ON THE LONGEVITY OF CEMENTED HIP PROSTHESES AND THE INFLUENCE ON IMPLANT DESIGN

PhD thesis

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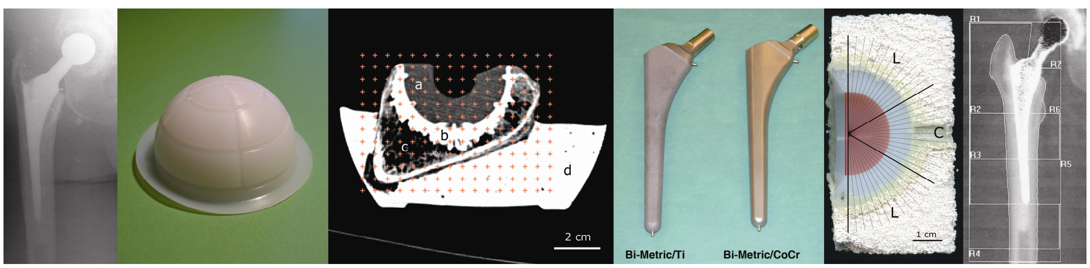

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Preface

The present thesis is conducted during my employment as a research fellow / PhD student at the Department of Orthopaedics, Ribe County Hospital, Esbjerg, Denmark from April 2002 to December 2006. The thesis comprises a comprehensive review in relation to aseptic loosening problems and the longevity of total hip prostheses with special focus on cemented titanium stems and flanged polyethylene cups. Afterwards, summaries of three individual original papers representing the work of the author will be presented, followed by a general discussion of the results.

The PhD thesis is based on following papers:

I. Titanium stem is more stable than cobalt chromium in cemented THA. Two year follow-up. Mette Ørskov, Per Riegels-Nielsen, André Zawadzski, Christian Schlanbusch, Christian Smidt-Sivertsen, Kjeld Søballe. *Submitted*.

II. Early periprosthetic bone changes around cemented titanium and cobalt chromium stems. Mette Ørskov, Per Riegels-Nielsen, André Zawadzski, Christian Schlanbusch, Kjeld Søballe. *Submitted*.

III. Flanged *versus* unflanged acetabular cup design. An experimental study using ceramic and cadaveric acetabuli. Mette Ørskov, Saba Abdulghani, Ian McCarthy, Kjeld Søballe, Gunnar Flivik. *Manuscript in preparation*.

Abbreviations

BMD	bone mineral density
BMI	body mass index
CoCr	cobalt-chromium
CV	coefficient of variation
DEXA	dual-energy X-ray absorptiometry
HHS	Harris hip score
OA	osteoarthritis
PB	prosthesis-bone
PC	prosthesis-cement
PE	polyethylene
Ra	arithmetical mean surface roughness
RB	revision burden
Rot	rotation
RSA	radiostereometry
SD	standard deviation
SEM	standard error of the mean
THA	total hip arthroplasty
Trans	translation
Ti	titanium
3D	three-dimensional

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1. Introduction

1.1. Historical aspects

The most suitable technique on how to eradicate pain and restore motion and stability in a painful ankylosed joint has fascinated orthopaedic surgeons for almost two centuries. Five different areas of arthroplasty (osteotomy arthroplasty, interpositional arthroplasty, reconstructive arthroplasty, replacement arthroplasty and total arthroplasty) were investigated to develop the most appropriate treatment.

In 1826 the American surgeon *John Barton* performed an ***osteotomy arthroplasty*** when he treated a young man suffering from an ankylosed hip joint caused by an earlier severe hip trauma [1]. *Barton* made an intertrochanteric osteotomy and produced a pseudoarthrotic lesion through careful postoperative manipulation, hence preserving hip motion. After recovery, the patient managed to walk with crutches [1].

In the early 1900s, European and American surgeons widely experimented with ***interpositional arthroplasty***. Basically, arthrolysis was performed using a chisel, in attempt to restore normal anatomical surfaces, followed by interposition of either a metal sheet or a membrane consisting of fascia, muscle, pig bladder, celluloid, zinc, silver, rubber, etc. The aim of the procedure was to re-establish the cartilaginous surfaces to restore joint motion. However, most surgeons only performed a few cases, and the achieved motion was in general disappointing [2-4]. In 1923 the Norwegian borne, American surgeon, *Marius Smith-Petersen* [5] performed a mould arthroplasty when he inserted a glass socket in the acetabulum. Prior to implantation the surfaces of the femoral head and acetabulum were shaped to expose cancellous bone to permit articular cartilage repair. Due to mould fragility problems, however, glass was substituted with pyrex (1933), then bakelite (1937) and finally vitallium (an alloy of cobalt, chromium and molybdenum) in 1938, with the vitallium mould demonstrated outstanding results for years [5].

In 1917 the American surgeon *E.G. Brackett* performed a ***reconstructive arthroplasty*** when he treated a 53 year old man with non-union following an earlier femoral neck fracture [6]. During operation the free femoral head was transplanted onto the upper part of the lesser trochanter in combination with detachment of the greater trochanter muscles (including periostium and a thin bony layer). Subsequently, the superior greater trochanter was removed and the isolated greater trochanter muscles were reattached at an inferior femoral shaft level. Eight years after surgery it was reported that the patient managed to walk without support, and also demonstrated an acceptable range of motion in the hip joint [6]. In the same period the American surgeon *Royal Whitman* experimented with reconstructive arthroplasties too. *Whitman*, however, used a different technique with completely removal of the femoral head, transformation of the greater trochanter to a lower femoral shaft location, thereby establishing an articulation between the femoral neck and acetabulum [7].

In 1926 the British surgeon *Ernest W. Hey Groves* performed a ***replacement arthroplasty*** in a patient suffering from traumatic osteoarthritis (OA) when he exchanged an injured femoral head with an ivory nail [8]. In 1940 the American surgeon *Austin T. Moore* also performed a replacement arthroplasty when he resected the upper half of the femoral bone in a patient suffering from a bone tumour, and replaced the resected bone with a special designed hemi-prosthesis made from vitallium [9].

In 1890 the German professor *Themistocles Glück*, described how he performed ***total arthroplasty*** using prosthetic components made from ivory. The prosthetic devices were either inserted with cement (made from rosin in combination with pumice or gypsum) or fixated to the surrounding bone with catgut sutures [10, 11]. However, a milestone regarding total arthroplasty occurred in the early 1960s when the British orthopaedic surgeon, *Sir John Charnley* invented the low friction arthroplasty of the hip; a concept including a metal stem with a small femoral head attached (i.e., monoblock) and a polyethylene (PE) cup both fixated to the surrounding bone with acrylic bone cement [12]. Despite the fact that more than four decades has passed since *Charnley's* innovation, his ideas still dominate hip replacement surgery today.

1.2. Why register?

Total hip arthroplasty (THA) is a highly complex procedure. Numerous potential risk factors may reduce prosthetic longevity. Inferior prosthetic design, inappropriate material, poor surface characteristics, inadequate bone cement, improper technique, unfavourable prosthetic compilation, etc. may be the crucial factors initiating prosthetic failure [13-15], but also patient related risk factors should be taken into consideration [16, 17]. Aseptic loosening is the most common side effect following a THA [18-20]. Solving the problem of aseptic loosening, however, is complicated due to variations in time from prosthetic inserting and to the observation of failure, but also the use of numerous prosthetic implants and compilations, in combination with different surgical techniques, makes a challenge.

An optimal way to assess prosthetic longevity seems to be through a nationwide register, if possible containing all primary THAs and revisions performed in the country, and linked together through the patient's unique national security number [18, 21-23]. The Swedish orthopaedic hip surgeons were pioneers when they initiated the Swedish Total Hip Replacement Register in 1979, with the main aim to improve THA outcome in the country [18]. In 1980 a similar register was established in Finland, followed by Norway in 1987, and more recently registers have also been started in Denmark (1995), New Zealand (1997), Hungary (1998), Australia (2000) and Canada (2001) [24].

Revision burden (RB) has been suggested to be a simple and valuable parameter to compare the different national registers in general, with RB being the fraction of revisions in relation to all primary and revision procedures performed [20]. Based on findings from the four Scandinavian registers (all with a minimum of 10 years follow-up), Swedish surgeons have demonstrated an overall RB as low as 8.5% (1979-2003) [20]. In contrast, the overall RB was observed to be 14.7% in Denmark (1995-2004) [25] and 15.5% in Finland (1980-1999) [22]. In Norway (1987-1998) the estimated fraction of revision in relation to all primary procedures was found to be 15% [21]. The lower RB in Sweden is set in relation with a general acceptance among orthopaedic hip surgeons to use few prosthetic designs with a well documented long term durability in combination with a general cautiousness concerning experimentation with new implants lacking clinical evidence [18, 26]. In contrast, orthopaedic hip surgeons in the remaining three Scandinavian countries use a broad prosthetic assortment, and demonstrate less conservatism concerning the introduction of new implants without clinical evaluation [21, 22, 25]. However, one must be aware of register limitations since only the overall findings can be described. Detailed questions must be answered from specific designed (randomized) studies where a specific group of patients is followed over time with conventional radiographic examinations, radiostereometry, dual-energy X-ray absorptiometry, etc. depending on the specific issue.

1.3. Total hip arthroplasty in Denmark

The recent validation of the Danish Hip Arthroplasty Register has documented that the particular database is reliable [23]. During the first 10 years of registration, a total of 54,142 primary THAs and 9,317 revision operations have been reported. In 2004, Danish hip surgeons performed 6,687 primary THAs (124 per 100,000) and 989 revision operations, with 80% of the patients operated due to primary OA [25]. The overall prosthetic survival after 10 years follow-up was observed to be approximately 92%. In spite of a general surgical improvement over the years (e.g., reduced operation time, increased use of laminar air flow in theatres, utilization of cement with antibiotics, and administration of prophylactic antibiotics and anti-thrombosis treatment regimes), no significant differences regarding prosthetic survival has been observed when implants inserted in 1995-1999 were compared with prostheses implanted in 2000-2004 [25].

During the last two decades, the yearly number of primary THAs has increased gradually both in Denmark and worldwide [27]. The demand for THA, however, may increase in near future due to demographic changes towards an older population, a higher body mass index (BMI) and a tendency to treat recent hip fractures with THA on behalf of osteosynthesis [16, 17, 24, 25]. Also, changes in patient expectations may increase the future need for THA.

1.4. Aseptic loosening

Approximately 2/3 of the Danish THA revisions are performed because of aseptic loosening. Due to the identified reduced durability among revised hips [25], the onset of aseptic loosening should preferably be postponed as long as possible. In fact, revision may harm the aged patient and revision is also costly. Solving the problem of aseptic loosening, however, is complicated through a multi-factorial mechanical / biological genesis and a varying interval between prosthesis insertion and onset of symptoms [15]. Different theories have been suggested to explain aseptic loosening [28], though today prosthetic loosening is mainly believed to be preceded by early prosthetic instability [28-31].

Owing to bone bed preparation (with rasps and reamers), the capillary circulation will be disturbed / disrupted under the production of bone necroses, with further possible aggravation caused by high pressure lavage, cement curing heat and monomer leak [31-33]. If the subsequent necrotic bone remodelling fails due to continuous prosthetic instability, a persistent fibrous membrane will be created between the interfaces [34]. In addition, loosening may be initiated by prosthetic detachment inside the cement mantle [35]. When loaded the prosthesis start fretting under the production of wear particles arising from prosthesis and cement, respectively [36]. Wear particles may also be generated from the articulating surfaces, with a possible accelerated wear rate owing to third body wear [37]. The presence of wear particles in the joint space may induce an inflammatory response through macrophage activation followed by osteolysis [38, 39]. Furthermore, the inflammatory response seems to increase the intra-capsular pressure [40] which may initiate bone resorption as well [31, 41]. Most certainly, however, particles and increased intra-capsular pressures exert a synergistic effect on bone resorption [42].

1.5. Cemented titanium stems

Introduction of cemented titanium (Ti) stems in the mid 1970s were associated with high expectations due to the superior mechanical strength and biocompatibility of the Ti alloy. Ti is approximately half as rigid as other commonly used stem materials including stainless steel and cobalt chromium (CoCr), thus fewer stem stresses will be produced when a Ti stem is inserted. With the introduction of the Ti alloy it became possible to implant smaller stems surrounded by a corresponding thicker and more sufficient cement mantle without increasing the risk of stem fracture [43]. Finite element analyses have predicted an increased cortical calcar load transfer with a stem made from Ti, which may reduce proximal medial bone loss caused by stress shielding [44, 45], and further bone preservations were expected if the stem was supplied with a collar [44, 46]. In theory, implantation of Ti stems was also set in relation with the production of increased stresses in the proximal cement, and thus an elevated cement fracture risk [44, 45]. During the last two decades divagating cemented Ti stem revision rates have been published (as reviewed below), and the rational concerning further use of cemented Ti stems has been debated. However, the main focus has been on the Ti alloy with less attention on the operative technique, stem geometry, surface characteristics, bearing surfaces, cement brand, prosthetic compilation, patient related factors, etc.

The early cemented Ti stems were monoblock collared prosthesis, i.e., the STH, DF-80 and McKee-Arden prostheses. The STH stem was available in a curved and a straight version, and after two to six years follow-up the straight stem was observed to be superior concerning radiographic evidence of loosening and calcar resorption when compared with the curved stem [47]. Eleven years after surgery the straight STH stem demonstrated 96.4% survivorship concerning radiographic progressive loosening [48]. In contrast, less optimistic results were obtained with the DF-80 (48.9% of the prostheses demonstrated radiographic loosening 3.1 years after surgery) [49] and the McKee-Arden stem (median time to revision was 7.8 years) [50].

With the introduction of modular cemented Ti stems it became possible to combine the stem with different femoral heads with the most common combination being a Ti head articulating against PE. However, when revision was performed due to aseptic loosening, Ti head burnishing in combination with a fractured femoral cement mantel and a polished PE surface with cement particles embedded was frequently observed [51, 52]. In addition, Ti heads were noted to be less resistant against third body particles (i.e., cement or metal debris), and a burnished Ti head was observed to produced more PE wear [53-55]. No correlation, however, was observed between head burnishing and prosthetic implantation time [52], and differences in patient activity was suggested to be the main cause [56]. Since CoCr heads has been observed to produce less wear than both Ti and stainless steel when articulating against PE [57], Ti heads are no longer used and CoCr has turned out to be the most commonly used femoral head metal.

Conflicting findings concerning cemented Ti stem longevity continued despite the introduction of CoCr heads, and inferior results were observed with both the 3M Capital (29% were radiological loose 4 years after surgery) [58], the ITH (5 years after surgery 9.2% of the prostheses were radiological loose and had migrated more than 5 mm) [59] and the Triad prostheses (89% survival 4.8 years after surgery) [60]. The 3M Capital prostheses articulated against PE, whereas the articulating surfaces in both the ITH and Triad study were unreported. It may, however, have influenced the outcome that all stems were inserted without using modern cementing technique [18]. The ITH and some of the 3M capital stems were, in addition, inserted with CMW cement which may have contributed to the increased failure rate observed [61]. Regardless of CoCr-PE bearing surfaces and modern cementing technique (but unreported cement brand) the KMW stem demonstrated inferior results (5.5 years after surgery 11.5% of the inserted stems had failed due to aseptic loosening) [62]. In contrast, superior results were obtained with the BiContact stem in combination with CoCr-PE bearing surfaces (97.5% survival after 11 years), but cement and cementing technique was unreported [63]. Also the Bi-Metric stem (collared version) demonstrated good results (98% survival 7 years after surgery) when CoCr-PE bearing surfaces, modern cementing technique and Palacos cement were used [64]. The Howse MkII / Ultima stem has shown acceptable results (97% survival after 7.5 years) in combination with modern cementing technique and Palacos cement [65], though it should be taken into consideration that the Howse MkII and Ultima stem used Ti and CoCr heads, respectively. Another study investigating the Ultima stem showed less impressing results (92% survival after 8 years) [66], even when CoCr-PE bearing surfaces and modern cementing technique was used (though cement was CMW).

Divagating outcomes have been reported for the straight Müller stem too. Good results (98.4% survival after 9 years regarding aseptic loosening) were obtained when Palacos cement and ceramic-PE bearing surfaces were used [67]. An acceptable outcome was also demonstrated in another study when the stem was inserted with Palacos cement using modern cementing technique (but unreported bearing surfaces): 2.2% stem revision after 5.7 years and minimal stem subsidence [68]. In contrast, the stem showed an unacceptable high aseptic loosening rate (13.4% revision after 7.7 years) [69] and inferior survival due to aseptic loosening (80.9% survival after 10 years) [70] when past cementing techniques (i.e., not modern) was used in combination with different cement brands and unknown bearing surfaces.

Promising results have been achieved with the smooth Marburg stem (95.4% survival after 13 years), but when the same stem was supplied with a rough surface, less impressive results were observed (76.7% survival after 11 years) [71]. Both stems had a ceramic head, whereas the bearing surface on the cup, the cementing technique and cement brand were unreported. Superior results have also been achieved with the Osteal stem in combination with ceramic-ceramic bearing surfaces (99% stem survival 9 to 11 years after surgery) [72, 73], declining to 87.3% survival after 20 years [74] despite absence of modern cementing technique. It should be considered, however, that the particular design was a conical channel filling stem inserted with a minimum amount of cement.

As demonstrated when reviewing the literature concerning cemented Ti stem durability, detailed information regarding the inserted prosthetic components, the applied cementing technique, etc., is scarce. Hence it remains difficult to determine whether the Ti alloy is associated with an increased loosing rate or not. In fact, Ti stem survival seems to benefit from high viscosity cement and the application of modern cementing technique, but also stem geometry and surface characteristics should be taken into consideration. Due to the divagating revision rates reported during the last two decades, the further use of cemented Ti stems has been debated, and today CoCr has widely replaced the Ti alloy in new cemented stem designs, although clinical evaluation is scarce.

1.6. Flanged acetabular cups

In general, cemented stems have been observed to do better than cemented cups, excluding the flanged Charnley Ogee cup which has demonstrated superior outcome [20]. Sufficient cement-bone interdigitation, preferably with a three to five mm penetration depth into cancellous bone and formation of a uniform cement mantle (i.e., cement penetration excluded) with a minimum of two mm thickness have been stated to be crucial factors regarding cemented acetabular cup durability [29, 75-79]. A clean, porous bony surface and cement pressurization prior to prosthetic implantation has been observed to improve cement penetration depth, thus creating a stronger cement-bone interface [80-83]. Timing of the cup insertion is also important as the viscosity of the polymer may have attained a level where further penetration might be complicated [76, 84, 85].

Absence of postoperative demarcation at the acetabular cement-bone interface has been set in relation to a reduced risk of aseptic cup loosening [86-89]. The use of a flanged cup made from PE has demonstrated both less postoperative demarcation at the above interface [90], and a superior survival regarding aseptic loosening [91]. The success of the flanged cup has mainly been addressed to its ability to increase cement pressurization at the time of implantation and thereby penetration depth, though conflicting experimental findings have been reported [92-94]. The previous studies addressing the use of flanged cups have all inserted the cups without prior cement pressurization, and only *Parsch* et al. [94] implanted the cup into a general porous material (cadaveric bone).

1.7. Aim of thesis

The aims of the present thesis were:

1) To investigate whether a specific cemented Ti stem demonstrates increased early instability when compared to a similar, but more rigid CoCr stem in a randomized group of patients 60-75 years old with primary OA (Paper I).

2) To determine if the particular cemented Ti stem, due to reduced alloy rigidity, reduces early periprosthetic bone resorption when compared with a specific CoCr stem in a randomized group of patients 60-75 years old with primary OA (Paper II).

3) To evaluate a cemented flanged cup *versus* an unflanged cup with focus on intra-acetabular pressures, cement mantel thickness and penetration depths in an experimental setup using ceramic acetabular models and paired cadaveric acetabuli (Paper III).

2. Methods

2.1. Radiostereometry (RSA)

More than 30 years ago radiostereometry (today commonly known as RSA) was invented by the Swedish radiologist *Göran Selvik* [95], and with his findings it became possible to study skeletal kinematics in three-dimensions (3D) [96]. Soon RSA turned out to be a mile stone in the evaluation of new prosthetic THA components, and it still remains a very valuable tool today [97]. Early prosthetic migration within the first two years of observation has been claimed to be the best predictor of later prosthetic revision due to aseptic loosening, with special attention on stem subsidence [30]. RSA has been validated to have high technical and clinical precision (between 0.05 and 0.5 mm for translations, and between 0.15 and 1.15º for rotations) [98], thus making it is possible to verify new implants, bone cements and different fixation principles in small patient materials, thereby reducing the number of patients who has to be exposed to a potential hazard [13, 83, 89, 97]. Also PE wear can be evaluated on RSA takings [99, 100].

RSA is based on reproducible measurements of specific identifiable markers which keep their position between the radiographic takings. For that purpose, spherical tantalum markers are used, typically with a diameter of either 0.8 (Figure 1) or 1.0 mm if the hip is the region of interest. Due to its radio-opaque characteristics, tantalum is quite easy to recognize on radiographic images, and the metal has a high biocompatibility too. High kilo-voltage and low

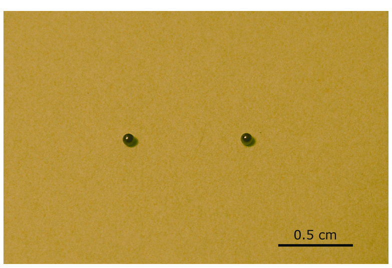

Figure 1. Photography of two tantalum markers (0.8 mm diameter).

milli-ampere is used to visualize the tantalum markers, but the radiation dose from an RSA examination is only 1/10 of that of a conventional radiographic examination of the hip (antero-posterior, lateral and pelvic view) [97]. If one wishes to measure the migration between e.g. an inserted prosthesis and the surrounding bone, tantalum markers must be inserted in both segments. The surgeon only needs to place tantalum markers in the bone, as the prosthesis will be prepared for RSA by the manufacturer (i.e., in a femoral stem every tantalum marker will be embedded in a small peg to ease later identification on the radiographic images, and usually pegs will be located at the prosthetic shoulder, proximal medial, and at the tip, respectively). A minimum of 3 tantalum markers, but preferable 7 - 9, should be placed in the bone with a good scatter to ensure optimal precision in the analysis [97].

The RSA set-up consists of two synchronized roentgen tubes and a reference box (Figure 2) positioned on top of two roentgen cassettes. Both roentgen tubes are placed above the calibration box, positioned at a 20^{o} angle to the vertical, and approximately 1.60 m above the two roentgen cassettes. The reference box is constructed with tantalum markers (control and

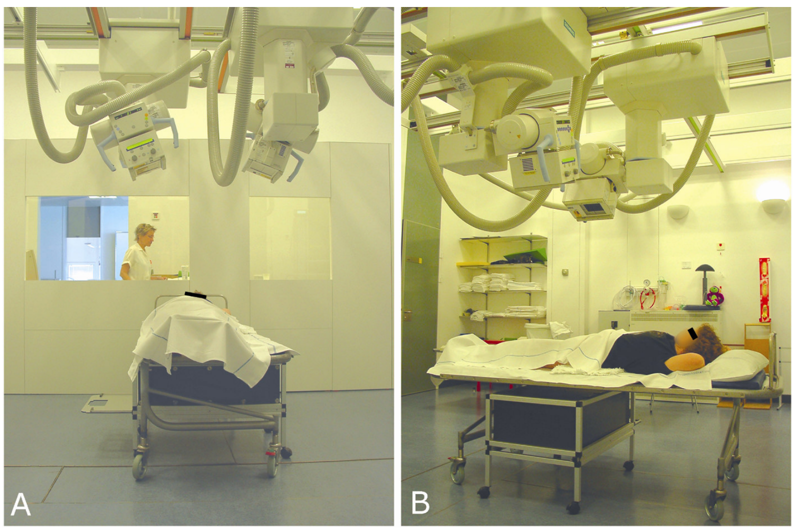

Figure 2. RSA set-up. *Panel A*: the synchronized roentgen tubes are positioned above the patient. *Panel B*: the reference box is seen below the patient.

fiducial markers, respectively) organized in two planes with a known 3D position. Control markers, located in the superficial plane, verify the roentgen focus, whereas fiducial markers, located in the profound plane, determine the 3D fiducial coordinate system. Following an RSA taking, the two images (Figure 3) can either be saved digitally or secondary digitized using a conventional scanner. With use of special analytical RSA software, fiducial markers depicted on the RSA radiographs will be transformed to the 3D fiducial coordinate system, with the transformation quality expressed as the distance between the fiducial markers and their transformed projections (i.e., the transformation error). To asses the foci of the two roentgen tubes, lines through the control markers and their transformed projections are created and the foci positions are determined (i.e., the focus error).

If the aim is to determine 3D prosthetic migration in relation to the surrounding bone, the patient is simply positioned between the two roentgen foci and the calibration box with the joint of interest located at the intersection of the two roentgen bundles. Using the RSA

Figure 3. Example of an RSA taking of a hip joint (one image from each roentgen tube).

software, the 3D position of every tantalum marker in prosthesis and bone, respectively, will be estimated similar to the determination of the roentgen focus. These specific 3D coordinates will create two rigid bodies (prosthesis and bone, respectively), and when the patient is followed over time, the 3D prosthetic rigid body motion in relation to the bony rigid body can be assessed using a transformation vector and a rotation matrix [98]. Usually the initial RSA examination (which is used as reference) is performed immediately after surgery, with typical follow-up intervals after 3, 6, 12 and 24 months, using identical tantalum markers to define the rigid body during the entire follow-up period.

2.2. Dual-energy X-ray absorptiometry (DEXA)

Periprosthetic bone loss, in especially in the calcar region, is frequently observed following THA [48, 67]. To be visualized on ordinary radiographs, the bone mineral density (BMD) loss needs to be approximately 30% [101]. Introduction of DEXA, however, facilitated the detection of even small BMD changes around inserted hip stems, while maintaining high precision with the particular femur positioned in a controlled neutral rotation (Figure 4) [102]. Typically, periprosthetic BMD around a femoral stem is assessed in accordance with the seven Gruen zones [103], and, if possible, an early postoperative DEXA examination of the

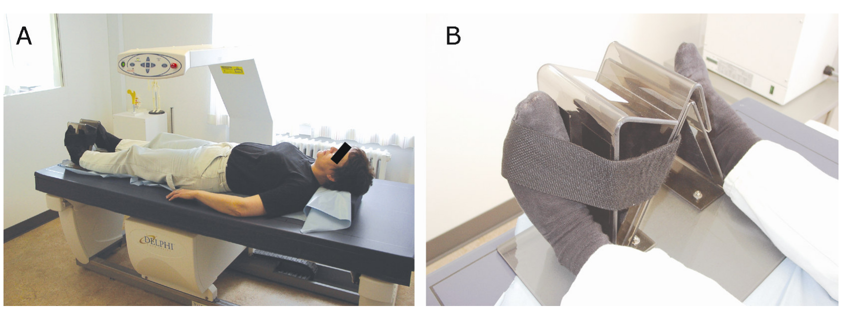

Figure 4. DEXA set-up

involved region should be used as reference [104]. However, when a cemented stem is evaluated with DEXA, it remains impossible to distinguish cement from bone [104-106], and to attain high precision of the examination, cement should preferably be included in the BMD measurements [107]. For cemented stems the precision of the BMD measurements, i.e. the coefficient of variation (CV%), has been observed to vary between 1.0% and 5.3%, when evaluated with respect to the seven Gruen zones [104, 107, 108],

The most likely candidate for the periprosthetic bone resorption subsequent to THA is stress shielding due to altered mechanical loading patterns [44], owing to differences in rigidity in the femoral bone and stem, respectively [109, 110]. Femoral bone rigidity is mainly influenced by the quantity and distribution of cortical bone [111], whereas stem rigidity is a consequence of stem geometry, cross sectional area and rigidity of the particular alloy [112]. However, the implicated reduced BMD resorption around inserted prosthetic implants may protect against periprosthetic bone fractures, and might improve revision surgery outcome as well.

2.3. Intra-acetabular pressure measurements in experimental cup study

During cemented cup insertion and subsequent pressurization the obtained intra-acetabular pressures can be measured with pressure sensors [94, 113]. Preferably the sensor tip should be covered with tape to protect it from polymer induced damage, and must, in addition, be levelled with the acetabular surface to obtain optimum measurements [94]. Early studies addressing intra-acetabular pressure measurements during cemented cup insertion did not utilize acetabular models with a general open-pore structure [92, 93]. However, to ease interpretation of experimental intra-acetabular pressure measurements, the acetabular model should be of a universal open porous structure to resemble human cancellous bone. Though preferably, paired cadaveric pelvises should be utilized [94]. The use of a material

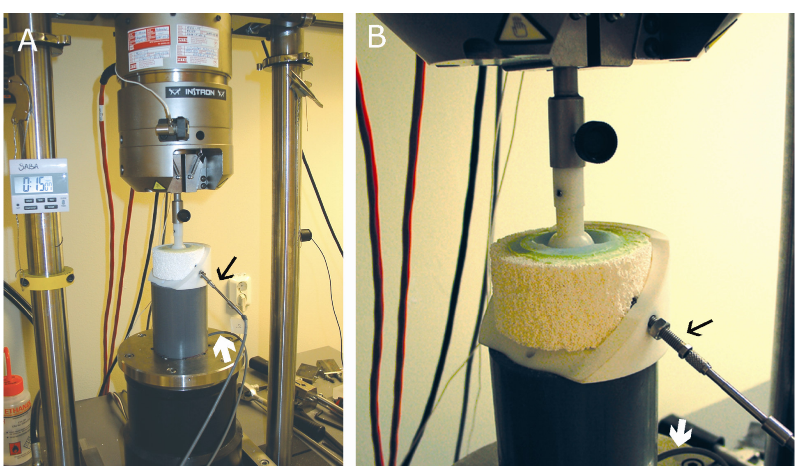

Figure 5. Cup pressurization (ceramic acetabular model) with use of an Instron machine. Pressure sensors are placed at the rim (*small arrows*) and acetabular pole (hidden by the hollow pressure sensor holder), respectively. The *large arrows* show the pole pressure sensor cable.

test machine (e.g., an Instron machine, Figure 5) remains a very valuable tool in experimental studies to control either cup position during insertion (i.e., position-controlled), or the applied force (i.e., force-controlled) in combination with continuous cup displacement measurements.

2.4. Cement mantle and penetration measurements in experimental cup study

After the cementing procedures, cutting the sample longitudinally along the centre of the cup with an electric saw and then digitizing it using a digital scanner enables inspection of the cement mantle and penetration depth, respectively. In the particular experimental study using ceramic acetabular models, a hemisphere template was created in Adobe Photoshop 7.0 (Adobe System Inc.) to divide the acetabulum into three 60º segments (two laterals and one central). Each segment was afterwards divided into 12 sub-regions by adding a radial test line for every five degrees (Figure 6A). Cement mantle thickness and penetration depth were measured along every test line, with the exception of the central zone, where only six measurements were performed in the lateral part of the region to avoid uncertainty caused by the pole pressure sensor channel. Accordingly, the median mantle thickness and penetration depth could be calculated. The lateral and central mantle and penetration area for every five degrees were also estimated. Penetration was defined to begin at the base of a proximal penetration sprout, and to end at the most distal point of cement along a radial test line. All measurements were performed with the Image J software (ImageJ 1.31i, W. Rasband, NIH, USA).

In the paired cadaveric acetabular study every bone pair was reversely aligned and CT scanned in the coronal plane to enable estimation of the total cement volume (mantle

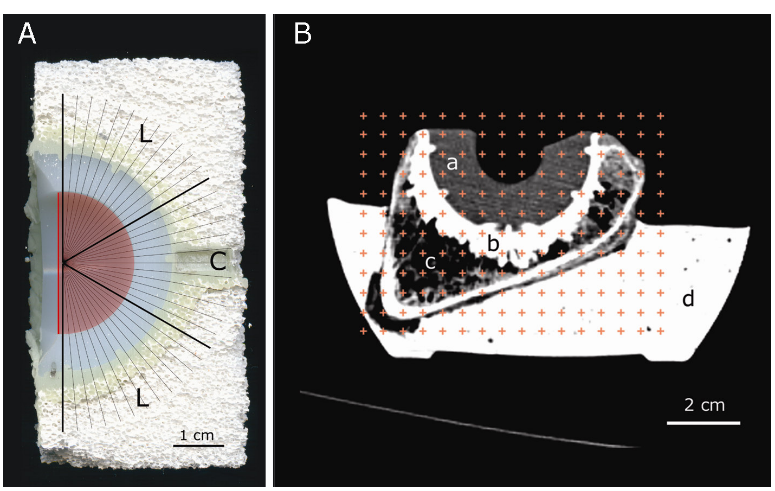

Figure 6. *Panel A* shows the template with test lines placed on a ceramic sample (note the close contact between the unflanged cup and the ceramic). (L) lateral segments, (C) central segment. *Panel B* shows the counting grid placed on a CT cadaveric bone image. (a) cup, (b) cement, (c) cadaveric bone, and (d) Vel-Mix Stone.

thickness plus penetration depth) using Cavalieri's direct estimator [114]. Basically, a grid containing points covering a known area was created (Adobe Photoshop 7.0), and the total upper right corner of each point overlaying the cement were counted in every 12th CT slide (Figure 6B). The starting point was random, and 12 to 15 slides were analyzed in all samples using an equal number of slides for the other half of the bone pair. All analyses were performed blinded.

When estimating cement penetration a medial and a lateral anchorage hole were localized for every sample on the CT sections, and the images visualizing the most prominent diameter were chosen. In the opposite cadaveric bone pair the corresponding anchorage hole was selected. The diameter of each chosen anchorage hole (i.e., the diameter of the drill hole plus penetration at both sides of the hole) was measured three times at its thickest location (with ImageJ). Penetration was subsequently calculated as the half of the difference between the median measured diameter and the known size of the drill hole (6 mm) [113]. All analyses were performed blinded.

3. Summary of papers

Paper I: **Titanium stem is more stable than cobalt chromium in cemented THA. Two year follow-up**

Patients and methods

In a prospective randomized study we compared two rough cemented Bi-Metric stems (tapered, collarless, and ceramic beat blasted, with identical geometry, but different alloy (CoCr (n=20), *versus* Ti (n=20), Figure 7), using RSA to investigate stem instability between prosthesis-cement and prosthesis-bone. The arithmetical mean surface roughness (Ra) was 7.64 and 2.63 microns for the Ti and CoCr stems, respectively. All participating patients were 60–75 years old, and had a cemented THA performed due to primary OA between January 2003 and October 2004. All patients received a modular 28 mm CoCr femoral head, a

Figure 7. The two inserted Bi-Metric stems

Sleeve centralizer, a Buck Femoral Restrictor and a SHP cup (made from PE). All components were inserted with vacuum mixed Refobacin-Palacos R cement using modern cementing technique. To enable RSA, stems were supplied with tantalum markers by the manufacturer and during operation tantalum markers were positioned in the cement and surrounding bone as well. RSA was performed two days after surgery, and repeated after 3, 6, 12, and 24 months with all takings performed with the patient in the supine position. Migration (compared to baseline) between prosthesis-bone and between prosthesis-cement were analyzed, and subsequently instability (numerical migration between each follow-up) was calculated. Data is presented as median values (interquartile range).

Results

Two years after surgery both stems (Ti and CoCr) had subsided and rotated into retroversion between both prosthesis-bone and prosthesis-cement. CoCr was found to be significantly more unstable than Ti at rotation around y-axis (1.95º (0.85 – 2.86) *versus* 0.29º (0.11 – 1.06), p=0.01, respectively) three months after surgery and around z-axis (0.25º (0.07 – 0.54) *versus* 0.07º (0.02 – 0.16), p=0.04, respectively, Figure 8A) two years after surgery, both at the prosthesis-cement interface. CoCr also demonstrated higher rotational instability between prosthesis-bone around y-axis two years after surgery when compared with Ti (3.91º (1.85 – 5.14) *versus* 1.04º (0.71 – 2.58), p=0.05, respectively, Figure 8B). When comparing prosthesis-bone and prosthesis-cement instabilities two years after surgery, Ti stems were found to be significantly more unstable between prosthesis-bone than between prosthesis-cement in translation along x- and y-axis, as well as in rotation around x- and z-axis (Table 1). In contrast, CoCr stems showed no such differences.

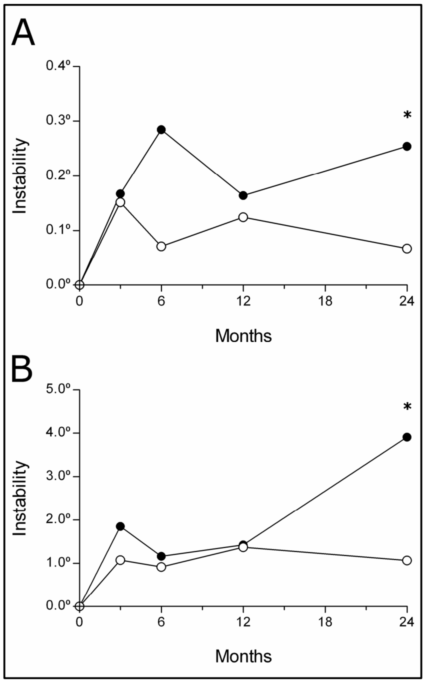

Figure 8. Stem instability obtained from RSA measurements for prosthesis-cement rotation around z-axis (*panel A*) and prosthesis-bone rotation around y-axis (*panel B*). Open circles (○) denote Ti stems, and closed circles (●) CoCr stems. Median values are shown. * p≤0.05 Ti *versus* CoCr.

Conclusions

Two years after surgery the Ti stem demonstrated significantly more instability between prosthesis-bone compared with prosthesis-cement in translation along x- and y-axis, and rotation around x- and z-axis (Table 1), thereby suggesting a superior prosthesis-cement anchoring for the Ti stem. In contrast, no significant differences were observed for the CoCr stem between prosthesis-bone and prosthesis-cement instabilities during the same period

(Table 1); this indicates that the main instability for the CoCr stems occurred at the prosthesis-cement interface as the magnitude of the prosthesis-bone instability reflected the instability observed for prosthesis-cement. Two years after surgery CoCr stems were, in addition, observed to be significantly more unstable in rotation around z- (prosthesis-cement) and y-axis (prosthesis-bone) when compared to Ti, indicating that CoCr stems might be inferior to Ti.

Table 1. RSA instability within 12 – 24 months

	CoCr PB Trans n=18, Rot n=10	**CoCr PC** Trans n=14, Rot n=11	**p-value**
Trans x (mm)	0.20 (0.11 – 0.48)	0.15 (0.08 – 0.32)	0.31
Trans y (mm)	0.12 (0.04 – 0.28)	0.07 (0.03 – 0.25)	0.48
Trans z (mm)	0.41 (0.13 – 0.84)	0.28 (0.09 – 0.73)	0.56
Rot x (°)	0.55 (0.17 – 1.22)	0.53 (0.20 – 0.98)	0.97
Rot y (°)	3.91 (1.85 – 5.14)	1.78 (0.50 – 4.45)	0.15
Rot z (°)	0.26 (0.05 – 0.69)	0.25 (0.07 – 0.54)	0.97
	Ti PB Trans n=17, Rot n=13	**Ti PC** Trans n=16, Rot n=9	
Trans x (mm)	0.30 (0.16 – 0.40)	0.14 (0.07 – 0.22)	0.02
Trans y (mm)	0.26 (0.15 – 0.31)	0.06 (0.03 – 0.16)	0.004
Trans z (mm)	0.66 (0.27 – 0.87)	0.38 (0.16 – 0.53)	0.08
Rot x (°)	0.47 (0.25 – 1.71)	0.11 (0.06 – 0.31)	0.04
Rot y (°)	1.04 (0.71 – 2.58)*	0.50 (0.34 – 0.88)	0.22
Rot z (°)	0.31 (0.17 – 0.52)	0.07 (0.02 – 0.16)*	0.02

Abbreviations: PB denotes prosthesis-bone, PC denotes prosthesis-cement, Trans denotes translation and Rot denotes rotation. Data is presented as median values with the interquartile range in brackets. * p≤0.05 CoCr *versus* Ti

Paper II: Early periprosthetic bone changes around cemented titanium and cobalt chromium stems

Patients and methods

In a prospective randomized study two rough cemented Bi-Metric stems (tapered, collarless, and ceramic beat blasted, with identical geometry, but different alloy (CoCr (n=20), *versus* Ti (n=20)), were examined using DEXA to investigate the early periprosthetic bone changes (Ra was 7.64 and 2.63 microns for the Ti and CoCr stems, respectively). All participating

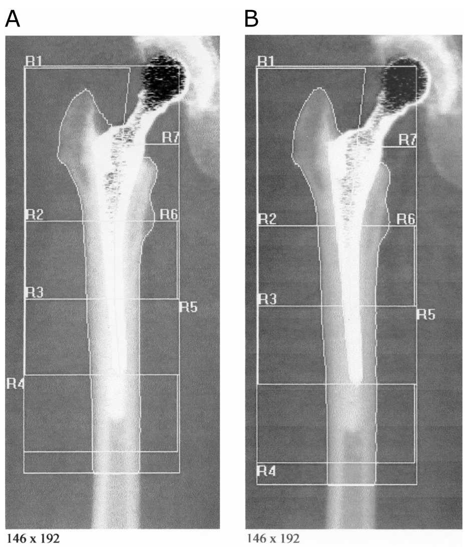

Figure 9. DEXA scans of the same patient performed post-operatively (panel A) and after 12 months (panel B).

patients were 60–75 years old, and had a cemented THA performed due to primary OA between January 2003 and October 2004. All patients also received a modular 28 mm CoCr femoral head, a Sleeve centralizer, a Buck Femoral Restrictor and an all-polyethylene SHP cup. All components were inserted with vacuum mixed Refobacin-Palacos R cement using modern cementing technique. DEXA was performed during the first postoperative week, and repeated 12 month later with the patient placed in a supine position including foot immobilization to ensure neutral femoral rotation. Cement and bone were included in all DEXA analyses, and the periprosthetic BMD was calculated in respect to the seven Gruen zones [9]. The 'compare function' was used for follow-up examinations to ensure identical pixel size on both images (Figure 9) and relative BMD changes were calculated with a negative value indicating bone loss. Data is presented as mean values and standard deviation (SD).

Results

Twelve months after surgery the Ti stems demonstrated significant BMD losses in zone III ($p=0.02$), zone VI ($p=0.01$) and zone VII ($p<0.001$), whereas CoCr stems showed significant BMD losses in zone II ($p=0.02$), zone III ($p=0.01$), zone IV ($p=0.01$) and zone VII ($p<0.001$) when compared to baseline (Table 2). However, no significant differences in the absolute BMD changes were observed between the two stems either postoperative or after 12 months.

Tabel 2. BMD postoperative and after 12 months

Gruen zone	CoCr (postoperative)	Ti (postoperative)	p-value
I	1.26 (0.20)	1.30 (0.23)	0.61
II	2.39 (0.23)	2.27 (0.31)	0.21
III	2.32 (0.21)	2.27 (0.23)	0.54
IV	2.21 (0.23)	2.15 (0.21)	0.41
V	2.00 (0.29)	2.08 (0.17)	0.37
VI	1.83 (0.22)	1.93 (0.16)	0.14
VII	1.63 (0.25)	1.63 (0.14)	0.93
Gruen zone	**CoCr (12 months)**	**Ti (12 months)**	**p-value**
I	1.28 (0.21)	1.33 (0.26)	0.59
II	2.27 (0.34)[a]	2.44 (0.34)	0.75
III	2.24 (0.23)[a]	2.21 (0.23)[a]	0.68
IV	2.16 (0.22)[a]	2.11 (0.20)	0.46
V	1.95 (0.30)	2.03 (0.18)	0.36
VI	1.77 (0.31)	1.85 (0.21)[a]	0.36
VII	1.44 (0.34)[b]	1.41 (0.24)[b]	0.79

Mean g/cm^2 values (SD) are expressed. [a] $p<0.05$, [b] $p<0.001$ for 12 months *versus* postoperative BMD.

Defining relative BMD change as the absolute loss (or gain) divided by the initial value, a universal relative BMD loss was observed around both stems twelve months after surgery with the main loss noted in zone VII (except in zone I where a small bone gain was seen) (Figure 10). However, none of the changes showed statistical significance between the two stems.

Conclusions

A general periprosthetic BMD loss was observed around both stems investigated with the exception of zone I where gain was seen. For both stems the largest mean BMD loss was seen in Gruen zone VII (13.6% and 12.7%, Ti and CoCr, respectively). No significant differences, however, were found between Ti and CoCr stems, suggesting that the particular Ti stem was too rigid to reduce periprosthetic bone loss.

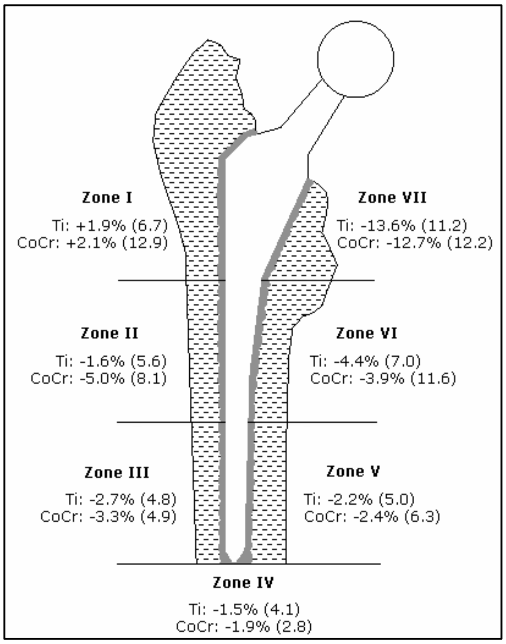

Figure 10. Relative periprosthetic BMD differences (%) one year after surgery. Mean and SD values are expressed.

Paper III: Flanged *versus* unflanged acetabular cup design. An experimental study using ceramic and cadaveric acetabuli

Materials and methods

The performance of a flanged Opera cup (Figure 11) *versus* an unflanged cup (same cup but with the flange cut off) was investigated with focus on intra-acetabular pressures, cement mantle thickness, and penetration depth. Both cups were without cement spacers. Using an

Figure 11. A flanged Opera cup.

Instron maschine, cups were inserted position-controlled into open pore ceramic acetabular models (flanged=10, unflanged=10) as well as in paired cadaveric acetabuli (flanged=10, unflanged=10) with prior pressurization of the cement, followed by force-controlled pressurization of the inserted cups. Forces, intra-acetabular pressures and displacements were recorded continuously during the cementing procedures. Subsequently all ceramic samples were cut longitudinally along the centre of the cup with an electric saw, and digitized to enable inspection of the cement mantle and penetration depth, respectively. Every cadaveric bone pair was reversely aligned and CT scanned in the coronal plane to enable estimation of the total cement volume and penetration depth, respectively.

Table 3. Intra-acetabular pressures in ceramic acetabular models

	Flanged	Unflanged	p-value
Position controlled cup insertion			
Force applied (N)	68.0 (64.9 – 74.4)	56.7 (42.7 – 83)	0.5
Pole pressure (mmHg)	353.3 (281.1 – 355.5)	402.3 (298.0 – 568.1)	0.3
Rim pressure (mmHg)	283.2 (281.9 – 292.9)	252.4 (188.6 – 331.6)	0.5
Force controlled pressurization			
Cup displacement (mm)[a]	-0.1 (-0.2 – 0.0)	-0.2 (-0.4 – -0.2)	0.049
Pole pressure (mmHg)	86.3 (0.0 – 108.4)	140.5 (113.9 – 159.5)	0.049
Rim pressure (mmHg)	76.1 (7.7 – 85.3)	24.7 (23.5 – 54.8)[b]	0.5

Median values (interquartile range) are shown. [a] Negative displacement indicates cup migration toward acetabular pole. [b] p<0.05 for pole *versus* rim pressures.

Table 4. Intra-acetabular pressures in paired cadaveric acetabuli

	Flanged	Unflanged	p-value
Position controlled cup insertion			
Force applied (N)	89.7 (52.3 – 133.6)	75.4 (38.9 – 134.7)	0.8
Pole pressure (mmHg)	218.5 (172.2 – 337.3)	470.3 (213.3 – 739.9)	0.1
Rim pressure (mmHg)	155.6 (42.8 – 224.6)	196.4 (114.0 – 269.1)	0.7
Force controlled pressurization			
Cup displacement (mm)[a]	-0.1 (-0.3 – 0.1)	-1.0 (-1.4 – -0.2)	0.04
Pole pressure (mmHg)	12.3 (10.2 –60.2)	129.8 (88.0 – 269.9)	0.005
Rim pressure (mmHg)	17.1 (14.3 – 37.9)	23.0 (13.2 –84.1)[b]	0.5

Median values (interquartile range) are shown. [a] Negative displacement indicates cup migration toward acetabular pole. [b] $p<0.05$ for pole *versus* rim pressures.

Results

During position-controlled insertion with equivalent forces, no significant differences regarding intra-acetabular pressures were found between flanged and unflanged cups either when inserted in ceramic (Tabel 3) or paired cadaveric acetabuli (Tabel 4). When cups were further pressurized (using force-control) the unflanged cups migrated significantly more towards the acetabular pole than the flanged cups did under the production of higher pole pressures when inserted in either ceramic acetabular models (Tabel 3) or paired cadaveric acetabuli (Tabel 4). Flanged cups inserted in ceramic acetabular models were surrounded by a significantly thicker cement mantle than unflanged cups (Table 5), whereas no significant differences were found in regard to cement penetration depths (Table 5). In the paired cadaveric acetabuli flanged cups were also found to be enclosed by significantly more cement than unflanged cups (70.26 cm^3 (66.41 – 73.91) *versus* 57.38 cm^3 (54.18 – 61.69),

Table 5. Cement mantle thickness, penetration depth and areas in ceramic acetabular models

	Flanged	Unflanged	p-value
Cement mantle			
Lateral thickness (mm)	2.37 (1.78 – 3.19)	1.50 (1.23 – 1.94)	0.002
Central thickness (mm)	3.33 (2.32 – 3.77)	1.64 (0.88 – 1.80)	<0.001
Lateral area (mm^2/5º)	4.65 (3.85 – 5.34)	2.88 (2.50 – 3.16)	<0.001
Central area (mm^2/5º)	5.83 (4.25 – 6.55)	2.43 (1.96 – 3.33)	<0.001
Cement penetration			
Lateral depth (mm)	3.59 (3.53 – 3.85)	3.80 (3.38 – 4.02)	0.5
Central depth (mm)	4.22 (4.13 – 4.78)[a]	4.67 (4.07 – 4.79)[a]	0.6
Lateral area (mm^2/5º)	9.16 (8.84 – 9.28)	8.81 (8.36 – 8.85)	0.2
Central area (mm^2/5º)	10.18 (9.41 – 10.42)[a]	10.44 (9.52 – 10.85)[b]	0.4

Median values (interquartile range) are shown. [a] $p<0.01$, [b] $p<0.001$ for lateral *versus* central measurements.

p=0.02, respectively), whereas no significant difference in cement penetration between the two cup types (0.92 mm (0.57 – 1.65) *versus* 0.99 mm (0.83 – 1.70), p=0.8, respectively) was observed.

Conclusions

When inserted in ceramic acetabular models as well as in paired cadaveric acetabuli, the unflanged cups migrated significantly more towards the acetabular pole and created a thinner cement mantle than the flanged cups did, whereas no significant differences regarding cement penetration depths were observed between the cups. Most certainly the main cement penetration takes place when the cement is pressurized prior to cup insertion causing the cement to become too viscous to permit further penetration when cups are inserted. Based on the findings in the present study it seems doubtful that the superior outcome observed among flanged cups is caused by an improved cement penetration, and we suggest that the main role of the flange is to protect the interfaces against joint fluid pressure and wear debris, thereby increasing cup durability.

4. Discussion

Finite element studies have predicted that Ti stems may induce elevated stress levels in the proximal cement mantle, and thus an increased risk of cement fracture, when compared to CoCr [44, 45]. However, reduced rigidity may not necessarily be the provoking factor if a cemented Ti stem demonstrates early loosening [115] as cross sectional area and stem geometry has been observed to dominate over alloy rigidity in the mechanical behaviour of cemented femoral stems [112]. Accordingly, a stem made from CoCr is nearly twice as rigid as a Ti stem (the alloy rigidity is 200 and 110 GPa, respectively [45]), only if the two stems are comparable in regard to stem geometry and cross-sectional area.

Since aseptic loosening is multifactorial, prosthetic design (i.e., alloy, geometry and surface characteristics [48, 49, 71]), cementing technique [68-70], cement mantle thickness [115], type of bone cement [13, 61], prosthetic compilation [116] and patient related factors [16] should all be taken into consideration when evaluating prosthetic longevity. In general, when reviewing the literature concerning cemented Ti stem durability, the main focus has been on the particular stem geometry whereas information on the remaining, but crucial parameters is scarce. When evaluating prosthetic survival, revision is usually used to define failure end point. Though an unrevised prosthetic component may not be well functioning, a loose component might be painless and surgeons might not have similar revision criteria [91], which further complicate the interpretation of results derived from observational studies.

Traditionally, implant migration in RSA studies is calculated as the migrated distance obtained at a specific time point compared to baseline by the use of signed values (signed values facilitate the differentiation of motion direction along / around a given axis), thereby making it possible to asses the dominating migration direction. However, it may be difficult to asses the true median (mean) migration under these circumstances, as the outcome might be close to zero even if large migrations along / around zero are observed. Consequently, we decided to calculate the prosthetic instability by computing the numerical migration compared to the last follow-up. Based on findings that early prosthetic slipping inside the cement mantle is a normal outcome due to loading [117, 118], this estimation also makes it possible to distinguish whether slipping is stabile or seems to increase due to increased debonding and development of cement fractures.

In the present RSA study (Paper I) we observed that the two stems had subsided and retroverted two years after surgery between both prosthesis-bone and prosthesis-cement when compared to baseline. For both stems (prosthesis-bone and prosthesis-cement) rotation around y-axis was the main observed instability. Most certainly the noted rotation around y-axis is a natural occurrence in any femoral stem due to the direction of forces acting on the hip joint [119]. Also retrieved stems (fixed and loose) have indicated possible stem rotation around y-axis due to an observation of increased surface wear on the antero-lateral and postero-medial stem side [120].

The Ti stem in our study demonstrated significantly more instability two years after surgery between prosthesis-bone than between prosthesis-cement in translation along x- and y-axis, and rotation around x- and z-axis, thereby suggesting a superior prosthesis-cement anchoring for the Ti stem. In contrast to Ti, no significant differences were observed for the CoCr stem between prosthesis-bone and prosthesis-cement instabilities during the same period; this indicates that the main instability occurred at the prosthesis-cement interface. In addition, prosthesis-cement instability was significantly higher for the CoCr stem three months after surgery (rotation around y-axis) and at two years follow-up (rotation around z-axis) when compared with the Ti stem. We did not observe any significant differences between the two stems regarding rotational prosthesis-cement instability around x- and y-axis two years postoperative. However, in relation to our power estimation a minimum sample size of 13 was calculated to achieve sufficient power (>80%), hence a type II error can not be ruled out (n=11 and n=9, CoCr and Ti, respectively) for this particular instability measure. Since it is more demanding to detect changes in rotations compared with translations, and the fact that we estimated three rigid bodies (i.e., prosthesis, cement and bone), another 10 patients should preferably have been included in every group to compensate for potentially inferior RSA images. Though, when assessing prosthesis-bone instability, CoCr rotated significantly more around y-axis than Ti did. It should be considered, however, that improved RSA images are expected in the future owing to the recent introduction of model-based RSA which do not require any prosthetic tantalum markers to asses the prosthetic rigid body [121]. Hence, care will only need to be taken to ensure optimal marker visualization in the cement and bone, respectively. This is likely to reduce the number of drop-outs usually encountered due to inferior RSA image quality.

It is well known that surface characteristics influences prosthesis-cement fixation strength, i.e. the rougher surface, the higher adhesion strength [122, 123]. The CoCr stem is supplied with a less rough beat blasted surface than the Ti stem, and this might be the main reason regarding the increased prosthesis cement instability observed in CoCr stems. In contrast, one must also take into consideration that increasing surface roughness may cause higher wear potential when the stem loosens [36, 122]. The ideal surface for cemented stems remains controversial, and stem durability may either be prolonged by an extension of the period with prosthesis-cement adhesion (obtained with a rougher surface), or through a prolonged stem function after prosthesis-cement loosening (achieved with a smoother surface) [122]. However, due to the increased wear potential observed for polished Ti alloy heads [51-54, 57, 124] it seems reasonable to suggest that Ti stem durability preferably should be achieved through a rough surface.

The Bi-Metric Ti stem has recently been evaluated in a different RSA study performed by *Ström* et al. [125]. In that study the stem was inserted with the same cement as in our study, and modern cementing technique was also applied. However, their mean migration between prosthesis-bone compared to baseline two years after surgery was different compared to our findings. Our Ti stem subsided 0.38 mm compared with their 0.06 mm migration in proximal direction, and our stems showed a higher rotation into retroversion (2.11º *versus* 0.47º, respectively). Some of the differences may be explained through different study designs (e.g., our patients were older, and our surgical approach was postero-lateral). In theory, periprosthetic bone necroses caused by mechanical, vascular and chemical induced damages [33] are unavoidable following a cemented THA, hence older age may result in a higher sensitivity due to reduced regeneration. Older age may in addition correlate with inferior bone quality, thus lowering the interfacial strength between cement and bone [126], but also the particular approach may have influenced the results [127].

One may ask what the clinical consequence of the observed migration obtained from RSA studies is? Stem subsidence two years after surgery has been claimed to be the best predictor of later revision [30]. Two years after surgery, both stems in the present study showed only minimal median subsidence both inside the cement mantle (0.10 *versus* 0.25 mm for Ti and CoCr, respectively), and between prosthesis-bone (0.38 *versus* 0.25 mm, respectively) with no significant differences between the two stems. However, several RSA studies have demonstrated that different stem designs show contrasting migration patterns (Table 6). In the study by *Alfaro-Adrián* et al. [135], the Charnley Elite stem demonstrated an early increased posterior head migration when compared to the Exeter stem, with the latter subsiding significantly more than the former. Recently, it has been shown that the 10-year survival for the Charnley Elite stems is only 83%, and early increased posterior head migration has been observed to be associated with reduced prosthetic longevity for that particular stem design [138]. In contrast, the Exeter stem demonstrates excellent survival despite increased subsidence [139]. Consequently, stem geometry and surface finish should be taken into consideration when later revision is predicted [117].

Author	Hips [a]	Stem	Surface (Ra)	Cement	Variation [g]
CoCr					
Nivbrandt et al. 1999 [128]	19 / 13	SHP	3.8 / 2.0 [e]	? [f]	1 [h]
Nivbrandt et al. 1999 [128]	20 / 18	Lubinus SP2	1.5	? [f]	1
Catani et al. 2005 [129] [b]	25 / 25	Lubinus SP2	1.5	Simplex	2
Ørskov et al. 2006 [130]	18 / 10	Bi-Metric	2.63	Palacos [f]	2
Ti					
Kärrholm et al. 1998 [131]	20 / 16	Tifit	grit-blasted	?	1 [i]
Alfaro-Adrián 1999 [132] [c]	? / ?	Hinek	matt / polish [e]	?	- [c]
Ørskov et al. 2006 [130]	17 / 13	Bi-Metric	7.64	Palacos [f]	2
Ström et al. 2006 [125]	16 / 16	Bi-Metric	7.64	Palacos [f]	3
Stainless steel					
Sundberg et al. 2005 [133]	32 / 21	C-stem	polished	Palacos [f]	3
Grant et al. 2005 [134]	17 / 17	Charnley Elite	matt	? [f]	- [j]
Alfaro-Adrián 2001 [135] [c]	13 [d] / 13 [d]	Charnley Elite	matt	CMW	- [c]
Alfaro-Adrián 2001 [135] [c]	14 [d] / 14 [d]	Exeter	polished	CMW	- [c]
Stefánsdóttir et al. 2004 [136]	22 / 22	Exeter	polished	Palacos [f]	4
Glyn-Jones et al. 2005 [137] [b]	21 / 21	Exeter	polished	CMW3G [f]	3
Glyn-Jones et al. 2005 [137] [b]	21 / 21	CPS-Plus	polished	CMW3G [f]	3

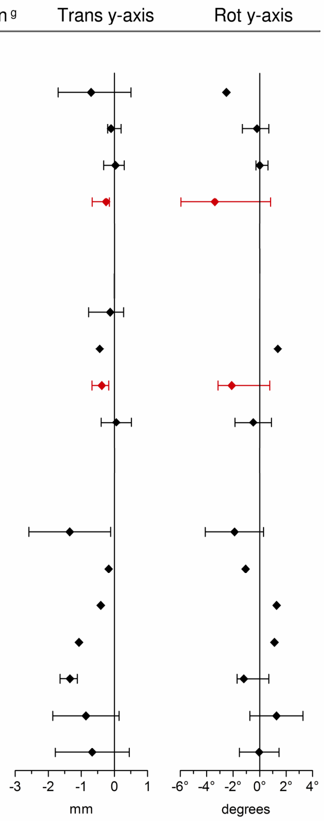

Table 6. Published stem translations (Trans) and rotations (Rot) along y-axis two years after surgery when compared to baseline. Negative values indicate subsidence and retroversion, respectively.

[a] Number of hips included for the Trans and Rot measurements, respectively.
[b] Tip of the stem was used instead of centroid measurements.
[c] The published migration rates at 1 and 2 years after surgery were accumulated and subsequently converted into absolute values to obtain comparable Trans and Rot data for the present analysis. Accordingly, variation data could not be presented.
[d] These values indicate number of hips investigated after 2 years follow-up (see note C).
[e] Surface roughness at proximal and distal part of the stem, respectively.
[f] Modern cementing technique was applied.
[g] Variation of the Trans and Rot data presented is shown as (1) range, (2) interquartile range, (3) 2SD calculated from published SD or SEM values, or (4) 95% confidence interval.
[h] In this study the published median Rot value exceeded the range noted in the same paper.
[i] No data was provided in the paper for the Rot values at two years follow-up.
[j] Variation data not specified in the paper.

The survival rate of the Bi-Metric Ti stem (collared version with unreported surface characteristics) has been reported to be 98% seven years after surgery [64], whereas no survival data regarding the later introduced CoCr stem has been published yet. Unfortunately, in our study both alloy and surface roughness differed between the two stems evaluated. To asses how alloy influence stem longevity both stems should have been supplemented with identical surface characteristics whereas identical alloy should have been used to evaluate the influence of surface characteristics. On the other hand, our study design did allow us to investigate differences in migration patterns between the particular Bi-Metric CoCr and Ti stem.

A universal periprosthetic bone resorption is a common observation following both cemented and cementless THA [48, 67, 140], with the most likely candidate being stress shielding due to alterations in the mechanical loading of the bone [44]. The largest amount of bone is mainly lost during the first six months after surgery, especially in Gruen zone VII, and is followed by only minor changes [106]. The latter resembles normal age related bone resorption (approximately 1% yearly) [141]. Accordingly, we only considered a 12 month follow-up period with DEXA (Paper II). We observed a general periprosthetic BMD loss around both stems investigated, except in zone I where a BMD gain was seen. The latter has been claimed to be caused by heterotropic ossification [142]. For both the Ti and CoCr stem, the largest BMD loss was seen in Gruen zone VII (13.6% and 12.7%, Ti and CoCr, respectively).

Also *Arabmotlagh* et al. [142] and *Venesmaa* et al. [106] measured the greatest BMD loss one year after surgery in that particular Gruen zone when they evaluated a Euroform and a Lubinus SPII stem, respectively. Both stems were cemented, and the reported BMD loss was 16.4% and 24.8%, respectively. In contrast, *Cohen* and *Rushton* [105] found a BMD resorption of only 6.7% in Gruen zone VII when they evaluated a cemented Charnley stem one year after surgery. The results should be reviewed in context with published survival data; the ten year survival rate of the Lubinus SP and Charnley stem have been reported to be 96.4% and 93%, respectively, when inserted due to OA and revised on behalf of aseptic loosening [24]. Accordingly, it is tempting to suggest that periprosthetic BMD evaluation around cemented stems, in a small group of patients, shows little correlation with stem survival in a whole population.

In our study no significant BMD differences were observed between the two stems in any of the seven Gruen zones investigated, either postoperative or after 12 months. As the observed SD in most Gruen zones was larger than the corresponding mean, a type II error can not be excluded. The precision of our DEXA measurements (i.e., CV%) were comparable to other studies [104, 107, 108]. However, due to huge biological BMD variations among patients during the follow-up period (average BMD around Ti stems varies from -0.14 g/cm^2 (loss) to +0.05 g/cm^2 (gain), and CoCr from -0.22 g/cm^2 to +0.11 g/cm^2, respectively) quite large sample sizes are needed. With a minimum sample size of 14 the present study demonstrates sufficient power (>80%) to determine a 0.1 g/cm^2 difference in the obtained average BMD between Ti and CoCr stems. It should also be taken into consideration that despite lesser rigidity of the investigated Ti stem (compared with a similar CoCr stem), the Ti stem still remains very much rigid in relation to cortical bone which has an average cortical bone rigidity of approximately 17 GPa [45]. In addition, DEXA does not differentiate whether a particular BMD loos is due to cortical bone loss (i.e., stress shielding) or increased bone porosity. The precise significance of reduced BMD resorption on primary prosthetic longevity remains unknown, but reduced BMD resorption may protect against periprosthetic bone fractures, and may improve revision surgery outcome as well.

Increased cement penetration into the acetabular bone has been observed to improve cup stability [89]. However, many factors influence cement penetration including magnitude and duration of the applied force, properties of the bone cement used, amount of bone bleeding, and also anatomy, porosity and not least preparation of the acetabular bone [76, 83, 126, 143, 144].

The success of a flanged cup has mainly been addressed to its hypothesized ability to increase cement pressurization at the time of implantation, thus improving cement penetration [92, 93]. When we inserted a flanged and an unflanged cup position-controlled using equivalent forces (Paper III) no significant differences regarding intra-acetabular pressures were found between flanged and unflanged cups inserted in either ceramic or paired cadaveric acetabuli. At this point no differences were found between rim and pole pressures in the cups investigated. When the cups were further pressurized (using force-control) the unflanged cups migrated significantly more towards the acetabular pole than flanged cups did when inserted in ceramic and paired cadaveric acetabuli, despite of a minimal force application (25 N). Most certainly, however, the migration susceptibility observed for the particular unflanged cup design is further increased due to the lack of cement spacers. We are aware that the sample size used to evaluate forces, intra-acetabular pressures and displacements in ceramic acetabular models was very small (the few samples were caused by technical computer problems). It should be considered, however, that the main aim of the study was to evaluate cement mantle thickness and penetration depths.

It has been suggested that the use of a flanged cup may correlate to a lower incidence of bottoming out [93]. To the best of our knowledge, there is no consistent classification concerning bottoming out. Using a tentative definition being cement mantle thickness less than 1 mm along any of the 29 test lines (in the ceramic acetabular model study), nine out of ten unflanged cups, and just two out of ten flanged cups demonstrated bottoming out ($p=0.002$). Close contact between PE and bone has been set in relation with reduced cup longevity [145]. It is thus tempting to suggest that the reduced cement mantle thickness observed in the unflanged cup experiments may have a negative impact on cup durability, but again the lack of cement spacers may have influenced the results. However, it should be taken into consideration that the use of a flanged cup may increase the incidence of an eccentric cement mantle [146]. Accordingly, care needs to be taking when adjusting the flanged cup to the particular acetabulum.

The porosity and preparation of the acetabular bone bed is set in relation with the degree of cement interdigitation, and removal of the subchondral bone plate has been observed to improve the cement-bone interface and to lower the interfacial stresses without impairing prosthetic stability [83, 147, 148]. We are aware that all cups inserted in both ceramic and cadaveric bone were implanted under superior conditions due to a dry acetabulum without any blood or bone-marrow to disrupt cement penetration [80, 86]. However, all prostheses were inserted under identical conditions, and the error is therefore systematic. To adjust for the improved conditions regarding a dry acetabulum we pressurized cement and prostheses with lesser force than usually performed in the clinic.

The overall cement penetration was higher in the ceramic study compared with cadaveric bone. The reason may lie in larger pore diameters and a completely open porous structure in ceramic. According to Poiseuille's law ($R = 8\eta L \times (\pi r^4)^{-1}$) where R denotes flow resistance, η viscosity, and L length of the pores with radius r [149], larger pore diameters give lesser flow resistance, thereby facilitating higher penetration. The deeper central penetration observed in the ceramic study can be explained by the higher pressure gradient at this location. In fact, this is confirmed by the second part of Poiseuille's law ($f = \Delta P \times R^{-1}$), in which the flow ($f$) of the liquid is governed by the pressure gradient (ΔP) and the flow resistance (R).

Since no differences in penetration depths were found between the cups tested when inserted in either ceramic or paired cadaveric acetabuli, it may indicate that cement penetration occurs primarily during cement pressurization prior to cup insertion. Thus, when it is time to insert the cup the cement might simply be too viscous to permit further penetration even with a flanged cup design. Apparently, the flanged cup reduces cement leakage during insertion; especially when compared to a cup design lacking cement spacers, and the increased cement volume observed around the flanged cups in the present cadaveric study must have been caused by a thicker cement mantle. In most studies, however, cement penetration depth and cement mantle thickness are not differentiated, and the total is usually referred as the cement mantle. Though, if possible, both cement penetration depth and cement mantle thickness should be taking into consideration. As flanged cups did not induce increased cement penetration, it seems unlikely that the superior clinical outcome observed among flanged cups [90, 91] may originate from increased cement penetration. Both wear and joint fluid pressure, however, has been suggested to influence aseptic loosening [31, 40-42], and it is thus tempting to suggest that the flange may protect the interfaces against these specific parameters, hence increasing cup longevity.

In conclusion, Ti and CoCr stems were inserted in comparable groups of patients using modern cementing technique, a centralizer and Palacos cement. A minimum two mm cement mantle around the stems was obtained, and both stems had a rough surface finish (7.64 and 2.63 microns, Ti and CoCr, respectively). Under these circumstances the Ti stem demonstrated less rotational instability around z- (prosthesis-cement) and y-axis (prosthesis-bone) two years after surgery when compared with the CoCr stem. Further follow-up (clinical and with RSA) at 5-10 years will help determine if the increased early instability observed for the CoCr stems may indeed affect stem survival compared to the Ti stem. When assessing periprosthetic BMD changes around Ti and CoCr no significant differences were observed between stems suggesting that even this particular Ti stem was too rigid to reduce periprosthetic bone loss. Flanged and unflanged cups produced similar (and even) intra-acetabular pressures during position-controlled insertion. During force-controlled pressurization the unflanged cups migrated significantly more towards the acetabular pole (under the production of an increased pole pressure) and created a thinner cement mantle than the flanged cups did. However, no significant differences were observed between cups regarding cement penetration depth. Most certainly the main cement penetration occurs when the cement is pressurized prior to cup insertion; when it is time to insert the cup, the cement is too viscous to permit further penetration. It seems doubtful that the superior outcome observed among flanged cups is caused by an improved cement penetration, and the main role of the flange might be to protect the interfaces against joint fluid pressure and wear debris, thereby increasing cup durability.

5. Summary

Aseptic loosening is well known to be the main limiting factor regarding THA longevity. Solving the problem of aseptic loosening, however, is complicated through a multi-factorial mechanical / biological genesis. During the last two decades, divagating stem revision rates have been reported for cemented Ti stems, and their further use have been debated. Today CoCr has widely replaced Ti in new cemented stem designs, but clinical evaluation is scarce. For a given stem size Ti is less rigid than CoCr, and computer simulation studies have predicted increased interfacial stresses, but also reduced periprosthetic bone loss if a Ti stem (when compared to CoCr) is inserted.

In a prospective randomized study we compared two rough cemented stems with the same geometry, but different alloy (CoCr (n=20) *versus* Ti (n=20)), using RSA to investigate stem instability between prosthesis-cement and between prosthesis-bone. All participating patients were 60-75 years old, and had a cemented THA performed due to primary OA. Two years after surgery CoCr stems were significantly more unstable than Ti in prosthesis-cement rotation around z-axis, and in prosthesis-bone rotation around y-axis, indicating that, for this particular stem design, inserted under the given circumstances, CoCr might be inferior to Ti. Further follow-up at 5–10 years (clinical and with RSA) will help determine if the increased early instability observed for CoCr stems may affect stem longevity compared to Ti.

Furthermore, periprosthetic BMD was assessed in the same patients using DEXA. One year after surgery, however, no significant BMD differences were found between the two groups in any of the seven Gruen zones investigated. These results indicated that even this particular Ti stem was too rigid to reduce periprosthetic bone loss.

The use of a flanged PE cup has demonstrated both less postoperative demarcation at the cement-bone interface and superior survival regarding aseptic loosening. The success of the flanged cup has mainly been addressed to its ability to increase cement pressurization at the time of implantation and thereby cement penetration. In an experimental study employing both ceramic acetabular models and paired cadaveric acetabuli we observed that flanged cups produced a significantly thicker cement mantle with less bottoming out than unflanged cups did. In contrast, no significant differences in cement penetration depths were found between the cups. The latter may indicate that the main penetration occurs during cement pressurization prior to cup insertion, and when it is time to insert the cup, the cement has turned too viscous to permit further penetration. It thus seems doubtful that the better outcome associated with flanged cups is due to improved cement penetration. In contrast,

the main function of the flange might be to protect the interfaces against joint fluid pressure and wear particles, hence increasing cup longevity.

6. Summary in Danish

Aseptisk proteseløsning udløses af såvel biologiske som mekaniske faktorer og er den hyppigste årsag til at en kunstig hofte skal udskiftes. I løbet af de sidste 20 år er der offentliggjort varierende holdbarheder af cementerede lårbensproteser, der er fabrikeret i Ti, og metallets fremtidige relevans i kombination med cement er derfor uklar. CoCr har i dag stort set erstattet Ti i nydesignede cementerede lårbensproteser, men den kliniske evaluering af disse protesers holdbarhed er endnu begrænset. For en given protesestørrelse er Ti mere elastisk end CoCr, og computer-simuleringsstudier har forudsagt en øget belastning af interfaserne, men også et reduceret periprostetisk knogletab, hvis en Ti lårbensprotese, sammenlignet med CoCr, indsættes.

I et prospektivt randomiseret RSA studie sammenlignedes protese-knogle og protese-cement instabiliteten hos to cementerede lårbensproteser med ru overflade og ens geometri, men fremstillet i hhv. Ti (n=20) og CoCr (n=20). Samtlige patienter var 60-75 år gamle, og alle fik indsat en total cementeret hofteprotese p.g.a. primær slidgigt i hoften. To år efter operationen var CoCr proteserne signifikant mere ustabile end Ti i protese-cement rotationen omkrig z-axen og i protese-knogle rotationen omkring y-axen, hvilket tyder på at den pågældende CoCr protese muligvis har dårligere holdbarhed end Ti. Yderligere opfølgning efter 5–10 år (klinisk og med RSA) vil bidrage til at bestemme om den øgede tidlige instabilitet, som blev observeret for CoCr proteserne, vil påvirke protesens langstids-holdbarhed sammenlignet med Ti.

Periprostetisk BMD (målt ved DEXA) blev undersøgt hos de samme patienter. Et år efter operationen var der ingen signifikant forskel i periprostetisk BMD i de syv undersøgte Gruen zoner hos de to grupper. Resultaterne peger på at den pågældende Ti lårbensprotese var for rigid til at kunne reducere det periprostetiske knogletab.

Der er rapporteret om såvel mindre postoperativ opklaring mellem cement-knogle interfasen som øget modstandsdygtighed overfor aseptisk proteseløsning, såfremt der anvendes en PE hofteskålsprotese med krave. Ovennævnte succes er blevet tilskrevet kravens evne til at øge cementtrykket under implantationen og dermed også cementpenetrationen. I et eksperimentielt studie, hvor der anvendtes såvel en keramisk hofteskålsmodel som parrede kadaver hofteskåle, blev det observeret at hofteskålsproteser med krave var omgivet af en signifikat tykkere cementkappe med mindre 'bottoming out' end hofteskålsproteser uden krave. Kraven formåede derimod ikke at øge penetrationsdybden, hvilket synes at indikere at hovedparten af penetrationen fortrinsvis finder sted når cementen trykkes mod knoglen før hofteskålsprotesen indsættes; når det er tid til at indsætte protesen, er cementen sandsynligvis blevet for viskøs til at yderligere penetration er mulig. Det er derfor tvivlsomt at den bedre holdbarhed, som er observeret for hofteskålsproteser med krave, skyldes bedre cementpenetration. Det må derimod formodes at kravens funktion hovedsagelig består i at beskytte interfaserne mod øget ledvæsketryk og slidpartikler, hvorved hofteskålsprotesernes holdbarhed øges.

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Paper I

Titanium stem is more stable than cobalt chromium in cemented THA

Two-year follow-up

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Abstract

Background During the last two decades, divagating stem revision rates have been reported for cemented titanium (Ti) stems, and their further use have been debated. Today cobalt chromium (CoCr) has widely replaced the Ti alloy in new cemented stem design, but clinical evidence is scarce.

Methods In a prospective study we randomly allocated forty patients (60 to 75 years old) with primary hip osteoarthritis to receive a CoCr stem (n=20) or a Ti stem (n=20) for total cemented hip arthroplasty. Both stems were rough and had equal geometry. Patients were followed for 2 years using RSA to investigate stem instability between prosthesis-cement and between prosthesis-bone.

Results Two years after surgery CoCr stems were significantly more unstable than Ti stems in prosthesis-cement rotation around z-axis ($p=0.04$) and in prosthesis-bone rotation around y-axis ($p=0.05$).

Interpretation Since CoCr stems demonstrated higher rotational instability between both prosthesis-cement and prosthesis-bone two years after surgery, it may indicate that, for this particular stem design, inserted under the given circumstances, CoCr was inferior to Ti.

Introduction

Aseptic loosening is well known to be the main limiting factor regarding longevity of a total hip arthroplasty (THA). Solving the problem of aseptic loosening, however, is complicated through a multi-factorial mechanical/biological genesis, and a varying interval between prosthesis insertion and onset of symptoms (Barrack 2000).

Due to superior mechanical strength, high biocompatibility and reduced rigidity of the titanium (Ti) alloy, introduction of the cemented Ti stems in the mid 1970s were associated with high expectations (Sarmiento et al. 1979). However, during the last two decades, divagating stem revision rates have been reported, and further use of cemented Ti stems has been debated. Among the early cemented monoblock Ti stems, the straight STH stem demonstrated 96.4% radiographic survivorship 11 years after surgery (Sarmiento et al. 1988), whereas less optimistic results were obtained with both the DF-80 (Robinson et al. 1989) and McKee-Arden stem (Sott and Rosson 2002). Later modularity was introduced, with a Ti head articulating against polyethylene (PE) constituting the most common bearing surfaces. From retrieval studies and wear measurements it became evident that Ti heads were highly susceptible to third-body damage and tended to produce more PE wear than cobalt chromium (CoCr) heads (Nasser et al. 1990, Minakawa et al. 1998, Lombardi Jr. et al. 1989, Buly et al. 1992, McKellop et al. 1990, Bankston et al. 1993), and the Ti head became abandoned. However, conflicting findings regarding the durability of cemented Ti stems continued. Inferior results were obtained with the 3M Capital (Harvey et al. 2002), the ITH (Jacobsson et al. 1995) and the Triad stem (Tompkins et al. 1994) despite of CoCr-PE bearing surfaces. The main cause was considered to be the reduced rigidity of Ti alloy, yet, modern cementing technique was not used, which may have influenced the outcome (Herberts and Malchau 2000). In fact, Ti stems inserted with high viscosity cement have shown excellent stem survival (Acklin et al. 2001). We therefore hypothesized that a crucial factor regarding the survival of a Ti stem depends on the establishment of high-quality interfaces between prosthesis-cement and cement-bone. We designed a prospective randomized study to compare two cemented stems produced from different alloy (Ti *versus* CoCr) using radiostereometry (RSA) to investigate fixation.

Patients and Methods

The study was accepted by the local ethical committee (Ref: M-2351-02, January 23rd 2002), and was carried out in full agreement with the Helsinki declaration. Eligible for the study were patients between 60 and 75 years old who were to have a cemented THA performed due to primary hip osteoarthritis. Patients with a priori known neurovascular disorders in the leg of interest and patients with a priori known malignant diseases were not included into the study. Each patient could only enter the study once, and only with one hip.

After informed oral and written consent, forty patients were randomized, using sealed envelopes, to receive a femoral stem of either Ti (n=20) or CoCr (n=20). All patients were operated in spinal anaesthesia by one out of three experienced hip surgeons (AZ, CS or PR) between January 2003 and October 2004. The patients were mobilized the day after surgery without any weight bearing restrictions. Prophylactic antibiotics and anti-thrombosis treatment were given, and postoperative pain was treated in accordance with the standard regime in the orthopaedic department, with the exception of NSAID which were avoided.

All patients received a Bi-Metric stem (Biomet, Warsaw, IN, USA), with identical geometry (tapered, collarless, and ceramic beat blasted), only differing in alloy (Ti6Al4V or CoCrMo) and surface roughness (Figure 1). To enable RSA, the manufacturer had supplied every stem with three towers (each one containing a 0.8 mm tantalum bead), located at the stem tip, shoulder and proximal medial, respectively. The arithmetical mean surface roughness (Ra) was 7.64 and 2.63 microns for the Ti and CoCr stems, respectively. In addition, every patient obtained 1) a modular 28 mm CoCr femoral head (Biomet), 2) a Sleeve centralizer (Biomet), 3) a Buck Femoral Restrictor (Smith & Nephew, Inc., Andover, MA, USA), and 4) an all-polyethylene SHP cup (Biomet). All components were inserted with Refobacin-Palacos R cement (Biomet), vacuum mixed in the Optivac mixing system (Biomet).

The operating room temperature was 21^{o} C. The cement was stored at 4º C, and was delivered to the operating room just prior to the acetabular and femoral reaming, respectively. All prosthetic components were stored at room temperature. The approach was postero-lateral, and the posterior joint capsule was removed in all cases.

Acetabulum was over-reamed to give a final 3 mm cement mantle, and eight to ten anchoring holes (6 mm in diameter and 6 mm deep) were drilled in the superior acetabulum. Afterwards, anchoring holes were cleaned with a curette followed by pulse lavage, and drying with gaze. Depending on size, acetabulum was cemented with either 40 or 60 g cement. Two minutes after the onset of mixing, cement was applied in the acetabulum, pressurized for two minutes, followed by insertion of the acetabular prosthesis, and finally pressurized till curing.

The femoral canal was over-reamed to provide a final 2 mm cement mantle. After test reposition, the bone canal was cleaned with pulse lavage, followed by suction, and application of a restrictor 2 cm distal to the tip of the final stem. Afterwards, a 0.8 mm tantalum bead was positioned on top of the plug using a small plastic tube. Depending on size, the femoral canal was cemented with either 80 or 120 g cement. Twenty 0.8 mm tantalum beads were applied to the mixing container in case of 80 g cement; whereas 30 beads were used if 120 g cement were mixed. Two minutes after onset of mixing, the femoral canal was retrograde filled with cement, followed by pressurization for two minutes. The stem was inserted, and two additional 0.8 mm tantalum beads were positioned in the superior cement (medial and lateral to the stem, respectively), followed by pressurization till cement curing. Finally, a minimum of 3 tantalum beads (0.8 mm) were inserted in both the smaller and lesser trochanter. No capsule plasty was performed after insertion of components.

Radiostereometry (RSA)

RSA was performed two days after surgery, and repeated after 3, 6, 12, and 24 months. All takings were performed with the patient in the supine position. Both X-ray tubes were above the patient, positioned at a 20^{o} angle to the vertical, and approximately 1.60 m above the two roentgen cassettes. The calibration box (Carbon Box Esbjerg, Medis Medical Imaging Systems bv, Leiden, The Netherlands), was placed between the patient and the radiographic films. All images were digitized with an exception of 8 takings; these radiographies were secondary digitized (200 dpi resolution) using an Epson Twain Pro, GT-1200 scanner. Migration between prosthesis-bone and prosthesis-cement (x,y,z translations and rotations, see Figure 2) were analyzed blinded and were performed by the same person (MØ) using the software RSA-CMS version 4:0 (Medis medical imaging systems bv), which allows a maximum rigid body error of 0.3 mm (Vrooman et al. 1998). For the individual patient, identical tantalum markers were always used to define the rigid body.

Precision was based on ten random patients who had double examinations performed (including reposition) within 10 minutes. The smallest detectable numerical migration was defined as the upper 99% confidence interval of the precision measurements (Stefánsdóttir et al. 2004).

Migration was calculated as the median signed translation or rotation after two years compared to baseline, and was evaluated for both prosthesis-bone and prosthesis-cement.

Instability was calculated as the numerical translation or rotation compared with the last follow-up, and was estimated for both prosthesis-bone and prosthesis-cement. Patients with incomplete data (due to inferior quality of RSA images) were assumed to have the same monthly migration between two analyzable follow-ups.

Harris Hip Score (HHS)

Daily function and pain in the affected hip joint was evaluated through HHS (Harris 1969) preoperative and repeated 12 months after surgery.

Statistical Analysis

A minimum sample size of 13 was calculated to achieve sufficient power in the RSA study (>80%) based on published y rotational variation data (signed values) between prosthesis-bone (Thanner et al. 1995) and assuming a 0.8º difference in the obtained y rotation between Ti and CoCr stems. Repeated measurements were evaluated with the Friedman repeated measures ANOVA on ranks test, groups were compared with the Mann-Whitney U test, and correlations were made with the Spearman rank correlation test, with values for $p \leq 0.05$ being regarded as significant. Data is presented as median values with the interquartile range in brackets, unless otherwise stated.

Results

No intra-operative complications were observed. A male patient with a CoCr stem and a female patient with a Ti stem were excluded from the study due to a cup revision based on re-occurring dislocations, and withdrawal of consent, respectively, thus leaving 19 patients in both groups. No significant differences of baseline characteristics and HHS were found between the groups (Table 1). Also no differences were found between neck lengths; stem or cup sizes (data not shown). The precision of the RSA examinations were 0.10, 0.11 and 0.27 mm for translations along x-, y- and z-axis, respectively, and 0.25, 0.49 and 0.17° for rotations around x-, y- and z-axis, respectively.

Stem migration

Two years after surgery both stems (Ti and CoCr) had subsided and rotated into retroversion between both prosthesis-bone and prosthesis-cement (Table 2). Additionally, both stems showed posterior translation and varus tilting between prosthesis and bone. No significant differences, however, were found between the two stems regarding these migrations (Table 2).

Stem instability

For both stems, the level of instability did not change significantly throughout the four recorded periods in any of the six directions. This was observed for both prosthesis-bone and prosthesis-cement instabilities (ANOVA on ranks: $p>0.05$ in all analyses). CoCr was found to be significantly more unstable than Ti at rotation around y-axis (1.95º (0.85 – 2.86) *versus* 0.29º (0.11 – 1.06), p=0.01, respectively) three months after surgery and around z-axis (0.25º (0.07 – 0.54) *versus* 0.07º (0.02 – 0.16), p=0.04, respectively, Figure 3a) two years after surgery, both at the prosthesis-cement interface. CoCr also demonstrated higher rotational instability between prosthesis-bone around y-axis two years after surgery when compared with Ti (3.91º (1.85 – 5.14) *versus* 1.04º (0.71 – 2.58), p=0.05, respectively, Figure 3b). For the remaining translations and rotations at both prosthesis-bone and prosthesis-cement, no significant differences were found between the two stems. Comparing prosthesis-bone and prosthesis cement instabilities two years after surgery, Ti stems were found to be significantly more unstable between prosthesis-bone than between prosthesis-cement in translation along x- and y-axis, as well as in rotation around x- and z-axis (Table 3). In contrast, CoCr stems showed no such differences. BMI, gender, stem sizes, neck lengths and postoperative HHS did not correlate to any of the prosthesis-bone or prosthesis-cement instability measures.

Discussion

Finite element studies have predicted an elevated stress level in the proximal cement mantle, and thus an increased risk of cement fracture for cemented Ti stems when compared to CoCr (Huiskes 1990, Lewis et al. 1984). However, reduced rigidity may not necessarily be the provoking factor if a cemented Ti stem demonstrates early loosening (Ramaniraka et al. 2000) as cross sectional area and stem geometry has been observed to dominate over alloy rigidity in the mechanical behaviour of cemented femoral stems (Christel et al. 1988). Accordingly, a stem made from CoCr is nearly twice as rigid as a Ti stem (the alloy rigidity is 200 and 110 GPa, respectively, (Huiskes 1990)), only if the two stems are comparable in regard to stem geometry and cross-sectional area.

Since aseptic loosening is multifactorial, prosthetic design, i.e. alloy, geometry and surface characteristics (Hinrichs et al. 2003, Robinson et al. 1989, Sarmiento et al. 1988), cementing technique (Hendrich et al. 2005, Maurer et al. 2001, Schweizer et al. 2003), cement mantle thickness (Ramaniraka et al. 2000), type of bone cement (Espehaug et al. 2002, Thanner et al. 1995), prosthetic compilation (Emerson Jr. et al. 2002) and patient related factors (Flugsrud et al. 2006) should all be taken into consideration when evaluating prosthetic longevity. In general, when reviewing the literature concerning cemented Ti stem durability, the main focus has been on the particular stem geometry whereas information on the remaining, but crucial parameters is scarce.

Traditionally, implant migration in RSA studies is calculated as the migrated distance obtained at a specific time point compared to baseline by the use of signed values (signed values facilitate the differentiation of motion direction along/around a given axis), thus making it possible to asses the dominating migration direction. However, it may be difficult to asses the true median (mean) migration under these circumstances, as the outcome might be close to zero even if large migrations along/around zero are observed. Consequently, we decided to calculate the prosthetic instability by computing the numerical migration compared to the last follow-up. Based on findings that early prosthetic slipping inside the cement mantle is a normal outcome due to loading (Duffy et al. 2006, Huiskes et al. 1998), this estimation also makes it possible to distinguish whether slipping is stabile or seems to increase due to increased debonding and development of cement fractures.

In the present study we observed that the two stems had subsided and retroverted two years after surgery between both prosthesis-bone and prosthesis-cement when compared to baseline (Table 2). For both stems (prosthesis-bone and prosthesis-cement) rotation around y-axis was the main observed instability (Table 3). Most certainly the noted rotation around y-axis is a natural occurrence in any femoral stem due to the direction of forces acting on the hip joint (Berme and Paul 1979). Also retrieved stems (fixed and loose) have indicated possible stem rotation around y-axis due to an observation of increased surface wear on the antero-lateral and postero-medial stem side (Howell et al. 2004).

The Ti stem in the present study demonstrated significantly more instability two years after surgery between prosthesis-bone compared with prosthesis-cement in translation along x- and y-axis, and rotation around x- and z-axis (Table 3), thereby suggesting a superior prosthesis-cement anchoring for the Ti stem. In contrast to Ti, no significant differences were observed for the CoCr stem between prosthesis-bone and prosthesis-cement instability during the same period (Table 3); this indicates that the main instability occurred at the prosthesis-cement interface. Also, prosthesis-cement instability was significantly higher for the CoCr stem after three months (rotation around y-axis) and after two years (rotation around z-axis, Figure 3a) compared with the Ti stem. We did not observe any significant differences between the two stems regarding rotational prosthesis-cement instability around x- and y-axis two years postoperative, though a type II error can not be ruled out (n=11 and n=9, CoCr and Ti, respectively). However, when assessing prosthesis-bone instability, CoCr rotated significantly more around y-axis than Ti did (Figure 3b).

It is well known that surface characteristics influences prosthesis-cement fixation strength, i.e. the rougher surface, the higher adhesion strength (Crowninshield et al. 1998, Wang et al. 2003). The CoCr stem is supplied with a less rough beat blasted surface than the Ti stem, and this might be the main reason regarding the increased prosthesis cement instability observed in CoCr stems. In contrast, one must also take into consideration that increasing surface roughness may cause higher wear potential when the stem loosens (Verdonschot and Huiskes 1998, Crowninshield et al. 1998). The ideal surface for cemented stems remains controversial, and stem durability may either be prolonged by an extension of the period with prosthesis-cement adhesion (obtained with a rougher surface), or through a prolonged stem function after prosthesis-cement loosening (achieved with a smoother surface) (Crowninshield et al. 1998). However, due to the increased wear potential observed for polished Ti alloy heads (Bankston et al. 1993, Buly et al. 1992, Lombardi Jr. et al. 1989, McKellop et al. 1990, Minakawa et al. 1998, Nasser et al. 1990) it seems reasonable to suggest that Ti stem durability preferably should be achieved through a rough surface.

The Bi-Metric Ti stem has recently been evaluated in a different RSA study performed by Ström et al. (2006). In that study the stem was inserted with the same cement as in our study, and modern cementing technique was also applied. However, their mean migration between prosthesis-bone compared to baseline two years after surgery was different compared to our findings. Our Ti stem subsided 0.38 mm compared with their 0.06 mm migration in proximal direction, and our stems showed a higher rotation into retroversion (2.11º *versus* 0.47º, respectively). Some of the differences may be explained through different study designs (e.g., our patients were older, and our surgical approach was postero-lateral). In theory, periprosthetic bone necroses caused by mechanical, vascular, and chemical damages (Jefferiss et al. 1975) are unavoidable following a cemented THA; hence older age may result in a higher sensitivity due to reduced regeneration. Older age may in addition correlate with inferior bone quality, thus lowering the interfacial strength between cement and bone (Graham et al. 2003).

One may ask what the clinical consequence of the observed migration obtained from RSA studies is? Stem subsidence at two years after surgery has been claimed to be the best predictor of later revision (Kärrholm et al. 1994). Two years after surgery, both stems in the present study showed only minimal median subsidence both inside the cement mantle (0.10 vs. 0.25 mm for Ti and CoCr, respectively), and between prosthesis-bone (0.38 vs. 0.25 mm, respectively) with no significant differences between the two stems. However, several RSA studies have demonstrated that different stem designs show contrasting migration patterns (Kärrholm et al. 1998, Stefánsdóttir et al. 2004, Sundberg et al. 2005, Thanner et al. 1995) and consequently, stem geometry and surface finish should be taken into consideration when later revision is predicted (Huiskes et al. 1998). The survival rate of the Bi-Metric Ti stem (collared version) has been reported to be 98% seven years after surgery (Tarasevičius et al. 2005), whereas no survival data regarding the later introduced CoCr stem has been published yet.

In the present study Ti and CoCr stems were inserted in comparable groups of patients using modern cementing technique, a centralizer and Palacos cement. A minimum two mm cement mantle around the stem was obtained, and both stems had a rough surface finish (7.64 and 2.63 microns, Ti and CoCr, respectively). Under these circumstances the Ti stem demonstrated less rotational instability around z (prosthesis-cement) and y-axis (prosthesis-bone) two years after surgery when compared with the CoCr stem. Further follow-up (clinical and with RSA) at 5-10 years will illustrate if the increased early instability observed for the CoCr stems may affect stem survival compared to the Ti stem.

Contributions of authors

MØ contributed in study design, patient recruitment, patient randomization, data acquisition, data analysis, and manuscript preparation. AZ, CS and PR contributed in study design, patient recruitment, operative procedures, and manuscript revision. CSS contributed in study design, data acquisition, and manuscript revision. KS contributed in study design and manuscript revision.

Conflict of interest and funding

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Table 1. Baseline characteristics and Harris Hip Scores (HHS)

	CoCr (n=19)	Ti (n=19)
Age (years)	70.2 (67.9 – 72.6)	69.8 (66.4 – 72.7)
Gender (female/male)	9 / 10	12 / 7
BMI (kg x m^{-2})	27.6 (25.5 – 30.3)	27.3 (23.2 – 29.8)
HHS preoperative	49 (38 – 55)	48 (36 – 57)
HHS one year postoperative	97 (92 – 100)	98 (83 – 98)

Median values with interquartile rage in brackets are expressed. No significant differences were found between groups.

Table 2. RSA migration after two years

	CoCr PB Trans n=18, Rot n=10	Ti PB Trans n=17, Rot n=13	p-value
Trans x (mm)	-0.06 (-0.40 – 0.34)	-0.01 (-0.37 – 0.35)	0.83
Trans y (mm)	-0.25 (-0.67 – -0.15)	-0.38 (-0.68 – -0.17)	0.82
Trans z (mm)	-0.41 (-0.69 – 0.23)	-0.22 (-1.15 – 0.15)	0.55
Rot x (°)	-0.04 (-0.20 – 0.19)	0.22 (-0.71 – 1.03)	0.35
Rot y (°)	-3.39 (-5.95 – 0.83)	-2.11 (-3.14 – 0.78)	0.29
Rot z (°)	0.76 (0.24 – 1.48)	0.45 (-0.28 – 0.75)	0.14
	CoCr PC Trans n=14, Rot n=11	**Ti PC** Trans n=16, Rot n=9	
Trans x (mm)	0.04 (-0.23 – 0.14)	-0.04 (-0.18 – 0.16)	0.97
Trans y (mm)	-0.25 (-0.43 – -0.15)	-0.10 (-0.35 – -0.01)	0.21
Trans z (mm)	-0.26 (-0.71 – 0.15)	0.31 (-0.40 – 0.46)	0.07
Rot x (°)	0.18 (-0.67 – 0.48)	-0.37 (-0.73 – 0.12)	0.16
Rot y (°)	-1.66 (-3.91 – 1.10)	-0.69 (-2.02 – -0.15)	0.91
Rot z (°)	-0.03 (-0.16 – 0.51)	0.09 (-0.02 – 0.36)	0.38

Abbreviations: PB denotes prosthesis-bone, PC denotes prosthesis-cement, Trans denotes translation and Rot denotes rotation. Migration directions (negative values/positive values) are: Trans x, medial/lateral; Trans y, caudal/cranial; Trans z, posterior/anterior; Rot x, posterior tilt/anterior tilt; Rot y, retroversion/anteversion; Rot z, valgus/varus. Data is presented as median values with the interquartile range in brackets.

Table 3. RSA instability within 12 – 24 months

	CoCr PB Trans n=18, Rot n=10	CoCr PC Trans n=14, Rot n=11	p-value
Trans x (mm)	0.20 (0.11 – 0.48)	0.15 (0.08 – 0.32)	0.31
Trans y (mm)	0.12 (0.04 – 0.28)	0.07 (0.03 – 0.25)	0.48
Trans z (mm)	0.41 (0.13 – 0.84)	0.28 (0.09 – 0.73)	0.56
Rot x (°)	0.55 (0.17 – 1.22)	0.53 (0.20 – 0.98)	0.97
Rot y (°)	3.91 (1.85 – 5.14)	1.78 (0.50 – 4.45)	0.15
Rot z (°)	0.26 (0.05 – 0.69)	0.25 (0.07 – 0.54)	0.97
	Ti PB Trans n=17, Rot n=13	**Ti PC** Trans n=16, Rot n=9	
Trans x (mm)	0.30 (0.16 – 0.40)	0.14 (0.07 – 0.22)	0.02
Trans y (mm)	0.26 (0.15 – 0.31)	0.06 (0.03 – 0.16)	0.004
Trans z (mm)	0.66 (0.27 – 0.87)	0.38 (0.16 – 0.53)	0.08
Rot x (°)	0.47 (0.25 – 1.71)	0.11 (0.06 – 0.31)	0.04
Rot y (°)	1.04 (0.71 – 2.58)*	0.50 (0.34 – 0.88)	0.22
Rot z (°)	0.31 (0.17 – 0.52)	0.07 (0.02 – 0.16)*	0.02

Abbreviations: PB denotes prosthesis-bone, PC denotes prosthesis-cement, Trans denotes translation and Rot denotes rotation. Data is presented as median values with the interquartile range in brackets. * $p \leq 0.05$ CoCr *versus* Ti

Figure 1

Photograph of the inserted Bi-Metric stems made from either Ti or CoCr.

Figure 2

Migration directions of the prosthesis measured with RSA.

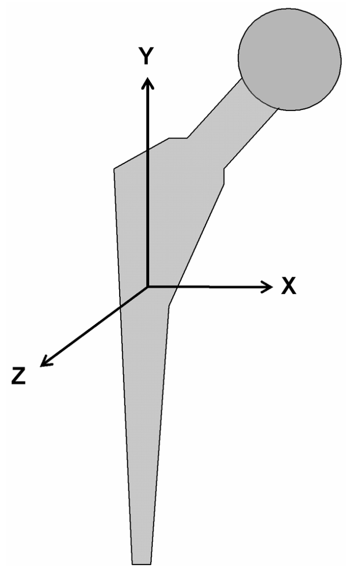
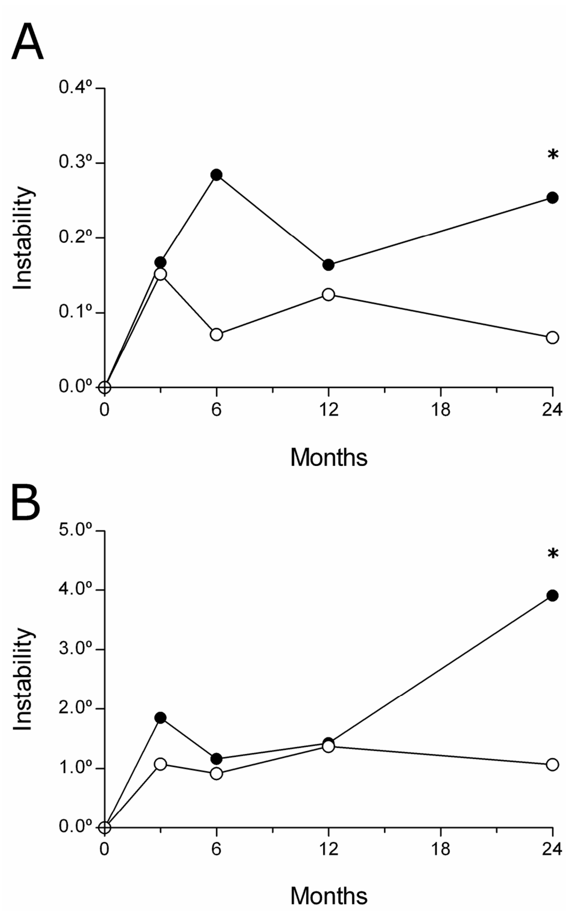


Figure 3 (A+B)

Stem instability obtained from RSA measurements for prosthesis-cement rotation around z-axis (panel A) and prosthesis-bone rotation around y-axis (panel B). Open circles (○) denote Ti stems, and closed circles (●) CoCr stems. Median values are expressed (interquartile ranges are shown in Table 3). * $p \leq 0.05$ Ti *versus* CoCr.



Paper II

Early periprosthetic bone changes around cemented titanium and cobalt chromium stems

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Abstract

Reduced periprosthetic bone mineral density, especially in the calcar region, is a common observation following cemented total hip arthroplasty, with the most likely candidate being stress shielding due to an altered mechanical loading pattern. As a titanium (Ti) stem is nearly half as rigid as an identical stem manufactured from cobalt chromium (CoCr), reduced stress shielding and bone resorption has been predicted for a Ti stem when compared to CoCr. In a prospective randomized study we evaluated two cemented stems with equal geometry made from either Ti (n=20) or CoCr (n=20) using dual-energy X-ray absorptiometry to estimate periprosthetic bone mineral density changes in patients who had a primary total hip arthroplasty performed due to osteoarthritis. Twelve months after surgery, a universal relative bone mineral density loss was observed around both stems, whereas bone gain was seen in Gruen zone I. For both stems the main resorption was noted in Gruen zone VII. No significant differences, however, were found between Ti and CoCr stems, suggesting that the particular Ti stem was too rigid to reduce periprosthetic bone loss.

Introduction

Periprosthetic bone loss, in particular in the calcar region, is frequently observed following total hip arthroplasty (THA) [1, 20]. To be visualized on ordinary radiographs, the bone mineral density (BMD) loss needs to be approximately 30% [7]. By the introduction of dual-energy X-ray absorptiometry (DEXA), however, it became possible to detect even small BMD changes around inserted hip stems, while keeping a high accuracy with the particular femur positioned in a controlled neutral rotation [5]. An early postoperative DEXA examination of the involved region should be used as reference if possible [17]. The most likely candidate for periprosthetic bone resorption subsequent to THA is stress shielding due to altered mechanical loading pattern [18], owing to different rigidity in the femoral bone and stem, respectively [21, 24]. Femoral bone rigidity is mainly influenced by the quantity and distribution of cortical bone [3], whereas stem rigidity is a consequence of stem geometry, cross sectional area and rigidity of the particular alloy [4]. Accordingly, a stem made from cobalt chromium (CoCr) is nearly twice as rigid as a titanium (Ti) stem (the alloy rigidity is 200 and 110 GPa, respectively [14]), only if the two stems are comparable in regard to stem geometry and cross-sectional area.

Finite element studies have predicted reduced periprosthetic bone resorption around Ti stems (cemented and cementless) when compared to similar stems manufactured from CoCr [14, 18]. Clinical studies have observed less bone resorption around Ti stems *versus* CoCr stems in both cemented [20] and cementless studies [8, 13, 16], but only Kim [16] evaluated stems (cementless) with identical geometry. It remains unknown whether a cemented Ti stem may reduce bone resorption as well. Consequently we designed a prospective randomized study to compare two cemented stems (Ti *versus* CoCr) with the same geometry to investigate the early periprosthetic BMD changes.

Patients and Methods

The study was accepted by the local ethical committee (Ref: M-2351-02), and was carried out in full agreement with the Helsinki declaration. After informed oral and written consent, forty patients between 60 and 75 years with primary hip osteoarthritis were randomized, using sealed envelopes, to receive a femoral stem of either Ti (n=20) or cobalt-chromium (CoCr, n=20). All patients were operated in spinal anaesthesia by one out of three experienced hip surgeons (AZ, CS or PR) between January 2003 and October 2004. The patients were mobilized the day after surgery without any weight bearing restrictions. Prophylactic antibiotics and anti-thrombosis treatment were given, and postoperative pain was treated in accordance with the standard regime in the orthopaedic department, with the exception of NSAID which were avoided.

All patients received a Bi-Metric stem (Biomet, Warsaw, IN, USA), with an identical design (tapered, collarless, and ceramic beat blasted), only differing in alloy (Ti6Al4V or CoCrMo) and surface roughness. The arithmetical mean surface roughness (Ra) was 7.64 and 2.63 microns for Ti and CoCr, respectively. In addition, every patient obtained 1) a modular 28 mm CoCr femoral head (Biomet), 2) a Sleeve centralizer (Biomet), 3) a Buck femoral restrictor (Smith & Nephew, Inc., Andover, MA, USA), and 4) an all-polyethylene SHP cup (Biomet). All components were inserted with Refobacin-Palacos R cement (Biomet), vacuum mixed in the Optivac mixing system (Biomet).

The operating room temperature was 21^{o} C. The cement was stored at 4º C, and was delivered to the operating room just prior to the acetabular and femoral reaming, respectively. All prosthetic components were stored at room temperature. The approach was postero-lateral, and the posterior joint capsule was removed in all cases.

Acetabulum was over-reamed to give a final 3 mm cement mantle, and eight to ten anchoring holes (6 mm in diameter and 6 mm deep) were drilled in the superior acetabulum. Afterwards, anchoring holes were cleaned with a curette followed by pulse lavage, and drying with gaze. Depending on size, acetabulum was cemented with either 40 or 60 g cement. Two minutes after the onset of mixing, cement was applied in the acetabulum, pressurized for two minutes, followed by insertion of the acetabular prosthesis, and finally pressurized till curing.

The femoral canal was over-reamed to provide a final 2 mm cement mantle. After test reposition, the bone canal was cleaned with pulse lavage, followed by suction, and application of a restrictor 2 cm distal to the tip of the final stem. Depending on size, the femoral canal was cemented with either 80 or 120 g cement. Two minutes after onset of mixing, the femoral canal was retrograde filled with cement, followed by pressurisation for two minutes. The stem was inserted followed by pressurisation till cement curing. No capsule plasty was performed after insertion of components.

DEXA

DEXA-scans were performed during the first postoperative week, and repeated 12 month later. The scanner was a Hologic Delphi W - S/N 70148 (Hologic Inc., Bedford, MA, USA), and the scan function ‘metal removal’ was used. The patient was placed in a supine position with the foot immobilized to ensure neutral femoral rotation, thus minimizing measurement error. All analyses were performed blinded and were made by the same person (MØ) using Hologic’s analytical software, version 11.2. Cement and bone were included in all analyses, and the periprosthetic BMD was calculated in respect to the seven Gruen zones [9]. The ‘compare function’ was used for follow-up examinations to ensure identical pixel size on both images (Fig. 1). The precision of the BMD measurements, i.e. the coefficient of variation (CV %) was calculated as described by Wilkinson et al. [25], and was determined for every Gruen zone utilizing ten random patients who had double measurements performed (including reposition) within 10 minutes. BMD changes were calculated as the relative BMD difference with a negative number indicating bone loss.

Harris Hip Score (HHS)

Daily function and pain in the affected hip joint was evaluated through HHS [11] preoperative and repeated 12 months after surgery.

Statistical Analysis

STATA version 7 (StataCorp LP, Texas, USA) was used for all statistical analyses, with values for $p<0.05$ being regarded as significant. The Shapiro-Wilk W test assessed normality. Groups were compared with the two-sample t-test, paired data with the paired t-test and correlations were made with the Pearson correlation test. Data is presented as mean and standard deviation (SD) unless otherwise stated.

Results

No intra-operative complications were observed. Two male patients in the CoCr group were excluded from the study during the follow-up period due to 1) cup revision based on re-occurring dislocations, and 2) inferior quality of DEXA images, respectively. In addition, a female patient in the Ti group was excluded due to withdrawal of consent, thus leaving 18 patients in the CoCr group and 19 patients in the Ti group. No significant differences of baseline characteristics including HHS 12 months after surgery were found between groups (Table 1). Also, no differences were found between neck lengths, stem or cup sizes (data not shown). The precision of the periprosthetic BMD measurements (i.e. the CV %) for every seven Gruen zone was found to vary between 1.3% and 5.0%.

Twelve months after surgery the Ti stems demonstrated a significant BMD loss in zone III ($p=0.02$), zone VI ($p=0.01$) and zone VII ($p<0.001$), whereas CoCr stems showed significant BMD losses in zone II ($p=0.02$), zone III ($p=0.01$), zone IV ($p=0.01$) and zone VII ($p<0.001$) when compared to baseline (Table 2). No significant differences, however, were observed between the two stems either postoperative or after 12 months.

Defining relative BMD change as the absolute loss (or gain) divided by the initial value, a universal relative BMD loss was observed around both stems, twelve months after surgery, (except zone I where a small bone gain was seen) with the main loss noted in zone VII (Fig. 2). However, none of the changes showed statistical significance between the two stems, and no correlations were found between the relative BMD changes and BMI, gender, neck lengths and stem sizes.

Discussion

A universal periprosthetic bone resorption is a common observation following both cemented and cementless THA [1, 20], with the most likely candidate being stress shielding due to alterations in the mechanical loading of the bone [18]. The largest amount of bone is mainly lost during the first six months after surgery, especially in Gruen zone VII, and is followed by only minor changes [23]. The latter resembles normal age related bone resorption (approximately 1% yearly) [10]. Accordingly, we only considered a 12 month follow-up period. When a cemented stem is evaluated with DEXA, it remains impossible to distinguish cement from bone [6, 17, 23]. To attain high accuracy of the examination, cement should preferably be included in the BMD measurements [25].

In the present study we found a general periprosthetic BMD loss around both stems investigated, except in zone I where a BMD gain was seen. The latter has been claimed to be caused by heterotropic ossification [2]. For both the Ti and CoCr stem, the largest mean BMD loss was seen in Gruen zone VII (13.6% and 12.7%, Ti and CoCr, respectively). Also Arabmotlagh et al. [2] and Venesmaa et al. [23] measured the greatest mean BMD loss one year after surgery in that particular Gruen zone, when they evaluated a Euroform and a Lubinus SPII stem, respectively. Both stems were cemented, and the reported BMD loss was 16.4% and 24.8%, respectively. In contrast, Cohen and Rushton [6] found a mean BMD resorption of only 6.7% in Gruen zone VII, when they evaluated a cemented Charnley stem one year after surgery. The results should be reviewed in context with published survival data. The ten year survival rate of the Lubinus SP and Charnley stem have been reported to be 96.4% and 93%, respectively, when inserted due to osteoarthritis and revised on behalf of aseptic loosening [19]. Accordingly, it is tempting to suggest that periprosthetic BMD evaluation around cemented stems, in a small group of patients, shows little correlation with stem survival in a whole population. However, reduced BMD resorption may protect against periprosthetic bone fractures, and may improve revision surgery outcome.

In the present study no significant BMD differences were observed between the two stems in any of the seven Gruen zones investigated, either postoperative or after 12 months. As the observed SD in most Gruen zones was larger than the corresponding mean, a type two error can not be excluded. However, it should also be taken into consideration that despite lesser rigidity of the investigated Ti stem, when compared to a similar CoCr stem, the Ti stem still remains rigid in relation to cortical bone which has an average cortical bone rigidity of approximately 17 GPa [14]. A hollow cementless Ti stem has been observed to preserve periprosthetic bone significantly better than a similar cementless CoCr stem when evaluated in a paired canine study [3]; however, a hollow stem is less rigid than a composite stem manufactured from the same alloy. Also cementless isoelastic stems (i.e. stems with rigidity close to cortical bone) inserted in humans has been observed to exert better periprosthetic bone preservation than cementless Ti stems [15]. Since increased interfacial stresses has been predicted with reduced stem rigidity [14] an isoelastic stem inserted with cement should be avoided. During the last two decades also the rational concerning further use of cemented Ti stems has been debated, though modern cementing technique and use of high viscosity cement does seem to favour longevity of cemented Ti stems [1, 12]. In fact, the survival rate of the Bi-Metric Ti stem (collared version) has been reported to be 98% seven years after surgery [22], although no survival data regarding the later introduced CoCr stem has been published yet.

In conclusion, we observed a general periprosthetic bone loss around both stems investigated with the exception of zone I where bone gain was seen. As expected the most pronounced bone resorption was noted in Gruen zone VII. However, no significant differences were found between the Ti and CoCr stems showing that even this particular Ti was too rigid to reduce periprosthetic bone loss.

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Table 1. Baseline characteristics and Harris Hip Scores (HHS)

	CoCr (n=18)	Ti (n=19)
Age (years)	69.9 (3.4)	69.4 (3.7)
Gender (female/male)	9 / 9	12 / 7
BMI (kg x m^{-2})	28.5 (3.5)	26.9 (3.3)
HHS preoperative	47.6 (14.5)	47.3 (15.9)
HHS 12 months postoperative	95.7 (3.6)	92.2 (9.9)

Mean values (SD) are expressed. No significant differences were found between groups. BMI denotes body mass index.

Table 2. BMD postoperative and after 12 months

Gruen zone	CoCr (postoperative)	Ti (postoperative)	p-value
I	1.26 (0.20)	1.30 (0.23)	0.61
II	2.39 (0.23)	2.27 (0.31)	0.21
III	2.32 (0.21)	2.27 (0.23)	0.54
IV	2.21 (0.23)	2.15 (0.21)	0.41
V	2.00 (0.29)	2.08 (0.17)	0.37
VI	1.83 (0.22)	1.93 (0.16)	0.14
VII	1.63 (0.25)	1.63 (0.14)	0.93
Gruen zone	**CoCr (12 months)**	**Ti (12 months)**	**p-value**
I	1.28 (0.21)	1.33 (0.26)	0.59
II	2.27 (0.34)[a]	2.44 (0.34)	0.75
III	2.24 (0.23)[a]	2.21 (0.23)[a]	0.68
IV	2.16 (0.22)[a]	2.11 (0.20)	0.46
V	1.95 (0.30)	2.03 (0.18)	0.36
VI	1.77 (0.31)	1.85 (0.21)[a]	0.36
VII	1.44 (0.34)[b]	1.41 (0.24)[b]	0.79

Mean g/cm^2 values (SD) are expressed. [a] $p<0.05$, [b] $p<0.001$ for 12 months *versus* postoperative BMD.

Fig. 1

DEXA scans of the same patient performed postoperative (panel a) and after 12 months (panel b).

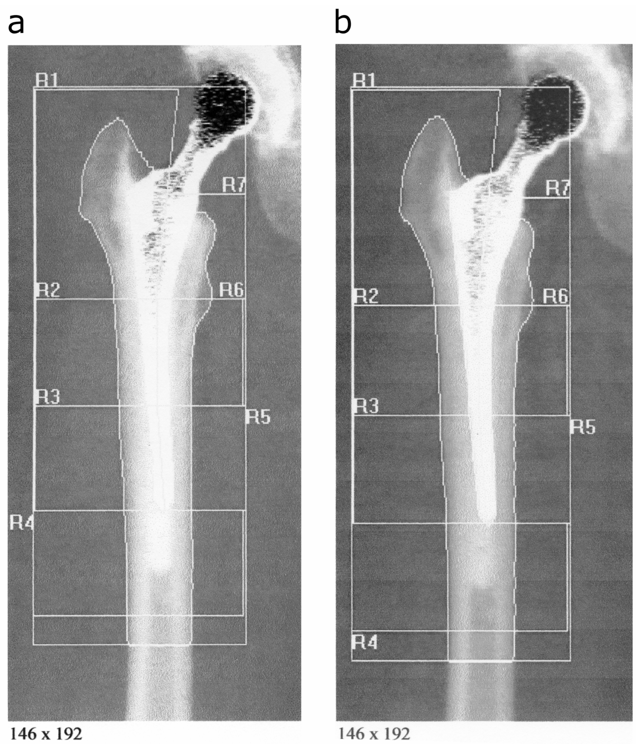
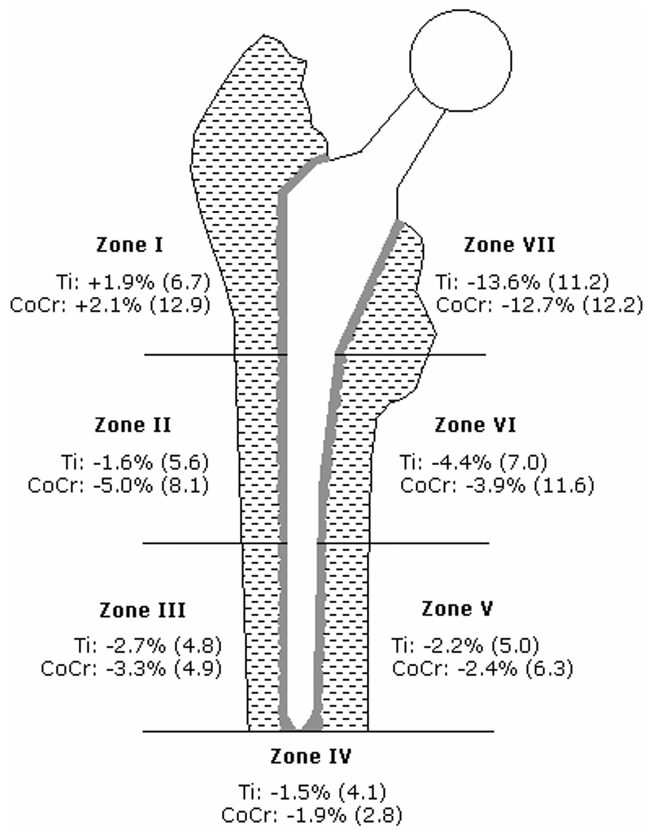


Fig. 2

Relative periprosthetic BMD differences (%) one year after surgery. Mean and SD are expressed.



Paper III

Flanged versus unflanged acetabular cup design

An experimental study using ceramic and cadaveric acetabuli

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Abstract

Background Optimum cement penetration depth and cement mantle thickness may be important regarding cemented cup durability. A flanged cup is expected to render a uniform cement mantle with reduced risk of bottoming out as well as superior cement pressurization at the time of implantation, thus improving cement penetration depth.

Methods The performance of a flanged versus unflanged cup (both without cement spacers) was investigated with focus on intra-acetabular pressures, cement mantle thickness and penetration depths. The cups were inserted in open pore ceramic acetabular models (flanged=10, unflanged=10) as well as in paired cadaveric acetabuli (flanged=10, unflanged=10) with prior pressurization of the cement.

Results Whilst intra-acetabular pressures were even during cup insertion (position controlled); unflanged cups migrated significantly more towards the acetabular pole and produced significantly higher intra-acetabular pole pressures than flanged cups did during the subsequent force-controlled pressurization. Flanged cups resulted in significantly thicker cement mantles with less bottoming out when compared with unflanged cups, whereas no differences in cement penetrations were observed between the cups.

Interpretation The benefit from flanged cups may in part originate from the production of thicker cement mantles and thereby to protect from bottoming out, but does not seem to derive from increased cement pressurization abilities. As the main cement penetration is likely to occur during cement pressurization, little is gained during cup insertion. Studies are needed that investigate whether a flange may serve additional properties besides improving cement mantle thicknesses.

Introduction

Aseptic loosening is well known to be the main limiting factor regarding prosthetic longevity, with inadequate surgical techniques and inferior prosthetic implants being the main causes (Herberts and Malchau 2000). Sufficient cement-bone interdigitation, preferably with a three to five mm penetration depth into cancellous bone and formation of a uniform cement mantle (i.e., cement penetration excluded) with a minimal two mm thickness have been stated to be crucial regarding cemented acetabular cup durability (Huiskes and Slooff 1981, Lichtinger and Muller 1998, Mjoberg 1994, Noble and Swarts 1983, Ranawat et al. 1997, Schmalzried et al. 1993). A clean, porous bony surface and cement pressurization prior to prosthetic implantation has been observed to improve cement penetration depth, thus creating a stronger cement-bone interface (Krause et al. 1982, Rey, Jr. et al. 1987, Mann et al. 1997, Flivik et al. 2006). Timing of the cup insertion is also important as the viscosity of the polymer may have attained a level where further penetration might be complicated (Noble and Swarts 1983, Stone et al. 1996, Reading et al. 2000).

Absence of postoperative demarcation at the acetabular cement-bone interface has been set in relation to a reduced risk of aseptic cup loosening (Ranawat et al. 1995, Garcia-Cimbrelo et al. 1997, Ritter et al. 1999, Flivik et al. 2005). The use of a flanged polyethylene cup has demonstrated both less postoperative demarcation at the above interface (Hodgkinson et al. 1993), and a superior survival regarding aseptic loosening (Garellick et al. 2000). The success of the flanged cup has mainly been addressed to its ability to increase cement pressurization at the time of implantation and thereby penetration depth, though conflicting experimental findings have been reported (Shelley and Wroblewski 1988, Oh et al. 1985, Parsch et al. 2004). The previous studies addressing the use of flanged cups have all inserted the cups without prior cement pressurization, and only Parsch et al. (2004) implanted the cup into a general porous material (cadaveric bone).

Accordingly, we decided to investigate the performance of a flanged versus an unflanged cup with the same basic design, inserted in an open pore ceramic acetabular model or paired cadaveric acetabuli using pressurization of the cement before implantation and with focus on intra-acetabular pressures, cement mantle thickness and cement penetration depth.

Materials and Methods

Ceramic study

Twenty ceramic acetabular models with a 49 mm diameter were produced from Sivex ceramic foam filter plates (filter grade 80, cell size 600-700 microns, Pyrotek SA, Sierre, Switzerland). Two custom made pressure sensors (modified Entran, EPB, Entran Sensors & Electronics, Garston, UK) with a 3.6 mm diameter and a 100 mm shaft were inserted through a standardized drill hole located at the acetabular pole, and 2.5 cm from the rim, respectively (holes were drilled using a special designed drill guide). The tip of each sensor was covered with tape to protect it from polymer induced damage, and was levelled with the acetabular surface. Twenty cross-linked-polyethylene XLPE Opera cups (Smith & Nephew, Inc., Andover, MA, USA) with a 43 mm outer (flange excluded) and a 28 mm inner diameter and no orientation wire were used (Figure 1). Ten cups had the flange cut off (unflanged sockets), and the remaining ten had the flange trimmed (flanged prostheses) to fit just on top of the acetabular model. To protect the brittle ceramic rim, the flange was not trimmed to fit inside the reamed hemisphere. Every cup was inserted with 40 grams of prechilled (5º C) Refobacin-Palacos R cement (Biomet, Warsaw, IN, USA) using an Instron 851120 materials testing machine (Instron Corporation, Norwood, MA, USA). The room temperature was kept a 20º C, and the cement was removed from the refrigerator just prior to vacuum mixing in the Optivac mixing system (Biomet). Two and a half minute after the onset of mixing, cement was applied in the acetabular model, and pressurized with 80 N for 1.5 minutes using a conventional pressurizer (Smith&Nephew) which was fitted into the Instron machine. Five minutes after the onset of mixing, the cup was inserted position-controlled by the use of a femoral head and a specially designed device to avoid cup tilting during introduction. Thereafter the cup was held in place with force-control (25 N) until the cement had cured. The resultant forces, pressures and cup displacements were recorded continuously every

0.02 second during cementation using the Spider8 software (HBN, Inc., Marlborough, MA, USA). After the cementing procedures, all samples were cut longitudinally along the centre of the cup with an electric saw, and digitized using an hp scanjet 4470c digital flatbed scanner (1200 dpi) to enable inspection of the cement mantle and penetration depth, respectively.

Cadaver study

Ten human cadaver pelvises embalmed in (v/v) 5% formalin, 45% ethanol, 27% glycerine, and 5% glyoxide-glutaraldehyde were on loan from the Anatomical Institute, Aarhus University, Århus, Denmark. All pelvises were from male donors (82.8 years (73 – 86), median and inter-quartile range, respectively) without any previous hip surgery or signs of osteoarthritis. The left and right acetabulum was randomly allocated to receive either an XLPE Opera cup with or without flange. The flange was either trimmed to fit inside the acetabulum (flanged cup) or cut off (unflanged cup). In all cases, the inner cup diameter was 28 mm, and the orientation wire was removed. All acetabuli were over-reamed according to the manufacturer's recommendations using a conventional reamer to provide a final cement mantle between 2.5 and 3.5 mm, depending on the size of the last reamer, and the most suitable cup size (Opera cups were available in size 40, 43, 47, 50 and 53 mm). Every acetabulum in a pair was equally over-reamed, and the same cup size was inserted on both sides. During reaming, the aim was to remove at least 75% of the subchondral bone plate area in order to optimize the possibility for cement penetration by exposing cancellous bone (Flivik et al. 2006). Nine anchorage holes with a 6 mm diameter and a 6 mm depth were drilled with an unanimous distribution, i.e. one anchorage hole in os pubis and os ischii, respectively, and the remaining seven holes drilled in os ilium. All acetabular preparations were performed by an experienced orthopaedic hip surgeon (GF). Afterwards, every acetabular bone was potted into Vel-Mix Stone (Kerr Italia S.p.A., Scafati, Italy) to ensure horizontal alignment of the acetabular opening during further cadaveric handling, and finally, two additional channels for the later application of pressure sensors were drilled at the pole and 10 mm from the iliac rim (opposite the transverse ligament, using a special designed device), respectively. All acetabuli were then cleaned with pulse lavage, and prior to cementation, the acetabular bone bed was dried with gaze as well (Figure 2). Subsequently, the previous used pressure sensors were inserted (the sensor tips were again levelled with the cancellous bone surface), and an XLPE Opera cup (flanged or unflanged) was implanted using 40 grams of prechilled (5º C) Refobacin-Palacos R cement (Biomet) under identical conditions with pressurization of the cement prior to insertion as described for the ceramic study. After cementation, every cadaveric bone pair was reversely aligned and CT scanned in the coronal plane using a Philips Mx8000 IDT 16 CT scanner (Philips Medical Systems, Andover, MA, USA) with the following settings: 120 Kv, 158 mA, and a 0.8 mm slice thickness to enable estimation of the total cement volume and penetration depth, respectively. Bones were stored in a cold room between cadaveric handling.

Data management

Intra-acetabular pressures and cup displacements in ceramic and cadaveric acetabuli

Insertion forces and intra-acetabular pressure measurements were obtained during position-controlled cup insertion within the last 3 mm prior to the final cup position. Resultant intra-acetabular pressures and cup displacements were, in addition, assessed during force-controlled pressurization. Area under the curve (AUC) was computed for every insertion force and pressure measurement (with use of the trapezoid rule), and subsequently the calculated value was divided by the observed time period (Flivik et al. 2004). Cup displacements obtained under a constant force were evaluated for 45 and 150 seconds, ceramic and cadaveric study, respectively, with a negative number indicating cup migration towards the acetabular pole.

Cement mantle thickness, penetration depth and areas in ceramic

A hemisphere template was created in Adobe Photoshop 7.0 (Adobe System Inc.) to divide the acetabulum into three 60º segments (two laterals and one central). Each segment was afterwards divided into 12 sub-regions by adding a radial test line for every five degrees

(Figure 3). Cement mantle thickness and penetration depth were measured along every test line, with the exception of the central zone, where only six measurements were performed in the lateral part of the region to avoid uncertainty caused by the pole pressure sensor channel. Accordingly, the median mantle thickness and penetration depth could be calculated. The lateral and central mantle and penetration area for every five degrees were also estimated. Penetration was defined to begin at the base of a proximal penetration sprout, and to end at the most distal point of cement along a radial test line. All measurements were performed with the Image J software (ImageJ 1.31i, W. Rasband, NIH, USA).

Total cement volume and penetration in cadaveric acetabuli

The total cement volume (mantle thickness plus penetration depth) was estimated using Cavalieri's direct estimator (Gundersen et al. 1988). Basically, a grid containing points covering a known area was created (Adobe Photoshop 7.0), then the total upper right corner of the points overlaying the cement were counted in every 12th CT slide (Figure 4). The starting point was random, and 12 to 15 slides were analyzed in a sample using an equal number of slides for the other half of the bone pair. All analyses were performed blinded. When estimating cement penetration a medial and a lateral anchorage hole were localized for every sample on the CT sections, and the images visualizing the most prominent diameter were chosen. In the opposite cadaveric bone pair the corresponding anchorage hole was selected. The diameter of each chosen anchorage hole (i.e., the diameter of the drill hole plus penetration at both sides of the hole) was measured three times at its thickest location (with ImageJ). Penetration was subsequently calculated as the half of the difference between the median measured diameter and the known size of the drill hole (6 mm). All analyses were performed blinded.

Statistical Analysis

A minimum sample size of 8 in the cadaveric study was calculated to achieve sufficient power (>80%) based on published pressure variation data (Parsch et al. 2004) and assuming a 100 mmHg difference in the obtained median pole pressures between flanged and unflanged cups. STATA version 7 (StataCorp LP, Texas, USA) was used for all statistical analyses, with values for $p<0.05$ being regarded as significant. Groups were compared with the Mann-Whitney U test, and data is presented as median values with the inter-quartile range in brackets, unless otherwise stated.

Results

Intra-acetabular pressures, forces and cup displacements in ceramic

Forces, pressures and cup displacements were collected in three flanged and three unflanged cups, respectively (Tabel 1). During position-controlled cup insertion no significant differences were obtained between the insertion forces or intra-acetabular pressures when comparing a flanged with an unflanged cup. In addition, both cups produced even intra-acetabular pressures ($p=0.5$ and $p=0.1$, flanged and unflanged, respectively) i.e., no differences were found between pole and rim pressures. However, during force-controlled pressurization (Table 1) the unflanged cup showed significantly deeper displacement in the direction towards the acetabular pole and produced a significantly higher pole pressure than the flanged cup did. In addition, the intra-acetabular pressures turned out to be unevenly distributed only in the unflanged cup, with a higher pressure obtained at the pole.

Cement mantle thickness, penetration depth and areas in ceramic

Mantle thickness, penetration depth and the respective areas were measured in 10 flanged and 10 unflanged samples (Table 2). The central and the lateral cement mantle thickness was significantly thicker when a flanged cup was inserted compared with an unflanged cup, and also the central and lateral cement mantle area was significantly larger when a flanged cup was used. The mantle thickness and area were equally distributed for the flanged cup (p=0.1 and p=0.2 for thickness and area, respectively), as well as for the unflanged cup (p=0.8 and p=0.3, respectively). No significant differences in the cement penetration depth or cement penetration area were found between the two cups (Table 2). Both cups were observed to have significantly deeper penetration central than lateral (p=0.002 and p=0.003 for the flanged and unflanged cups, respectively), and similar findings were observed for the penetration area (p=0.003 and p<0.001, respectively).

Intra-acetabular pressures, force and cup displacements in cadaveric acetabuli

During position-controlled cup insertion, forces and pressures were collected in 10 paired samples (Table 3). No significant differences were observed between the two cups regarding insertion forces and intra-acetabular pressures, and both cups produced even intra-acetabular pressures (p=0.3 and p=0.07, flanged and unflanged cups, respectively). During force-controlled pressurization (Table 3) cup displacements were collected in eight paired samples and pressures were obtained in nine paired samples. Again the unflanged cup migrated significantly more towards the acetabular pole, and produced a significantly higher pole pressure than the flanged cup did. Once more uneven pressures were noted in the unflanged cup (p=0.01), with the highest pressure obtained at the pole, whereas pressures were evenly distributed in the flanged cups (p=0.9).

Total cement volume and penetration depth in cadaveric acetabuli

Total cement volume and penetration were measured in 10 paired samples. Flanged cups were found to be enclosed by significantly more cement than unflanged cups (70.26 cm^3 (66.41 – 73.91) *versus* 57.38 cm^3 (54.18 – 61.69), p=0.02, respectively), whereas no significant difference in cement penetration was observed between the two cup types (0.92 mm (0.57 – 1.65) *versus* 0.99 mm (0.83 – 1.70), p=0.8, respectively).

Discussion

Increased cement penetration into the acetabular bone has been observed to improve cup stability (Flivik et al. 2005). However, many factors influence cement penetration including magnitude and duration of the applied force, properties of the bone cement used, amount of bone bleeding, and anatomy, porosity and not least preparation of the acetabular bone. (Noble and Swarts 1983, Juliusson et al. 1994, Graham et al. 2003, Hogan et al. 2005, Flivik et al. 2006).

The success of a flanged cup has mainly been addressed to its hypothesized ability to increase cement pressurization at the time of implantation, thus improving cement penetration (Oh et al. 1985, Shelley and Wroblewski 1988). When we inserted a flanged and an unflanged cup position-controlled using equivalent forces no significant differences regarding intra-acetabular pressures were found between flanged and unflanged cups inserted in either ceramic (Tabel 1) or paired cadaveric acetabuli (Tabel 3), and both cups produced equal intra-acetabular pressures as well. When the cups were further pressurized (using force-control) the unflanged cups migrated significantly more towards the acetabular pole than the flanged cup did when inserted in ceramic (Tabel 1) and paired cadaveric acetabuli (Tabel 3), despite of a minimal force application (25 N). Most certainly, however, the migration susceptibility observed for the particular unflanged cup design is further increased due to the lack of cement spacers.

It has been suggested that the use of a flanged cup may correlate to a lower incidence of bottoming out (Oh et al. 1985). To the best of our knowledge, there is no consistent classification concerning bottoming out. Using a tentative definition being cement mantle thickness less than 1 mm along any of the 29 test lines (in the ceramic study), nine out of ten unflanged cups, and just two out of ten flanged sockets demonstrated bottoming out ($p=0.002$). Close contact between polyethylene and bone has been set in relation with reduced cup longevity, (Wroblewski et al. 1987). It is thus tempting to suggest that the reduced cement mantle thickness observed in the unflanged cup experiments may reduce cup durability, but again the lack of cement spacers may have influenced the results.

However, it should be taken into consideration that the use of a flanged cup may increase the incidence of an eccentric cement mantle (Sandhu et al., 2006), accordingly care needs to be taking when adjusting the flanged cup to the particular acetabulum.

The porosity and preparation of the acetabular bone bed is set in relation with the degree of cement interdigitation, and removal of the subchondral bone plate has been observed to improve the cement-bone interface and to lower the interfacial stresses without impairing prosthetic stability (Volz and Wilson 1977, Sutherland et al. 2000, Flivik et al. 2006). We are aware that all sockets inserted in both ceramic and cadaveric bone were implanted under very good conditions due to a dry acetabulum without any blood or bone-marrow to disrupt cement penetration (Ranawat et al. 1995, Krause et al. 1982). However, all prostheses were inserted under the same conditions, and the error is therefore systematic. To adjust for the improved conditions regarding a dry acetabulum we pressurized cement and prostheses with lesser force than usually performed in the clinic.

The overall cement penetration was higher in the ceramic study compared with cadaveric bone. The reason may lie in larger pore diameters and a completely open porous structure in ceramic. According to Poiseuille's law ($R = 8\eta L \times (\pi r^4)^{-1}$) where R denotes flow resistance, η viscosity, and L length of the pores with radius r (Alkafeef et al. 2006), larger pore diameters give lesser flow resistance, thereby facilitating higher penetration. The deeper central penetration observed in the ceramic study can be explained by the higher pressure gradient at this location. In fact, this is confirmed by the second part of Poiseuille's law ($f = \Delta P \times R^{-1}$), in which the flow ($f$) of the liquid is governed by the pressure gradient (ΔP) and the flow resistance (R).

Since no differences in penetration depth were found between the cups tested when inserted in either ceramic or paired cadaveric acetabuli, it may indicate that cement penetration occurs primarily during cement pressurization prior to cup insertion. Thus, when it is time to insert the cup the cement might simply be too viscous to permit further penetration even with a flanged cup design. Apparently, the flanged cup reduces cement leakage during insertion; especially when compared to a cup design lacking cement spacers, and the increased cement volume observed around the flanged cup in the present cadaveric study must have been caused by a thicker cement mantle. In most studies, however, cement penetration depth and cement mantle thickness are not differentiated, and the total is usually referred as the cement mantle. Though, if possible, both cement penetration depth and cement mantle thickness should be taking into consideration. As flanged cups did not induce increased cement penetration, it seems unlikely that the superior clinical outcome observed among flanged cups (Hodgkinson et al. 1993, Garellick et al. 2000) may originate from increased cement penetration. Both wear and joint fluid pressure, however, has been suggested to influence aseptic loosening (Robertsson et al. 1997, Aspenberg and Van Der Vis 1998, Van Der Vis et al. 1998, McEvoy et al. 2002), and it is thus tempting to suggest that the flange may protect the interfaces against these specific parameters, hence increasing cup longevity.

In conclusion, both cups produced similar (and even) intra-acetabular pressures during position-controlled insertion. During force-controlled pressurization the unflanged cup migrated significantly more towards the acetabular pole (under the production of an increased pole pressure) and created a thinner cement mantle than the flanged cup did. However, no significant differences were observed between cups regarding cement penetration depth. Most certainly the main cement penetration occurs when the cement is pressurized prior to cup insertion; when it is time to insert the cup, the cement is too viscous to permit further penetration. Based on the present study it seems doubtful that the superior outcome observed among flanged cups is caused by an improved cement penetration, and we suggest that the main role of the flange is to protect the interfaces against joint fluid pressure and wear debris, thereby increasing cup durability.

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Contributions of authors

MØ contributed in study design, data acquisition, data analyses and manuscript preparation. SA, IM and KS contributed in study design and manuscript revision. GF contributed in study design, data acquisition and manuscript revision.

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Table 1

Intra-acetabular pressures in ceramic.

	Flanged	Unflanged	p-value
Position-controlled cup insertion			
Force applied (N)	68.0 (64.9 – 74.4)	56.7 (42.7 – 83)	0.5
Pole pressure (mmHg)	353.3 (281.1 – 355.5)	402.3 (298.0 – 568.1)	0.3
Rim pressure (mmHg)	283.2 (281.9 – 292.9)	252.4 (188.6 – 331.6)	0.5
Force-controlled pressurization			
Cup displacement (mm)[a]	-0.1 (-0.2 – 0.0)	-0.2 (-0.4 – -0.2)	0.049
Pole pressure (mmHg)	86.3 (0.0 – 108.4)	140.5 (113.9 – 159.5)	0.049
Rim pressure (mmHg)	76.1 (7.7 – 85.3)	24.7 (23.5 – 54.8)[b]	0.5

Median values (interquartile range) are shown. [a] Negative displacement indicates cup migration toward acetabular pole. [b] $p<0.05$ for pole *versus* rim pressures.

Table 2

Cement mantle thickness, penetration depth and areas in ceramic

	Flanged	Unflanged	p-value
Cement mantle			
Lateral thickness (mm)	2.37 (1.78 – 3.19)	1.50 (1.23 – 1.94)	0.002
Central thickness (mm)	3.33 (2.32 – 3.77)	1.64 (0.88 – 1.80)	<0.001
Lateral area (mm^2/5º)	4.65 (3.85 – 5.34)	2.88 (2.50 – 3.16)	<0.001
Central area (mm^2/5º)	5.83 (4.25 – 6.55)	2.43 (1.96 – 3.33)	<0.001
Cement penetration			
Lateral depth (mm)	3.59 (3.53 – 3.85)	3.80 (3.38 – 4.02)	0.5
Central depth (mm)	4.22 (4.13 – 4.78)[a]	4.67 (4.07 – 4.79)[a]	0.6
Lateral area (mm^2/5º)	9.16 (8.84 – 9.28)	8.81 (8.36 – 8.85)	0.2
Central area (mm^2/5º)	10.18 (9.41 – 10.42)[a]	10.44 (9.52 – 10.85)[b]	0.4

Median values (interquartile range) are shown. [a] $p<0.01$, [b] $p<0.001$ for lateral *versus* central measurements.

Table 3

Intra-acetabular pressures in cadaveric bone.

	Flanged	Unflanged	p-value
Position-controlled cup insertion			
Force applied (N)	89.7 (52.3 – 133.6)	75.4 (38.9 – 134.7)	0.8
Pole pressure (mmHg)	218.5 (172.2 – 337.3)	470.3 (213.3 – 739.9)	0.1
Rim pressure (mmHg)	155.6 (42.8 – 224.6)	196.4 (114.0 – 269.1)	0.7
Force-controlled pressurization			
Cup displacement (mm)[a]	-0.1 (-0.3 – 0.1)	-1.0 (-1.4 – -0.2)	0.04
Pole pressure (mmHg)	12.3 (10.2 –60.2)	129.8 (88.0 – 269.9)	0.005
Rim pressure (mmHg)	17.1 (14.3 – 37.9)	23.0 (13.2 –84.1)[b]	0.5

Median values (interquartile range) are shown. [a] Negative displacement indicates cup migration toward acetabular pole. [b] $p<0.05$ for pole *versus* rim pressures.

Figure 1

The inserted Opera cup (with flange)

Figure 2

Prepared cadaveric acetabular bone bed with the cancellous bone exposed.

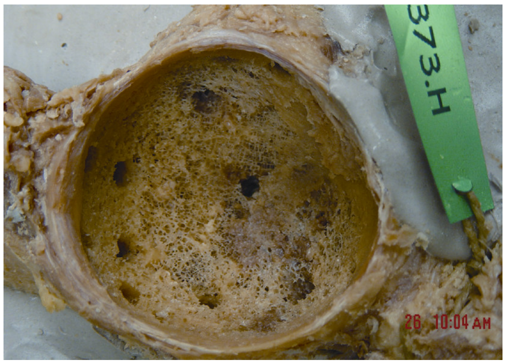

Figure 3

The template with test line placed on a ceramic sample (note the close contact between the unflanged cup and the ceramic). (L) lateral segments, and (C) central segment.

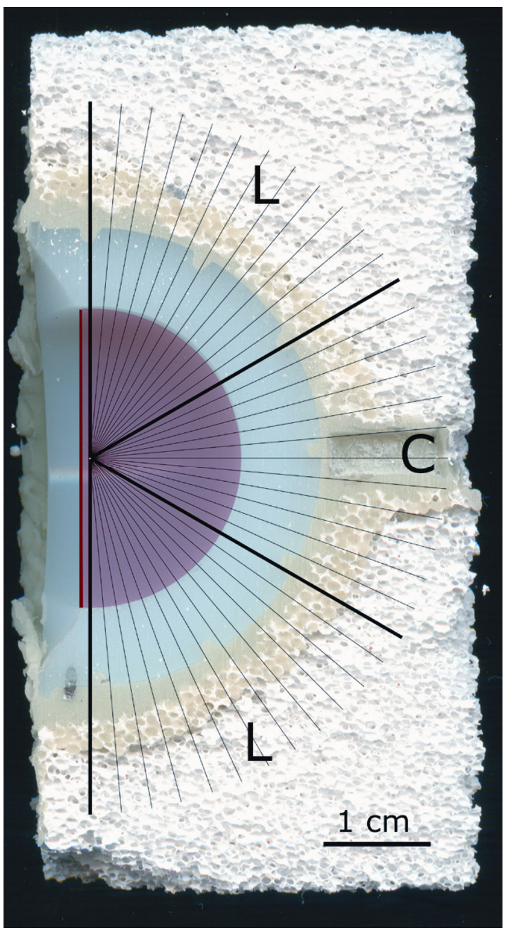

Figure 4

The counting grid placed on a CT cadaveric bone image. (a) Opera cup, (b) cement, (c) cadaveric bone, and (d) Vel-Mix Stone.