Thigh pain, subsidence and survival using a short cementless femoral stem with pure metaphyseal fixation at minimum 9-year follow-up

G. Cinotti*, A. Della Rocca, P. Sessa, F.R. Ripani, G. Giannicola

Orthopaedic Department, La Sapienza University, Piazzale Aldo Moro, 500185 Rome, Italy

Accepted: 21 September 2012

Summary

Background: Short femoral stems designed to spare bone stock and improve load transfer at the proximal femur level have been introduced in recent years. However, little is known on the long-term outcomes of these stems.

Hypothesis: Short cementless stems have low rate of thigh pain and subsidence as well as few revision needs at mid-term follow-up.

Materials and methods: We prospectively followed 64 patients (72 hips) undergoing total hip arthroplasty with a femoral stem designed to achieve a pure metaphyseal fixation. Patients with hip fracture, femoral neck deformity and osteoporotic bone were excluded. Clinical evaluations were performed annually until the last follow-up, a minimum of 9 years after surgery. At each follow-up, implant positioning was assessed on conventional plain films with a computer assisted radiographic evaluation.

Results: The Harris hip score improved from 43 points (range 19–50) before surgery to 88 points (range 73–100) at the final follow-up (P < 0.001), and the Womac score averaged 47 points (range 35–56 points) preoperatively and 76 points (range 63–84) at the last follow-up (P < 0.001). Thigh pain was reported by five patients (8%) at the 2-year follow-up, but only in two (3%) was still present, and related to the prosthesis, at last follow-up. Computer assisted radiographic analysis showed a neutral alignment of the stem in 56% of cases, a varus-valgus alignment less than 5° in 36% and equal to 5° in 8%. Stem subsidence was observed in 12 hips but was less than 4 mm in all cases (range 0–3 mm). Calcar height remained unchanged over time. Adaptive bone remodelling, including proximal bone resorption and distal cortical hypertrophy were not observed at follow-up. No patients had aseptic loosening of the stem nor were radiolucent lines detectable at the level of the porous coating. Survivorship analysis showed a 100% survival rate of the stem at nine years.

* Corresponding author. Department of Anatomy, Histology, Medico Legal and Orthopaedic Sciences, La Sapienza University, S, Piazzale Aldo Moro, 00185 Rome, Italy. Tel.: +347 8419319; fax: +06 6896088.
E-mail address: Md3581@mclink.it (G. Cinotti).

1877-0568/$ - see front matter © 2012 Elsevier Masson SAS. All rights reserved.
http://dx.doi.org/10.1016/j.otsr.2012.09.016
Introduction

Cementless femoral stems are known to provide a high rate of satisfactory clinical outcomes at long-term follow-ups [1–5]. Extensive and durable osteointegration of these implants has been reported in many series, despite stems with different geometry and porous coating extension have been used [1–5]. However, biomechanical and radiologic investigations have shown that cementless stems may cause a reduction of cortical strain over 80% [6] and of bone mineral density (BMD) over 40% in the proximal femur [7,8]. Most important, in contrast to previous investigations showing that proximal stress-shielding causes a BMD reduction in the first months after surgery and reaches a steady state within the second year [9–11], recent studies indicate that adaptive bone remodelling may progress even after long-term follow-ups [1,7,8].

Potential clinical consequences related to proximal bone resorption include more challenging revision procedures, higher incidence of periprosthetic fractures after minor trauma and an easier access pathway for wear debris [11]. In addition, as cementless stems usually imply a distal fixation in the femoral canal, a definite incidence of thigh pain has been associated with these stems [11–13]. Femoral stems aimed at transferring mechanical loads in the proximal femur have been introduced to preserve proximal bone stock, limit bone remodelling and reduce the incidence of thigh pain [14–17]. However, as clinical and radiographic performances of these stems have been investigated only in a few studies and at short-term follow-ups [16,18,19], it remains to be elucidated whether a short stem with anchorage limited to the proximal metaphysis shows a low incidence of implant loosening, stem misalignment and revision rate. In the present study we assessed, at medium term follow-up, the incidence of thigh pain, rate of loosening and stem alignment of a short cementless stem designed to achieve a pure proximal fixation with no endosteal contact at the proximal diaphysis. We hypothesized that a femoral stem designed to achieve a fixation only in the proximal femur, may provide satisfactory clinical results at medium term follow-up with limited bone remodelling around the implant.

Material and methods

Patients

Of 148 patients who underwent total hip replacement between January 2000 and December 2001, 76 non-consecutive patients (84 hips) had a short cementless femoral stem with a pure proximal fixation. The indications for this stem were primary and secondary osteoarthrosis in the absence of severe femoral neck deformities. Poor bone quality, including reduced cortical thickness on preoperative radiographs and/or femoral neck osteoporosis on preoperative BMD were thought to be a contraindication for the stem. Further exclusion criteria were the presence of concomitant conditions, outside the hip, that would have affected the ability to walk or perform common daily activities, including high comorbidity and psychiatric conditions. Of the initial group of 76 patients three later died due to causes unrelated to the hip surgery and nine other patients were lost after the 2-year follow-up. The remaining 64 patients (72 hips), 36 women and 28 men, with an average age of 68 years at the time of surgery (range 29–84 years), were prospectively followed and included in the study. Preoperative diagnosis included primary osteoarthrosis in 44 patients, avascular necrosis in 11, developmental dysplasia in five and rheumatoid arthritis in four. Average BMI was 26.8 (range 23–34); it was greater than 30 in eight patients.

The implant used (IPS™, DePuy, Warsaw, USA) consisted of a Titanium stem with a metaphyseal anatomical portion including a wedge shape, a pronounced lateral flare and a circumferential porous coating covered with a 30 µ layer of hydroxyapatite (Fig. 1). The diaphyseal portion included a short, cylindrical, straight polished stem with a reduced diameter to prevent contact with the endosteal bone; it was designed to provide a sort of ”secondary stabilizer”

Discussion: This study showed that a femoral stem designed to achieve a pure metaphyseal fixation may obtain, in a selected group of patients with adequate bone quality, satisfactory clinical outcomes without compromising implant stability. The limited periprosthetic bone remodelling observed after a minimum of 9 years follow-up suggests that this type of implant may improve mechanical stresses on host bone compared with standard stems requiring diaphyseal fixation.

Level of evidence: Level IV. Historical series.
© 2012 Elsevier Masson SAS. All rights reserved.

Figure 1  The IPS stem in lateral and frontal view. Note the narrow polished stem designed to avoid diaphyseal fixation.
in case the metaphyseal fixation was initially insufficient, rather than to transfer loading in the femoral diaphysis. Before stem insertion, the femoral canal was reamed and a distal reabsorbable centralizer made of polyactic acid was present to avoid a varus-valgus or sagittal plane misalignment. Femoral stem features included: a neck-shaft angle of 126°, a femoral neck anteversion of 8°, and a femoral neck diameter of 12 mm.

All patients received a cementless porous cup (Duraloc Sector™, DePuy, Warsaw, USA) with a conventional polyethylene and ceramic liner (Biolox forte™, Ceramtec, Plochingen, Germany) in 48 and 24 hips, respectively. Metal and ceramic 28- or 36-mm femoral heads were implanted in 31 and 41 hips, respectively. Indications for a ceramic-on-ceramic articulation were young (less than 65 years) active or obese patients. Polyethylene liners were implanted with metal head in patients older than 75 years and with ceramic head in the remaining patients. Three experienced surgeons using a direct lateral approach performed all surgical procedures. Antibiotic prophylaxis was administered one hour before surgery; antithrombotic prophylaxis with low molecular weight heparin was started the day of surgery and continued for the following 5 weeks.

The rehabilitation program included exercises from the first day after surgery and walking on the second postoperative day. All patients were discharged an average of 7 days (range 4–14 days) after the operation. Hip abduction exercises were performed throughout this period.

Methods of assessment

Clinical and radiographic follow-ups were carried out after 1, 3, 6, 12 months after surgery and yearly through the last follow-up after a minimum of 9 years. Clinical evaluation included Harris Hip Score (HHS) [20], Western Ontario and Mc Master Universities (WOMAC) [21] and SF-36 [22] questionnaires.

Antero-posterior and axial view radiographs of the hip were taken using a specific frame to maintain the foot positioned in neutral rotation. X-rays of poor quality or showing intra-external rotation of the proximal femur were excluded. The assessment of calcar changes included calcar height and morphology on radiographs taken postoperatively and at each follow-up. In particular, calcar height was calculated as the distance between the femoral neck osteotomy at the calcar level and a line, parallel to it, tangent to the proximal and medial border of the lesser trochanter (Fig. 2). It was expressed as a percentage of the diameter of the femoral neck of the implant to avoid potential errors caused by different magnification. Calcar morphology was considered to be unchanged when a sharp edge was still present at the osteotomy level; as mildly or markedly changed, when a round edge or more pronounced changes, respectively, were observed at the osteotomy level. Cortical thickness was measured in Gruen 2-6 zones [23] (Fig. 2) and expressed as percentage of the stem neck diameter. Pedestal formation was diagnosed in the presence of bone formation bridging partially or completely the intramedullary canal [2].

Stem alignment was considered to be neutral when the vertical axis of the stem was within 0–2° compared to the diaphyseal femoral axis. A varus-valgus alignment was rated as mild and severe when stem misalignment was less and more than 5°, respectively. The presence of any endosteal stem contact was recorded based on its extension in one or more zones of Gruen; if a focal endosteal stem contact was found, it was considered as a single zone contact. Radiolucent lines and osteolysis were also assessed to identify potential loosening of the implant [4].

Stem subsidence was diagnosed in the presence of a stem sinking greater than 4 mm, measured on a perpendicular line drawn from the greater trochanter to the lateral border of the implant (Fig. 2). Implant loosening was diagnosed when a stem subsidence greater than 4 mm and/or varus/valgus migration greater than 5°, was seen after the 6-months follow-up. A possible stem loosening was diagnosed in the presence of a radiolucent line surrounding the porous coating surface [24]. Canal flare index was assessed and correlated with stem alignment, subsidence and periprosthetic bone changes.

All radiographic measurements were performed with Autocad™ software (Autodesk™ 2008, San Rafael, CA, USA). To test the reliability of the measurements, 20 subjects were randomly selected and the measurements of cortical thickness in the different Gruen zones and calcar height were performed by two independent examiners two times, the first time during the study and the second time after 4 weeks. Intra- and inter-rater reliability were assessed using intra-class correlation coefficients (ICC).

Statistics

Statistical analysis included unpaired student’s t test for parametric variables and Spearman’s rank test for correlation analysis. The Kaplan–Meier survivorship analysis was used for the endpoint of cup and stem revision for any
Results

Clinical results

Results of Harris Hip Score, Womac and SF-36 are reported on Fig. 3. There was a significant improvement between the clinical score reported before surgery and at the last follow-up. The mean Harris Hip Score improved from 43 points (range, 19–50) before surgery to 88 points (range 73–100) at the final follow-up (P = 0.001). The Womac score averaged 47 points (range 35–56 points) preoperatively and 76 points (range 63–84) at the last follow-up (P = 0.001). SF-36 physical and mental scores averaged 38.3 (range 34–43) and 41.2 (range 36–45), respectively, before surgery and 71 (range 55–95) and 74.4 (range 56–92), respectively, at last follow-up (P = 0.001).

Thigh pain was reported by five patients (8%) at the 2-year follow-up. Three of them also complained of pain in the anterior leg and MRI scans showed moderate lateral stenosis at L3-L4. These patients underwent L4 anaesthetic nerve block injection with complete temporal pain relief. The remaining two patients (3%) had no apparent cause for thigh pain other than hip surgery. At the last follow-up they still complain of thigh pain but of minor intensity and no pain medications were needed.

Radiographic results

Radiographic results are summarized in Table 1. Stem alignment was neutral in 40 hips (56%), varus in 27 (37%) and valgus in five (7%). The varus-valgus misalignment was present in the radiographs taken soon after surgery in 19 hips, while in the remaining 13 it occurred in the first months after the operation and did not change after the 6-month follow-up. The intra- and inter-observer reliability related to the measurements of cortical thickness was 0.94 (0.88–0.97) and 0.96 (0.91–0.98), respectively. In the six patients showing a varus/valgus misalignment greater than 5°, the Harris hip score was, on average, 86 points (range 74–98); in the 40 patients with neutral stem alignment the mean Harris hip score was 88 points (range 77–100) (P = 0.07).

A stem subsidence was observed in 12 cases but in all of them was less than 4 mm (Table 1). In all cases, subsidence occurred soon after surgery and did not progress later on. No patients showed evidence of stem loosening. Canal

Figure 3  Graph showing Harris, Womac and SF-36 scores before surgery and at the last follow-up. A significant improvement was found in each score (P = 0.001).

Figure 4  Preoperative (A) and postoperative radiographs taken 1 month (B) and 9.8 years (C) after surgery. Despite the narrow femoral canal, a contact of the stem with endosteal cortex is present only in zone 3. A thin endosteal reaction is present in the distal portion of the stem. There is no evidence of proximal bone resorption; cortical thickness in zone 3-4-5 is unchanged.
Table 1 Radiographic results at the last follow-up in 72 hips (64 patients).

<table>
<thead>
<tr>
<th>Stem alignment</th>
<th>Neutral</th>
<th>Varus-valgus &lt; 5°</th>
<th>Varus-valgus &gt; 5°</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>40 (56%)</td>
<td>26 (36%)</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>Stem subsidence</td>
<td>n (%)</td>
<td>mean (mm)</td>
<td>≥ 4 mm</td>
</tr>
<tr>
<td></td>
<td>12 (17%)</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td>Calcar changes</td>
<td>No.</td>
<td>Mild smoothing</td>
<td>Marked resorption</td>
</tr>
<tr>
<td>n (%)</td>
<td>20 (28%)</td>
<td>52 (72%)</td>
<td>0</td>
</tr>
<tr>
<td>Calcar height</td>
<td>Preoperativea (mean)</td>
<td>Follow-upa (mean)</td>
<td>≠</td>
</tr>
<tr>
<td></td>
<td>161</td>
<td>158.46</td>
<td>2.54 (ns)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endosteal stem contact</th>
<th>Coronal plane</th>
<th>Sagittal plane</th>
<th>Extension (number of Gruen zones)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (%)</td>
<td>27 (37%)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

*: difference between preoperative mean calcar height and last follow-up mean calcar height. ns: non significant difference.

a Calcar measurements are expressed as percentage of calcar height with respect to the stem neck diameter.

flare index averaged 3.9 (range 2.8—5.9; 95%CI 3.4—4.6) in patients showing neutral stem alignment and 3.1 (range 2.2—5.4; 95%CI 2.8—3.7) in those with a varus-valgus alignment greater than 5°, (P=0.06).

Overall, 52 hips (72%) showed slight calcar changes including a smoothing of the calcar at the osteotomy level. There was no statistically significant difference in the calcar height measured soon after surgery and at the last follow-up (P=0.08) (Fig. 4) (Table 1).

In two asymptomatic patients, radiographs taken at 9 years follow-up showed osteolysis adjacent to the proximal stem without any evidence of implant loosening.

Endosteal stem contact was seen in 27 hips (37%) in the coronal plane in Gruen zones 3 and 5 (Table 1). No patient showed endosteal contact in the sagittal plane. Harris Hip Score averaged 89 points (range 75–100) in patients showing endosteal stem contact in the proximal diaphysis and 88 (range 77–99) in those with no endosteal contact of the stem (P=0.5) (Table 1). Medial and lateral cortical thickness, expressed as percentage of the femoral neck diameter, were, on average, 51.6 and 56.8, respectively, before surgery and 52.5 and 57.4, respectively, at the last follow-up (P=0.08) (Fig. 5). A partial or complete pedestal formation was not observed in any cases.

Survival and revisions

Three hips showing periacetabular osteolysis due to liner wear, without cup loosening, were scheduled for liner exchange. No femoral stems underwent revision. Kaplan–Meier survivorship analysis after 9 years revealed a 95.3% (95%CI, 95.04%—95.56%) survival rate for the cup (three cups scheduled for revision) and 100% for the stem, with revision as the endpoint for failure (Fig. 6).

Intraoperative incomplete fracture occurred at the calcar level in three cases and at the level of the anterior femoral neck cortex in two. In all patients a cable wiring was performed and postoperative weight bearing was delayed to the third week after surgery. The fracture united in all cases and none of these patients reported any evidence of implant loosening or subsidence nor did they complain of thigh pain after the operation.

Discussion

This study was undertaken to assess whether a short stem with pure proximal fixation may provide high rates of satisfactory clinical outcomes with limited bone remodelling, reduced aseptic loosening and revision rate. In keeping with our hypothesis, we found satisfactory clinical outcomes in most of the operated patients, with low rate of thigh pain
was less than 4 mm. In keeping with other authors [27, 28] we believe that, at least in a few cases, short stems may need initial settling in the host bone to gain mechanical stability and subsequent metaphyseal osteointegration of the implant.

Several investigations have analysed radiographic changes adjacent to proximally coated tapered implants [1, 4, 30, 31]. Capello et al. [1] reported adaptive bone remodelling including distal cortical hypertrophy and proximal cortical porosis in 70% of cases and such adaptive changes were found to progress even after the 10-year follow-up. Laine et al. [30] reported cortical hypertrophy in 49% and 27% of patients with straight and anatomic proximal porous-coated stems, respectively. In the current investigation, the computed radiographic analysis conducted after a minimum of 9 years showed subtle and non-progressive periprosthetic bone remodelling. In particular, in most of the patients, calcar morphology showed a mild smoothing, but calcar height was unchanged compared to postoperative radiographs. Furthermore, in contrast to previous studies on standard and tapered titanium stems with proximal porous coating [1, 4, 30, 31], we did not find any difference in cortical thickness before surgery and at final follow-up.

The current clinical outcomes (Harris, Womac and SF-36 scores) were in line with results of standard stems [1, 4, 29, 31]. Likewise, the stem 9-year survival (100%) compares favourably with former studies assessing standard stems [1, 4, 29, 31] indicating that the absence of diaphyseal stem fixation may not compromise the survival rate. The incidence persistent of thigh pain was 3%, which is among the lower rate of the reported incidence (between 0 and 17%) in cementless stems [32–34].

Kim et al. [14] reported on a large series of IPS stems implanted in Asiatic patients. There were several differences between the two series, including age, preoperative diagnosis, femoral morphologic types and surgical technique which, in our series, included the reaming of the femoral canal and the use of a distal stem centralizer. The clinical outcomes and survival rates were similar in the two series, meaning that a femoral stem with pure metaphyseal fixation may provide satisfactory long-term outcomes even in patients with different morphology of proximal femur as Asian and Caucasian populations [35, 36].

In conclusion, preserving bone quality around a well-fixed and painless implant should be the goal of total hip arthroplasty. A femoral stem designed to achieve a pure metaphyseal fixation may induce very limited bone remodelling, providing, at the same time, clinical performances at least comparable to those of standard cementless stems. Future investigations should evaluate whether such clinical and radiographic results may be maintained after a longer time and if femoral stems with such a design may better preserve periprosthetic bone mass compared to standard implants.

**Disclosure of interest**

The authors declare that they have no conflicts of interest concerning this article.
Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.otsr.2012.09.016.

References