Total hip arthroplasty using proximal porous coating stem with distal sleeve: mid-term outcome

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ABSTRACT

Purpose. To report mid-term results of total hip arthroplasty (THA) using the Opti-Fix Plus Hip System (Opti-Fix Hip), and to assess the correlations between peri-implant bone changes and the distal medullary occupancy rate.

Methods. 11 men (13 hips) and 53 women (58 hips) aged 24 to 87 (mean, 61) years underwent THA using the Opti-Fix Hip, with a modular stem and a distal sleeve, and were followed up for a mean of 6.5 (range, 4.8–9.6) years. Clinical outcomes were evaluated using the Japanese Orthopaedic Association (JOA) hip score. Implant stability, bone changes around the implant, and the occupancy rate of the stem in the medullary space were examined radiologically. Bone changes around the implant were assessed based on the radiological evidence of a pedestal, osteolysis, stress shielding, and radiolucent lines.

Results. The mean JOA score increased significantly after surgery and was maintained at the latest follow-up. Around the acetabular and femoral components respectively, 38 and 58 hips had radiolucent lines, whereas one and 54 hips developed osteolysis. A pedestal appeared in 21 hips and grade-III or higher stress shielding in 30 hips. Two hips showed loosening of the acetabular components, but none in the femoral components. Osteolysis around the stem was frequently observed in hips with poor distal medullary occupancy.

Conclusion. Clinical and radiological outcomes of the Opti-Fix Hip were favourable. The low incidence of osteolysis in the distal stem suggests that the proximal circumferential porous coating was effective. Minor osteolysis around the proximal stem was frequently observed, indicating early excessive wear of the polyethylene liner. Its high distal medullary occupancy rate could inhibit stem micromotion and aseptic loosening.

Key words: arthroplasty, replacement, hip; hip prosthesis; osteolysis
INTRODUCTION

Long-term results of cementless total hip arthroplasty (THA) is excellent. Modular cementless stems are designed to fit into medullary cavities, but metallic debris is produced on the contact surface of modular total hip systems due to wear. Although intermediate-term failure rates are reportedly 0 to 14%, long-term results remain unclear.

The Opti-Fix Plus Hip system (Smith & Nephew, Memphis [TN], USA) consists of a modular stem and a distal sleeve to increase the medullary occupancy rate and thus optimise fixation; a porous coating is applied circumferentially to the proximal region to achieve proximal fixation and prevent distal osteolysis. THA using the Opti-Fix Hip, and assess the correlations between peri-implant bone changes and the distal medullary occupancy rate.

MATERIALS AND METHODS

Between October 1996 and July 2001, 77 patients (84 hips) underwent THA using the Opti-Fix Hip. Of these, 11 men (13 hips) and 53 women (58 hips) aged 24 to 87 (mean, 61) years were followed up for a mean of 6.5 (range, 4.8–9.6) years. Their primary indications for THA were osteoarthritis (57 hips), osteonecrosis of the femoral head (11 hips), and rapidly destructive coxopathy (3 hips).

Patients were put in a lateral decubitus position; THAs were performed by one senior surgeon through a posterolateral approach, without a trochanteric osteotomy. The acetabular component was fixed with screws to the acetabular bone. Any gaps between the original acetabulum and components were filled with cancellous bone chips from the resected femoral head. The sizes of the femoral stem and distal sleeve were determined after reaming. The femoral component was implanted without cement. After surgery, partial weight-bearing was started within one week and total weight-bearing with a cane support was allowed within 4 weeks.

Clinical outcomes were evaluated using the Japanese Orthopaedic Association (JOA) hip score, which takes account of: ‘pain’ (up to 40 points), ‘range of motion’, ‘ability to walk’, and ‘activities of daily living’ (each up to 20 points); higher scores indicate a better condition. JOA scores before surgery, one year after THA, and at the latest follow-up were recorded, as were the incidences of complications (fracture around the implant, infection, and paralysis).

Implant stability, bone changes around the implant, and the occupancy rate of the stem in the medullary space were examined radiologically. Stability of the acetabular component was based on changes in the position angle, the vertical distance, and the horizontal distance from the inter-teardrop line. The position angle was the angle formed by the inter-teardrop line and a line drawn across the rims of the acetabular component. The vertical distance was the distance from the inter-teardrop line to the lower end of the acetabular component. The
horizontal distance was the distance between the line perpendicular to the inter-teardrop line and the medial end of the acetabular component. Stability of the stem was assessed based on changes in subsidence and the occupancy rate of the stem in the medullary cavity. Subsidence was measured between the top of the greater trochanter and the lower tip of the stem on radiographs. Direct measurement of the length of the stem on each radiograph was made to correct for magnification error. The occupancy rate of the stem in the medullary cavity was the ratio of the stem diameter to the diameter of the medullary cavity. The edge of the femoral neck osteotomy and the lower end of the stem were divided into 3 equal levels and the occupancy rate was measured at each level (Fig. 2). Component loosening was defined as radiolucent lines around the entire circumference, subsidence or a shift of ≥5 mm for the stem, or 5º for the acetabular component.

Bone changes around the implant were assessed based on the radiological evidence of a pedestal, osteolysis, stress shielding, and radiolucent lines. The pedestal was a shelf of endosteal new bone, either partially or completely bridging the intramedullary canal, in an attempt to support the tip of the prosthesis. A radiolucent line was a transparent layer of at least 1-mm width in the vicinity of the component. Stress shielding was categorised into degrees of severity according to the classification of Engh et al. To monitor radiolucent lines and osteolysis, the acetabular component was divided into 3 zones as indicated by DeLee and Charnley, and the stem was divided into 7 zones according to the classification of Gruen et al.

JOA scores at the latest follow-up and the incidence of bone changes around the stem were compared for postoperative medullary occupancy rate groups of ≤90% and >90% in level 3, using the non-parametric Mann-Whitney $U$ test. Correlations between incidence of bone changes and medullary occupancy rates were determined using Fisher’s Exact test. A $p$ value of <0.05 was considered statistically significant.

RESULTS

One hip was excluded from the analysis because of infection. The mean JOA score was 44 before surgery, improved to 81 one year after surgery and to 83 at the latest follow-up (Table 1). Intra-operative fractures of the proximal femur occurred in 6 hips when the femoral components were impacted. They were fixed with wiring, in which case partial weight-bearing was delayed. JOA scores of these patients were not significantly lower than those of others. One hip developed a fractured femoral diaphysis 2 years after the surgery, another had a postoperative infection. No patient displayed paralysis of the sciatic nerve. One hip had a polyethylene liner and femoral head revised 6 years after surgery (due to recurrent dislocation).

38 (54%) hips had radiolucent lines around the acetabular component; 13 of them were in multiple zones, usually expanding from non-weight-bearing areas; 2 hips had radiolucent lines around the entire circumference. 58 (83%) hips had radiolucent lines around the femoral component, most commonly in zone 4. These lines first appeared at the lower end of the stem and expanded to the proximal area; none were circumferential. Around the acetabular and femoral components respectively, one (1%) and 54 (77%) hips had osteolysis; 47 (67%) of them were in the proximal area only (zones 1 and 7) and 33 (47%) in zone 1 only. Seven (10%) of the hips had osteolysis in the distal area beyond the porous coating (zones 2–6); 21 (30%) showed a pedestal, and 30 (43%) a grade-III or higher stress shielding (Table 2).

The mean positional changes of the acetabular components were 1.1 mm horizontally and 1.4 mm vertically, and the mean change in the inclination

<table>
<thead>
<tr>
<th>Category</th>
<th>Preop</th>
<th>Postop year</th>
<th>Final follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total JOA score</td>
<td>44 (14)</td>
<td>81 (12)</td>
<td>83 (12)</td>
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<tr>
<td>Range of motion</td>
<td>12 (4)</td>
<td>16 (2)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Activity of daily living</td>
<td>11 (3)</td>
<td>15 (4)</td>
<td>16 (4)</td>
</tr>
<tr>
<td>Ability to walk</td>
<td>9 (5)</td>
<td>15 (5)</td>
<td>16 (4)</td>
</tr>
<tr>
<td>Pain</td>
<td>11 (8)</td>
<td>35 (8)</td>
<td>35 (5)</td>
</tr>
</tbody>
</table>

*p <0.01 versus preoperation

<table>
<thead>
<tr>
<th>Radiographic parameters</th>
<th>No. (%) of hips</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiolucent line (cup)</td>
<td>38 (54)</td>
</tr>
<tr>
<td>Radiolucent line (stem)</td>
<td>58 (83)</td>
</tr>
<tr>
<td>Osteolysis (cup)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Osteolysis (stem)</td>
<td>54 (77)</td>
</tr>
<tr>
<td>Pedestal</td>
<td>21 (30)</td>
</tr>
<tr>
<td>Stress shielding</td>
<td>30 (43)</td>
</tr>
</tbody>
</table>
angle was 1.7°. Only one (1%) hip showed a >5-mm positional change in the acetabular component. The mean subsidence of the stem was 0.87 mm; no hip subsided >5 mm. Two hips displayed loosening of the acetabular components, but none in the femoral components.

Immediately after surgery, the mean medullary occupancy rates were 79% in level 1, 94% in level 2, and 96% in level 3 (10 hips were ≤90%; 60 hips were >90%). At the latest follow-up, respectively in the ≤90% and >90% medullary occupancy rate groups, the JOA scores were 81 and 84 points (p=0.47). Osteolysis in the distal area beyond the porous coating (zones 2–6) occurred in 3 (30%) and 4 (7%) hips (p=0.06). Radiolucency lines around the stem appeared in 8 (80%) and 50 (83%) hips (p=0.68); a pedestal appeared in 4 (40%) and 17 (28%) hips (p=0.47), and grade-III or higher stress shielding was observed in 4 (40%) and 26 (43%) hips (p=1) Table 3.

### DISCUSSION

The distal sleeve of the Opti-Fix Hip contributes to the high distal medullary occupancy rate, and the proximal porous coating provides proximal stability. To reduce stress shielding and thigh pain induced by the stress concentration on the distal femur, the distal sleeve has a smooth surface. The distal sleeve mainly contributes to initial fixation and varus-valgus stability. Bone adhesion is achieved mainly at the proximal porous coating. In this modular system, the size of the distal sleeve is based on the diameter of the distal femoral canal and applied to various femoral shapes, resulting in a high medullary occupancy rate.

In a study using the Omniflex stem (the distal stem tip was based on the diameter of the distal medullary cavity), the short-term (mean, 3.4 years) and mid-term (mean, 8.6 years) rates of aseptic loosening were 3% and 10%, respectively. Its mid-term outcome was inferior to that of other cementless stems. The higher rate of aseptic loosening may be due to the limited contact of the stem surface with cortical bone, because the distal stem was thinner than the commonly-used tapered models. In our study using the Opti-Fix Hip, no aseptic stem loosening was observed over a mean follow-up period of 78 months. The length of the distal stem tip of the Omniflex ranged from 16 to 22 mm, whereas the length of the distal sleeve of the Opti-Fix Hip ranged from 58 to 76 mm. The larger contact area with cortical bone may explain the absence of early failure.

Although the Opti-Fix Hip was intended to acquire a high medullary occupancy rate, clinical results between the low and high distal occupancy rate groups were not significantly different. Nor were the incidences of radiolucent lines around stem or the presence of distal osteolysis. However, the incidence of distal osteolysis was higher in the low medullary

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Medullary occupancy rate at level 3</th>
<th>p value</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>≤90%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>No. of hips</td>
<td>10</td>
<td>60</td>
</tr>
<tr>
<td>Mean JOA score</td>
<td>81</td>
<td>84</td>
</tr>
<tr>
<td>No. (%) of radiolucent line</td>
<td>8 (80)</td>
<td>50 (83)</td>
</tr>
<tr>
<td>No. (%) of distal osteolysis (zones 2–6)</td>
<td>3 (30)</td>
<td>4 (7)</td>
</tr>
<tr>
<td>No. (%) of pedestal</td>
<td>4 (40)</td>
<td>17 (28)</td>
</tr>
<tr>
<td>No. (%) of stress shielding</td>
<td>4 (40)</td>
<td>26 (43)</td>
</tr>
</tbody>
</table>

* Non-parametric Mann-Whitney U test
† Fisher’s Exact test

![Figure 3 Osteolysis in the Gruen zone 1 (arrows).](image-url)
occupancy rate group. In the Opti-fix Hip, the proximal medullary occupancy rate was relatively low. Therefore, if distal fitting was not complete, stem micromotion could start early and cause migration of wear particles of the polyethylene liner into distal areas.

In our hospital, distal fixation stems (Richards modular hip system; Smith & Nephew, Memphis [TN], USA) resulted in good initial fixation. Nonetheless, osteolysis around the distal stem was observed in 26% of the hips during a mean follow-up of 5.6 years. Osteolysis was caused by the proximal porous coating not being circumferential. In the earlier generation of cementless stems, the entire stem surface had a porous coating yielding favourable results, but long-term proximal bone loss occurred due to stress shielding. Therefore, stems with a porous coating only at the proximal part were developed to maintain the proximal bone stock. Nonetheless, failure rates were high if the porous coatings were not circumferential. To avoid distal migration of wear debris, proximal circumferential porous coatings have become a standard feature for cementless stems. In our study, the low incidence of osteolysis beyond the porous coating suggested that the circumferential porous coating of the Opti-Fix Hip was effective in lowering distal osteolysis and the migration of wear debris to the distal region. Nonetheless, minor osteolysis was frequently observed around the proximal stem, despite there being no tendency to spread over time (Fig. 3). Eccentrically migrated femoral heads were observed in several hips, indicating excessive wear of conventional polyethylene liner (i.e. not highly cross-linked) in the Opti-Fix Hip.

In our study, the incidence of radiolucent lines was high, but no stem loosening occurred. The diameter of the distal stem above sleeve was thinner than that of the distal sleeve, and distal reaming was performed according to the diameter of distal sleeve. Because of this structure, radiolucrency around stem (zones 2 and 6) was common immediately after surgery. This radiolucency remained at the final follow-up, but did not relate to stem loosening. In addition, in most hips with pedestal formation, there was no radiolucency around the tip of the stem, which was considered stable.

Metallic debris from the sleeve-stem interface may cause osteolysis. In mechanical testing, modular junctions produce metallic wear particles after 10 to 20 million load cycles. Nonetheless, the theoretical concern regarding metallic wear debris and osteolysis was not been encountered in a clinical study. In a study using the Omniflex modular stem, 5% of femoral components were revised because of aseptic loosening, but findings regarding metallosis were not mentioned. In our study, no stem revision was performed and there was no evidence of metallisation at the sleeve-stem interface. The cause of osteolysis was wear of the polyethylene liner, not metallosis; osteolysis occurred mainly in the proximal area.

Full-porous cup cementless THA achieves excellent or good results. The Opti-Fix Hip also achieves good radiographic results and is commonly used in Japan for secondary osteoarthritis due to dysplasia of the hip. Most THAs use bone stock-conserving stems or single-piece proximal-fixation stems; modular stems such as the Opti-Fix Hip are used less often. Distal fixation stems may be more useful for THA patients with difficult proximal fixation, such as elderly patients with stove pipe canals. Clinical and radiographic results of the Opti-Fix Hip were favourable, despite early weight bearing. The low incidence of osteolysis in the distal stem suggested that the proximal circumferential porous coating was effective. Minor osteolysis around the proximal stem was frequently observed, indicating early excessive wear of the polyethylene liner. Its high distal medullary occupancy rate could have inhibited stem micromotion and aseptic loosening.

REFERENCES