Stress-shielding of the proximal femur using an extensively porous-coated femoral component without allograft in revision surgery
A 5- TO 17-YEAR FOLLOW-UP STUDY

E. Garcia-Cimbrelo, E. Garcia-Rey, A. Cruz-Pardos, R. Madero

From Hospital La Paz, Madrid, Spain

Revision surgery of the hip was performed on 114 hips using an extensively porous-coated femoral component. Of these, 95 hips (94 patients) had a mean follow-up of 10.2 years (5 to 17). No cortical struts were used and the cortical index and the femoral cortical width were measured at different levels.

There were two revisions for aseptic loosening. Survivorship at 12 years for all causes of failure was 96.9% (95% confidence interval 93.5 to 100) in the best-case scenario. Fibrous or unstable fixation was associated with major bone defects. The cortical index (p = 0.045) and the lateral cortical thickness (p = 0.008) decreased at the proximal level over time while the medial cortex increased (p = 0.001) at the proximal and distal levels. An increase in the proximal medial cortex was found in patients with an extended transtrochanteric osteotomy (p = 0.026) and in those with components shorter than 25 cm (p = 0.008).

The use of the extensively porous-coated femoral component can provide a solution for difficult cases in revision surgery. Radiological bony ingrowth is common. Although without clinical relevance at the end of follow-up, the thickness of the medial femoral cortex often increased while that of the lateral cortex decreased. In cases in which a shorter component was used and in those undertaken using an extended trochanteric osteotomy, there was a greater increase in thickness of the femoral cortex over time.

Loosening of the femoral component in total hip replacement (THR) often produces major defects in the proximal bone. Cementless long-stem components have been widely used in revision surgery to obtain a stable fixation of the stem, distal to the proximal bone deficiency.1-3

Although good clinical results for more than ten years have been reported using an extensively porous-coated stem in revision surgery, severe stress-shielding and radiological changes in the cortical bone in the proximal femur have always been major limitations in the long-term outcome.4-12 In order to address the question as to whether stress-shielding influences the durability of clinical results, we analysed the data from a consecutive series of patients with a follow-up of five to 17 years to assess the evolution of the femoral cortex at three levels. We also determined whether factors such as gender, age, bone defect, the surgical approach or the length and diameter of the component influenced stress-shielding.

Patients and Methods
Between 1992 and 2004, 352 femoral revisions were performed in our institution. We have reviewed 113 consecutive patients (114 hips) who had a revision without cement or bone graft using a component with an extensively porous-coated stem (Solution System; DePuy, Johnson&Johnson, Warsaw, Indiana). The criterion for inclusion in the study was revision due to aseptic loosening of a cemented or cementless stem. The study was approved by our Institutional Review Board. Oral and written informed consent had been obtained from all patients. A minimum clinical and radiological follow-up of five years was required. One hip was excluded because of a deep infection and re-revised seven months after surgery and 18 patients were either lost to follow-up (14 hips) or died from causes unrelated to the operation (four hips) before five years.

The remaining 94 patients (95 hips) formed the basis of the follow-up study. There were 61 women and 33 men with a mean age at the time of surgery of 72.5 years (32.0 to 89.0). The original diagnosis was primary osteoarthritis in 70 hips, avascular necrosis of the femoral head in 11, post-traumatic arthritis in seven, developmental dysplasia of the hip in three, rheumatoid arthritis in three and ankylosing spondylitis in one. Table I gives the prostheses used for primary arthroplasty.
The status of the femoral bone was ascertained during the operation and the hips were classified according to the criteria of Paprosky et al., as follows: type II, 31 hips; type IIIA, 36 hips; type IIIB, 25 hips; and type IV, three hips. The revision was the first in 69 hips, the second in 24, and the third and fourth in one hip each. In a total of 74 (77.9%) hips the acetabular component was also revised. The mean time between the initial replacement and the femoral revision was 9.6 years (1.0 to 20.0). The mean follow-up until revision or their latest evaluation was 10.2 years (5.0 to 17.0).

**Operative technique.** All the hips were templated pre-operatively to determine the appropriate width of stem. In the pre-operative planning a length of stem was chosen which allowed fixation of at least 5 cm to 7 cm in intact distal diaphyseal bone. A standard posterolateral approach was used with an additional extended trans-trochanteric osteotomy in 38 hips to facilitate extraction of the femoral component and cement. The bone defect was then defined by eye and palpation to determine the available healthy bone stock before reaming the femur. The median diameter of the component was 15 mm (10.5 to 19.5) and the median length was 8 inches (6 to 10). Longer stems with more porous coating were used as necessary in those femora with more deficiency of bone stock. The femur was usually under-reamed by 0.5 mm although when the component did not progress with impaction, line-to-line reaming or even over-reaming of 0.5 mm was done to accommodate bowing. A prophylactic circumferential wire was inserted to prevent fracture before insertion of the component. Table II shows the length and diameter of the types of stem used for the different bone defects in the entire series (114 hips). No strut grafts were used.

After bed rest for three to five days with the leg in abduction, the patients were mobilised partial weight-bearing for three to six weeks depending on the bone defect and the quality of the press-fit obtained. Full weight-bearing was allowed after three months. Antibiotic prophylaxis (1 g of cefazolin every six hours) was given for 48 hours. Subcutaneous heparin was used as a routine thromboembolic prophylaxis until the patients were fully mobile.

**Clinical and radiological analysis.** Clinical evaluation assessed pain, walking ability and movement of the hip according to the scale of Merle d’Aubigné and Postel (range 1 to 6). Clinical failure was considered as re-revision, pain (level 4 or less) or both. Moderate pain was considered to be level 4 and severe pain as less than level 4. Extensive questioning about pain and its location was carried out. Thigh pain was considered to be related to the femoral component. Leg-length discrepancy over 1 cm was also noted.
Standard anteroposterior (AP) and lateral radiographs of the pelvis and the operated femur were taken immediately after the operation and at three, six and 12 months, and then annually thereafter. In clinical practice, assessment of the cortical index and cortical width from the post-operative radiographs is very inaccurate and inconsistent. There are other problems inherent in those radiological techniques, such as the quality of the exposure and the positioning of the femur, which are prone to variability of measurement due to rotation of the femur when cortical dimensions are involved. In order to minimise the contribution of each of the potential errors, all post-operative and follow-up radiographs were taken using a standard protocol. The patient was positioned supine, with the feet together. The x-ray tube was placed over the symphysis pubis 1 m from and perpendicular to the table and to reduce interobserver error, measurements were made by a single experienced reader (EGR) who had not been involved in the surgery. Variations in magnification were corrected using the known diameter of the femoral head as the internal reference. The proximal femur was divided into the zones of Gruen, McNeice and Amstutz. Filling of the femoral canal was measured as the ratio of the width of the stem to that of the intramedullary canal and was determined at three levels as follows: level A was 1 cm distal to the inferior margin of the lesser trochanter, level B at a point equidistant from the lower edge of the collar and the tip of the prosthesis and level C at the distal point of the prosthesis. The radiographs taken immediately after the operation were compared with those taken during follow-up in order to assess remodelling of bone. The quality of the bone and restoration of the femur were quantitatively assessed on AP radiographs at follow-up by measuring the femoral cortical index as well as the width of the femoral cortex at levels A, B and C. The cortical index is calculated by measuring the quotient of the outside diameter of the shaft to the width of the canal. We did not grade stress-shielding according to the criteria of Engh, Bobyn and Glassman because it seemed that they determined the area of stress-shielding rather than the intensity of bone loss. The existence of residual osteolytic areas in the femoral cortex was recorded, followed and assessed, according to Böhm and Bischel, as increasing defects, constant defects or osseous restoration. Migration was assessed by measuring the vertical subsidence of the femoral component according to the method of Callaghan et al. Subsidence was not considered to be significant unless it exceeded 10 mm. Fixation of the component was graded as radiological ingrowth and fibrous stable or unstable, according to the criteria described by Engh, Glassman and Suthers.

Qualitative data were compared using the chi-squared test and the McNemar test for paired data. The evolution of the mean cortical index as well as the width of the cortical bone of the femoral shaft at different levels was assessed using a general linear model with repeated measures, the Greenhouse-Geisser correction, and also to compare gender, hips in which a posterolateral or an extended transtrochanteric osteotomy had been made, those with major or minor intra-operative bone defects, those in which stems with different lengths and diameters were implanted, and patients with an age below and above 70 years. A p-value ≤ 0.05 was considered to be significant. Statistical analysis was performed with SAS 9.1 (SAS Institute Inc., Cary, North Carolina).

Results

Operative complications. These included five fractures of the greater trochanter, two pseudarthroses of the greater trochanter, two intra-operative fractures, treated by cerclage wires, and two fissures at the level of the tip of the stem which consolidated after conservative treatment. Two femoral shafts were perforated during reaming, but this did not affect the reconstruction of these hips. There was one case of deep infection, which was excluded from the study after early revision. One hip had a haematoma for 45 days after the operation but at one year had no clinical or biological signs of infection. There were also two dislocations within two months of surgery. The acetabular components were revised with a constrained liner with a good result. Clinical findings. Two loose femoral components were revised. The first was in a 74-year-old man with a Paprosky type-3B bone defect. He had a stem 15 mm in diameter and 10 inches in length. He presented with thigh pain, progressive subsidence and loosening at five years after surgery. The second was a 72-year-old woman with a Paprosky type-3B bone defect and previous failed impaction grafting. She had a stem 13.5 mm in diameter and 8 inches in length and presented with progressive subsidence and loosening after four years. These cases were due to poor femoral filling and the hips were revised using a wider stem. For the whole series (114 hips), the cumulative probability of not having a further revision of the femoral component for any reason was 96.9 (95% CI 93.5 to 100) at 12 years in the best-case and 84.8 (95% CI 78.2 to 91.5) at 12 years in the worst-case scenario (Fig. 1).

The mean pre-operative Merle d’Aubigné and Postel score was 2.2 (SD 0.7) for pain, 1.9 (SD 0.6) for function and 1.9 (SD 0.6) for range of movement. The mean score at the latest follow-up study was 5.7 (SD 0.6) for pain, 5.1 (SD 0.7) for function and 4.9 (SD 0.7) for range of movement. The best improvement was related to pain. Level-3 pain was
found in loosened and re-revised components and mild pain (level 4) was present in two components with fibrous stability and one with bony ingrowth. All these patients had pain in the thigh. Patients often had difficulty in flexing their knees during the first weeks after operation but this had recovered by the three-month review. These clinical results should be interpreted cautiously since factors other than the revised femoral component, such as advanced age, bilaterality or polyarthritis, may be involved. There was a leg-length discrepancy greater than 1 cm in 27 hips (28.4%), in five of 2 cm and in one of 2.5 cm. In 32 (33.7%) patients, limping was observed and 15 of these required the use of one (11 patients) or two crutches (four patients).

Radiological findings. Radiolucent lines were seen in only seven hips and affected only one or two Gruen zones. Proximal osteopenia was difficult to assess because of the frequent sclerosis of the proximal femur, although osteopenia was found in Gruen zone 1 in 21 hips, including 15 which also had osteopenia in Gruen zone 7. All the hips with an extended transtrochanteric osteotomy showed bone formation and bone healing in the previously scalloped and osteotomised areas. Fracture of the thin ventral osteotomised portion of the proximal part of the femur occurred in five of the 38 hips treated by this approach, but these fractures affected neither the stability of the stem nor the healing of the osteotomy. Residual osteolytic cavities in the femoral cortex showed osseous restoration in most cases, but it was slower in the lateral cortex and incomplete at the latest follow-up. Only the two components re-revised for aseptic loosening showed an increasing defect. The AP radiograph showed that the tip of the stem was well centred in all hips, but in the 57 in which a posterolateral approach had been made, the stem of eight (14.0%) impinged on the anterior cortex, resulting in a mean loss of femoral cortex of 18% (10% to 22%). No fractures were detected at the tip of the stem. No hip with an extended transtrochanteric osteotomy had a stem which impinged on the anterior cortex. In six hips there was non-progressive subsidence greater than 10 mm (11 to 25) and progressive subsidence in two. The mean filling of the canal at different levels in the whole series was 88.1% (SD 13.9) at level A and 95.1% (SD 5.7) at level B. Filling was greater in hips without than in those with subsidence (Table III). In all, 89 hips had bony ingrowth and four had fibrous stable fixation. The two migrated components showed unstable fixation (Paprosky type-3B bone defect) and were re-revised. Of the four with fibrous stable fixation, three had a Paprosky type-3B bone defect and the other a Paprosky type-3A defect. Five of the 25 hips with a Paprosky type-3B bone defect had fibrous stable or unstable fixation.

Radiological bone remodelling. Changes in the cortical index and in the femoral cortical bone were common at the final follow-up (Fig. 2). The cortical index (Greenhouse-Geisser, p = 0.045) and lateral cortex (Greenhouse-Geisser,
oral bone loss. Nadaud et al reported good results with the mismatch in the diameter of the intramedullary canal of proximal bone loss, none were found in our patients. The stem have been reported in heavy patients with extensive fractures of available allografts in revision surgery makes it difficult to achieve a tight press-fit in the host bone. Although fractures of the stem have been reported in heavy patients with extensive proximal bone loss, none were found in our patients.

Table IV. Mean variations (sd) in the cortical index and femoral cortex at the three levels in the 95 hips

<table>
<thead>
<tr>
<th>Level</th>
<th>Post-surgery</th>
<th>At 6 months</th>
<th>At 12 months</th>
<th>At latest follow-up</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical index</td>
<td>1.614 (0.20)</td>
<td>1.607 (0.20)</td>
<td>1.604 (0.21)</td>
<td>1.602 (0.21)</td>
<td>0.045</td>
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<tr>
<td>Lateral cortex</td>
<td>5.26 (2.31)</td>
<td>5.19 (2.43)</td>
<td>4.92 (2.56)</td>
<td>4.74 (2.64)</td>
<td>0.008</td>
</tr>
<tr>
<td>Medial cortex</td>
<td>6.40 (3.30)</td>
<td>6.64 (3.24)</td>
<td>6.84 (3.12)</td>
<td>7.10 (3.32)</td>
<td>0.001</td>
</tr>
<tr>
<td>Level B</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical index</td>
<td>1.703 (0.22)</td>
<td>1.702 (0.22)</td>
<td>1.704 (0.21)</td>
<td>1.705 (0.22)</td>
<td>0.891</td>
</tr>
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<td>Lateral cortex</td>
<td>5.69 (2.20)</td>
<td>5.65 (2.21)</td>
<td>5.72 (2.19)</td>
<td>5.74 (2.37)</td>
<td>0.836</td>
</tr>
<tr>
<td>Medial cortex</td>
<td>6.43 (2.76)</td>
<td>6.70 (2.65)</td>
<td>6.80 (2.57)</td>
<td>7.13 (2.68)</td>
<td>&lt; 0.001</td>
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<tr>
<td>Level C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cortical index</td>
<td>1.697 (0.22)</td>
<td>1.699 (0.21)</td>
<td>1.697 (0.21)</td>
<td>1.689 (0.23)</td>
<td>0.572</td>
</tr>
<tr>
<td>Lateral cortex</td>
<td>6.11 (2.00)</td>
<td>6.21 (1.86)</td>
<td>6.42 (2.06)</td>
<td>6.82 (2.40)</td>
<td>0.002</td>
</tr>
<tr>
<td>Medial cortex</td>
<td>6.89 (2.38)</td>
<td>7.18 (2.38)</td>
<td>7.73 (2.76)</td>
<td>8.10 (3.20)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* Greenhouse-Geisser correction test

p = 0.008) decreased at the proximal level over time, while in the medial cortex it increased (Greenhouse-Geisser, p = 0.001) at the proximal and distal levels (Table IV). An increase in the index at the proximal medial cortex was found in patients with an extended transtrochanteric osteotomy compared with those with a posterolateral approach and in patients with a stem less than 25 cm long. With the number of available hips, no significant differences were found in regard to gender, intra-operative bone defect or diameter of the stem.

Discussion
Cementless femoral components have been widely used in revision surgery. As in other series, our results showed good clinical and radiological results in most hips which seemed to be permanent. Thigh pain was less common in patients with components which achieved bony ingrowth. Fibrous or unstable fixation was significantly associated with major bone defects (chi-squared, p = 0.008). The presence of bony ingrowth correlated with a pre-operative bone defect across the series and with the ability of the surgeon to fill the femoral canal with the component. This series represented our first experience using this component. A better surgical technique will probably improve the percentage of good clinical and radiological results because it will produce a better filling of the canal. The patients mean age of 72 years did not have a negative effect on the results. We did not use grafts although lateral cortical strut grafting probably would have improved the results in hips with thin lateral cortices and massive femoral bone loss. Nadaud et al reported good results with the use of 46 extensively porous-coated stems without allograft in severe proximal femoral defects. At a mean of 6.4 years only two hips required revision. We agree with Nadaud et al that the mismatch in the diameter of the intramedullary canal of available allografts in revision surgery makes it difficult to achieve a tight press-fit in the host bone. Although fractures of the stem have been reported in heavy patients with extensive proximal bone loss, none were found in our patients.

Stress-shielding of the proximal femur has been a cause for concern in extensively coated femoral components in revision surgery. In clinical practice, qualitative and quantitative assessment of cortical width from radiographs is an inaccurate and inconsistent method for the evaluation of stress-shielding. Other problems inherent in the radiological techniques are the quality of exposure and positioning of the femur which are prone to variability of measurement due to rotation of the femur when cortical dimensions are involved. Stress-shielding did occur at times. It is difficult to evaluate bone regeneration radiologically, but it seems definite as judged by the medial cortical width which increased over time while that of the lateral cortex decreased proximally. The increase in the medial cortical width probably reflected the proximal osteopenia of stress-shielding and distal cortical hypertrophy of stress transfer with a large, stiff femoral component. Components with shorter stems and those with an extended trochanteric osteotomy both showed a greater increase in femoral cortical thickness over time. Currently our patients have no symptoms related to stress-shielding, and therefore this cannot be construed as a clinical failure. Böhm and Bischel stressed the importance of mechanical stability as well as of the careful removal of cement, scar and granulation tissue to allow restoration of the bone stock. In difficult cases a transfemoral approach produces a fracture-like situation in the proximal femur, but keeping the fracture fragments well vascularised stimulates new bone formation. Stable distal anchoring of the stem, which seems to create a new biomechanical balance for the metaphysis, is the best way to consolidate the osteotomy and to allow neoproducitve remodelling of the femur. These different biological conditions in a hip in which a transfemoral approach was used could explain the cortical thickening. We do not know whether bone remodelling is caused by decreased stress-shielding or by changes in the local environment at the time of the revision. It is difficult to measure changes in bone density in retrospective com-
parison of serial radiographs in these patients. Future studies using dual-energy x-ray absorptiometry (DXA) could be very useful. However, although world-wide there are more than 6000 DXA systems, revision hip surgeons still have limited access to them.

Successful femoral reconstruction requires insertion of a component which will be axially and rotationally stable. Weeden and Paprosky reported a mechanical failure rate of 21% in patients with a Paprosky type-3B defect. Our study has shown that five of the 25 hips with a Paprosky type-3B bone defect had stable fibrous or unstable fixation. Sporer and Paprosky suggested that the poor results observed in patients with major bone defects and a long cementless porous-coated component wider than 19 mm, and in all type-4 femora, were due to the difficulty of obtaining initial stability. As a consequence, they recommended the use of a modular tapered stem or impaction grafting in patients with these defects. The latter has been used successfully in patients with femoral bone loss. It has the potential to restore bone stock and can be used in patients with irregular endosteal surfaces and ectatic canals. Because of the proximal stress-shielding observed with uncemented femoral components during revision surgery, in active and younger patients (< 70 years old) we currently prefer to reconstruct the femur using an impaction allografting procedure with a technique similar to that described by Gie et al. We believe that it is reasonable to reconstruct the femur using morcellised bone allografts and cement when hips have a femoral defect, especially in young patients who will probably require a further femoral revision at some time. Since impaction grafting is a demanding technique which requires access to banked bone, we use uncemented femoral components for revision surgery in older and inactive patients with an endosteal canal less than 19 mm wide.

There were several limitations to our study. The primary disadvantage was the relatively small number of available patients and the incompleteness of the clinical outcome data. We did not randomise these components with other designs for comparison. We performed no analysis of inter- and intra-observer variability for the radiological measurements. The investigating surgeon studied the radiographs and entered the data on forms on the day of the clinic visit. It was not feasible to perform measurements of alignment, fit, fill and of femoral cortical changes in the clinic. These detailed measurements were performed by another unblinded reviewer at a different time. Thus, some bias may have been introduced in the radiological assessment. We recognise that our radiological measurements of variations of the femoral cortex may not have been sufficiently reliable, but clinically and radiologically we observed changes of remodelling in the femoral cortex.

Supplementary material
A table showing the risk factors regarding the cortical index and femoral cortex at level A in the 95 hips is available with the electronic version of this article on our website at www.jbjs.org.uk

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


