On Fixation of Hip Prostheses

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Initial stability of two different hip revision concepts. A biomechanical study.
L. Palm, I. Ivarsson, S-A Jacobsson
Hip International 1999; No1: 7-13

II
Hydroxyapatite coating improves 8- to 10-year performance of the Link RS cementless femoral stem.
L. Palm, S-A Jacobsson, I. Ivarsson
The Journal of Arthroplasty 2002; No2: 172-175

III
Acetabular revision with extensive allograft impaction and uncemented hydroxyapatite-coated implants. Results after 9 (7-11) years follow-up.
L. Palm, S-A Jacobsson, J. Kvist, A. Lindholm, A. Öjersjö, I. Ivarsson
The Journal of Arthroplasty 2007, Accepted

IV
No difference in migration or wear between cemented low-profile cups and standard cups. A randomized radiostereographic study of 53 patients over 3 years.
L. Palm, J. Olofsson, S-E Åström, I. Ivarsson

V
Early radiolucent lines around cemented cups do not reliably predict increased migration as measured by radiostereometry.
L. Palm, I. Ivarsson
Submitted.
Abstract
This thesis, comprising 5 separate studies, is concerned with fixation of prosthetic components in total hip arthroplasty. The results and conclusions of the studies follow;

The initial stability of femoral revision components, the long cementless PCA stem and the Exeter standard stem cemented in a bed of impacted bone graft, was compared in an experimental study. The PCA stem was more stable than the Exeter stem. However, for both stems initial stability may not be sufficient to allow bone ingrowth. Initial fixation is especially vulnerable to torsion.

Identical femoral stems with or without HA-coating were compared in a prospective randomized clinical trial. The long-term stable fixation of a cementless Link RS femoral component was improved by application of hydroxyapatite coating to the femoral stem.

In a clinical study the method of extensive impaction of morsellized bone allograft and a hydroxyapatite-coated cementless Mallory-Head acetabular component was found to be advantageous for acetabular revision in the presence of contained or acetabular wall defects. The limited contact between the HA-coated implant and living host bone did not seem to compromise long-term stable fixation.

Two different cup designs were compared in a prospective randomized RSA study. At 3 years after implantation the cemented low profile Lubinus FAL cup performed as well as the cemented Lubinus Standard cup in terms of migration and polyethylene wear.

In a study of the relationship between radiolucent lines and migration the Lubinus FAL cup displayed more radiolucent lines in the cement bone interface than the Lubinus Standard cup but no difference in migration was found. Early appearance of such radiolucent lines represents an unspecific finding without reliable correlation to 3-year migration of the acetabular component.
**Introduction**

Initial stable fixation is a prerequisite for adequate function of any hip arthroplasty. If sufficient initial fixation is not obtained at the time of surgery, the implant will, no matter how well designed, fail relatively quickly. If, on the other hand, initial stable fixation is achieved – although ultimately the hip prosthesis may still fail, it will do this having provided the patient with substantially improved quality of life over a very long time.

The process of achieving and maintaining fixation is influenced by several factors which, much simplified, can be related to the patient, to the surgical technique and to the implant. Presuming we cannot significantly change the patient-related factors, we must focus on factors relating to surgical technique and implants. We must continue to refine and improve our surgical techniques, research and develop improved implants and learn to perform the most appropriate methods using materials to suite the demands of the individual patients. This process of refining techniques and materials is not meaningful without critical evaluation of the clinical results.

This thesis is the result of the efforts to address specific clinical questions arising in our daily arthroplasty work. Questions, pertaining to aspects of fixation of hip prostheses, in primary as well as revision settings, to which we have sought answers by means of clinical research.

**Femoral revision and allograft impaction**

At the time of introduction, by Gie, Ling and co-workers, of their novel concept of femoral revision, the clinical performance of cementless revisions using long stemmed femoral components had already been well investigated. The reported short-term revision rates of 5-10 %, (Engh et al. 1988, Gustilo and Pasternak 1988, Hedley et al. 1988, Hungerford and Jones 1988, Hussamy and Lachiewicz 1994) were generally considered good as compared to results of cemented revisions (Strömberg et al. 1992, Mulroy and Harris 1996). The technique of impaction of cancellous bone graft into which was placed a cemented implant, previously described by Slooff et al. (1984) in the context of acetabular reinforcement, was now adapted to femoral revision using a straight, double tapered stem (Gie et al. 1993a).

Preliminary clinical reports were promising, although significant early radiographic subsidence was recorded (Gie et al. 1993b, Elting et al. 1995). No specific analysis was made regarding the amount of rotational displacement although this was considered an important cause of stem loosening.
Early radiostereometry studies (RSA) of the impaction-grafting stem, by Franzén et al. (1995) showed that 5 out of 5 stems subsided and that 4 out of 5 displaced posteriorly during the first year. In a 1-2- year report, subsidence was recorded in all, and posterior displacement in 12 out of 13 stems (Franzén et al. 1997). Experimental studies of impaction grafting have yielded variable data regarding initial stability. Malkani et al. (1996) reported immediate stability of the implant while Berzinicz et al. (1996) found stability to be intermediate between that of conventional cemented stems and uncemented stems. Smith and co-workers (1995) suggested caution in premature weight bearing since initial stability was found to support only moderate loading. An animal study by Schreurs et al. (1994) concluded that postoperative stability improved within 6 weeks but integration was not completed after 12 weeks.

At the time of introduction of impaction grafting, our own results of cemented revisions or cementless revisions with long stems, the concepts available at our department at the time, were not fully satisfactory. There was a need for a better femoral revision concept but there was also concern regarding the biomechanical ability of the new method to achieve sufficient initial stability. In addition very little was known about the biological processes determining the long-term fate of the allograft-cement construct. We therefore decided to investigate the initial stability- i.e. the stability of the construct before any beneficial effects of secondary bone ingrowth or remodeling of the graft occurred - of the impaction grafting method and to compare it with the femoral revision concepts at hand.

**Total hip replacement in young patients**

The average life expectancy of a Swedish woman is 83 years and 78 years for men. The average age of a Swedish woman receiving a cemented total hip replacement (THR) is 70 years with men slightly younger, 68. The average 14-year survival rate for cemented THR in patients older than 75 at surgery is 95% for females and 93% for males. Thus, there is a good chance that the average patient will live the rest of their life without a revision. This is not the case for younger patients. In addition to their longer life expectancy, the 14-year survival-rate of their THR reaches a modest 78% in women and 80% in men provided they had a cemented arthroplasty. If our young patient received an uncemented implant, which we tend to use more often in young patients, the 14-year survival rate declines to 56 % for females and 72% for males (Swedish National Hip Arthroplasty Register 2005). There is therefore only a slim chance of our young patients fulfilling their life expectancy without the need for a revision.
Explanations to these inferior results have been sought in terms of higher activity level as well as a higher incidence of certain preoperative diagnoses that may influence the long-term outcome of this age group. With increased activity follows higher demands on the fixation of prosthetic components and on the durability of bearing surfaces. However recent data have failed to show any increased activity level in a young patient group 5 years after THR as compared to older THR patients (Sechriest et al. 2007), implying young patients with primary THR may not be as active as thought. Increased polyethylene wear rates have been reported among younger patients (Kim et al. 2003, Schneider and Knahr 2004, Kearns et al. 2006). With increased wear of bearing surfaces follows production of particulate wear debris. Particulate wear debris, in combination with other mechanisms such as pumping of fluids is probably the most important contributor to aseptic loosening. This younger patient group would potentially benefit the most from more wear resistant bearing surfaces such as metal on metal.

The preoperative diagnosis may also adversely affect the outcome of THR. Developmental dysplasia of the hip (DDH) and avascular necrosis (AVN) of the femoral head have been associated to an increased rate of aseptic loosening. These diagnoses also occur more frequently in the younger patient groups and may thus contribute to their higher failure rate. However, a recent report by Schneider and Knaehr (2004) could not confirm any increased failure rate associated to AVN. Promising results and long term survival rates of contemporary prosthetic designs, both cemented and cementless, in young patients with AVN have now been reported (Kim et al. 2003, Mont et al. 2006), but still with high polyethylene wear rates. Because of the inferior long-term survival rate in young and young adults, alternative fixation principles and prosthetic designs have historically been performed on these patients in an attempt to find a more enduring arthroplasty solution. Despite all the good intentions, this effort might also, to some extent, have contributed to the less successful result in the past.

**Hydroxyapatite coating of femoral stems**

In the late 1980’s orthopaedic surgeons were even more reluctant to total hip replacement in young patients than today since, apart from the inferior long-term results in the younger age groups, there were no reliable and well-proven concepts to allow for a successful revision available. Hydroxyapatite (HA) coatings were initially established as a method of improving fixation of dental implants. Subsequent experimental findings of beneficial effects of HA on orthopaedic implant fixation, led to the HA-coated cementless hip prostheses emerging as a way of improving fixation but long-term data on clinical outcome and prosthetic survival was lacking. When the cement-
less femoral prosthesis, which we used for primary THR in the young, was made available with HA-coating we had the opportunity to compare identical femoral stems with or without HA-coating in young patients in a prospective randomized clinical trial.

At that time, some authors had reported no clinical or radiographic advantages with HA-coating (McPherson et al. 1995, Rothman et al. 1996, Yee et al. 1999). Others had reported improvements in radiographic appearance (Dorr et al. 1998), clinical results (Incavo et al. 1998), and radiographic and clinical outcome (Huracek and Spirig 1994) with HA-coated stems. One RSA study described less migration in HA-coated implants (Søballe et al. 1993). Two non-randomized cohort studies had shown better radiographic appearance and higher survival rate of HA-coated stems compared to identical non-coated press fit stems (Donnelly et al. 1997) and less migration (Kroon and Freeman 1992). Thus, despite a number of randomized controlled or matched pair studies, comparing identical cementless femoral components with different surface coating, the question whether HA-coating of cementless stems offered a clinical advantage or not remained un-answered.

Cementless acetabular revision with allograft impaction

The concept of impaction grafting and cement fixation (Gie et al. 1993a), originally reported by Slooff et al. (1984) for acetabular protrusion, gained a wider acceptance during the early 1990’s and became a common procedure in acetabular revision surgery. Although the biological mechanisms of impaction grafting and cement fixation were not known, it obviously seemed to work in practice. Why would then, from a biological point of view, elimination of bone-cement in favor of a hydroxyapatite coated titanium implant not be a viable option? Bone-cement is toxic and may cause heat-induced injury to the bone graft and surrounding bone while HA has osteoconductive as well as osteoinductive properties.

At the time, our department had gained significant experience of cementless acetabular revision. Utilization of morselized allograft had also been extended from impaction of localized defects to involve the entire acetabulum, thus resulting in an implant seated entirely in allograft without host-bone contact. This method, combining the benefit of bone grafting to reconstitute bone stock, and immediate stable fixation by press-fit and screws to allow secondary bone ingrowth, seemed a promising and attractive alternative in cases with significant bone loss. Our preliminary clinical experience with this concept was promising, patients experienced good pain relief and radiographic findings were generally highly satisfactory. However, the
principles of this method were not in accordance with the general belief; that cementless implants needed maximum host-bone contact for stable fixation and subsequent bone ingrowth.

Bone grafting of contained defects and the use of an uncemented porous coated component with adjunct screw fixation is a well-established method for acetabular revision in the presence of bone stock deficiency. Favorable long-term results have been reported (Wolson and Adamson 1996, Lachiewicz and Poon 1998, Leopold et al. 2000, Della Valle et al. 2004, Lie et al. 2004, Jones and Lachiewicz 2004) and a high rate of graft incorporation can be expected when morselized bone is used for contained acetabular defects (Tanzer et al. 1992, Etienne et al. 2004). However, the minimum host-bone contact, or maximum amount of bone graft, which may be tolerated without risk of compromising stability and bone ingrowth of an uncemented acetabular component has not yet been sufficiently established.

In contrast to our technique, where morselized allograft is firmly impacted, not only into localized defects but also into the entire acetabular cavity, the importance of minimizing interposition of bone graft between host-bone and implant has been emphasized by many authors (Wolson and Adamson 1996, Lachiewicz, Poon 1998, Leopold et al. 2000, Della Valle et al. 2004). A minimum of 50 % - 70 % host-bone contact area has been considered necessary to enable stable fixation of porous coated acetabular components (Paprosky et al. 1994, Garcia-Cimbrello 1999, Gross 1999).

Radiostereometric (RSA) data has associated the use of morselized bone grafting of contained defects with increased proximal migration of the uncemented acetabular component (Nivbrant et al. 1996). More recent RSA data implies that neither the size of the acetabular defects nor the amount of morselized bone graft had any influence on migration (Nivbrant and Kärrholm 1997). Host-bone contact of less than 50% did not seem to compromise implant stability, provided HA-coated acetabular implants were used in combination with more forceful impaction of morselized graft (Hultmark et al. 1997). Interestingly, the combined use of bone allograft and HA-coated implants has actually been shown to improve early fixation to a level comparable to a primary implant in an experimental setting (Söballe et al. 2003).

Prosthetic design
Through the history of hip arthroplasty it seems as if serendipity, as much as dedicated scientific efforts, has contributed to the evolution of successful orthopaedic implants and there is no obvious logical relationship between
implant design and performance. As an example, the two most commonly used and best performing femoral components in Sweden (Swedish National Hip Arthroplasty Register 2005) are fundamentally different. One, the Lubinus SP II femoral component, has a curved cobalt-chrome alloy stem with a matte surface and collar while the other, the Exeter femoral component, features a straight, double tapered, polished stainless steel stem and has no collar. The former is intended to function through stable fixation with cement. The latter is designed to – or rather, has been found to – subside within the cement mantle, obviously with no detrimental effect to clinical function. This may give the false impression that design does not matter but on the contrary, design and manufacturing do matter.

There are numerous historical examples of newly introduced implants, which have failed to meet expectations in terms of performance and prosthetic survival. The Christiansen hip prosthesis in the 1970’s, the PCA uni-compartmental knee prosthesis in the 1980’s and the Boneloc cement in the 1990’s have unfortunately all contributed to a large number of “unnecessary” revision procedures. The inferior performance of the matte-surface version of the otherwise successful Exeter stem serves as another example of how a seemingly minor change in design can significantly alter the performance of implants.

Should new innovations and “improvements” in implants be discarded then? Should we, as a consequence of a, thankfully limited, number of failed innovations, remain with evidence based methods and well documented, well performing implants? If we knew that future implant refinements would, at best only result in marginal improvement of the already good results of total hip arthroplasty - the answer is probably; yes, let us remain with what we have. But, because we do not know what the future holds, the answer must be no. We must continue to try to improve methods, implants and results. But importantly in this process, great care must be taken to minimize risks whilst still seeking the advantages of a potentially better functioning implant. According to Herberts and Malchau (2000) the effectiveness of large-scale routine hip replacement surgery is better evaluated in observational studies, i.e. the Swedish National Hip Arthroplasty Register, than in randomized trials, since results from such trials cannot be directly extrapolated to improve clinical practice. The Arthroplasty Register has indeed improved the overall quality of total hip replacement in Sweden and aided in development of a much rewarding conservative attitude of the individual surgeon, towards new un-tested implants. However, randomized clinical trials on small patient groups, using sensitive methods for assessment, are essential for minimizing patient risks in the necessary process of evaluation of new techniques and
implants. A certain element of trial and error cannot be avoided, since the basic mechanisms behind loosening are still not fully elucidated.

Certain design features have for a considerable time been considered prerequisites for successful cup fixation. These include grooves to improve fixation between cup and cement, spacers or distance pegs to enable a concentric cement mantle and a flange to provide concentric placement and cement pressurization (Oh et al. 1984). In clinical practice many cup designs adhere to these concepts, which seem to work: cup loosening almost invariably occurs between cement and bone and not between cup and cement. To optimize the cement-bone interface the present opinion seems to favor a complete, “sufficiently thick”, concentric cement mantle. The importance of a concentric cement mantle, as well as the benefit of spacers to achieve it, is however a subject of controversy. Sandhu et al. (2006) reported that even with spacers, the preferred concentric cement mantle was seldom attained. Faris et al. (2006) concluded that spacers did give a more uniform cement mantle but were associated to a higher initial failure rate.

One theoretical advantage with low profile acetabular components is the higher degree of containment within the bony acetabulum, especially in shallow or dysplastic acetabuli. Complete bony containment of cups may reduce the incidence of cement-bone radiolucency and wear (Sarmiento et al. 1990) while lack of containment may adversely influence long-term stability (Laursen et al. 1998). The range of motion of a THR is ultimately determined by the range of motion of the prosthetic head within the cup. The low-profile geometry allows a larger range of free motion without impingement between the neck of the femoral component and the rim of the cup. Impingement can cause local abrasive wear of the cup, dislocation of the head out of the cup, and might also influence the long-term stability of cup fixation. The low-profile geometry also implies a lesser degree of containment of the prosthetic head within the cup, making it more susceptible to instability or ultimately dislocation in the case of mal-positioning. When a low-profile version of a well-documented cemented cup was introduced, we therefore performed a prospective randomized controlled comparison between the low-profile and the original version.

Radiolucent lines, migration and loosening
Generally accepted radiographic criteria for prosthetic loosening do not exist. Radiographic examinations have been reported as inadequate in assessing mechanical loosening (Mjöberg et al. 1986) and unreliable for studies of the cement bone interface (Jacobs et al. 1989). Still, radiography
in combination with the patients' subjective description of symptoms is the most common clinically available method to evaluate a hip prosthesis in terms of fixation and wear.

Radiolucent lines (RLL) adjacent to cemented acetabular components have been generally recognized as a sign of failing implant fixation, as they imply that tissues other than bone occupy the cement-bone interface (Lee and Ling 1983). Migration of cemented cups, as measured by RSA, has also been closely associated to failing fixation. Mjöberg et al. (1985) even suggested that mechanical loosening should be defined as migration. Analysis of radiographs is not an accurate method for assessment of prosthetic migration. Cup migration is detectable on conventional radiographs when it exceeds 3-4 mm and for femoral stems a subsidence of more than 4 mm is considered necessary for detection (Malchau et al. 1995). The accuracy of RSA is approximately 10 times higher.

If loosening, defined as migration, is the change in position of an implant, then the definition of migration is determined by the accuracy of the method by which it is assessed. Thus the number of loose prostheses according to conventional radiography may be none while the more sensitive RSA may detect a significant number of loosenings. In the future, significantly more sensitive measures may find that all of them are loose, or, may alternatively, show that stable fixation exists. From a more practical point of view, fixation may be regarded a continuous entity, ranging from stable fixation to migration and ultimately gross mechanical loosening. At some stage the degree of fixation, or lack of, may ultimately bother the patient causing clinical symptoms. For the clinician and the patient there is, regardless of definition, a distinct difference between loose implants causing, or not causing, symptoms enough to warrant revision surgery.

If a critical threshold for acceptable early migration, with regards to increased risk of early loosening, exists, it is not well defined. Regarding femoral stems there are studies suggesting that early subsidence is associated with increased risk of failure. Freeman and Plante-Bordeneuve (1994), using a smooth press-fit stem, specifically designed to allow measurement of vertical migration, with and without cement, reported that “hips later destined for revision” migrated more rapidly. A threshold migration of 1,2 mm/year was found to detect hips likely to fail with 86 % specificity and 78 % sensitivity. Only vertical migration, measured with a digitizing system less accurate than RSA, was used to determine this threshold value. Kärrholm et al. (1994) reported a 50 % greater probability of revision if subsidence of cemented Lubinus SP-1 stems reached 1,2 mm or more at 2 years. In this study both primary and revision procedures were included. A total of 9
hips were revised, 7 of these due to thigh pain and radiographic loosening and 6 of these 7 were revision procedures. The high failure rate of cemented revisions is well documented and may not be representative for the mode of failure of primary arthroplasties.

In contrast to findings in femoral stems, Ryd et al. (1995) concluded that early migration of knee prostheses, within the first year, was not indicative of future loosening but probably represents bone remodeling while migration occurring between 1 and 2-years was prognostic. Mechanical loosening of knee prostheses occurred exclusively in cases in which migration continued the second postoperative year, and only 20% of continuously migrating prostheses developed “clinical loosening”. However, in his thesis (1986), Ryd emphasized that the continuously migrating knee prostheses were not looser, in terms of inducible displacement, than the group without continuous migration and that no conclusions could be drawn as to what pattern or magnitude of migration may be ominous in the long run.

For acetabular components no reliable data exists regarding the relationship between early migration and late failure or loosening. The current opinion of the predictive value of early migration upon late loosening is based on data from three separate studies of three fundamentally different cup types, cemented Lubinus cups (Snorrason et al. 1993), porous, press-fit screw fixed Harris Galante I cups (Kärrholm and Snorrason 1992) and the Link V-type screw cup (Snorrason and Kärrholm 1990), all with a 2-year follow-up. The mean proximal migration in the study of the V-type cup was 1.3 mm at 2 years compared to approximately 0.2 mm proximal migration of the cups in the other two studies. In a subsequent review, 4 revisions due to pain were registered among the V-type cups after 5 years, but none in the other cup types, (Kärrholm et al. 1997).

Data from these studies of older types of prostheses, some implanted with obsolete techniques, both as primary and revision procedures do, in my opinion, not allow any general conclusions of a predictive value of early migration upon clinical failure of contemporary implants. Furthermore, the clinical importance of early migration may differ depending on prosthetic designs and modes of fixation (Kärrholm et al. 2006). The presumed relationship between radiolucent lines, migration and loosening is elusive. Hopefully future studies will provide us with a better understanding. Awaiting, we must rely on good clinical judgment and radiographs for clinical assessment of our patients and the state of their replaced hips.
Aims of the investigations

I
To compare two fundamentally different stems for femoral revision in an experimental setting, by measuring femoral head displacement under loading conditions mimicking rising from sitting.

II
To determine whether HA coating of a cementless femoral prosthesis would improve the long-term clinical and radiographic result.

III
To evaluate the long-term survival rate, and the clinical and radiographic outcome of acetabular revision arthroplasty with impaction grafting and a cementless HA coated implant.

IV
To compare the Lubinus Standard cup and the low-profile FAL cup in terms of clinical outcome, migration and wear during the first 3 years after implantation.

V
To investigate if a positive correlation existed between presence of radiolucent lines and migration in cemented acetabular components.
# Material

## Table

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Patients

I
Biomechanical study, no patients involved.

II
Prospective randomized controlled study, 20 patients younger than 60 awaiting THR.
HA-coated group; 6F / 6M, median age: 50 (43-56), weight: 84 (62-100).
Non-coated group; 3F / 5M, median age: 50 (43-60), weight: 75 (43-107).
Ref: Paper II, Table 1

III
Study of 87 hips in 79 consecutive patients, 7-11 years after acetabular revision.
48F / 31M, median age: 67 (30-81) weight: 74 (45-118)

IV & V
Prospective randomized controlled study, 53 patients, age 60-80 awaiting THR.
FAL; 14F / 14M, median age: 70 (60-80) weight: 80 (54-99)
STD; 14F / 11M, median age: 69 (60-78) weight: 77 (54-103)
Diagnosis; OA: 53
Ref: Paper IV, Table 1
Implants

\[I\]
PCA Long Stem and Exeter standard stem (Howmedica Ltd, London, UK) were tested in synthetic composite femurs (Sawbones Europe AB, Malmö, Sweden)

\[II\]
Link RS Stem, with or without hydroxyapatite coating according to randomization, was used in all patients. (Waldemar Link GmbH & Co, Hamburg, Germany)

\[III\]
Mallory Head acetabular component with hydroxyapatite coating was used in all patients. (Biomet Inc, Warzaw, IN, USA)

\[IV \& V\]
Lubinus Flanged Anti Luxation cup and Lubinus Standard eccentric cup, implanted according to a randomized allocation, were used for all patients. (Waldemar Link GmbH & Co, Hamburg, Germany).
Methods

**Mechanical testing (I)**

In paper I, three identically prepared synthetic composite femora were used to test the initial stability of two different stems. The femur, with implanted stem, was mounted in rigid steel fixture inclined 45°. An Alwetron TCT 10 material-testing machine (Alwetron twin cam, Lorenzen & Wettre, Stockholm, Sweden) was used to apply a vertical load on the prosthetic femoral head at a constant downward speed during registration of load and displacement of the femoral head. Axial and rotational displacement was calculated. The test procedures were repeated 3 times with each stem type in each femur, i.e. 9 PCA tests and 9 Exeter tests.

*Ref: Paper I, Figure 1*

**ROM (III)**

The complete Range of Motion (ROM) of the hip was registered using a goniometer. The average value of two measurements was used.

**Harris Hip Score (II, III)**

HHS (Harris 1969) is an old scoring system originally designed to assess pre- and post-operative data in 39 private patients treated between 1945 and 1965 with mold arthroplasty, due to traumatic arthritis following hip dislocation or acetabular fractures, at the Massachusetts General Hospital. Nevertheless the Harris Hip Score is one of the most widely used scores with documented high validity, reproducibility and reliability (Söderman et al. 2001). It is also intuitively understandable for clinicians. Harris Hip Score is a rating scale with a maximum of 100 points as the best possible result, distributed on four domains; pain (44), function (47), deformity (4) and ROM (5).

**WOMAC (III, IV):**

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a disease specific patient administered health status measure which we have used a validated Swedish version of (Söderman et al. 2000). WOMAC probes clinically important symptoms in patients with osteoarthritis of the hip or knee. The responses to the 24 questions – 5 for pain, 2 for stiffness and 17 for physical function - are assigned a score from 0 (extreme) to 4 (none). The raw score of maximum 96, is normalized by multiplying with 100/96 producing a score from 0 (worst) to 100 (best).
VAS (IV)
Visual –Analogue-pain Scale is a patient administered pain assessment. The patient sets a mark on a 100 mm ruler where zero represents “no pain” and 100 represents “worst conceivable pain”.

Timed Up and Go Test (III)
Timed Up and Go test (TUG) is the time, measured in seconds, needed to rise from a chair, walk a 3-metre distance, turn around, return to and reseat in the chair, all at a self-chosen comfortable speed and with required walking aids. (Podsialo and Richardson 1991).

Patient satisfaction (III)
Each patient answered the question “if you were to live the rest of your life with the present state of your hip, would you then feel; unhappy, not satisfied, mixed feelings, mostly satisfied, satisfied, happy”, by checking the most appropriate alternative.

Radiographic evaluation (II, III, IV, V)
Our radiographic analyses were made on conventional radiographs (II, III) and on digital images (III, IV, V). Analyses comprised changes in the peri-prosthetic bone, e.g. RLL, calcar atrophy, pedestal formation, and cup orientation. No assessment of migration was made on radiographs. In paper II, presence and extent of radiolucent lines, RLL, around femoral stems were assessed in the 7 zones described by Gruen et al. (1979) and in addition in 7 zones, zone 8-14, on the lateral view. Prosthetic fill of the medullary canal was measured and calculated as proposed by Kim and Kim (1992). All detectable zones were recorded as positive findings and the width of the RLL was measured. In study III and V, measurements on the acetabular side were made using the 3 zones of DeLee and Charnley (1976). In study III the width of RLL was measured while in study V only the presence of RLL was recorded. In study IV analysis on plain radiographs only comprised cup orientation.

Wear (III, IV)
In paper III, linear wear of the polyethylene liner was measured on AP pelvic radiographs as described by Dorr and Wan (1995) and Dorr et al. (1998) and the annual wear was calculated simply by dividing the measured wear with the number of years in situ. In paper IV RSA was used to measure total
linear three-dimensional wear of polyethylene cups. The point motion mode was used to calculate movement of the center of the femoral head in reference to the cup markers.

**Radiosterometric Analysis (RSA) (IV, V)**

Göran Selvik (1974) constructed the original roentgen stereophotogrammetric system and later named it roentgen stereophotogrammetric analysis (RSA). The method has since been developed and has found numerous applications, not only in orthopaedics. RSA is presently the most accurate clinically applicable method available to measure change of position between implants or between implant and patient. It is considered the method of choice for studies of fixation and wear of orthopaedic implants (Kärrholm 1989). A number of updated descriptions and proposed guidelines for standardization of the RSA methodology have been published elsewhere (Kärrholm et al. 1997, 2006, Valstar et al. 2005).

The method requires implantation of a number of spherical tantalum markers into the respective segments of interest, generally the patient and the implant. Simultaneous exposures from two angled x-ray tubes, to produce a radiographic image of tantalum markers in the patient and implant, and similar markers in a calibration cage, are the second prerequisite.

Finally specific software is needed to compute the three-dimensional coordinates of the spherical tantalum markers. These tantalum markers, inserted into e.g. the cup and the patients’ peri-acetabular bone, constitute two rigid bodies. By performing serial RSA investigations the change in relative position between these rigid bodies can be calculated. The movement of one rigid body relative to another is expressed as translations along and rotations about the X-, Y- and Z-axis of a three-dimensional coordinate system. In our studies radiographic films were scanned with a UMAX Mirage II scanner, digitalized using Digitable 1.1 software and analysed using UmRSA 4.1 software (RSA Biomedical Innovations AB, Sweden). Accuracy of our RSA system was calculated based on 100 double examinations.
Results

I

Prosthetic displacement under load

The Exeter stem, in the impaction-grafting concept, displayed a significantly larger average displacement, for all loading conditions, than did the long cementless PCA stem (p< 0.001). Both revision concepts showed considerable displacement compared to a cemented stem without bone graft. In all tests displacement of the prosthetic head was mainly rotational. Thus the stem displayed retroversion without detectable axial displacement. Ref: Paper I, Figure 2, 3 and 4.

II

Clinical and radiographic result

At the 8- to 10-year follow up there was a significant difference in outcome with failures in 7 out of 8 of the non-coated protheses (the non-coated group) compared with 1 failure out of 12 of the hydroxyapatite coated protheses (the HA-coated group) (p=0.0008). In the non-coated group 6 stem revisions were performed due to aseptic loosening and one due to late haematogenous infection occurring in a previously loose prosthesis. One patient remains unrevised, with HHS of 100 and no radiographic sign of stem loosening. One patient in the HA-coated group underwent stem and cup revision due to mechanical failure of the cup. The remaining 11 stems are unrevised with median HHS of 100 (92-100) and no radiographic signs of loosening. Ref: Paper II, Table 1

III

Cup survival-rate

During the study period (7-11 years) 10 patients (10 hips) died with well functioning implants, 1 patient (1 hip) was lost to follow-up and 7 patients (7 hips) underwent acetabular revision. The 9-year survival rate was 90.5 % (95 %CI; 83.4 - 97.6 %) using cup revision for any reason as end point. Of the 7 revisions, 1 was due to early postoperative infection, 1 due to mechanical failure and 5 revisions were due to aseptic loosening. Using cup revision due to aseptic loosening as endpoint, the 9-year survival rate was 94 % (95 %CI; 89,0 - 99.1 %). Of the 5 aseptic loosenings 3 were early due to insufficient primary stability and 2 were due to late aseptic loosening. Ref: Paper III, Table 1 and Figures 4 and 5.
Clinical results
The median HHS was 85 (34-100) and the median pain score 40 (10-44). 32 hips were reported as “pain free” and 21 had ”slight occasional pain with no compromise of daily activity”. The median WOMAC score was 70 (22-100) and in 42 hips the reported pain was “none” or “slight” for all 5 parameters of the WOMAC pain score.

Radiographic results
A complete absence of radiolucent lines was recorded in 48 hips, 11 had lucencies confined to 1 zone, 5 hips in two zones and 5 hips had continuous radiolucencies in all three zones. The calculated average annual polyethylene wear was 0.09 mm/year with no difference between Ring Loc- and Hex Loc-liners.

IV
Migration
Migration, measured as MTPM (maximum total point motion), did not differ between the FAL-cup group and the Standard-cup group (p=0.7 at one year and p=0.8 at 3 years). MTPM values exceeding mean +2SD, were seen in 3 cups (2 FAL, 1 Standard). Analysis of translations along and rotations around the x-y-z axis showed minimal differences between the groups. The 3 cups that showed increased MTPM values also displayed increased proximal migration, in 2 cups exceeding and in 1 cup close to mean +2SD. The range of proximal migration of these 3 cups was 0.85-1.75 mm. Ref: Paper IV, Figure 2 and Table 5.

Wear
Wear, measured as total 3-dimensional femoral head penetration, did not differ between the two cups (p=0.9 and p=0.7 at 1 and 3 years respectively), nor did the femoral head penetration in medial, proximal or posterior direction. The progression of wear between 1 and 3 years was negligible. Two cups, one of each type, showed wear exceeding mean +2SD, ranging 0.62 – 0.88 mm. Ref: Paper IV, Table 6.

Clinical results
The overall clinical results were excellent in both groups. Ref: Paper IV, Table 7.
Migration
No influence of cup-type upon migration was found. At 3 years, MTPM and proximal migration values showed no difference between the two cup-types. Both displayed the same pattern of translation and rotation along x-y-z axis, i.e. lateral, proximal and posterior translations, together with posterior tilt, retroversion and increased lateral inclination. 
Ref: Paper V, Figure 5

Radiographic evaluation
The cup-type did influence the presence of RLL, which were more common in the FAL-cup group both postoperatively and at 1 year. Complete absence of RLL postoperatively was only recorded in 3 cups, all Standard. At 1-year 45 out of 53 cups displayed an increased number of RLL. The inter-observer correlation was best at 1-year but the difference of mean indicated a systematic difference between observers. Ref: Paper V, Figure 5.

Correlation between RLL and migration
No reliable influence of RLL upon migration was found. A statistically significant correlation was found in 2 of 4 analyses but in different outcome measures and at different times. The adjusted R-square values show that the correlation, when present, is weak and of no predictive value for individual cups. Ref: Paper V, Figures 8, 9 and 10.
Discussion

I

We used synthetic composite femora, which can be prepared to a state closely resembling the revision situation. This is difficult to achieve with cadaver femora without further compromising mechanical properties, which already seem low when torsional loading is applied (Nunn et al. 1989, Burke et al. 1991). Torsional testing in cadaver femora (Malkani et al. 1996) has resulted in spiral cracking of the femoral cortex without displacement in the stem-cement-graft interface. The torsional strength and stiffness was found to be more dependent on the pair of femora being tested than on the type of implantation - namely primary or revision. Such interference, due to variability in strength, size and quality of cadaver bone can be diminished by using synthetic femora (Cristofolini et al. 1996).

Axial loading and the concomitant subsidence of stems have been suggested to enhance rotational stability (Mjöberg et al. 1984, McKellop et al. 1991, Gie et al. 1993). In-vivo studies with instrumented prostheses indicate that the ratio between posteriorly directed force and axial force varies in a complex way with activity and force magnitude although the axial force is always the larger (Davy et al. 1988, Bergman et al. 1993, Kotzar et al. 1995). Due to their overall geometry, femoral stems are more susceptible to torsional loading than axial loading. Therefore torsional load seems the most important factor influencing implant stability, and a main contributor to loosening and mechanical failure of femoral stems (Mjöberg et al. 1984, Nunn et al. 1989, Sugiyama et al. 1989, Harris et al. 1991, Nistor et al. 1991, Phillips et al. 1991, Sugiyama et al. 1992, Bergman et al. 1993).

Our model, with femur inclined 45º up from horizontal, allows this axial loading to take place with a constant and relatively high ratio between posteriorly directed force and axial force, corresponding to a slightly more out-of-plane loading situation than what has been reported from in vivo measurements with instrumented prostheses during gait (Kotzar et al. 1995). Models employing pure torsional load, or torsional load with limited axial loading have resulted in stem loosening or cadaver bone fractures at very small loads (Nunn et al. 1989, Malkani et al. 1996). We believe such a loading situation lacks equivalence in vivo.

In-vivo studies with instrumented prostheses have demonstrated resultant forces transmitted over the hip joint reaching 3-4 times body weights. (Rydell 1966, Davy et al. 1988, Hodge et al. 1989) Reports of calculated forces generally give even larger values, approaching 6 times body weight (Bergman et al. 1993). Forces of considerably lower magnitude were tested
in our model, yet rotational displacement of several degrees occurred. However, stems did not show any significant subsidence. A similar observation was made in a model with the femur inclined approximately 30° up from horizontal and vertically loaded in simulated stair climb (Burke et al. 1991).

The negligible subsidence in our study could be ascribed to the fact that impaction of bone graft in the Exeter tests, as well as the insertion of the PCA stem, was made with considerable force, certainly not less than in the clinical situation. Thus the potential for further subsidence during testing immediately after this firm implantation is small, if any, and we have a situation, which in practice allows mainly rotational displacement of the stem. Our opinion is that this might well represent the in vivo situation immediately after implantation, with a stem capable of withstanding axial loads but to a lesser extent torsional loads, resulting in rotational displacement. Continuing torsional loading with corresponding rotational displacement might in due time cause subsidence of the stem. An RSA study by Franzén et al. (1995) showed that all stems subsided between 0.4 - 4.9 mm and 4 out of 5 displaced posteriorly between 1.1 - 6.9 mm during the first year. Another report showed subsidence in all and posterior displacement in 12 out of 13 stems at 1-2 years (Franzén et al. 1997).

Good clinical long-term results of impaction grafting have been reported (Halliday et al. 2003, Schreurs et al. 2005) but so has migration, both axial and rotational (Eldridge et al. 1997, Kärrholm et al. 1999, Mikhail et al. 1999, Ornstein et al. 2001). These observations are in accordance with our experimental findings of low initial stability of these stems, under loads less than those encountered in activities of daily living, allowing micromotion of a magnitude exceeding what is considered tolerable to allow bone ingrowth.

Despite recent research efforts, mechanical, physiological and biological processes involved in the impaction grafting procedure are still far from fully understood. Results from animal studies have added to our knowledge but care must be taken when extrapolating these results to the clinical situation. As an example: in order to achieve maximum initial stability “vigorous” impaction of bone graft is advocated (Gie et al. 1993). Yet, animal models show that impaction delays ingrowth of host bone into the bone graft (Tägil and Aspenberg 1998), implying that the mechanical prerequisites for initial stability could theoretically delay the subsequent process of bone ingrowth. Growth factors, such as OP-1 have been shown to reverse this delay in an unloaded animal model (Tägil et al. 2000) but not in a weight-bearing model (Tägil et al. 2003). Studies employing positron emission tomography (PET) technique have shown regeneration of blood flow and
increased bone metabolism in the bone-grafted area, within a few weeks after the surgical procedure, with blood flow returning to normal at 1 year (Sörensen et al. 2003). At 6 years bone formation activity seem to have normalized compared to the contralateral hip, indicating full graft regeneration according to PET analysis (Ullmark et al. 2007).

Retrieval studies and biopsies, from 3 months to 8 years after impaction grafting (Linder 2000) have shown a viable cortical shell and a medullary front-zone of fibrovascular tissue growing from the periphery, leaving behind a layer of viable trabecular bone. Central to this zone, reaching various depths into the graft, a composite of bone graft particles embedded by fibrous tissue, avascular areas with necrotic bone graft or incomplete fibrous membranes were found. Complete bony restitution was only seen in one case. Similar findings of incomplete and variable bone graft incorporation have been reported from other retrievals (Weidenhielm et al. 2001) and biopsies (Mikhail et al. 1999).

Whatever mechanisms involved, fixation stable enough to provide good clinical results, even in the absence of complete incorporation of bone graft, can be achieved with impaction grafting.

II

After the publication in 2002 of our data supporting the long-term beneficial effects of HA-coating, good or excellent 10-year results, with stem-survival of 99-100 %, have been reported with HA-coated stems in relatively young patients (Effenberger et al. 2004, Lee et al. 2005, Bodén et al. 2006). A retrieval analysis of one stem retrieved after 9,5 years showed complete disappearance of the HA with living bone in direct contact with the denuded titanium surface (Aebli et al. 2003). No adverse tissue effects of HA were seen. Meanwhile, reports of short to mid-term data show no advantage of HA-coating (Kim et al. 2003, Park et al. 2003) and at 15 to 18 years, Lombardi et al. (2006) found neither benefit nor detriment from HA coating of femoral stems. So, it seems the controversy is, as yet, un-resolved.

The only previous study of HA-coated Link RS stems known to us (Thabe et al. 1993) presented good results with no revisions in 104 stems after a short follow up of average 1,9 years. Three studies of the non-coated RS stem report unfavorable results with 9 %, 17 % and 58 % revisions for aseptic loosening at short- or medium-term follow up (Savilahti et al. 1995, Jensen et al. 1994, Sweetnam et al. 1995) while Thabe et al. (1993) report satisfactory results with 3 % revisions after minimum 3,3 years follow-up. Inferior proximal fit and distal canal fill have been pointed out
as possible reasons for the high loosening rate of the RS-stem (Savilahti et al. 1995, Sweetnam et al. 1995). These factors, however, did not affect the result in our series, at least not in the HA-coated group.

In studies where HA-coating was found to improve performance, differences with and without HA-coating were not as striking as in our material (Kroon and Freeman 1992, Søballe et al. 1993, Huracek and Spirig 1994, Donnelly et al. 1997, Dorr et al. 1998, Incavo et al. 1998). This is probably attributable to the presence of a porous or micro-textured surface, which in contrast to a smooth surfaced stem provides some potential for stable fixation even in absence of HA-coating. We believe the smooth, although ribbed, surface of the RS stem may have contributed to the high failure rate (Savilahti et al. 1995). Studies of other smooth surfaced non-coated stems have yielded similar, unacceptable results (Duparc and Massin 1992, Kitamura et al. 1999). In an RSA-study (Kärrholm and Snorrason 1993) the non-coated Link RS stem was found stable in most patients for the first 6-12 weeks but then migration started parallel to increased activity and weight bearing. The authors pointed out the potential for bone ingrowth or bonding during this initial stable period if the stems had been HA-coated. We believe the difference in performance seen in our study is due to such early apposition of bone to the HA-coated surface. For stable fixation, we believe a cementless stem requires either a porous or micro-textured surface or HA-coating. Both features might not be necessary.

III

Excellent early results have been reported by Dorairajan et al. (2005) in a series of 50 acetabular revisions with implants identical to ours, including 12 cases with limited use of morselized allograft. Our series included cases with more extensive acetabular bony defects all treated with massive impaction of morselized allograft into the entire acetabular cavity and the results indicate that this may be done without compromise of implant survival in the 7-11 year perspective. In this setting, in which the implant is allowed only a minimum of host bone contact, the proposed osteoinductive and osteoconductive properties of HA-coating (Söballe 1993, Söballe et al. 1999, Habibovic et al. 2006) may be of particular importance.

In our series sufficient initial stability for bone ingrowth is provided by over-sizing the acetabular component in combination with supplementary screw fixation, despite the large amount of allo-graft interposed between host and implant.
The 3 hips in our series that did not receive 2 mm oversized acetabular components have all been revised. Although one, which was revised after 9 years due to liner and shell wear, proved to be solidly fixed by bone ingrowth, the other 2 displayed early radiographic loosening. We believe this was due to insufficient primary stability.

The initial stability is influenced by the particle size and pre-treatment of morselized bone graft as well as the force used to impact it. Experimental studies have shown less subsidence of the bone bed with larger bone chips and more forceful impaction (Ullmark and Nilsson 1999). Inclusion of even larger pieces, up to 10 mm diameter, nibbled with a rongeur and impacted with a mallet (Bolder et al. 2003) as well as rinsing of the morselized bone (Ullmark 2000, van der Donk et al. 2003) also improved stability. We used smaller chips than what has been recommended above, prepared in a bone mill (Tracer Designs Inc. Santa Monica, CA). We did not incorporate larger rongeur nibbled pieces and did not routinely rinse the bone graft, which was, however, vigorously impacted. At present, however, we do routinely rinse the bone graft.

The Hexloc liner locking mechanism, which the first 45 of our patients received, has been associated with high polyethylene wear-rates (Puolakka et al. 2001) and peri-acetabular osteolysis (Yamamoto et al. 2003). The hemispheric inside and the hexagonal outside results in insufficient polyethylene thickness in some areas, a phenomenon more or less pronounced depending on how the large range of shells are matched to the 3 sizes of liners. Our study did not confirm these findings of excessive wear and osteolysis. Wear rates were low and there was no difference between the two types of liner locking mechanism.

Peri-acetabular osteolysis was limited to 10 patients and lesions were generally smaller than 10x10 mm as measured on AP films. This was an interesting finding, bearing in mind the large number of screw-holes in the acetabular component, which would put it at greater risk of developing local osteolysis (Walter et al. 2004, Kitamura et al. 2005, Walter et al. 2005). On the basis of these findings one might speculate that a thick layer of allograft may act as some kind of inert bone-seal, less susceptible to osteolysis and therefore protecting the underlying host-bone from wear particles and fluid-pressure.
We found no clinically important difference in our primary outcome variables, MTPM and wear, between the Lubinus FAL cup and the Lubinus Standard cup at 1 and 3 years after implantation. Both cup types displayed the same pattern of translation and rotation along x-y-z axis at 1 and 3 years, i.e. lateral, proximal and posterior translations, together with posterior tilt, retroversion and increased lateral inclination. The medial translation was the only individual migration parameter where the 95% CI did not include the zero value, thus suggesting a difference between groups. However this difference of 0.15 mm, which may well be a random finding due to multiple comparisons, was small and therefore of no or limited clinical importance. The mean proximal migration in our study is comparable to previous studies of the Lubinus cup reporting proximal migration of 0.2 mm at 2 years (Nivbrant et al. 1999) and 0.27 mm at 5 years (Nivbrant et al. 2001). At 3 years 3 cups (2 FAL and 1 Standard) displayed large migration, increasing over time. Although tolerable limits of early migration of cemented cups in relationship to increased risk of clinical failure remain to be clearly established (Kärrholm et al. 1997) we believe the magnitude of migration of these 3 cups may indicate an increased risk of early loosening.

Excessive wear was not seen in any of these 3 excessively migrating cups. Wear rates of 0.27-0.3 mm at 2 years have been reported for Lubinus cups with CoCr heads (Digas et al. 2003, Nivbrant et al. 1999) and 0.39 mm at 5 years with Biolox® heads (Nivbrant et al. 2001) Although 2 cups in our study-material displayed wear in excess of the respective group mean +2SD, the overall mean wear rate of 0.27 mm at 1 year and 0.28 mm at 3 years, is even lower than what has been previously reported. We found no correlation between excessive wear and increased migration, a finding indicating that the cause of migration and loosening involves factors other than polyethylene-wear.

Although it seems intuitively reasonable that a relationship between radiographic signs and migration, and mechanical loosening, this has yet to be unequivocally established.

We found a significant difference in the incidence of RLL in the two groups but we found no difference in migration. Similar findings were reported by Flivik et al. (2006), who found no correlation between 2-year migration and extension of RLL in a study where removal of the subchondral bone plate resulted in less RLL but no difference in cup-migration as measured by RSA. However, two previous RSA studies have reported a correlation between RLL and migration. In one, a study of different cementing techniques (Flivik
et al. 2005), a strong relation was found between postoperative RLL and migration at 2 and 5 years. Proximal migration (translation along the Y-axis) and changes in inclination (rotation around the Z-axis) were used as effect variables. In the other study, Kneiff et al. (2006) reported a moderate correlation between RLL in DeLee zone 3 on postoperative and 6 months radiographs, and migration measured with RSA, without specification of their effect variables for migration. No significant correlation was found between RLL in zone 1 and 2 and migration.

In both these studies a dichotomy between migrating cups and stable cups was introduced and the material was also grouped according to increasing presence of RLL. The chosen cut-off level, above which significant migration was said to occur, was calculated based on the precision of their respective RSA measurements. This cut-off level varied in the two studies and so did the definition of positive radiographic findings. We believe these variations will influence both the number of cups considered stable or migrating and the number of RLL, which in turn may influence the chances of finding a correlation between RLL and migration.

A number of studies have suggested the presence of a relationship between RLL and radiographic loosening. A higher incidence of radiographic cup loosening at 9-10 years has been reported when RLL were present on postoperative radiographs (Ranawat et al. 1995, Garcia-Cimbrelo et al. 1997). Ritter et al. (1999) found that postoperative RLL in DeLee and Charnley zone 1 carried a 39 times increased risk of radiographic loosening at a mean follow-up of 12 years. Hodgkinson et al. (1988) found that the presence of radiographic demarcation on pre-revision radiographs correlated to inferior mechanical stability of the cup as tested intra-operatively.

In the present study we have increased the sensitivity of RLL detection by using two different radiographic views as proposed by Schmalzried et al. (1992). We used digital images visualized on a monitor, which, for evaluation of radiolucenties is comparable to conventional radiography (Testoni et al. 2000). Radiographic assessment of RLL around cemented acetabular components is a method with low sensitivity and specificity (Temmerman et al. 2007). Substantial intra- and inter-observer variations have been recorded (Brand et al. 1985, Kramhoft et al. 1996, Kneiff et al. 2005). The subjective nature of the analysis, with variations in radiographic image quality and varying definitions of positive findings may explain the large range, from 8% to 62%, in reported incidence of RLL on postoperative radiographs (Kneif et al. 2006, Flivik et al. 2005). Our strict definition of RLL - including all detectable lines regardless of width - in combination with the use of two different radiographic views may explain the higher incidence of RLL in our study. However, the inclusion of thin RLL is in accordance with the opinion
that the progress and extent of RLL is a more important factor than the width of the gap (Ryd 1986, Hodgkinson et al. 1988, Schmalzried et al. 1992, Garcia-Cimbrelo et al. 1997, Hultmark et al. 2003).

Our finding of more RLL in the FAL group may be associated with differences in design and/or manufacturers recommendations for implantation. The FAL cup has more shallow grooves compared to the standard cup and also a smooth circumferential area without grooves, just beneath the flange. Adherence to manufacturers advice regarding implantation will, in theory, result in a 2.5 mm cement mantle around the FAL cup, provided line-to-line reaming, as recommended, is performed. For the Standard cup, downsizing 2mm from the last reamer, as recommended and practiced in this series, will not even in theory give a 1 mm cement mantle. Due to the position of the 2 mm distance-pegs, the result is a slightly non-concentric cement mantle ranging from a, theoretical, minimum of 1 mm in the region of the widest diameter, i.e. a few mm below the opening face of the cup, to 2 mm in the region of the pegs to slightly more than 2 mm at the “north-pole” of the cup. In practice, our clinical impression is that the bulkier standard cup contains the cement more efficiently in the acetabulum during insertion than does the FAL cup. The low profile and the smaller diameter of the FAL cup, relative to the reamed cavity, contributes less efficiently than the standard cup to contain and compress the cement and the flange does not engage in cement containment until the very end of insertion. The implications of a non-concentric cement mantle are not fully established in the literature. Sandhu et al. (2006) has reported that, even with spacers the preferred concentric cement mantle is seldom attained and Faris et al. (2006) concluded that spacers did give a more uniform cement mantle but were associated with a higher initial failure rate. Follow-up continues to elucidate the-long-term implications of our 3-year findings.

Hitherto compiled data does not imply any clinically useful predictive value of early RLL regarding increased cup-migration. It may be that the early appearance, within the first year, of thin RLL represents an unspecific finding well compatible with a mechanically well-fixed implant. Our findings of quite extensive RLL in the vast majority of cups in which migration is low and comparable to other reports (Nivbrant et al.1999, 2001) raises an interesting question; how to differentiate an early unspecific RLL from a radiographic demarcation signaling failure of fixation? This question, and the general relationship between RLL, migration and loosening, needs further study.
Conclusions

I
Our experimental findings of low initial stability, most pronounced for the Exeter stem but also observed with the PCA stem, justify some concerns regarding long-term fixation. Stem displacement, already occurring under loads less than those encountered in activities of daily living, reached a magnitude, which would exceed what is tolerable to allow bone ingrowth. Unrestricted mobilization should be avoided during the early postoperative period.

II
The Link RS stem is, due to its design features, inappropriate for use without HA-coating. However, HA-coating improves the long-term clinical and radiographic performance to a level comparable to contemporary cementless stem designs, suggesting that HA-coating has a beneficial effect on long-term stem fixation.

III
Acetabular revision with extensive impaction of allograft and HA-coated cementless implants seems to be a useful and safe method of treating contained or combined contained and acetabular wall defects. Results from our clinical and radiographic review indicate that such extensive use of morselized allograft can yield promising results. The limited contact between a HA-coated implant and living host bone does not seem to compromise implant survival in the 7-11 year perspective.

IV
Three years after implantation the low-profile FAL cup performs as well as the Standard eccentric Lubinus cup in terms of clinical results, migration and wear. The FAL cup is safe to use when acetabular anatomy makes a cemented low-profile implant suitable.
Presence of RLL on postoperative radiographs is not a reliable indicator of increased migration as measured by RSA at 3 years. Also at 1 year, when the presence and extent of RLL has increased, we failed to associate these findings with 3-year migration results. Thin RLL appearing within the first year is an unspecific radiographic finding well compatible with a mechanically well-fixed implant. The presumed relationship between RLL, migration and loosening needs further study.
Clinical consequences of our findings

I
Our postoperative regime for patients undergoing hip revision arthroplasty with impaction grafting prescribes protected weight bearing for minimum 6 weeks.

II
For uncemented arthroplasty we only use HA-coated implants.

III
We use extensive impaction of morselized allograft and HA-coated implant in the presence of bone loss at acetabular revision.

IV
The FAL cup is used when acetabular anatomy makes a cemented low-profile implant a suitable option.

V
We do not consider thin RLL on postoperative radiographs alarming but continue our clinical and RSA follow-up of the study population to search the long-term implication of such findings.
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