Comparison of Different Distal Designs of Femoral Components and Their Effects on Bone Remodeling in 1-Stage Bilateral Total Hip Arthroplasty

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Abstract: To evaluate the effects of distal design of a proximally coated femoral component on periprosthetic bone remodeling, we prospectively performed 21 one-stage bilateral total hip arthroplasties using a distally tapered and a distally cylindrical stem with the same proximal design, randomized to side. All hips showed good outcomes clinically and radiographically at the final follow-up, average of 7 years postoperatively. Cancellous condensation was always found in Gruen’s zones 2 and 6 around the cylindrical stem and in regions between zones 2 and 3 and between zones 6 and 5 around the tapered stem. Bone mineral density of Gruen’s zones 2 and 6 was significantly lower around the tapered stem. These results suggested more distal loading in hips with the tapered stem than in those with the cylindrical stem. Keywords: 1-stage bilateral total hip arthroplasty, cylindrical stem, tapered stem, cementless femoral component, stress shielding, periprosthetic bone remodeling.

Choosing an optimal implant is one of the most important steps in total hip arthroplasty (THA) and thus requires careful consideration. Although many excellent clinical and radiographic outcomes of cementless THA have been reported [1-5], periprosthetic bone loss is still an issue of concern, especially when considering that cementless THA is typically indicated in younger patients who have higher possibility of receiving revision surgeries. Wear-related osteolysis, which is one of the main causes of late periprosthetic bone loss, seems to have been greatly reduced by introducing highly cross-linked polyethylene liners [1,6-9]. Another important cause of late periprosthetic bone loss especially of the femoral side is bone resorption due to stress shielding [5,10,11]. Postoperative thigh pain also is suggested to be related to distal loading and fixation [12]. Thus, stems with surface modification (e.g., hydroxyapatite [HA] and porous coatings) on only the proximal part are commonly used for primary cementless THA to accelerate proximal osseointegration and to maintain proximal loading, with the intention of reducing the risk of osteopenia due to stress shielding [2,13-15]. On the contrary, a variety of the distal designs of the stem have been applied and the optimal distal design of the stem remains unclear. To examine the effects of the difference of stem geometry on periprosthetic bone remodeling, different stems have been compared in previous studies [13,14]. However, these studies had limitations in that they could not completely eliminate the effects of aging [4] as well as the individual difference. Comparison using 1-stage bilateral THA would be an option to minimize the effects of such confounders [16].

To investigate the optimal shape of the distal part of cementless proximally coated stems, a prospective, randomized study was performed using 1-stage bilateral THA. We report the midterm results of the study using a distally cylindrical stem (VerSys HA/TCP Fiber Metal Midcoat stem; Zimmer, Warsaw, Ind) and a distally tapered stem (VerSys HA/TCP Fiber Metal Taper stem; Zimmer) that have the same proximal configurations.
Materials and Methods

Subjects

Twenty-one consenting patients (3 men and 18 women; 42 hips; mean age at surgery, 59.2 years; range, 49-77 years) who underwent 1-stage bilateral THA between 2002 and 2004 were included in the study. They received a VerSys Fiber Metal Midcoat stem (Midcoat stem) in one hip and a VerSys Fiber Metal Taper stem (Taper stem) in the other hip, randomized to side. Twenty patients had osteoarthritis, and the remaining one patient had rheumatoid arthritis. No patients dropped out throughout the study. This prospective, randomized study was approved by the institutional research ethics committee and performed in compliance with the Helsinki Declaration. On the basis of a preliminary study, the effect size had been calculated to be 0.95. A power analysis, with a power of 80% and an α of .05, had demonstrated that a sample size of 17 patients was needed, and 21 patients were enrolled in the study assuming 20% of exclusion.

Implants and Surgical Procedure

The VerSys HA/TCP FiberMetal stems were cementless femoral components made of titanium alloy (Ti6Al4V) with a proximal circumferential coating of fiber metal commercially pure titanium. Additional calcium phosphate coating (65% HA and 35% tricalcium phosphate [17]) was also applied.

There were 2 types of distal shape options. The first was the Midcoat stem (Fig. 1A), which had a near-cylindrical distal stem with distal splines and flutes for reduced stem stiffness and increased rotational stability. The stem was inserted after hand reaming of the medullary canal with cylindrical reamers followed by rasping. The second was the Taper stem (Fig. 1B), which had the same proximal configuration as the Midcoat stem but was tapered distally. This stem was inserted after reaming with only a thin starter reamer and rasping. Another distinct feature was its corundumized surface in the area between the proximal coating and distal polished tip. The corundumized area of the Taper stem was larger distally compared with that of the Midcoat stem. This extra surface modification was intended to promote secure bony fixation.

Standard metaphysis and large metaphysis versions were available for both the Midcoat and the Taper stem. The large metaphysis versions had an increased medial curve compared with the standard metaphysis versions, maximum 4 to 5 mm larger at the base of the neck (proximal end of the body) depending on the stem size. The selection of standard or large metaphysis version was decided intraoperatively to achieve maximum filling by the stem at the proximal end of the canal.

All surgeries were performed using a posterolateral approach by or under the supervision of the senior author (TJ). An HA/TCP Trilogy Acetabular cup (Zimmer), a Longevity polyethylene liner (Zimmer), and a 26-mm cobalt-chromium femoral head were used. A standardized postoperative protocol was used, and all patients were encouraged to ambulate and bear weight as tolerated starting on the second postoperative day after removal of a suction drain.

Methods

Hip function was assessed clinically using the Japanese Orthopaedic Association (JOA) hip score [18-20] at the final follow-up (mean time of 7.0 years after surgery; range, 6.0-8.0 years) and was compared with the preoperative JOA score. The JOA scoring system comprises 4 categories; namely pain (0-40 points), range of motion (ROM: flexion/extension and abduction/adduction, 0-20 points), walking ability (0-20 points), and activities of daily living (0-20 points); a higher total score (of 100) indicates better hip function. Scores of pain and ROM are evaluated separately for each hip, and scores of walking ability and activities of daily living are evaluated per patient. Thigh pain...
defined as any postoperative pain in the anterior thigh, was also recorded.

Radiographically, fixation of the stem was graded as bone-ingrown stable, fibrous stable, and unstable according to the classification given by Engh et al [23] using anteroposterior and lateral radiographs. The prevalence of cancellous condensation, radiopaque lines, cortical hypertrophy, and atrophy of the femur attributed to stress shielding in each zone were assessed according to Gruen’s zone [24] and used to grade the fixation of the stem [23,25]. Cortical hypertrophy was defined if there was more than 2-mm increase in the outside diameter of the cortex as seen on the final follow-up radiographs compared with the appearance on the radiographs made immediately postoperatively [25]. When cancellous condensation was found, the distance between the apex of greater trochanter and the proximal end of the cancellous condensation seen laterally (in Gruen’s zones 2 and 3) was measured. The distance was used to analyze the location of cancellous condensation more quantitatively and to eliminate the influence of slight difference of the stem length (the Midcoat stem was 5-20 mm longer than the Taper stem). All the radiographs were examined by 2 independent experienced hip surgeons (DK, YY). The qualitative parameters resulted in inconsistent assessment were re-evaluated by consensus by the 2 observers. The results of quantitative assessment were averaged.

Bone mineral density (BMD) in each Gruen’s zone at the final follow-up was measured using dual-energy x-ray absorptiometry (DEXA) (Lunar iDEXA; GE Healthcare, Buckinghamshire, England) (Fig. 2). Scanning was performed in a slightly internally rotated position constantly to obtain a frontal view of the femur [26]. Bone mineral density in each zone was compared with each side.

The JOA scores were compared using paired t tests between preoperative and at the final follow-up and between the Midcoat side and the Taper side. Quantitative radiographic data and BMD data were also compared between the Midcoat side and the Taper side using paired t test. Data were analyzed using StatView for Windows ver.5.0 (SAS Institute Inc, Cary, NC), and a P < .05 was considered significant.

Results

The overall JOA scores that combined the results of the Midcoat and the Taper sides were significantly improved (paired t test, P < .0001) at the final follow-up (88.2 ± 9.9 points) compared with the preoperative score (47.5 ± 12.4 points). The differences in JOA scores between the Midcoat and the Taper sides were not significantly different preoperatively (Midcoat side, 48.8 ± 12.0 points; Taper side, 46.1 ± 12.9 points) and at the final follow-up (Midcoat side, 88.5 ± 9.7 points; Taper side, 87.8 ± 10.4 points) by the paired t test (P = .43 and .45, respectively). Increase of the pain score (final score – preoperative score) was not significantly different between the Midcoat side (18.8 ± 8.2 points) and the Taper side (20.7 ± 9.9 points) (P = .32), as was that of ROM score (5.7 ± 2.8 for Midcoat side and 6.2 ± 3.1 for Taper side) (P = .36). No patients had thigh pain in either side throughout the follow-up period.

Radiographic analysis revealed that the fixation of all stems were bone ingrown stable according to Engh’s classification. There were no stems that were fibrous stable or unstable. Cortical hypertrophy was seen on both sides.
sides of one patient; in Gruen’s zone 2 on the Midcoat side, and in slightly more distal regions between zones 2 and 3 and between zones 6 and 5 on the Taper side. Fig. 3 shows a typical radiograph demonstrating cancellous condensation. Cancellous condensation was found in all 21 cases in zones 2 and 6 with the Midcoat side and in slightly more distal regions between zones 2 and 3 and between zones 6 and 5 with the Taper side. Focal bone apposition to the stem surface at proximal edge of coating (Gruen’s zone 1) was found in 20 of 21 hips with the Midcoat stem and in 19 of 21 hips with the Taper stem. The mean values of the distance between the apex of greater trochanter and the lateral cancellous condensation on the Midcoat and Taper sides were 98.2 ± 9.3 and 123.0 ± 12.7 mm, respectively. The distance was significantly smaller \( (P < .0001) \) on the Midcoat side than on the Taper side, meaning that the cancellous condensation on the Midcoat side was more proximally located than on the Taper side. Osteolysis was not seen in any hips.

Signs of stress shielding were observed in all femurs in the area above the region of cancellous condensation. Bone atrophy was confined to zones 1 and 7 on the Midcoat side, whereas it was seen in zones 1 to 2 and zones 6 to 7 on the Taper side (Fig. 3). On the contrary, radiopaque lines around the stem were typically seen in the area below the region of cancellous condensation (Gruen’s zones 2-6 for the Midcoat stem and zones 3-5 for the Taper stem).

The mean values and standard deviations of BMD (g/cm²) are shown in Fig. 2. The values of BMD at the Midcoat side in zones 2 and 6 were significantly greater than those at the Taper side (zone 2, \( P = .0072 \); zone 6, \( P = .0032 \)).

**Discussion**

In this study, we compared Midcoat and Taper stems, both of which were designed to achieve proximal fixation. The Taper stem was designed to reduce distal canal filling and to enhance proximal fit and fill by distally tapered geometry, whereas the Midcoat stem was designed to increase rotational stability by modification of the distal filling stem. Because of its characteristic cylinder-shaped distal end of the Midcoat stem, the size of the stem may be decided by the size of diaphyseal medullary canal. This might have been associated with even lower canal filling in the proximal region when the diaphyseal canal was narrow. Our radiographic findings, however, did not suggest that the distally cylindrical design of the Midcoat stem was implicated in distal fixation. In fact, differences in the regions of cancellous condensation suggested that load transfer occurred at a slightly more distal region in the Taper stem than in the Midcoat stem. Periprosthetic BMD data supported these results.

Different operative procedures may have caused such positional differences of load transfer (Fig. 4). In cementless femoral preparation, the femoral canal is prepared so that the stem of the maximum size can be inserted and the initial stability of the stem is expected. This was achieved by the reamers and the rasps for the Midcoat stem and by only the rasps for the Taper stem.

**Fig. 3.** A hip radiograph of a 58-year-old woman, taken 7 years after surgery. Cancellous condensation (arrows) was found in zones 2 and 6 on the Midcoat (M) side and in the border regions between zones 2 and 3 and between zones 6 and 5 on the Taper (T) side. The areas above the region of cancellous condensation showed bone atrophy due to stress shielding. Ratios of cancellous condensation according to Gruen’s zone are also shown.

**Fig. 4.** Schematic differences in operative procedure and load distribution. (A) Cylindrical stem. The reaming of the diaphyseal canal by cylindrical reamers (R) before the insertion of the stem (S) may contribute to proximal loading. (B) Tapered stem. The insertion of the stem (S) without diaphyseal reaming may result in slightly more distal loading.
The endocortical bone may have been reamed away slightly by the cylindrical reamers, and the cylindrical reaming to a depth equal to or more than the stem length may have contributed to proximal loading of the Midcoat stem [2] (Fig. 4A). On the contrary, diaphyseal canal was not reamed before implantation of the Taper stem, and it might have resulted in a shift in stem-to-bone load transfer to slightly more distal area (Fig. 4B). The difference in the distal shape of the stem itself—tapered vs cylindrical—may also have contributed to the differences in load transfer and the positions of cancellous condensation. It would be assumed that the load transfer from a stem to the surrounding bone can be more proximally concentrated by distal cylindrical geometry than by tapered geometry (Fig. 5).

In addition to the difference of distal stem geometry, the difference of surface texture might be another reason for load transfer occurring in the more distal region in the femur with the Taper stem when compared with the Midcoat stem. It is generally known that the surface blasting of metal implants enhances osteocondensation at the bone-implant interface [27,28]. The Taper stem had a larger grit-blasted area than the Midcoat stem (Fig. 1), and the areas in which cancellous condensation was always seen were exactly the areas of distal end of grit-blasted surface.

Bone density in zones 2 and 6 evaluated using DEXA was greater on the Midcoat side than on the Taper side, which can be naturally explained by cancellous condensation found in a more distal region in femurs with the Taper stem. Although greater bone density in zones 3 and 5 on the Taper side also was expected from the Taper stem. Although greater bone density in zones 3 and 5 on the Taper side also was expected from the Taper stem, and it might have resulted in a shift in stem-to-bone load transfer to slightly more distal area (Fig. 4B). The difference in the distal shape of the stem itself—tapered vs cylindrical—may also have contributed to the differences in load transfer and the positions of cancellous condensation. It would be assumed that the load transfer from a stem to the surrounding bone can be more proximally concentrated by distal cylindrical geometry than by tapered geometry (Fig. 5).

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Bone density in zones 2 and 6 evaluated using DEXA was greater on the Midcoat side than on the Taper side, which can be naturally explained by cancellous condensation found in a more distal region in femurs with the Taper stem. Although greater bone density in zones 3 and 5 on the Taper side also was expected from the radiographic evaluation, actual measurements of bone density were not significantly different between the 2 stems. Lower canal filling of the Taper stem in the distal femur when compared with the Midcoat stem and the subsequent increase in the proportion of cancellous bone may be the reason for the lower bone density than expected on the Taper side. The possible influence of femur rotation on bone density measurement [29] also may have affected the results and could be one of the limitations of this study, although we strongly intended to make the same position and rotation when the measurements were performed.

We attributed the proximal femoral osteopenia to stress shielding, but differentiating stress shielding from wear-related osteolysis would not always be easy [30], and this should be noted in interpreting the results of DEXA and radiographic evaluation. However, the wear rate of the same polyethylene liner that was highly cross-linked have been reported very low [1,31,32], and a 5-year to 10-year follow-up study using the same liner also demonstrated a very low rate of incidence of osteolysis (2%) [6]. Therefore, we believe the effect of osteolysis, if any, on the BMD data was negligible.

Although some tapered stems have not been associated with severe osteopenia due to stress shielding [30,33], it has also been reported that the bone remodeling around a tapered stem can be continuous even after 10 years [4,34]. Longer follow-up would be needed to see if the different loading patterns of the 2 stems identified in this study is permanent or not.

The differences of design between the 2 stems compared in this study included not only the distal geometry but also the surface structure (area of grit blasting). It was not possible to decide which characteristic, distal tapered geometry or distally larger area of surface blasting was more responsible for distal loading. Nevertheless, it would be noted that a stem with distally tapered geometry, which was intended to reduce the risk of distal fixation and distal loading, did demonstrate more distal fixation and loading compared with a stem with distally cylindrical, nontapered geometry.

In conclusion, although clinical and radiographic results indicated good 6-year to 8-year outcomes of THA with both the Midcoat and the Taper stems, the radiographic loading pattern was different between the 2 stems. This study suggested that the tapered geometry alone does not necessarily achieve the proximal loading and that other factors including the surface structure and the surgical techniques also should be considered.

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**References**

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