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

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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.

KEYWORDS
Total hip arthroplasty; Femoral stem; Proximal fixation; Bone remodeling; Thigh pain

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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 µm 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"
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. Antimicrobial 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

Figure 2  Computed radiographic measurements performed postoperatively and at follow-up. CH: calcar height; S: stem subsidence; \*: cortical thickness; dotted line: coronal stem alignment; continuous line: diaphyseal femoral axis.
why did the patient have pain after surgery? was it due to the implant or something else? was it short-lived or lasting? what were the symptoms? did the patient report any other issues? were there any complications during the surgery? did the patient experience any adverse reactions? did the patient have any medical history that could have contributed to the pain? did the patient have any other surgeries or treatments prior to this one? what were the goals of the surgery? was the surgery successful in achieving those goals? were there any unexpected outcomes? did the patient follow any postoperative instructions? how long did the patient have to wait before seeing a doctor? was the pain managed effectively? did the patient notice any changes in mobility or function? what was the patient's overall experience? did the patient have any concerns or questions about the surgery or recovery? did the patient have any advice for others undergoing similar procedures? did the patient have any recommendations for improvements in the surgical process or patient care?
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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>12 (17%)</td>
<td>2.2</td>
<td>0</td>
</tr>
<tr>
<td>Calcar changes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td>20 (28%)</td>
<td>52 (72%)</td>
<td>0</td>
</tr>
<tr>
<td>Calcar height</td>
<td>Preoperative a (mean)</td>
<td>Follow-up a (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 24 (33%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 3 (4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3 0</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.
Figure 6  Kaplan–Meier femoral stem survival (continuous line) and acetabular cup survival (dotted line). Errors bars indicate 95% CI. Survival rate at 9 years was 95.3% (95%CI, 95.04%–95.56%) for the cup (three cups scheduled for revision) and 100% for the stem, considering the revision for any reason as the endpoint.

(3% persistent at follow-up), limited bone remodelling and no need of stem revision at a minimum 9-year follow-up.

This study includes some limitations. First, as this was not a comparative study we may not substantiate the potential benefits of IPS stem compared with more traditional implants. Second, we performed a computed radiographic measurement to assess any difference between postoperative radiographs and those taken at follow-ups; nevertheless, it cannot be infer from our study that this stem leads to more physiological mechanical stresses on proximal femur since we were not able to perform a BMD analysis. Third, different bearing materials were used based on age, BMI and level of physical activity; this may have introduced a potential bias on the clinical outcomes or osteolysis occurrence. Finally, we included a selected group of patients with adequate bone quality, which makes that our results may not be extended to a general non-selected group.

Short stems with fixation limited to the proximal metaphysis have been introduced to improve loading transfer in the operated femur, to reduce the incidence of thigh pain and preserve femoral bone stock for revision procedures [14–19]. However, a major concern in reducing diaphyseal fixation of the femoral stem is the concomitant reduction of implant stability and the increase of interface micromotion which, by encumbering osteointegration, increases the risk of implant loosening and thigh pain [25,26]. In the present series, we did not observe any aseptic loosening of the implant, nor did we find progressive radiolucent lines suggesting stem instability. A minority of patients exhibited changes in varus/valgus stem alignments in the first months after surgery that could alert for a potential stem loosening. However, no further radiographic changes were noted after the 6-months follow-up nor did we find any correlation between clinical results and stem alignment.

Stem subsidence greater than 5 mm has been reported in 0 to 6.4% of second-generation cementless stems [14,17,27,28]. Röhrl et al. [29], through an RSA study found that CFP short stems underwent slight retroversion in the first postoperative period but were stabilized at 12 months. In the present series, mild stem subsidence was observed in the first postoperative months but in all cases 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.otstr.2012.09.016.

References


