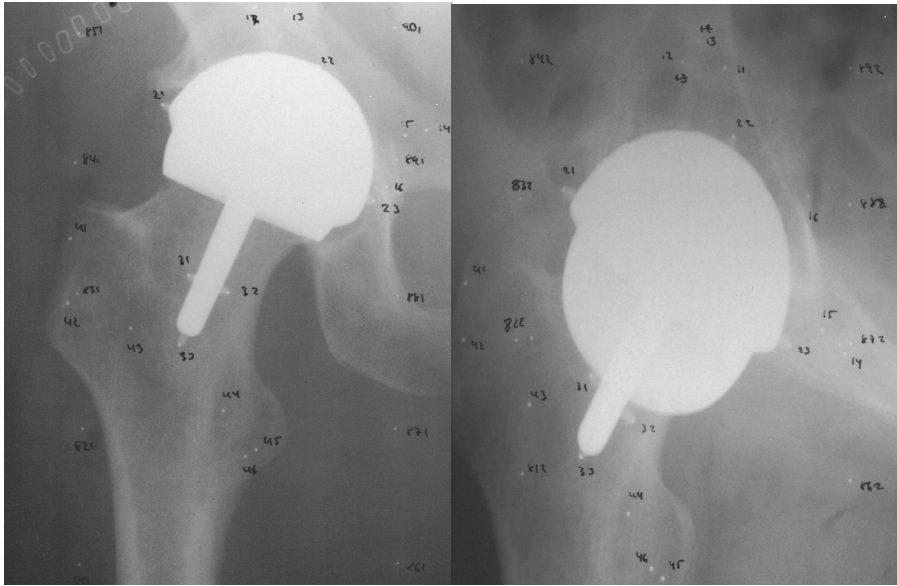
Figure 3. Radiograph couple with markers visible in the calibration device (800 series), pelvis, femur, acetabular component and femoral component. The acetabular component has two rim markers and one polar marker.

The centre of the acetabular cup in the post-operative examination was calculated as an approximation of the centre of the head of the implant. The cup was used because of the difficulties encountered in making an elliptic fit onto the small portion of the surface of the head which was visible on the radiographs (see femoral head surface protruding medially and laterally from acetabular cup in the left image in Figure 3). The centre of the cup was considered to approximate the centre of the head with sufficient accuracy to allow a description of migration of the head. The cup was only used in the first examination. In later examinations this point was recreated from the markers fixed to the femoral component. In addition to all migrations being described in relation to the global coordinate system, with one axis aligned to the long axis of the X- ray table, a second axis being mediolateral and a third being anteroposterior, migration of the centre of the head was also determined in relation to the anatomical long axis of the femoral neck.

The accuracy of the RSA technique in measuring non-zero movement was tested on pairs of radiographs taken on the same occasion. ME and CN were calculated for each examination.

The initial measurement for statistical analysis was the Student´s *t-test* for dependent sample. Rotations and translations were calculated at two years (Study I). Five year

migration (Study II) was determined relative to the two months analysis to allow for eventual initial settling of the acetabular component.

Differences in rotations and translations of the cup in relation to the pelvis, rotations of the femoral component and translations of the head centre were calculated and the level of significance was set at $p \leq 0.05$.

3. 2 STUDY III

The initial plan was to include 20 hips with BMHR devices, but due to a design change, inclusion was ceased after 13 devices had been implanted. A power analysis was performed which indicated that with the observed spread of values, 90% power to identify migration exceeding 1.2 mm (which has been identified as unfavourable in conventional THR) could be obtained.

The study comprised 13 hips in 12 physically active patients (11 male, 1 female), treated with the curved stem BMHR (Figure 4) device at the Birmingham Nuffield Hospital, UK. All operations were performed by the same surgeon.

Figure 4. The BMHR femoral stem design.

The inclusion criteria

- Male and non-pregnant female participants aged 30-65 years at time of surgery - subject to the listed contra-indications for use.

 - Patients presenting with Ficat grade IV AVN of the femoral head or osteoarthritis with severe cystic change or significant femoral head flattening or loss.

 - Patients capable of giving informed consent, understanding the aims of the study and expressing willingness to comply with the post-operative review programme.

The exclusion criteria

- Individuals with severe anatomical abnormality in the proximal femur or acetabulum, such as severe coxa vara or valga or retro- or anteversion deformities.

 - Severe leg length discrepancies.

 - Individuals likely to have a successful outcome with a BHR (good bone quality) or a THR (older less active patients).

 - Individuals with active or suspected infection.

 - Individuals with a known sensitivity to device materials.

 - Individuals who were in renal failure.

The mean patient age at surgery was 52 years (range: 30-62 years). Five patients had AVN of the femoral head. Two patients (one bilateral) had developmental hip dysplasia with superolateral femoral head osteopenia. One patient with congenital dislocation of the hip had been treated with femoral osteotomy during childhood. Two patients had destructive OA, two patients had OA with cystic destruction of the femoral head. All treated patients were included in the two years follow - up.

The femoral prosthesis segment (stem) was equipped with three 0.8 mm diameter tantalum markers attached on the tip and sides of the stem on titanium towers (Figure 5). During surgery five to eight additional markers were placed in the greater and the lesser trochanter (Figure 5). No tantalum markers were introduced into the pelvis nor attached to the cup.
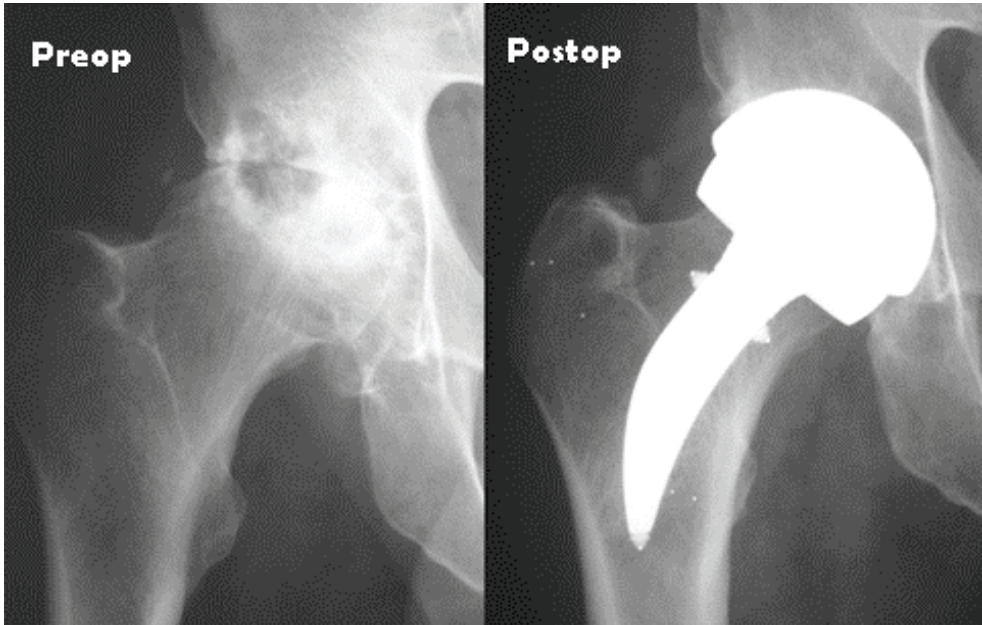
Figure 5. Pre-operative and post-operative follow-up radiographs of the BMHR device. Tantalum markers were inserted in the femur and mounted on the stem of the femoral component.

Radiographic examinations for RSA were performed postoperatively and at 2, 6, 12 and 24 months postoperatively. Data were analysed using the UmRSA digital software (RSA biomedical, Umeå, Sweden).

The head centre was estimated from the cup circumference at the postoperative examination and calculated from the three femoral component markers in subsequent examinations as previously described for the BHR in Studies I and II. Translations and rotations of the femoral segment and of the centre of the head were calculated relative to the femur at the time points mentioned. Differences in rotation and translation between two months and two years were tested using the Student's *t-test* for dependent samples with a level of significance set at $p \leq 0.05$. Means and 95% confidence intervals were calculated at two years.

The two months follow - up examination was chosen as starting point for the statistical analysis in order to avoid the effects of any early settling-in directly post-operatively.

3. 3 STUDY IV

Five sets of paired fresh frozen cadaver femora (3 males, 2 females; mean age 77.8 years) were used in the study. None of the femora had previously been operated on. Plastic ASR replicas (DePuy, Leeds, UK) with femoral head size 47Ø, were used instead of the surgical metal components to enable subsequent cutting of the specimen

and to avoid metallic scatter artefacts during the CT analysis. The femoral heads were prepared for an ASR femoral component size 47Ø.

The bone cement (Cemex®) was mixed with a closed non-vacuum system (Tecres medical, Verona, Italy). The LV technique was used for the right femora (Group A) while the HV technique was used for left femora (Group B). For the LV technique, the cement was poured into the femoral component, filling it to half, one minute after the start of mixing and the implant was in place two minutes after the start of mixing. For the HV technique, the cement was applied to the femoral head surface three minutes after the start of manual mixing (finger packed). The femoral component was in place five minutes after the start of mixing. A standard impactor was used for seating in both techniques. In all cases the complete cementing procedure was conducted by a single surgeon experienced in hip resurfacing surgery.

After cement polymerization, the head and neck segments were cut into halves with a band saw. An initial, visual, qualitative evaluation was performed. The specimens were subsequently cut into quarters representing the anterior, posterior, superior and inferior quadrants of the femoral head. The central pin of the plastic cast was represented in its full length in each quarter, indicating an accurate and reproducible cutting procedure. The central pin border represented the inner border for each quarter. The following regions of interest (ROI's) were defined (Figure 6):

I: The upper cement mantle and the chamfer parts.
II: Cement penetration into the femoral head (bone-cement mixture).
III: The interior area of the femoral head where no cement penetration was found.
IV: The cement mantle at the outer wall circumference between the implant and the prepared femoral head.
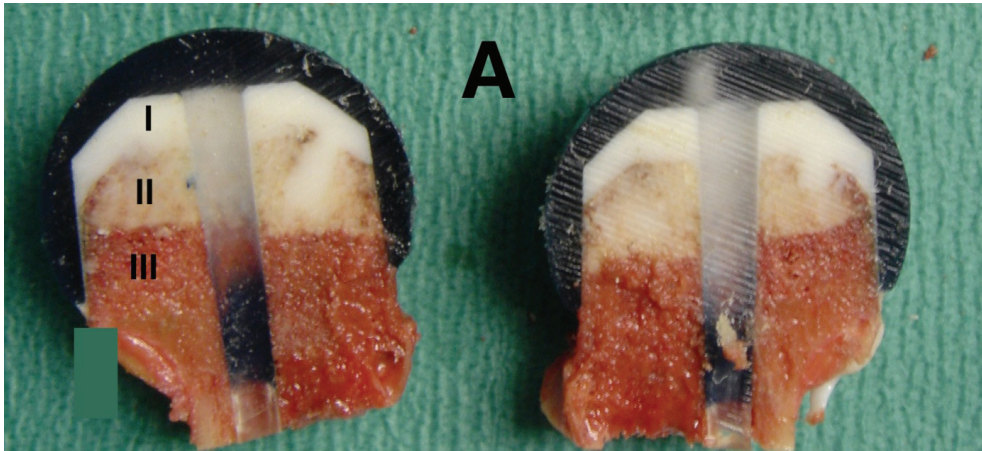
Figure 6. Photographs of the surface of a saw cut showing the regions of interest. Group A with low viscosity (LV) cementing and group B with high viscosity (HV) cementing.

Cement penetration was analysed and measured at the inner border in each quarter. CT scans with 1 mm thickness were performed with a Tomoscan single spiral AV (Philips, The Netherlands) using the bone algorithm provided by the manufacturer (Fig 7). The total area (mm^2) for each head quadrant under the femoral component and ROI's I, II, III and IV where measured using the PACS IDS5 version 10.2p3 (Sectra Imtec, Linköping, Sweden). The percentage of each area in relation to the total area was calculated. The mean height (mm) of the cement mantle over the top surface of the head in Area I was measured in all quadrants using the same software. The Student's *t-test* with a level of significance set at $p \leq 0.05$ was used to test for statistically significant differences between the LV and HV groups.
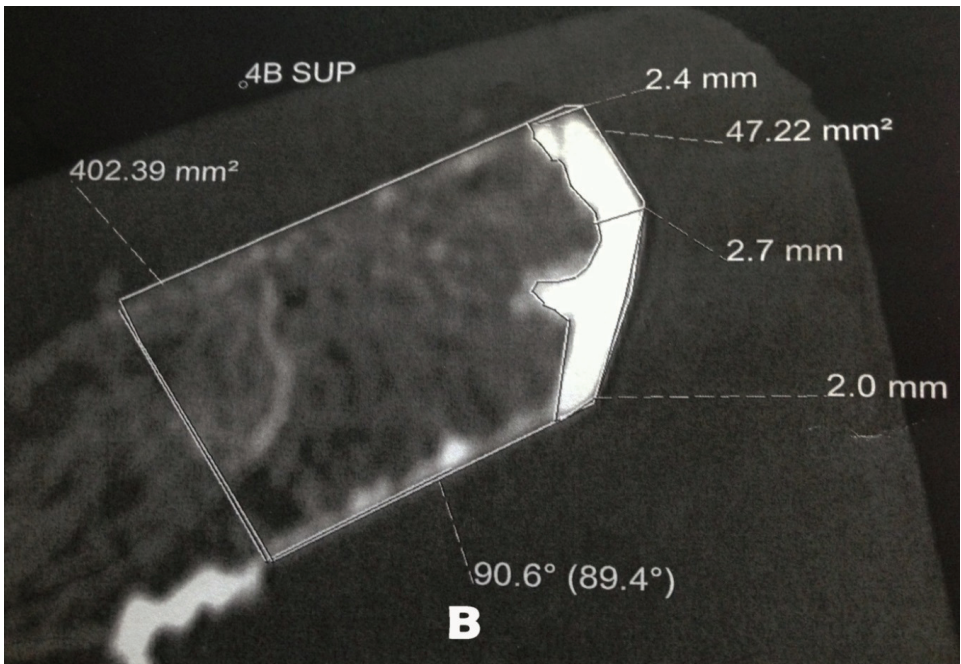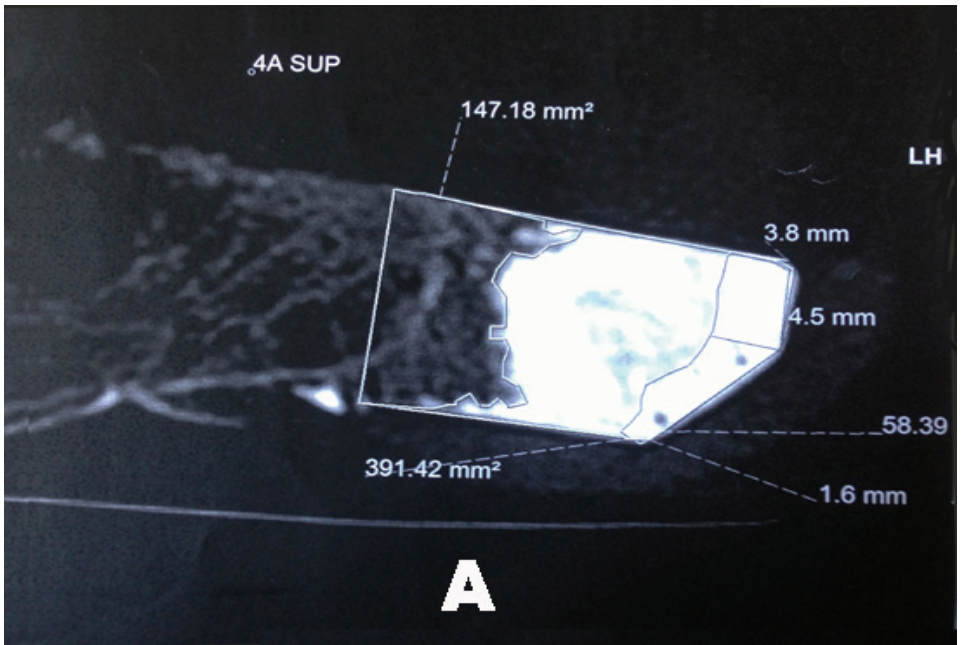
Figure 7. Computed tomography pictures of LV and HV cementation respectively, from the superior quarter of a femoral head pair. Height (mm) and area (mm^2) measurements are indicated.

4 RESULTS

4. 1 STUDY I

Precision and migration detection threshold

The non-optimal marker configuration of the femoral stem gave the greatest mean error of non-zero movement around the femoral longitudinal axis and the lowest mean error along the vertical axis. The definition of the femoral head component by the calculation of a single point within the femoral head provided high accuracy (Table 2). The cup was well identified by the three attached markers if the X-ray tubes were positioned at angles which ensured that all three markers were visible.

Table 2: The mean error (95% confidence interval) of non–zero movement of the cup relative to the pelvis, the femoral component relative to the femur and the point calculated in the femoral component relative to the femur.

	Axis	Cup	Head	Point
Rotation [°]	**Mediolateral**	0.253 (0.084)	0.459 (0.111)	
	Distal proximal	0.201 (0.083)	0.466 (0.112)	
	Anteroposterior	0.074 (0.022)	0.155 (0.036)	
Translation [mm]	**Mediolateral**	0.035 (0.011)	0.118 (0.038)	0.107 (0.035)
	Distal proximal	0.048 (0.019)	0.108 (0.029)	0.083 (0.019)
	Anteroposterior	0.092 (0.027)	0.156 (0.032)	0.329 (0.098)
	Resultant			0.383 (0.098)

Translation and rotation of the cup

Migration values for the cup over time were small. There was no consistent pattern of proximal migration (Table 3).

Table 3: Mean (SD) rotations and translations of the cup. Positive values indicate extension (equivalent to hip extension), internal rotation, adduction, medial, cranial and anterior translation. All movements are of the cup in relation to the pelvis.

Months after surgery

	Axis	2	6	12	24
Rotation [°]	**Mediolateral**	0.128 (0.608)	0.241 (0.618)	0.199 (0.650)	0.213 (0.716)
	Distal proximal	0.069 (0.349)	0.020 (0.357)	0.025 (0.366)	0.150 (0.391)
	Anteroposterior	0.052 (0.312)	0.069 (0.304)	-0.002 (0.352)	0.048 (0.352)
Translation [mm]	**Mediolateral**	-0.018 (0.112)	-0.006 (0.098)	-0.019 (0.210)	-0.080 (0.155)
	Distal proximal	0.081 (0.096)	0.075 (0.106)	0.054 (0.096)	0.048 (0.105)
	Anteroposterior	-0.001 (0.240)	0.021 (0.264)	-0.045 (0.266)	-0.048 (0.309)

Translation and rotation of the head

The pattern of migration over time indicated limited subsidence (Table 4). Values for migration in a mediolateral direction were also small, as were those for migration calculated in the direction of the femoral neck. No consistent pattern over time was detected.

Table 4: Mean (SD) translation (mm) of the centre of the head. Positive values indicate medial, cranial and anterior translation. All movements are of the calculated prosthetic centre of the head in relation to the femur.

Months after surgery

Axis	2	6	12	24
Mediolateral	-0.008 (0.188)	-0.060 (0.244)	-0.071 (0.254)	-0.113 (0.232)
Distal proximal	0.037 (0.122)	0.052 (0.171)	0.038 (0.150)	-0.040 (0.161)
Anteroposterior	0.046 (0.422)	-0.101 (0.714)	-0.191 (0.604)	-0.023 (0.506)
Along neck	-0.028 (0.096)	-0.071 (0.174)	-0.055 (0.177)	-0.024 (0.176)

Values for rotation of the femoral component were small as were those for its migration along the vertical axis (Table 5).

Table 5: Mean (SD) rotations (º) of the femoral component. Positive values indicate extension (equivalent to hip extension), internal rotation and adduction. All movements are of the femoral component in relation to the femur.

<div align="center">

Months after surgery

</div>

Axis	2	6	12	24
Mediolateral	0.037 (0.564)	0.001 (0.757)	0.155 (0.469)	0.018 (0.488)
Distal proximal	0.134 (0.690)	-0.021 (0.996)	0.101 (0.850)	0.064 (0.712)
Anteroposterior	-0.078 (0.217)	0.060 (0.180)	0.013 (0.191)	0.001 (0.224)

4. 2 STUDY II

Translation of the cup

The rotation data for the acetabular component in three subjects were excluded because of high condition numbers. In these three patients translation of this component was calculated only by the polar marker, as the other two markers were insufficiently defined. Another patient was excluded from all acetabular component calculations because of missing pelvis segment data.

The mean (SD) translation of the acetabular component at five years was 0.00 mm (0.19) medially, 0.06 mm (0.17) superiorly and 0.11 mm (0.26) anteriorly (Table 6). The mean translation of the polar acetabular marker in the three patients with incomplete data was 0.23 mm (0.30) medially, 0.24 mm (0.46) inferiorly and 0.30 mm (0.26) anteriorly. The mean rotation at five years was 0.52º (0.86º) in relation to the transverse axis, but without a statistical significance (p = 0.057) compared with the two month follow - up measurements. Rotations in relation to the other axes were not statistically significant at either interval (Table 6).

Table 6: Mean (SD) translation and rotation values of the acetabular component. The translation calculations at five years were from 18 patients (the measurements from the patients were from one marker and were excluded from the main calculation). The rotational analysis at five years included 15 patients (three patients had condition numbers exceeding 200 and were excluded). **P∗** calculated between two months and two years, **P+** calculated between two months and five years, **CI#** 95% confidence interval.

Months after surgery

	Axis	2	6	12	24	60	P∗	P+	CI#
Translation [mm]	Transverse	-0.01 (0.09)	-0.03 (0.22)	-0.04 (0.28)	-0.06 (0.23)	-0.06 (0.33)	0.624	0.800	-0.10 to 0.09
	Vertical	0.08 (0.10)	0.06 (0.18)	0.03 (0.17)	0.03 (0.16)	0.03 (0.23)	0.163	0.430	-0.03 to -0.15
	Anteroposterior	-0.01 (0.26)	-0.06 (0.43)	-0.19 (0.43)	-0.18 (0.35)	-0.08 (0.57)	0.088	0.341	-0.02to 0.24
Rotation. [°]	Transverse	0.26 (0.84)	0.33 (0.85)	0.35 (0.80)	0.45 (0.85)	0.75 (1.09)	0.067	0.057	0.08 to 0.95
	Vertical	0.07 (0.32)	-0.03 (0.23)	0.03 (0.25)	0.10 (0.26)	0.22 (0.54)	0.659	0.199	-0.02 to 0.47
	Anteroposterior	0.04 (0.20)	0.08 (0.22)	0.08 (0.30)	0.05 (0.28)	-0.09 (0.55)	0.442	0.467	-0.34 to 0.17

Translation of the head

The centre of the femoral head could be calculated in all patients. The mean values for translation of the femoral components were low (Table 7)**.**

Table 7: Mean (SD) translation values of the femoral component. The translation calculations include all 18 patients at the five year follow - up. **P∗** calculated between two months and two years, **P+** calculated between two months and five years, **CI#** 95% confidence interval.

Months after surgery

Axis	2	6	12	24	60	P∗	P+	CI#
Tansverse	0.01 (0.24)	-0.04 (0.27)	-0.05 (0.26)	-0.08 (0.31)	-0.15 (0.34)	0.288	0.062	-0.30 to 00
Vertical	0.06 (0.14)	0.07 (0.16)	0.03 (0.13)	-0.01 (0.16)	0.00 (0.25)	0.769	0.930	-0.30 to 0.11
Antero-posterior	0.07 (0.64)	-0.01 (0.70)	-0.10 (0.55)	0.10 (0.69)	0.05 (0.56)	0.684	0.677	-0.19 to 0.31

4. 3 STUDY III

Migration and rotations of the femoral component

Values for translations and rotations of the femoral component were small and not statistically significant.

The average (SD) translation at two years was 0.067 mm (0.130) medially, -0.035 mm (0.145) inferiorly and 0.012 mm (0.174) anteriorly The average rotation at two years was 0.184° (0.375) about the transverse axis, corresponding to a rotation in the anterior tilt direction; 0.236° (0.390) about the vertical axis, corresponding to internal rotation and -0.109° (0.183) about the anteroposterior axis, corresponding to a rotation in the medial (varus) tilt direction (Table 8).

Table 8: Mean (SD) translations (mm) and rotations (°) of the femoral component. Positive values indicate medial, cranial, anterior translation and anterior tilt, internal rotation, lateral tilt. The p values refer to differences between two months and 24 months. CI denotes 95% confidence intervals for the population mean at 24 months.

Months after surgery

	Axis	2	6	12	24	P	CI
Translation [mm]	Mediolateral	0.056 (0.151)	0.041 (0.122)	0.037 (0.153)	0.067 (0.130)	0.223	-0.003 to 0.138
	Distal proximal	-0.109 (0.137)	-0.055 (0.140)	-0.051 (0.142)	-0.035 (0.145)	0.676	-0.113 to 0.044
	Anteroposterior	0.055 (0.115)	0.032 (0.216)	0.062 (0.298)	0.012 (0.174)	0.095	-0.083 to 0.106
Rotation [°]	Anteroposterior tilt	0.132 (0.195)	-0.067 (0.421)	0.035 (0.455)	0.184 (0.375)	0.726	-0.019 to 0.387
	Internal-external rotation	0.272 (0.558)	0.277 (0.444)	-0.009 (1.445)	0.236 (0.390)	0.896	0.024 to 0.448
	Mediolateral tilt	-0.069 (0.244)	-0.127 (0.214)	-0.075 (0.238)	-0.109 (0.183)	0.400	-0.209 to 0.009

Migration of the centre of the head

Migration values in all planes were small and not statistically significant. The average (SD) translation at two years was 0.140 mm (0.180) along the mediolateral axis, -0.066 mm (0.181) along the distal proximal axis and 0.079 mm (0.510) along the anteroposterior axis indicating a medial, caudal and anterior translation (Table 9).

Table 9: Mean (SD) translations (mm) of the centre of the head. Positive values indicate medial, cranial and anterior translation. The p values refer to differences between two months and 24 months. CI denotes 95% confidence intervals for the population mean at 24 months.

<p align="center">Months after surgery</p>

Axis	2	6	12	24	P	CI
Mediolateral	0.122 (0.254)	0.110 (0.183)	0.101 (0.219)	0.140 (0.180)	0.674	0.042 to 0.238
Distal proximal	-0.119 (0.106)	-0.108 (0.131)	-0.091 (0.192)	-0.066 (0.181)	0.794	-0.165 to 0.032
Antero-posterior	0.134 (0.335)	-0.096 (0.570)	0.071 (0.890)	0.079 (0.510)	0.443	-0.198 to 0.356

4. 4 STUDY IV

No statistically significant differences were seen between the four quadrants of the femoral head within each group.

Group A, low viscosity cement

A considerable penetration of cement was observed in Area II: 48.5% in relation to the total area. No cement penetration was observed in Area IV (Table 10). The mean height of the top area was 4.77 (± 0.51) mm (Table 11).

Group B, high viscosity cement

No cement penetration occurred in Area II or in Area III, indicating very superficial cement integration. Cement was represented in the outer wall (Area IV) in all quadrants in this group (Table 10). The mean height of the top area measured was 3.47 (± 0.43) mm (Table 11).

Table 10: Percentage of areas in relation to the total area in the deepest section under the femoral implant in each group. Area I: cranial part consisting of the top and the chamfer areas. Area II: proximal interior area. Area III: the distal interior area. Area VI: the outer wall. * $p < 0.05$.

	Group A Low viscosity	Group B High viscosity	p
Area I	17.96(2.57)	19.73(2.76)	0.5249
Area II	48.45(3.43)	0.00(0.00)	*
Area III	33.59(3.36)	76.95(2.81)	0.0002*
Area IV	0.00(0.00)	3.32(0.12)	*

Table 11: Mean height of the top region in Area I measured in mm for each quadrant in each group. Mean height of quadrants were 4.77 mm (0.51) and 3.47 mm (0.43).in groups A and B respectively. Differences were statistically significant ($p = 0.03$).

	Group A Low viscosity	Group B high viscosity
Anterior	5.26	3.09
Posterior	4.98	4.08
Superior	4.08	3.46
Inferior	4.75	3.24

5 DISCUSSION

The purpose of this project was to obtain better knowledge of the fixation aspects of the latest generation of resurfacing hip implants developed during the last 15 years. Today's resurfacing hip devices are manufactured of the same alloy that was used in the majority of the early MoM implants but with a more modern manufacturing process. After the introduction of these new generation implants concerns arose whether they would have similarly poor long-term results as their predecessors due to design and fixation aspects. No stability studies on the fixation of these implants had previously been published and observations relied on X-ray images that could only show loosening or subsidence in long term follow - up. RSA for clinical use was not developed until the late 1970's, when the use of MoM articulations had already been abandoned. Therefore no RSA studies existed on such articulations. Studies of hip implant stability were conducted on stemmed THR's, where subsidence and internal rotation are major indicators of failure. No studies of migration patterns have previously been published for hip resurfacing. Furthermore, no studies have provided information on which indicators of failure are present in terms of the direction and magnitude of translation and rotation.

The two and five year follow - up results (Studies I and II) for the BHR are reported in this thesis. Furthermore, the only RSA study on the first cohort of the first generation BMHR device is presented (Study III).

Performing RSA on MoM hip resurfacing implants was a challenge as the accuracy of this analysis has not previously been assessed for resurfacing implants. The precision and migration detection thresholds determined by calculating mean errors of non-zero movement between duplicate RSA examinations performed on the same occasion showed results similar to experimental arrangements with standard hip prostheses [77, 78]. Because of the large quantity of metal present in the images, the X-ray tubes were placed within a very limited range of suitable positions (one tube provided an almost pure anteroposterior view while the other was inclined cranially) available to visualise the three polar markers on the cup from both X-Ray foci. Furthermore, the metal cup covered a large portion of the femoral head, yielding only a small portion of the surface of the head visible on the radiographs. In order to solve this problem, the acetabular cup centre was used to approximate the centre of the femoral component head in the first examination. In addition, the geometry of the BHR femoral component did not provide the optimal rigid-body characteristics for RSA with a short narrow centering stem onto which the three tantalum markers were distally attached. Both the vertical axis and the long axis of the neck of the femur are possible directions of subsidence for hip

resurfacing. Translation was therefore calculated in relation to the long axis of the neck as well as to the axes of the anatomical coordinate system.

The results of the two year RSA follow - up of the BHR (Study I) showed low rotation and translation values of the cup with no pattern of proximal translation. The values obtained corresponded to values in earlier studies of press - fit acetabular cups [79, 80]. Migration of the femoral implant indicated limited subsidence and small values for translation in a mediolateral direction and in the direction of the femoral neck. Measurements of anteroposterior translation of the femoral component corresponding to external-internal rotation of a conventional THR showed higher standard deviations than the other directions of migration. This could be attributed to a combination of a limited distance between the X-ray tubes and the configuration of the three head segment markers. No pattern of settling in was observed.

At two years post-operatively, RSA studies of THR's have been accepted as prognostic of long- term survival, based on empirically-based experience of the prosthesis migration pattern. However, in surface replacement, no such RSA analyses existed, owing to the failure of the early designs, and thus there was no information available on the parameters that might indicate failure of the prosthesis. The migration values at two years were small when compared with earlier studies of uncemented acetabular cups and cemented femoral components in THR's. Although absence of migration in the two years RSA study does not guarantee good long-term results, it may be expected to be a favourable prognostic factor.

Translation values of the center of the head in the presumed direction of subsidence were low at two years along the transverse (-0.113 mm (0.232)) and vertical axes (-0.040 mm (0.161)). However, migration along the vertical axis increased slightly by the end of the study, and in some measurements the pattern of posterior translation exceeded the detection of migration. A midterm follow-up was therefore conducted at five years postoperatively in order to clarify the significance of this observation. This follow-up study did not detect any further distal migration with a mean (SD) translation of 0.00 mm (0.25). The relatively higher translations along the anteroposterior axis (0.05 mm (0.56)) were similar to the results in the two year follow - up measurements (-0.023 mm (0.506)) but there was no significant migration pattern. No statistically significant changes in either rotation or translation for the acetabular component were measured at the five year follow-up. The results obtained indicated that medium-term migration was not an expected mode of failure.

Technical advances were made in hip resurfacing implants in order to offer an alternative for young active patients with unsuitable bone conditions for available resurfacing devices (poor femoral bone quality and or anatomy). This resulted in a new

device, the BMHR. It used a more distal head resection line compared with other resurfacing implants, but kept other beneficial characteristics. The cup component was the same as in the BHR, while the femoral component was new. The load pattern of an uncemented short-stemmed femoral component was expected to be different compared to a cemented resurfacing implant such as the BHR. It was therefore important to analyse the BMHR with respect to early and late migration patterns. An RSA investigation was therefore performed (Study III). 13 hips were treated with the first generation femoral implants with curved stems. Due to a design change, no further patients were treated with the same implants giving a rather small cohort to study. A power analysis was performed which indicated that with the observed spread of values, 90% power to identify migration exceeding 1.2 mm (which has been identified as unfavourable in conventional THR) could be obtained. The two year follow - up results for the BMHR were presented in Study III. The experimental RSA design was similar to Study I except that migration of the acetabular cup was not analysed because of stable patterns presented in Studies I and II. The results of Study III indicated a tendency for retroversion and varus tilt of the femoral segment and distal, medial migration of the head centre after two years. The values were, however, low and not statistically significant over time. This was comparable with results for the BHR in Studies I and II.

Varying results have been reported on the magnitude of early revision rates due to neck fractures and loosening between resurfacing implants. ASR dominated in comparisons of revision rate while the BHR showed a good survival rate with few early complications. One major difference that may have contributed to the poor early results for the ASR was the different cementing technique and viscosity used. While the LV indirect technique was used for the BHR, the HV direct technique was recommended for the ASR. Information on what was believed to be the optimal implant cementation technique had been gained from cemented THR's and total knee replacements. Retrieved resurfacing hip implants showed large variations in cement interface and penetration into the femoral head [81]. The dearth of information concerning cementation of hip resurfacing femoral heads needed to be addressed.

Study IV presented an in vitro experiment on cement mantle parameters and penetration into cadaveric femoral heads prepared for ASR. The aim was to improve the understanding of whether the ASR implant was sensitive to cementing techniques used in clinical practice and whether the results of cementing with the recommended HV direct technique may explain the high incidence of short-term revisions due to fractures. CT was used for quantitative evaluation of cement penetration. The results illustrated that the recommended HV cementation technique created a thin cement

mantle in the interface between the implant and the femoral head. No cement penetration was seen in the bone, nor an assembly of excessive cement on the top region, indicating a superficial cementation. In contrast the LV cementation technique resulted in substantial cement penetration in the femoral head and a gathering of excess cement in the top region. No cement mantle was observed around the circumference of the bone-implant interface.

The results of this study indicated that the recommended technique may result in only a superficial integration and subsequently suboptimal fixation to bone. The clinical outcome for resurfacing implants using LV cementation has been shown to be superior to the HV technique for the ASR. Cement penetration appeared to be less important than expected and reported in studies on conventional THR's. Considering that several studies have indicated disturbed circulation due to the surgical procedure [41, 42], and with the assumption that the LV cementing technique may give deep penetration into bone, the rates of early loosening and neck fractures were quite low (approx. 2%). The superficial cementation pattern seen with the recommended HV cementation may be a key factor for the poor results of ASR.

An RSA study on ASR has shown statistically significant rotation around the z-axis between baseline and two years postoperatively, while no significant rotation was measured around the same axis between one and two years postoperatively [82]. In this thesis' RSA studies I-III, no settling pattern was observed for the BHR or BMHR in either translation or rotation, indicating that the unstable conditions for the ASR may have contributed to the failure mode.

RSA results obtained from one resurfacing implant can not be assumed to apply for another device. In case of a design change of an existing implant, it is therefore important to realise that the altered device should be considered as a new product that needs to be investigated.

6 Summary

In the three RSA studies (I-III), low rotation and translation values indicating stable implant fixation were reported. The RSA results obtained for the BHR and BMHR can not be applied for other resurfacing hip devices as differences in several aspects exist despite some common characteristics. Study IV demonstrated considerable morphological differences between the LV and HV cementing techniques on ASR prepared femoral heads. The superficial cementing obtained by the recommended HV technique may be insufficient to obtain adequate fixation and early stability.

The ASR implant differed from its predecessor in geometry, clearance, metal properties and cementing technique. Its clinical failure may have been avoided if early RSA studies had been conducted prior to its introduction into the market.

7 Conclusions

The three RSA studies demonstrated no statistically significant translation or rotation patterns for the BHR or the BMHR during the periods studied. In study VI, different cementing techniques resulted in different cement morphology in bone and at the implant bone interface.

8 Future perspectives

An RSA study is being planned on the third version of the BMHR, which is equipped with a straight stem. The results will be compared with the original device studied in Study III. Furthermore, a ten year RSA follow - up for the BHR cohort in this thesis is planned to investigate whether the stable panorama seen at two and five years postoperatively has continued or if subsidence has occurred as a result of possible wear debris undermining the stability of implants and resulting in loosening.

The ASR experience has certainly played a substantial role in the declined use of the resurfacing method. However, functional resurfacing devices such as the BHR have been successful in providing a conservative mid term solution for active young patients requiring a new hip joint. It is still not clear what role issues such as hypersensitivity, pseudotumors and malignancy will play, since today's young patients receiving hip resurfacing implants may keep and wear these implants for longer than was the case with McKee-Farrar MoM articulations. Advances in metallurgy may result in optimised and safer alloys. New articulation surfaces made from alternative materials may reverse the present decreasing trend in hip resurfacing. In all cases, new studies, and in particular early RSA studies will be required each time a new implant is introduced before it is widely clinically used.

In hip joint surgery it is of utmost importance that the correctly selected patient receives the right implant by the right surgeon at the right time. This is of especial importance in hip resurfacing, since these implants do not forgive.

9 ACKNOWLEDGEMENTS

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