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ORIGINAL PAPER

T. Gosens · E. J. van Langelaan

Clinical and radiological outcome of hydroxyapatite-coated femoral stem in revision hip arthroplasty

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Abstract We used a proximally hydroxyapatite-coated femoral stem in revision arthroplasty of 48 cases with aseptic loosening and Paprosky defect class 1 or 2. We reviewed the outcome after 6.1 (4–9.3) years. The clinical outcome was good, with a mean postoperative HHS of 90 (51–100) points. There were five reoperations all on the acetabular side and none for the femoral stem. At follow-up, we observed cancellous sclerosis radiographically in 19 cases—especially in non-tightly fitted stems and mainly in Gruen zones 2 and 6. In 13 cases, cortical thickening was seen, mainly in Gruen zones 3 and 5 and especially in tightly fitted stems. These bony changes were significant and not related to any clinical parameter. They started to appear from 6 months onward, with increasing frequency with longer follow-up. We find that the standard Mallory–Head hydroxyapatite-coated femoral stem is suitable for revision in cases with lower-class femoral defects.

Résumé Nous avons utilisé une tige fémorale enduite d'hydroxyapatite proximale dans l'arthroplastie de révision de 48 cas avec descellement aseptique et défauts osseux de classe 1 ou 2 selon Paprosky. Nous avons examiné le résultat après 6,1 (4–9,3) années. Le résultat clinique était bon avec un score HHS postopératoire moyen de 90 (51–100) points. Il y avait cinq réopérations, toujours pour des problèmes acétabulaires et jamais pour des problèmes de tige fémorale. Àu dernier recul nous avons observé radiologiquement des densifications spongieuses dans 19 cas—surtout pour des tiges imparfaitement ajustées et principalement dans les zones 2 et 6 de Gruen. Dans 13 cas un épaississement cortical a été noté, principalement dans les zones 3 et 5 et surtout pour les prothèses bien ajustées. Ces différences osseuses étaient significatives, sans rapport avec aucun paramètre clinique. Elles ont commencé à paraître à 6 mois avec une fréquence croissante au cours du suivi. Nous trouvons que la tête-Mallory standard–tige fémorale enduite d'hydroxyapatite est convenable pour les révisions avec défauts osseux fémoraux de bas grade.

Study performed at the Rijnland Hospital, Leiderdorp, The Netherlands

T. Gosens (✉)
St. Elisabeth Hospital,
Hilvarenbeekseweg 60,
5022 GC Tilburg, The Netherlands
e-mail: t.gosens@elisabeth.nl
Tel.: +31-13-5392942
Fax: +31-13-5422547

E. J. van Langelaan
Rijnland Hospital,
Simon Smitweg 1,
2353 GA Leiderdorp, The Netherlands

Introduction

Revision hip arthroplasty after aseptic loosening is more expensive, can provide more technical problems, and has a higher rate of complications. The results of revision hip arthroplasty are less satisfactory than after primary hip replacement, but revision operations improve the quality of life significantly [18]. A survivorship of 95% at 10 years has been reported, but especially with cemented revisions, high re-revision rates are reported, even with improved cementing techniques [11]. After aseptic loosening, the femur no longer has the trabecular structure that is needed for cement interdigitation. The flat endosteal femoral canal surface leads to reduced cement–bone interface shear strength [4, 13]. For this reason, cementless femoral revision prostheses have been advocated. Specially designed revision prostheses with longer stems and extensive porous coating have been manufactured to bypass the damaged femoral part and provide stability by distal fixation [9, 15]. In lower-class femoral deficiencies, a standard proximally porous-coated prosthesis can provide sufficient stability. These minor deficiencies can be countered by using hydroxyapatite (HA) to obtain good bone in-growth, to create a small effective joint space, and to prevent subsidence.

This prospective study presents the clinical and radiological results in 48 revision procedures for aseptic loosening using the standard cementless Mallory–Head HA-coated femoral prosthesis (Biomet, Warsaw, IN, USA).

Patients and methods

Patient characteristics

We performed 48 revision procedures in 47 patients with a mean age of 59.6 (range 37–72) years and reviewed the results after a mean period of follow up of 6.1 (range 4–9.3) years. The diagnosis at revision was aseptic loosening in all cases: in 46 cases, a cementless prosthesis and in two cases a cemented prosthesis was revised. In 48 cases, 73 previous operations had been performed ranging from one to eight. For 42 cases, it was a first-time revision, for five cases a second-time and for one case a third-time revision. Most (*n*=46) cases had a femoral defect type 1 or 2, although two cases had a type 3A femoral defect according to Paprosky [15]. Higher Paprosky classes were treated with a different prosthesis having a longer stem and calcar replacement [9].

Geometry of the prosthesis

The Mallory–Head porous-coated femoral stem has a 3° taper that allows the prosthesis to achieve three-point fixation for immediate stem stability. The porous-coated primary stems are made of titanium alloy (Ti-6Al-4V) and are proportionally sized, ranging from 6 mm to 19 mm in width and from 135 mm to 180 mm in length with a neck angle of 135°. The proximal area is circumferentially porous coated with a titanium alloy plasma spray of a “closed pore” design. The middle one-third has a roughened finish created through a blasting technique while the distal portion is smooth. The coating has a thickness of 55±15 µm, a HA crystalline content of more than 98% with a crystallinity of 50–70%, and a tensile adhesion of more than 15 MPa.

The Mallory–Head stem was primarily combined with the HG cup (Zimmer, Warsaw, IN, USA) and a CoCr 28-mm head (*n*=40) then later on with the Ringlock cup (Biomet, Warsaw, Indiana, USA) and a ceramic 28-mm head (*n*=8).

Surgical technique

All patients were treated by the senior author (EJvL) using a straight lateral approach without trochanteric osteotomy. After careful extraction of the loose prosthesis and meticulous removal of fibrous membranes and cement, the femoral canal was reamed to cortical contact. To inhibit distal stem contact, we routinely performed distal over-reaming of at least 1.0 mm with flexible reamers over a guiding rod. Postoperatively, protected weight bearing with crutches was used in all cases. The use of a walking aid is recommended as a standard guideline by the senior author in prolonged walking after revision procedures.

Patient assessments

All patients were included in a prospective follow-up schedule and were evaluated preoperatively, and postoperatively at 3, 6, and 12 months and yearly thereafter using the Harris Hip Score (HHS) [8] and specific questions about functional items such as pain, limping, and use of walking aids were asked. At the latest follow-up, the modified Oxford Hip Score (OHS) [6] was added to the assessment to measure patient quality of life after the revision procedure.

Radiographic assessments

During each follow-up visit, antero-posterior and lateral radiograph were taken. These were evaluated using Gruen zones [7] for signs of bone resorption, subsidence, osteolysis, interface deterioration, cyst formation, radiolucencies, reactive line formation around the HA-coated and the non-coated parts of the femoral stem, cancellous bone sclerosis, cortical hypertrophy, and pedestal formation around the stem tip. Changes in these radiographic parameters with time were noted. All bony changes were estimated by eye. The stem was defined as completely filling the diaphysis when the diameter of the stem in the middle of zones 3 and 5 divided by the diameter between the inner cortices of the femur was more than 0.8. The stem was defined as having fixation by bone on-growth (osseointegration) when there was no subsidence or migration and no radiolucent or radiodense line formation along the HA-coated portion of the stem.

Statistical analysis

Statistical analysis of the results was performed, and the influences of clinical and radiographic variables were studied using chi-square test, two-tailed Student’s *t* test, or logistic regression, depending on group characteristics. Statistical significance was set at $p<0.05$.

Results

All patients but one were available for follow-up. One patient died 6.2 years after the operation. A perfect radiographic and clinical result was obtained at the 6-year follow-up before she died.

Complications

Recurrent dislocations were seen in four cases, and were managed by acetabular revision. One acetabular revision was performed for progressive polyethylene wear, and three other patients showed liner asymmetry and are being screened every 6 months for progression. In these patients, no osteolytic changes in the acetabulum or femur were seen. No stem revisions were performed or were pending at the latest follow-up.

Clinical results

The mean preoperative HHS was 39 (16–48) points, compared with 90 (51–100) at the latest follow-up, and no or only very mild pain was scored by 43 cases. In 17 cases, limping was present in varying intensity. Walking aids were regularly used by 19 cases. These figures decreased in comparison to preoperative values. The average Visual Analogue Scale (VAS) for pain amounted to 1.65 (range: 0–8) at the latest review. Quality of life after the revision procedure measured by the modified OHS was good.

Radiological results

Except for the patients with asymmetric liners due to wear, analysis of the acetabular bone showed no progressive radiolucent line formation. The femoral stem position was within 2° varus or valgus in all patients. We could not detect stem migration or subsidence in the first 3 months postoperatively or at further follow-up. Structural changes of the femoral bone became apparent at 6 months, starting with the formation of sclerosis of the cancellous bone. This was seen along the femoral stem at the point of transition between the coated and noncoated parts in Gruen zones 2 and 6, and progressed in 19 cases at 6 years. The areas of bone apposition slowly expanded distally into the upper parts of Gruen zones 3 and 5 to 11 cases at 6 years. Endosteal reactive lines became radiographically visible in Gruen zone 4 between 6 and 12 months postoperatively. They increased in incidence in zones 3, 4, and 5 until the fifth year, after which a slight decline in frequency was seen due to expansion of the bone apposition from the more proximal zones. Progressive resorption of bone and radiolucent line formation were not observed. Thickening of the cortical bone was observed in Gruen zones 2, 3, 5, and 6 from 1 year onward and progressed distally in the next follow-up to 4, 14, 13, and four cases at 6 years in zones 2, 3, 5, and 6 respectively. The pattern of peripheral thickening of the femoral cortex followed that of endosteal bone sclerosis.

A total of 13 stems were tightly fitted in the femoral canal, and the remaining 35 were non-tightly fitted. Symmetrical cortical thickening was seen in nine out of 13 stems with a tight femoral canal fit ($p<0.0001$ chi-square test) but only in four out of 35 stems with a non-tight fit. Cancellous sclerosis predominated (18 of 35 stems) in cases with a non-tight stem fit ($p<0.0001$ chi-square test, Table 1) while it was hardly seen (one of 13 stems) in cases with a tight fit. There were no correlations between the clinical parameters (OHS, Charnley class, and VAS for pain) and the radiographic changes.

Table 1 Distribution of radiological findings with regard to the femoral stem fit

Radiographic findings	Femoral stem fit		
	Tight fit	Nontight fit	All stems
None	3	13	16
Cancellous sclerosis	1	18	19
Cortical thickening	9	4	13
Total	13	35	48

Discussion

The overall results are excellent, and pain relief (89%) and stem survival is comparable to several other cementless prostheses [1, 3, 5, 14] used in primary hip replacements. The function of the hip (limping and the use of walking aids) is, however, less satisfactory than in the primary procedures. These differences can be explained by changes imposed by multiple operations. Preoperatively, all patients were limping, whereas postoperatively 17 were still limping and 19 used walking aids regularly.

Adding the OHS to our study illustrated that patients' opinions were better than the HHS. The OHS showed that apart from limping and use of walking aids, the ability to perform household shopping and sexual activities are frequently difficult.

The outcome in our study is better than in other proximally porous-coated revision procedures reported in the literature [16]. These authors describe loosening and re-revision rates above 10%, but they reported the use of proximally porous-coated stems in more extensively (class

Fig. 1 Nine-year post-revision radiograph for the left hip. The tight femoral canal fit leads to cortical thickening. No proximal osteolysis is visible. The right hip is 13 years post-primary implantation of a Mallory–Head hydroxyapatite (HA)-coated femoral stem.

3 and worse) damaged femora. Woolson and Delaney [22], however, noted 48% of subsidence in a study with only classes 1 and 2 femoral defects, a study comparable to ours.

It has been shown that an HA-coated femoral stem may prevent peri-implant particle migration [2] and has superior potential in sealing the proximal femur in comparison to the use of cement [12]. HA coatings have been shown to provide a secure, reliable bond between prosthesis and bone, even under loaded conditions and over long periods of time without the formation of an intermediate layer of fibrous tissue [19, 20]. The bone on-growth even occurs in damaged and sclerotic proximal femurs as in revision procedures. The efficacy of this seal needs prolonged follow-up, however, since Yee et al. [23] were unable to show any difference. Their follow-up of 4.4–4.9 years might have been too short.

The radiographic osseo-integration is characterized by a specific pattern of remodelling of the proximal femur (Fig. 1). Positive bone remodelling in the form of endosteal bone apposition in Gruen zones 2 and 6 may suggest that the transfer from stem to femoral bone occurs in this area and that the femoral stem is securely bonded. When transferring stresses from the proximal to the distal stem, a slow process of bone resorption (negative bone remodelling) in the region of the lesser and greater trochanter should be expected. We did not detect any femoral resorption in our study. This may be explained by the fact that a substantial percentage of the bone mineral content has to be resorbed before it becomes visible on plain radiographs. On the other hand, proximal bone resorption has been reported after a similar follow-up based on visual interpretation of the radiographs [20, 21], and bone loss has also been shown in a study using dual-energy X-ray absorptiometry [17]. After 6.1 years, most of the bone apposition occurs adjacent to that part of the femoral stem where the HA coating ends, the so-called transitional zone. Formation of new bone in the area near the lower edge of HA coatings was predicted by Huiskes et al. [10] using finite element analysis. The explanation was that, particularly in this area, endosteal stress concentrations are caused by the abrupt transition from a bonded to a loose interface.

In our study, the incidence of cortical thickening at 6 years is mainly symmetrically distributed around tight-fitting stems in zones 3 and 5. Cortical sclerosis at 6 years is mainly symmetrically distributed around non-tightly fitted stems in zones 2 and 6. This is different from other studies even with identical prostheses [1, 3, 5, 14, 15, 21]. We think that these widely varying numbers quoted for periosteal or endosteal bone apposition are merely a function of the tightness of the fit of the stem, a fact that is not reported in most of the literature on radiographic changes around the femoral stem.

We suggest that the concept of transitional load transfer from proximal to distal can morphologically be predicted by the way the femoral stem fills the medullary canal. Stem fit thus seems to predict the quality of bone remodelling. We did not find a relation between the quantity of bone remodelling and a tight distal fit, but predominance of stress transfer more distally in the femur leads to an augmented proximal stress-shielding-induced bone resorption [10]. Therefore, we also advise diaphyseal overreaming and aiming for perfect metaphyseal press fit. A smaller-sized prosthesis should not be used, to avoid over reaming, as there will not be a perfect metaphyseal press fit, allowing the stem to subside.

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