Non-Cemented Revision of a Femoral Component with a Fully Porous-Coated Stem. 41 Cases with a Mean Follow-up of 3.5 Years

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Purpose. To study the clinical results, femoral component stability, and development of protective forces in a non-cemented fully porous-coated revision stem fixed distally in the femoral shaft. We wanted to determine whether distal fixation is safe in cases of proximal bone deficiency.

Materials and methods. We carried out a prospective study with clinical exams and X-rays on 41 patients with symptomatic loosening of a femoral stem.

Results: thirty-two patients (78%) were satisfied with the results, reporting significant improvement of pain. Using the criteria of Engh et al, 27 cases showed signs of osteointegration (66%), there was stable fibrous fixation in 8 (19%) and stem instability in 6 (15%). There was significant association between pain decrease, medullary canal filling and osteointegration. Stress shielding was more severe in the stems of greater diameter, but was not related to clinical variables. There were 9 intraoperative fractures (21.9%), 3 dislocations (7.3%), and one arterial lesion. Three patients had an acute early infection, and another had a late fracture of the femoral stem. With a mean follow-up of 3.5 years, 6 patients had non-stable stems. Two patients have undergone review of their implants, 2 are waiting for review and another 2 have refused further surgery.

Conclusions. Our results are not as good as those seen in the literature, therefore we have revised our surgical technique.

Key words: hip, arthroplasty, femoral implant, revision.

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Recambio no cementado del componente femoral con vástago de recubrimiento poroso completo. Cuarenta y un casos con un seguimiento medio de 3,5 años

Objetivo. Estudiar los resultados con relación a parámetros clínicos, estabilidad del componente femoral y desarrollo de fuerzas protectoras, de un vástago de revisión no cementado, con recubrimiento poroso completo y fijación distal diafisaria. Observar si la fijación distal constituye un método de fijación segura en caso de deficiencia ósea proximal.

Material y método. Estudio prospectivo con análisis clínico y radiográfico en 41 pacientes con aflojamiento sintomático del vástago femoral.

Resultados. Treinta y dos pacientes (78%) manifestaron sentirse satisfechos con el resultado, refiriendo una mejoría significativa del dolor. Aplicando los criterios de Engh et al 27 casos mostraron signos de osteointegración (66%), 8 (19%) una fijación fibrosa estable y 6 (15%) un vástago inestable. Hubo asociación significativa entre la disminución del dolor, el relleno del canal medular y la osteointegración. El stress shielding fue más severo en los casos de vástagos de mayor diámetro, pero no se relacionó con variables clínicas. Se presentaron 9 fracturas intraoperatorias (21,9%), 3 luxaciones (7,3%) y una lesión arterial. Tres pacientes presentaron una infección aguda precoz y otro una rotura tardía del vástago femoral. Con un seguimiento medio de 3,5 años, 6 pacientes tenían un vástago inestable. Dos pacientes han sido revisados, dos pendientes de revisión y otros dos rehusaron una nueva intervención.

Conclusiones. Nuestros resultados son inferiores al resto de las publicaciones, por lo que hemos revisado la técnica quirúrgica.

Palabras clave: cadera, artroplastia, revisión, femoral.

Femoral reconstruction in hip revision surgery poses some unresolved issues. Significant bone loss in the proximal femur makes it very difficult to achieve stable initial fixation, be it cemented^{1,2} or not³.

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One of the alternatives to be considered during femur reconstruction is the use of non-cemented components with complete porous coating and initial diaphyseal fixation ("fit and fill")^{3,4}. Laboratory studies and histological analyses of retrieved prostheses show a greater area of bone growth surrounding the implant^{4,5} as well as distal anchorage to compact cortical bone, which permits a more solid fixation than cancellous metaphyseal bone⁵. Furthermore, distal fixation is the safest method in cases of proximal bone deficiency, which is present in most cases.

However, diaphyseal fixation with this type of fully porous coated stems (both in primary surgery as on revision) is not free of problems, especially as far as stress shielding⁶ which in some cases, may lead to massive cortex resorption.

The purpose of this study is to assess the clinical and Xray results (pain and gait) of osteointegration and the development of stress shielding in 41 patients in whom a revision fully porous coated stem was implanted, with a mean followup of 3.5 years (range 2-6 years).

MATERIALS AND METHODS

From 1995 to 1998 we performed 46 revision arthroplasties of femoral components. Two patients died and three had a deep infection that required a Girdlestone-type arthroplasty- excision, for which reason they were eliminated from followup. Therefore, there remained 41 cases available for a mean followup of 42 months (range: 24-72). Of these, 23 were men and 18 women. Mean age at surgery was 64 years (range: 27-78).

In 5 cases this was the second replacement. The most frequent diagnosis at the moment of first surgery was primary coxarthrosis in 29 cases. In 35 cases both components were replaced and in 6 only the femoral component. Fifteen arthroplasties were recovered that had both components cemented and 26 without cementation of both components.

For the diagnosis of non-septic loosening we used the X-ray criteria described by Engh et al⁷. In the cases of non-septic loosening we performed a preoperative assessment that included a detailed clinical history, X-rays, laboratory data (hemogram, globular sedimentation rate [GSR], C-reactive protein [Crp]) and aspiration and culture. During surgery we took samples for culture and histological studies, both during the first and the second step of femoral reconstruction. No preoperative scintigraphy was carried out during this study.

The most frequent reason for revision was non-septic loosening in 34 patients (83%). Six patients had septic loosening (15%) and one patient had component mal-position. As regards the 6 cases of septic loosening, in 2 patients replacement was done in 1 surgical step and in 4 patients re-

placement was done in 2 steps, using a spacer with cement mixed with 4 g of gentamycin both on the acetabular and on the femoral side for a minimum of 3 weeks; a cycle of an intravenous antibiotic was administered for at least 6 weeks. A femoral component with extensive porous coating was used in all patients, the Solution Stem (Depuy, Johnson & Johnson Company, Warsaw, IN) with a 32 mm metal head. For acetabular revision a hemispheric porous screw cup was used.

Before surgery an anteroposterior (AP) X-ray of the pelvis and an AP and axial X-ray of the hip and femur were taken, which allowed the use of molds to determine the approximate stem diameter and the femur offset.

Epidural anesthesia was used, except with 3 patients that required general anesthesia. An antibiotic prophylaxis protocol was used with 2 g of sodium cephalozine by the intravenous route during anesthesia induction; low molecular weight heparin was also used.

An anterolateral approach to the hip was used for revision surgery. In 6 patients an extended trochanteric osteotomy was performed, due to difficulties extracting the cement.

Postoperative treatment consisted in removing drainage and getting the patient into a sitting position at 48 hours, DVT prophylaxis with low molecular weight heparin for 1 month and antibiotic prophylaxis for 72 hours, except in cases of septic loosening, in which the cycle of antibiotics was maintained until laboratory values returned to normal. Hospital discharge was after 3 days free of fever, with a surgical wound of normal appearance and hemodynamic stability. A 10% of body weightbearing was allowed for 8 weeks and from then on progressive weightbearing.

All patients were followed up clinically and with Xrays during the preoperative period, the immediate postoperative period, at 3 months and thereafter annually. The D'Aubigne and Postel⁸, scale were used for clinical assessment and pain, gait and mobility.

To plan for femur reconstruction, the loss of femoral bone was estimated preoperatively and intraoperatively as was the quality of residual bone, using the Paprosky³ classification.

The results were registered in a statistical database (SPSS 12.0[®] for Windows). In the statistical analysis to compare 2 related samples, the Wilcoxon non-parametric test was used. For independent samples, the Mann-Whitney non-parametric test was used (level of significance \cdot ? = 0.05).

RESULTS

We have assessed clinical results, femoral component stability (osteointegration) and osteoporosis due to stress shielding.

Clinical assessment

Before revision 21 patients (51%) had pain on walking that did not allow them to carry out any activity and 16 (39%) reported intense nocturnal pain. The rest of the patients had intense pain controllable with the use of painkillers. With reference to preoperative walking 38 patients (92,7%) reported serious difficulties, and required at least two canes.

After revision surgery, 32 patients (78%) said they were satisfied with the results and reported a significant improvement in postoperative pain in comparison with the preoperative situation (mean preoperative score 1.5 to a score of 4.2 in the final assessment; p < 0.01; range test with Wilcoxon sign). Nine patients reported pain in their thigh and required painkillers. Of these, 5 had tolerable pain with limited activity, 3 had pain on walking that did not allow them to carry out any activity and 1 patient had severe pain. Of the 9 cases mentioned, 6 had signs of stem instability, 1 patient with pain and limited activity presented at the last assessment with a broken femoral stem, 1 case had symptoms of unstable acetabular component and 1 case had intense pain with symptoms of a fixed implant.

Comparing the capacity to walk before surgery, 38 patients (92%) required the support of at least 2 canes. After surgery, 27 cases (66%) improved their walking capacity and 14 (34%) did not improve their gait, but continued to require 2 canes for any type of activity.

Secondary stability

The most frequent femoral defect during the postoperative period was type II in 27 patients, 8 cases were type I, 4 were type IIIA and 2 were IIIB. The stem diameter was 14 mm (range: 10-16.5). The degree of fit obtained was determined by the relation between the diameter of the stem and the diameter of the medullary canal, with a mean of 88.4% (range: 75-99). The degree of mean fit for stable stems was 89%, in comparison with 84% of unstable stems.

Using stability criteria according to Engh et al⁹, 27 cases showed symptoms of osteointegration (66%), 8 (19%) showed symptoms for stable fibrous fixation and 6 (15%) had unstable stems. Two patients underwent revision and 2 are pending revision; the rest refused a new operation.

Subsidence of the femoral component was determined by the distance between the prosthetic collar and the distalmost point of the lesser trochanter. The range of stem subsidence was 0-14 mm. In 6 cases a major subsidence greater than 3 mm was seen. The mean subsidence of the unstable stems was 9.8 mm (range: 5-14).

Stress shielding

Stress shielding was assessed using the criteria of Engh et al⁷. *Stress shielding* types I and II were seen in 34% of cases. Severe *stress shielding* (Figure 1) was seen in 3 cases (7.3%), in 2 of them there was a greater proximal deficiency with type III defects that required longer stems, although in both cases fixation was good (Figure 2).

There was no relation between clinical variables and degree of stress shielding (p = 0.35), although there was a relation with the degree of fit achieved (p = 0.032). During the period assessed there was no sign of progression of stress shielding to the other cases.

Complications

There were several complications during extraction and insertion of components, including 9 intraoperative fractures (21.9%), 3 dislocations (7.3%) and an arterial lesion that was repaired. Three patients presented early acute infection, 2 were one-step replacements of septic loosening.

In the 3 cases a Girdlestone type excision-arthroplasty was performed. As has been mentioned, the late complications were: 1 patient had a breakage of the femoral stem after 6 years and underwent revision with another extensively porous-coasted stems.

DISCUSSION

In femoral component revisions, bone loss especially in the metaphysial region may make certain initial fixation difficult to achieve. One of the alternatives to solve this problem consists in the use of extensively coated porous stems (Solution), which, up to date, have shown some of the best results of femoral reconstruction¹⁰⁻¹².

Our results show that 78% of our patients were satisfied with surgery, and had significant improvement of pain. However, these results are inferior in comparison with comparable published series. Thus, FY Ng et al¹³, in 24 revision cases with a mean followup of 61 months, obtained a mean score on the Harris scale of 93.1 (range, 80-100). Engh et al¹⁰, in 21 cases of femoral revision with an AML prosthesis and a mean followup of 6.3 years, showed that 85% of their patients were satisfied with the results. In this study 19 patients (85%) reported they felt less pain than during the preoperative period and 16 (80%) did not require canes to walk. In our work we have seen that, in effect, pain is significantly related to unstable fixation due to stem subsidence.

According to Engh et al⁹, x-ray stability criteria, in our series 66% of patients showed signs of osteointegration and 19% of stable fibrous fixation. This means a rate of revision of 15%, with a followup of 3.5 years. These results are poorer than those of other studies. Thus, FY Ng et al¹³ reported that 83% of their patients presented with stem osteointegration with a low rate of residual pain in the thigh, and they related this to the use of stems of less than 13.5



Figure 1. Postoperative X-ray of a IIIA femoral defect. Well adjusted stem with signs of stable fixation due to osteointegration.



Figure 2. X-ray of the same patient 4 years after surgery. There is a marked loss of medial and lateral cortex density, with extension towards the diaphysis (degree IV stress shielding). The stem continues to have good fixation.

mm in diameter. Crawford et al¹⁴, in a more recent study of 49 patients revised with fully HA-coated stems and a mean followup of 3.3 years, found 98% of stem osteointegration, with only one case of loosening due to subsidence related to an intraoperative fracture. However, Engh et al⁹, in a longer term study of 26 hips with a minimum followup of 10 years, determined that 85% of the stems were stable, with a rate of non-septic loosening of 15% (4 of 26 hips) (Table 1).

It has been determined that osteointegration is more frequent when a greater degree of fit and fill of the femoral canal⁹⁻¹¹ is achieved. Moreland et al¹², in 111 surgeries with complete canal filling criteria had 99 cases (89%) of osteointegration. This fact has also been seen in our study, where canal filling for stable stems was 89%, in comparison with 84% for unstable stems. This may explain the higher rate of revision in comparison with other series^{3,9-11}, and can be related to the choice of an inadequate stem size.

Osteoporosis due to stress shielding has not been a clinically relevant problem in this study, and we have seen it in varying degrees in cases of osteointegrated stems. In cases of unstable fixation we have not seen any sing of remodelling. These findings coincide with those of Moreland et al^{12} , with a mean followup of 3.3 years, and those of Weeden et al¹⁵, with a followup of 14.2 years. We have also seen progressive bone stock recovery in some patients, with a wide medullary canal, thin cortices due to osteoporosis and a stem that wholly fills the medullary canal. This observation agrees with what has been suggested by Sugimura et al¹⁶ in the sense that bone repair processes may overcome bone resorption processes caused by stress shielding, with a progressive recovery of bone stock. However, we have seen a reverse process in 2 cases of type III defects, in which we used extremely lengthy stems. Here, there was progressive cortex thinning although this had no clinical significance until the last assessment. It is possible that in subsequent assessments a loss of fixation may be observed in this type of cases, such as was the case of Weeden et al¹⁵ who found that 19 patients with type IIIb defects suffered a rate of loosening of 21% during the assessment period.

To conclude, absence of postoperative pain was related to a greater degree of medullary canal filling and osteointegration. There was a relationship between degree of stem fit and the development of stress shielding. Stress shielding was not a relevant clinical problem. Our clinical results are poorer than those published in the literature, so we have revised our surgical technique.

Table 1. Clinical series of femoral revisions

Series	Technique	Nº. of cases	Follow-up (years)	Fixation stability (%)
FY Ng et al1 ³	HA-coated stem	24	5	83.3%
Crawford et al1 ⁴	Solution	49	3.3	97.9%
Moreland et al1 ²	AML	136	9.3	83%
Weeden et al1 ⁵	Solution	170	14.2	82%
Almenara et al (present study)	Solution	41	3.5	66%

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