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Hip revision using the Exeter stem, impacted morselized allograft bone and cement

A consecutive 5-year radiostereometric and radiographic study in 15 hips

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Background  Impaction grafting in hip revision surgery is widely used but studies with mid- and long-term follow-up are scarce.

Patients, methods and results  A 5-year radiostereometric (RSA) follow-up of 15 hip revisions with the Exeter stem, morselized impacted allograft bone and cement revealed that 3 stems had not migrated between 2 and 5 years after revision, 11 stems had migrated to a minor degree in at least 1 direction, and 1 stem was loose according to RSA but without any radiographic signs of loosening or pain. The pain score was comparable to primary arthroplasties. Interpretation  From a 5-year perspective, first-time hip revisions for aseptic loosening with impacted morselized allograft bone and cement appear to yield good clinical results, although stem migration continues to a minor degree 2 years after revision.

Stem revisions using the Spectron EF stem and the Exeter stem with impaction grafting and cement has been evaluated by radiostereometric analysis (RSA) for 3 and 2 years, respectively (Kärrholm et al. 1999, Ornstein et al. 2001). All 18 Exeter stems, but only 9 of 24 Spectron EF stems, subsided above the accuracy level. One third of the Exeter stems still migrated between 1.5 and 2 years after surgery, while the Spectron EF stems with a rough proximal surface had stabilized after 2 years.

The purpose of this study of consecutive hip revisions with the Exeter stem, morselized allograft bone and cement was to prospectively evaluate stem migration according to RSA, quality of the surgical procedure and clinical outcome for 5 years after surgery.

Patients and methods  During 1994 and 1995, femoral stem revision was done in 22 consecutive Exeter X-change hip revision arthroplasties (21 patients) with impacted morselized allograft bone and cement, operated on due to osteoarthritis. All hips were revised for the first time and because of aseptic loosening. 5 patients died of diseases not related to the hip before the 5-year endpoint of the current RSA study, 1 could not be evaluated by planned RSA due to detachment of the greater trochanter, and 1 denied follow-up beyond 3 years. Thus, 15 hips in 7 women (1 with bilateral surgery) and 7 men with mean age 74 (60–82) years at surgery could be followed for 5 years (Table 1). The 2-year RSA results in 18 of the original 22 stems have been reported previously (Ornstein et al. 2001).

Surgical technique  2 surgeons performed the revisions. A posterolateral approach was used without osteotomy of the
greater trochanter. Fresh-frozen femoral heads were morselized using the Tracer Bone Mill, with a medium-sized cutter and a hand crank (Tracer Designs Inc, Santa Paula, California, USA). This technique produces bone chips of approximately 3 mm in size. Before morselization, the femoral heads were thawed in a warm (50°–60° C) plain saline solution for approximately 20 minutes. The bone chips were compressed in a cotton cloth for delipidization. The X-change revision instruments system (Howmedica International, London, UK) was used for impaction of the allograft bone into the femur (Simon et al. 1991, Gie et al. 1993).

Prechilled, vacuum-mixed Palacos bone cement containing gentamycin (Schering-Plough International, Kenilworth, New Jersey, USA) was introduced with a cement gun (2 min after mixing was started), and the cavity was sealed and pressurized to force the cement dough into the graft. When the cement viscosity had risen to an appropriate level, a standard collarless, double-tapered and polished Exeter femoral stem was inserted. In all 15 hips, the socket was also revised with impacted morselized allograft bone and cement. Systemic cloxacinil and low molecular heparin were given as prophylaxis. Weight bearing was restricted for 3 months postoperatively.

**Radiostereometric analysis (RSA)**

To enable RSA follow-up according to the method described by Selvik (1989) and Kärrholm et al. (1997), 0.8-mm tantalum markers were implanted.

### Table 1. Data at surgery and at 5 years after 15 Exeter stem revisions with impacted morselized allograft bone and cement

<table>
<thead>
<tr>
<th>Case</th>
<th>1</th>
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<td>R</td>
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<td>G</td>
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<td>F</td>
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<td>1.2</td>
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<td>0.2</td>
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</table>

* according to Charnley (1979),
* according to Gustilo and Pasternak (1988),
* according to Gie et al. (1993),
* according to Selvik (1989) and Kärrholm et al. (1997),
* E = excellent, G = good, F = fair, P = poor, D = defective,
* according to Elldridge et al. 1997,
* E = excellent, G = good, F = fair, P = poor, D = defective,
* i = migration (mm) by RSA,
into the greater and lesser trochanters during surgery. The patients were examined in the supine position using two 40° angulated X-ray tubes facilitating simultaneous exposures of the hip with the implanted tantalum markers and a combined reference and calibration device with similar tantalum markers placed at known positions, on two separate uniplanar films. The 2-dimensional distances between the images of the tantalum markers on the 2 films provided the input data for computerized conversion to a 3-dimensional coordinate system using the Kinema software (RSA BioMedical Innovations AB, Umeå, Sweden). Thereafter, stem migrations, i.e. displacement of the center of the femoral head relative to the femoral bone, could be calculated. The first RSA examination was performed median 2 (1–5) days after surgery and before the patient was mobilized. The subsequent examinations were performed after 1.5, 3 and 6 months, and after 1, 1.5, 2, 3, 4, and 5 years.

The precision of this RSA set-up was determined at the 99% confidence limit by 2 repeated postoperative RSA examinations on the same occasion in 13 hips. Stem migrations were considered significant when they measured at least 0.3 mm in the distal-proximal direction, 0.5 mm in the medial-lateral direction, and 0.7 mm in the posterior-anterior direction. Absolute migration values below these levels were classified as not significant, i.e. no detectable migration in the individual case.

Radiographic assessment

Bone stock deficiency in the proximal femur was classified in conventional radiographs into 4 types (I-IV) according to Gustilo and Pasternak (1988), type I being least severe (Table 1). The radiographic evaluation concerning the surgical technique was performed by one of the authors (LL) with experience from similar evaluations using the protocol from previous studies (Gie et al. 1993, Linder 2000). Quality of graft packing, appearance of the allograft 5 years after surgery, and incidence of radiolucent lines 5 years after surgery were determined in 7 regions on AP radiographs around the stem according to the classification of Gruen et al. (1979); altogether, 105 regions in the 15 hips studied. The quality of graft packing was assessed using 5 grades according to Gie et al. (1993). The allograft appearance at 5-year follow-up was graded under 6 headings (Gie et al. 1993, Linder 2000). Cement filling and defects were defined. The stem positioning at surgery was recorded as neutral or ≥ 4° valgus/varus (Eldridge et al. 1997b).

Clinical assessment

Preoperatively, the patients were evaluated clinically and categorized according to the scheme of Merle d’Aubigné and Postel (1954), later modified by Charnley (1979), as: (A) 1 hip involved; (B) both hips involved; and (C) hip disease and concomitant disorders. The Charnley hip score, a six-point scale including pain, walking ability and range of motion (ROM) ranging from 1 (most severe impairment) to 6 (normal), was calculated preoperatively and at the 5-year follow-up. The operating surgeon performed the preoperative clinical evaluation (Table 1) and an orthopedic surgeon blinded as to the results of the RSA performed the clinical evaluations at follow-up.

Statistics

Spearman’s rank correlation test was used to correlate preoperative bone stock deficiency (Gustilo et al. 1988), quality of graft packing (Gie et al. 1993), cement mantle defect, cement beyond the tip of the stem, positioning of the stem and radiolucent lines with absolute stem migrations during the first 5 years after revision, as measured by RSA. P-values below 0.05 were considered significant.

Results

RSA migration

According to the results of RSA, all stems migrated and most of the migration occurred within the first 6 weeks after revision (Figures 1 and 2 A–C). In 3 stems, no migration was observed between 2 and 5 years after surgery, whereas in 12 migration continued in at least one direction. One of these stems (case no 15, Table 1) showed wobbling in the medial-lateral and posterior-anterior directions ranging from 1.7 mm medial to 3.3 mm lateral and 5.6 mm posterior to 7.0 mm anterior (Figures 2 B–C and 3). This stem, the only stem migrating distally above 5 mm (Figure 2A), was obviously loose according to RSA.
Figure 1. Distal migration of 15 individual Exeter stems followed for 5 years after hip revision. The broken line represents case no. 15, the wobbling one. Significant distal migration ≥ 0.3 mm.

Figure 2 A. Distal migration of 15 Exeter stems. Mean values ± SE for absolute distal migration of 14 stems (unbroken line) and case no. 15, the wobbling one, presented separately (broken line). Significant distal migration ≥ 0.3 mm.

Figure 2 B. Medial-lateral migration of 15 Exeter stems. Mean values ± SE for absolute medial-lateral migration of 14 stems (unbroken line) and case no. 15, the wobbling one, presented separately (broken line, medial (+), lateral (-)). Significant distal migration ≥ 0.5 mm.

Figure 2 C. Posterior-anterior migration of 15 Exeter stems. Mean values ± SE for absolute posterior-anterior migration of 14 stems (unbroken line) and case no. 15, the wobbling one, presented separately (broken line, posterior (+), anterior (-)). Significant distal migration ≥ 0.7 mm.
No significant correlation between bone stock deficiency and absolute stem migration in any direction during the first 5 years after revision was found ($r = -0.2$–$0.3$, $p > 0.3$).

Radiographic results

The predominant quality of the graft packing was good or fair in 14 hips, and defective in 1 (Table 1). The graft packing was excellent, good or fair in 78 of the 105 regions (Table 2). No significant correlation was observed between predominant quality of graft packing and absolute stem migration in any direction during the first 5 years after revision ($r = -0.3$–$0.3$, $p > 0.2$).

The cement mantle was complete in 5 hips and incomplete in 10 (Table 1). There was cement beyond the tip of the stem in 8 hips. No cement fracture was observed. 3 stems were positioned in varus ($\geq 4^\circ$) at surgery, but none in valgus (Table 1). 1 stem changed position from neutral to varus during the observation period. No significant correlation was observed between cement mantle defect, absence of cement beyond the tip of the stem or positioning of the stem in varus and absolute stem migration in any direction during the first 5 years after revision ($r = -0.3$–$0.3$, $p > 0.2$).

The predominant allograft appearance in 8 hips was trabecular incorporation, and 1 hip showed trabecular remodeling at 5 years (Table 1). More than half of the 105 regions revealed trabecular incorporation, approximately 20% trabecular remodeling and approximately 10% cortical repair (Table 3). Graft resorption was seen in region 1 in 1 hip and in region 7 in 3 hips. These resorptions occurred after only 2 years.

Radiolucent lines were noticed in 11 hips 5 years after surgery. The radiolucent lines were located in 24 of the 105 regions: in 5 regions at the cement-bone interface, in 13 at the cement-graft interface and in 6 regions at the graft-bone interface. 8 radiolucent lines were less than 1 mm wide and 14 were between 1 and 2 mm. 2 lines exceeded 2 mm, both at the cement-graft interface. One of the lines exceeding 2 mm occurred in the proximal third of region 1 in the hip with the loose stem according to RSA (Figure 3), and the other line in region 7 in another hip. No correlation between presence of any radiolucent line and absolute stem migration in any direction during the first 5 years after revision was discernible ($r = -0.17$–$0.21$, $p > 0.4$).

Clinical results

2 patients sustained a femoral shaft fracture at the tip of the stem, 1 and 3 months after the revision. Both fractures healed after open reduction and plating. 2 hips dislocated during the 5 years following surgery. After closed reduction, both were stable without further intervention. There were no re-revisions.

14 patients were pain-free, or had occasional slight pain (pain score 5 or 6), 5 years after surgery. 1 patient had pain at activity but not during rest (pain score 4) (Table 1). The patient with the loose stem according to RSA had no pain. 5 patients were not able to walk without 2 sticks or crutches (walking ability score 2). 1 patient needed the walking aids because of an aseptic loosening of the socket in the revised hip. As the patient was free from pain, and without threatened bone stock, no re-revision was contemplated. The other 4 patients either had problems with the opposite hip or were category C patients.

<table>
<thead>
<tr>
<th>Table 2. Quality of graft packing (Gie et al. 1993a). Predominant in 15 hips and in 105 regions (Gruen et al. 1988)</th>
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</thead>
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<tr>
<td>Grade</td>
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</tr>
<tr>
<td>Excellent</td>
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<td>Good</td>
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<td>Fair</td>
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<table>
<thead>
<tr>
<th>Table 3. Allograft appearance (Linder 2000) at 5 years after revision. Predominant in 15 hips and in 105 regions (Gruen et al. 1988)</th>
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<td>Allograft appearance</td>
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<td>Trabecular remodeling</td>
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<td>Not classified</td>
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In 11 regions cortical healing and in 4 regions localized resorption was observed.
Drop-out analysis

The 5 patients who died within 1–3 years of surgery had a pain-free hip with no clinical or radiographic deterioration until death. The patient with a fracture of the greater trochanter has been free from pain after fracture healing, with no clinical or radiographic deterioration after this event. The patient who declined participation beyond 3 years was pain-free, with no clinical or radiographic deterioration within the first 3 years after surgery.

Discussion

Hip revision with impacted morselized allograft bone and cement yielded good pain reduction similar to what is observed in primary arthroplasties (Fowler et al. 1988, Williams et al. 2002). Stem migration, in most cases to a minor degree and without clinical deterioration, occurred between 2 and 5 years after surgery in 12 of the 15 hips studied. In 1 of these stems, the RSA results were consistent with prosthetic loosening, although this was not detectable on conventional radiographs and there was no need for re-revision. The design of the Exeter stem with a double-tapered wedge shape, polished surface, and absence of collar permits not only gradually decreasing distal migration (Fowler et al. 1988, Gie et al. 1990, Gie et al. 1993), but also migration in other directions (Alfaro-Adrian et al. 1999, Ornstein et al. 2001). In primary arthroplasties, the stem subsidence has been shown to occur within the cement mantle (Fowler et al. 1988, Alfaro-Adrian et al. 1999, Ornstein et al. 1999, Stefánsdóttir et al. 1999, Williams et al. 2002). However, in revisions with impacted morselized allograft bone and cement, distal migration has been registered; not only of the stem within the cement mantle, but also of the stem-cement beam in relation to the femoral bone (Gie et al. 1993, Ornstein et al. 1999). Approximately half of the migration has been observed within the first 2 weeks after revision (Ornstein et al. 2000), but one third of the stems were still migrating between 1 and 2 years after revision (Ornstein et al. 2001).

All but 3 of the 15 stems in the current study...

**Settling into cement and allograft bone**

Malkani et al. (1996) showed experimentally that the first 5 loading cycles induced 0.36 mm distal stem migration and the following 4995 cycles induced a further 0.63 mm distal migration (Malkani et al. 1996). This early migration, called settling of the stem in the cement and settling of the stem-cement beam in the graft in the experimental study, may correspond to the spontaneous hip muscle activity successively resumed when the anesthesia is discontinued (Figure 4a). Although the patient is bedridden, the migration might then progress until the index radiographs are performed. Thus, although we have drawn attention to the importance of early index RSA investigation (Ornstein et al. 2000), there is probably a certain amount of stem movement immediately after the operation which has not been captured in this study. Compared to a RSA study of primary Exeter stems (Stefánsdóttir et al. 2002), the distal migration found in the current revisions was twice as much, i.e. the same proportions that were found in the above-mentioned experimental study by Malkani et al. (1996). Recoil of the allograft bone (Malkani et al. 1996, Ullmark and Nilsson 1999) may be one reason for this difference.

**Compression and slippage of the allograft bone**

Another possible explanation for early stem migration is further compression of and slippage in the morselized graft (Gie et al. 1993, Nilsson and Kärrholm 1996) (Figure 4b). This phenomenon
may be influenced by chip size (Eldridge et al. 1997a, Ullmark 2000), size distribution (Brewster et al. 1999), delipidization (Kärrholm et al. 1999, Ullmark 2000), and size and stiffness of the graft (Kuiper et al. 1998). In most studies neither the chip size (Gie et al. 1993, Weidenhielm et al. 1994, Eldridge et al. 1997b, Meding et al. 1997, Kärrholm et al. 1999, Mikhail et al. 1999, Knight et al. 2000) nor the type of morselizer used has been reported (Gie et al. 1993, Weidenhielm et al. 1994, Eldridge et al. 1997b, Meding et al. 1997, Kärrholm et al. 1999, Mikhail et al. 1999). Exceptions are Elting et al. (1995), Ornstein et al. (2001) and Nelissen et al. (1995). In the latter study, a chip diameter of 3–5 mm was recommended. In the present study, the chip size was 3 mm. The hardness of impaction has also been reported to be a critical factor for success, both experimentally (Ullmark and Nilsson 1999) and when using a rounded stem with a collar and non-polished surface in a clinical setting (Kärrholm et al. 1999). Experimentally, Tägil and Aspenberg (1998) reported that impaction could have a deleterious effect on osteoinduction. Therefore, the clinical situation may represent a balance between the favorable biological properties of morselized allograft bone and the impaction necessary to ensure primary stability (Haddad et al. 1999). The graft handling and impaction technique used in the present study followed the recommendations of the Exeter group at the time of the initiation of this study.

**Cold flow and creep of the cement**

Cold flow, plastic deformation or creep (Figure 4c) in the cement occurs most easily under tensile and shear loading, and faster in newly formed cement (i.e. in the first three months) (Lee et al. 1978, Lee 2000, Hughes et al. 1997). The design of the Exeter stem is consistent with migration within the cement leading to wedging and new settling in the cement mantle (Ling 1986, 1992, Fowler et al. 1988). This hypothesis is supported by experimental studies (Lee et al. 1978, Malkani et al. 1996, Lee 2000). Some authors have suggested that stem subsidence on these grounds is only marginal (Verdonschot and Huiskes 1997). A combination of the present data and data presented earlier (Ornstein et al. 1999, 2000, 2001), however, could support the idea of early creep in the cement being a prerequisite for more pronounced stem migration. The present data, however, do not support the idea of a defective cement mantle, the absence of cement beyond the tip of the stem, or varus positioning of the stem as being causes of stem migration.

**Shear strength of the femoral cancellous bone**

The shear strength between cement and femur in first-time revisions that have been cemented conventionally is decreased by 80% as compared to primary cemented arthroplasties (Dohmae et al. 1988), perhaps due to the lack of cancellous bone. Thus, it is plausible to presume that the lack of cancellous bone might also explain some of the migration in revisions with the Exeter stem, impacted morselized allograft bone and cement as compared to primary Exeter arthroplasties (Figure 4d). Another possible factor that might explain the continuous migration from both mid-term and long-term perspectives is fatigue failure of cancellous bone (Taylor and Tanner 1997). However, as there was hardly any cancellous bone left in the proximal femur at the revisions, we consider that this explanation is less probable.

**Allograft bone resorption**

The allograft bone is supposed to be replaced by new bone (Gie et al. 1993). This has been documented both experimentally (Roffman et al. 1983, Schreurs et al. 1994, 1996) and clinically (Ling et al. 1993, Nelissen et al. 1995). The bone regeneration process is preceded by revascularization, ingrowth of fibrous tissue into the allograft bone and graft resorption (Ling et al. 1993, Nelissen et al. 1995, Tägil 2000, Linder 2000, Ullmark and Obrant 2002). Absence of balance between these processes in favor of graft resorption could contribute to stem migration (Tägil 2000) (Figure 4e).

**Fatigue of cement**

In the long term, the cumulative effect of repeated applications of loading cycles below the level needed to cause failure with a single application of load might lead to fatigue of the cement (Lee et al. 1978, Hughes et al. 1997, Lee 2000) (Figure 4f). However, at the stress levels found in total hip replacements, it is likely that many millions of load cycles would have to be applied (corresponding to
several years of use) before failure would take place (Lee 2000).

**Femoral expansion**
The normal process of ageing includes a progressive physiological enlargement of both the medullary cavity and femoral bone width (Trotter and Peterson 1967, Ruff and Hayes 1984, 1988, Mosékilde and Mosékilde 1990, Beck et al. 1992). Some authors have reported that this phenomenon is associated with stem loosening (Poss et al. 1987, Hofmann et al. 1989, Robinson et al. 1994). Harris (1992) proposed that the age-related enlargement of the medullary femoral canal was altered by the introduction of a cemented stem. Enlargement of the medullary cavity and femoral bone width might create conditions for stem migration from both mid-term and long-term perspectives (Figure 4g).

**Comparisons**
The magnitude of the stem migrations in the current study was similar to data for similar revisions reported by Gie et al. (1993) and Franzén et al. (1995). There was, however only 2.5 years and 1 year, respectively, of follow-up in these studies. On the other hand, Eldridge et al. (1997b) and Meding et al. (1997) reported more pronounced migration during 0.5–3.5 years of follow-up than in the current study. Spectrum EF, collar supplied, rounded in shape and with a non-polished surface, is still the prosthesis with the lowest reported distal migration (Kärrholm et al. 1999). The migration rates in the 2 RSA studies cited may have been more pronounced than reported, as their RSA index examinations were performed 1 week and 5–10 days (respectively) postoperatively. These 2 studies might then have missed more of the early stem migration than the current study, in which the index examination was performed 2 days (median) after surgery (Ornstein et al. 2000). In a 1-year RSA study, the Exeter stem migrated in the distal direction twice the distance of the Charnley Elite stem (van Doorn et al. 2002). However, the migrations in the medial-lateral and posterior directions were several times greater for the Charnley Elite stem than for the Exeter stem. These variations in stem migration necessitate longer RSA follow-ups to evaluate the real importance of different stem designs.

From a 5-year perspective, first-time stem revisions for aseptic loosening with impacted morcellized allograft bone and cement seems to yield good clinical results, although migration continues to a minor degree even 2 years after revision. There have been no studies showing the clinical relevance of migration after 2–5 years.

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