

# Comparison of Periprosthetic Bone Remodeling between Cementless Tapered Wedge and Conventional Fit-and-Fill Stem: A Prospective Randomized Controlled Study

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**INTRODUCTION:** Tapered wedge stems are designed for metaphyseal fixation and preservation of proximal bone stock by transferring the load to the metaphysis, thereby preventing stress-shielding induced bone loss, while there have been few randomized controlled studies examining the superiority of tapered wedge stems with respect to their effectiveness in reducing bone loss. We hypothesized that the tapered wedge stem could provide more physiological bone remodeling with a lower periprosthetic bone loss than the conventional fit-and-fill stem. The purpose of this study was to evaluate implant-specific bone mineral density (BMD) changes of proximal femur and clinical outcomes after the implantation of the tapered wedge stem and the conventional fit-and-fill stem.

## **METHODS:**

From September 2017 to March 2020, 122 patients scheduled for total hip arthroplasty were prospectively enrolled and were randomly allocated at a ratio of 1:1 to either a tapered-wedge stem or a fit-and-fill stem. The tapered wedge stem is made of a titanium alloy with a proximal coating of porous titanium. The thickness of coating on the distal 10-mm length of sprayed area decreases gradationally from proximal (0.5 mm) to distal (0.2 mm). The conventional fit-and-fill stem is made of titanium alloy. The rough surface is coated with hydroxyapatite.

Patients underwent dual-energy x-ray absorptiometry scans within 1 week after surgery (baseline) and at 6, 12, and 24 months after surgery to assess periprosthetic BMD in the 7 Gruen zones (Figure 1). In addition, the Japanese Orthopaedic Association (JOA) hip score were routinely assessed before surgery and at 6, 12, and 24 months after surgery. At each follow-up timepoint, all patients underwent radiological evaluation.

## **Statistics**

The sample size of each group was initially determined as 100 subjects. Although we could not reach planned enrollment in the determined period, the enrollment had been stopped as originally planned.

## **RESULTS:**

Of 122 patients assessed for eligibility, 17 patients were excluded due to protocol deviation (including violation of inclusion or exclusion criteria), discontinuation (including one patient with a revision surgery due to periprosthetic fracture), and follow up lost. A total of 105 patients were included in the analysis (mean age: 61.6 years, 87 females, and 18 males). There were no significant differences in gender, age, body weight, height, body mass index, or hip diagnosis between the two groups. Of the 105 patients, 2 developed a dislocation, which were treated with closed reduction. There were no other complications. No revision surgeries were performed during the study period in the two groups.

The relative changes in BMD were shown in Figure 2. In Gruen zone 2, the fit-and-fill group showed a trend toward decrease in BMD during the study period and had a mean BMD decrease of 9.2% from baseline through 24 months after surgery, while the tapered wedge group showed a trend toward improvement in BMD after 12 months and had a mean BMD decrease of 2.9% from baseline through 24 months after surgery. At 24 months after surgery, there was a significant difference in the relative change in BMD between the two groups ( $p=0.0018$ ). Gruen zone 7 had the greatest mean BMD decrease in both groups, while the tapered wedge group has a significantly smaller relative change in BMD than the fit-and-fill group at all follow-up timepoints ( $p=0.040$  at 6 months,  $p=0.037$  at 12 months, and  $p=0.025$  at 24 months, respectively).

Both groups demonstrated similar improvement in JOA hip scores over the study period. Radiologically, radiolucent line was observed in 2 patients at 24 months after surgery, 1 (Gruen zone 1) in the tapered wedge group and 1 (zone 3) in the fit-and-fill group. Stem subsidence was observed in 3 hips, 1 in the tapered wedge group and 2 in the fit-and-fill group. In all of the 3 cases it stabilized within 1 year after surgery. Cortical hypertrophy was observed in 12 hips only in the tapered wedge group. In 11 of the 12 hips, cortical hypertrophy was found in areas containing either or both Gruen zone 2 or 3. There were no evidence of stem loosening or osteolysis around the stems during the study period.

**DISCUSSION AND CONCLUSION:** In this study, we prospectively examined the effects of a new tapered wedge stem on the periprosthetic bone remodeling. We found that the tapered wedge stem with proximal porous coating was superior to a conventional fit-and-fill stem with respect to the effectiveness in reducing periprosthetic bone loss.

