Effect of Robotic Milling on Periprosthetic Bone Remodeling

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ABSTRACT: The ROBODOC system has provided better fit and fill of the stem and less destruction of the bony architecture than with manual surgery. These benefits might affect femoral periprosthetic bone remodeling. We evaluated the effects of robotic milling in cementless total hip arthroplasty (THA) in a longitudinal 24-month follow-up study using dual energy X-ray absorptiometry (DEXA) and plain radiographs of 29 patients (31 hips) after ROBODOC THA and 24 patients (27 hips) after manual THA with the same stem design. To minimize the influence of other factors on bone remodeling, only female osteoarthritis patients, who had no drugs that might affect bone metabolism were enrolled. Significantly less bone loss occurred at the proximal periprosthetic areas in the ROBODOC group. In zone 1, the decrease was 15.5 versus 29.9% using conventional rasping; in zone 7, the loss was 17.0% with ROBODOC compared to 30.5% with conventional rasping ($p < 0.05$). On radiographs, endosteal spot welds in the proximal medial portion were more pronounced in the ROBODOC group (48 vs. 11% in the conventional group, $p < 0.05$). Our results suggest that robotic milling is effective in facilitating proximal load transfer around the femoral component and minimizing bone loss after cementless THA.

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Keywords: ROBODOC system; periprosthetic bone remodeling

INTRODUCTION

ROBODOC (Integrated Surgical Systems, Davis, CA) is an active system of computer-assisted surgery that helps surgeons to prepare the femoral canal for cementless total hip arthroplasty (THA) by using a five-axis robotic arm and a high-speed milling device.[1] Based on postoperative radiographic assessment, ROBODOC surgery provided better alignment and fit and fill of the stem than conventional surgery.[1–3] In addition, the robotic milling system provided less destruction of intramedullary trabecular architecture[4] and reduced the amount of fatty and bony debris introduced into the venous system, resulting in a lower incidence of severe intraoperative embolic events.[5] Because proximal bone remodeling is considered to be related to stem fit and fill[6] and preservation of endosteal trabecular architecture and vascularity,[7] robotic surgery could reduce the periprosthetic bone loss after THA. To the best of our knowledge, however, the effects of robotic surgery on periprosthetic bone remodeling have not been investigated quantitatively.

The aim of this study was to investigate periprosthetic bone remodeling after ROBODOC THA in a longitudinal follow-up study using dual-energy X-ray absorptiometry (DEXA) and plain radiographs in comparison with a control THA group performed without ROBODOC. To minimize the influence of other factors on bone remodeling, only female patients with a preoperative diagnosis of osteoarthritis were enrolled.

MATERIALS AND METHODS

From March 2001 to December 2003, 53 patients (58 hips) gave informed consent to be enrolled in this prospective study and underwent primary THA. Eligible patients included females with a diagnosis of osteoarthritis with no previous surgery and no administration of drugs that affect bone mineral metabolism. The patients were allowed to choose which group (with and without ROBODOC) to join. The femoral canal was prepared with the ROBODOC in 29 patients (31 hips), and with a standard rasp in 24 patients (27 hips). There were no significant differences between the two groups in age (ROBODOC = 56.7 ± 9.2 years, conventional = 57.4 ±

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7.1 years) and body mass index (ROBODOC = 22.6 ± 3.4, convetional = 22.5 ± 2.8).

In all patients, a VerSys Fiber Metal Taper (Zimmer, Warsaw, IN) titanium alloy stem was inserted without cement. This stem is a straight type component with a distal tapered design and has a proximal titanium fiber metal porous coating with hydroxyapatite and a polished distal portion. To minimize the difference in the decision criteria for stem size between the two groups, preoperative planning was done using the ORTHODOC system, a preoperative planning workstation of the ROBODOC,[8,9] which provides the optimal size and position of the femoral component for appropriate fit and fill. In the conventioal group, the surgeons were informed of the results of preoperative planning before the operation and were encouraged to use the recommended stem size. Because a larger size proximal porous-coated stem is associated with greater proximal bone loss,[10] we evaluated whether the size distribution between the two groups was comparable. The acetabular component (Trilogy; Zimmer) was implanted using a press-fit method after underreaming of 1 mm in both groups. The postoperative protocol was the same in both groups, with immediate full weight bearing as tolerated. From postoperative day 1, patients were allowed to transfer from bed to wheel chair with full weight bearing under control of a physical therapist. Then, patients were able to walk with a walker or T-cane, depending on the patient's recovery.

The patients were followed using clinical, radiographical, and bone mineral assessments. The clinical rating before the operation and postoperatively at 24 months was determined using the Merle d'Aubigné hip score.[11] All plain radiographs were scanned digitally with 300 dpi and were evaluated using Image-J software (NIH). On immediate postoperative radiographs, stem alignment was measured by means of the varus/valgus stem angle, defined as the difference between the axes of the femur and stem.[1] The medial fit of the stem[1] at the neck cut level was graded as good if there was contact between the stem and femoral medial cortex, fair if there was a 1- to 2-mm space, and poor if the space was more than 2 mm, based on a modification of the classification by Woolson et al.[12] The fill of the stem at the level of the lesser trochanter[1] was measured as the percentage of the width of the femoral component to that of the medullary cavity. Radiolucent lines around the proximal porous surface[13] and endosteal spot welds[14] were assessed on the 2-year follow-up radiographs. Heterotopic ossification was evaluated according to Brooker's classification.[15]

The radiographic assessment was performed by two orthopaedic surgeons in a blind fashion. We evaluated intraobserver and interobserver variability using Pearson correlation coefficient (r) for stem alignment and fit and Kappa coefficients (κ) for the appearance of spot welds. In the intraobserver variability of alignment, fit, and spot welds (from two measurements separated by a 3-week interval), r was 0.74 and 0.78, respectively, and κ was 0.76. In the interobserver variability, r was 0.70 and 0.83, and κ was 0.77.

Periprosthetic bone mineral density (BMD) surrounding the femoral component was measured in the 7 Gruen zones[16] using DEXA (DPX-L, Lunar Madison, WI) at 3 weeks and 12 and 24 months after surgery. Because the DEXA measurement was affected by the rotational position of the leg,[17] and patients with severe osteoarthritis had difficultly placing the leg in neutral position due to contracture, preoperative DEXA measurements were not performed. Instead, the DEXA measurements 3 weeks postoperatively, when patients were free from contracture, were used as baseline values.

Patients were placed supine on the table with standard knee and foot supports so that the femur was in a neutral position (0° of neck anteversion). DEXA measurements and the evaluation of the scans were all performed by the same medical assistant, who was blinded to patient selection. For quality control of the DEXA machine, the assistant performed the calibration before the initial examination of the measurement day. Longitudinal precision on a phantom estimated a coefficient of variation of <2% during the study period. According to the previous DEXA report, initial BMD 3 weeks postoperatively in zone 4 had significant influence on subsequent proximal bone loss.[17] Thus, BMDs around the distal portion of the prosthesis were compared between both groups. To analyze regional bone density change in each zone, the BMD ratio was calculated 12 and 24 months postoperatively in each zone as a percentage of the 3 week values.[17]

In previous articles assessing periprosthetic femoral bone remodeling with different factors or interventions,[18–24] a 5 to 10% difference in BMD decrease by DEXA between test groups was identified as significant. Therefore, we calculated a sample-size to detect the 5% difference in the BMD decrease. Twenty-five hips in each group were sufficient to determine whether there was a significant difference (power = 0.8 and $p < 0.05$).

For comparison between the two groups, we used univariate analysis for data grouped into distinct categories (spot welds, medial proximal fit, radiolucent lines, ectopic ossification, and intraoperative fracture) with Fisher's exact test. We used the Mann-Whitney U-test for continuous data (age, BMI, Merle d'Aubigné score, stem alignment, proximal fill ratio, and stem size). The difference of the BMD ratios between the two groups was examined using repeated measure ANOVA.

RESULTS

The median Merle d'Aubigné hip scores[11] before surgery was 9.5 (pain 1.9, mobility 4.1, ability 3.5) in the ROBODOC group and 9.9 (pain 1.8, mobility 4.2, ability 3.9) in the conventional group. At 24 months, these scores improved to 17.8 (pain 6.0, mobility 5.9, ability 5.9) and 17.7 (pain 6.0, mobility 5.8, ability 5.9), respectively (Table 1). There was no significant difference in these scores between the two groups at 24 months. In the

Table 1. Comparison of Clinical Results in ROBODOC and Conventional Groups

	ROBODOC Group ($n = 31$)	Conventional Group ($n = 27$)	p-Value
Clinical score (Merle d'Aubigné, average ± SD) before surgery	9.5 ± 2.7	9.9 ± 2.3	0.67
24 months after surgery	17.8 ± 0.6	17.7 ± 0.7	0.83
The average (range) size of used stem	12.8 (11–16)	13.3 (10–15)	0.17
No. of stems using different size compared with planned size	0	5	0.018*
No. of intraoperative femoral fracture	0	2	0.21

*$p < 0.05$ with Fisher's exact test.

ROBODOC group, a stem of the same size as suggested by preoperative planning was implanted in all hips. In the conventional group, a stem of the same size as suggested by preoperative planning was implanted in 22 hips, and an undersized stem was implanted in 5 hips. There were no significant differences in sizes between the groups. No intraoperative femoral fractures occurred in the ROBODOC group during stem fixation, while two patients in the conventional group had intraoperative fractures that required treatment with cable cerclage. No patients in either group underwent revision surgery by 24 months.

Radiographic examples are shown in Figure 1. Immediate postoperative radiographs showed that stem alignment was better in the ROBODOC group ($p = 0.01$) (Table 2). The number of hips rated with good proximal medial stem fit was significantly larger in the ROBODOC group ($p < 0.0001$). A significant difference in fill was found in favor of the ROBODOC group ($p = 0.04$). No radiolucent lines in the proximal portion or progressive subsidence occurred in any hip at 24 months. Endosteal spot welds in the proximal portion (zones 1 and 7) were detected in 26 (84%, zone 1) and 15 (48%, zone 7) of the ROBODOC cases and 23 (85%, zone 1) and 3 (11%, zone 7) of the conventional cases. The difference in endosteal spot welds in zone 7 was significant ($p = 0.004$). The radiographs also showed class 1 ectopic ossification in one patient in each group.

There was no significant difference between the groups in initial BMD in all zones (Table 3). However, repeated-measure ANOVA in all zones but zone 3 showed significant differences between the two groups (zone 1, $p = 0.010$; zone 2, $p = 0.012$; zone 3, $p = 0.23$; zone 4, $p = 0.044$; zone 5, $p = 0.034$; zone 6, $p = 0.020$; zone 7, $p = 0.0012$) (Fig. 2). Especially, the decrease in the BMD ratio at the proximal zones 24 months postoperatively was significantly smaller in the ROBODOC group (zone 1; −15.5%, zone 7; −17.0%) than the conventional group (zone 1; −29.9%, zone 7; −30.5%) (Table 4). The difference of the decrease in the BMD ratio at distal zones (zone 4 and 5) between the two groups was only 6%, but the ROBODOC group also showed a significantly smaller decrease of the BMD ratio.

DISCUSSION

Periprosthetic bone remodeling is influenced by gender,[18,19] perioperative density,[17,20,21] stem size,[10] and stem material.[22] To clarify the effects of robotic milling on adjacent bone remodeling, the effects of these other factors were minimized by enrolling only women with osteoarthritis and by using the same stem design and material and the same preoperative planning procedure in all patients. In addition, patient ages, stem size, and postoperative BMD of the femoral distal portion were comparable between groups.

DEXA assessments showed significant differences between the two groups in almost all zones, especially proximally, suggesting that differences in femoral preparation between robotic milling and manual rasping affected periprosthetic bone remodeling. Two mechanisms may account for the more favorable bone remodeling after robotic milling. First, 95% of the ROBODOC group had a good fit compared to 63% in the conventional group. Similarly, better fill occurred in the ROBODOC group. These findings agree with previous reports.[1–3] A favorable proximal fit and fill provides better bone ingrowth proximally.[6] Therefore, the better proximal fit and fill in the ROBODOC group might facilitate proximal load transfer from the stem to the surrounding bone with a high rate of

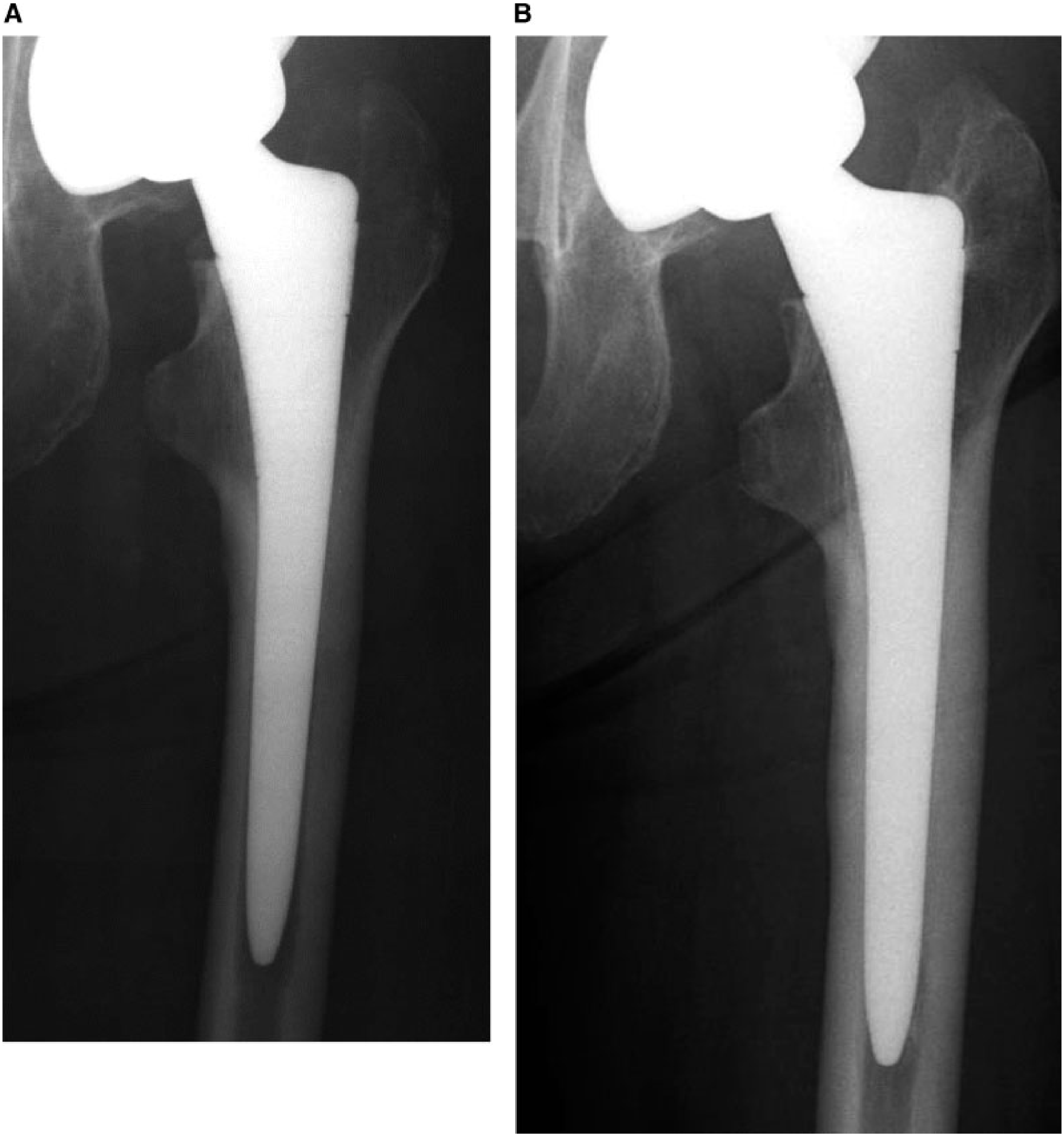

Figure 1. (a–c) Radiographs of a 66-year-old woman in the ROBODOC group. The 2-year postoperative radiograph (b) shows spot welds around the hydroxyapatite coating (c; white and black arrows). The medial femoral neck is unchanged from the immediate postoperative radiograph (a). (d,e) Radiographs of a 56-year-old woman in the conventional group. The 2-year postoperative radiograph (e) shows severe osteopenia in the proximal portion (zone 7) compared with the postoperative film (d).

ingrowth or ongrowth of periprosthetic bone. This favorable biomechanical environment could be reflected in the preservation of the BMD ratios in zones 1, 2, 6, and 7.

Second, robotic milling provides nearly intact trabecular architecture between the stem and adjacent cortical bone, whereas with rasp preparation, the bone microstructure is grossly destroyed.[4]

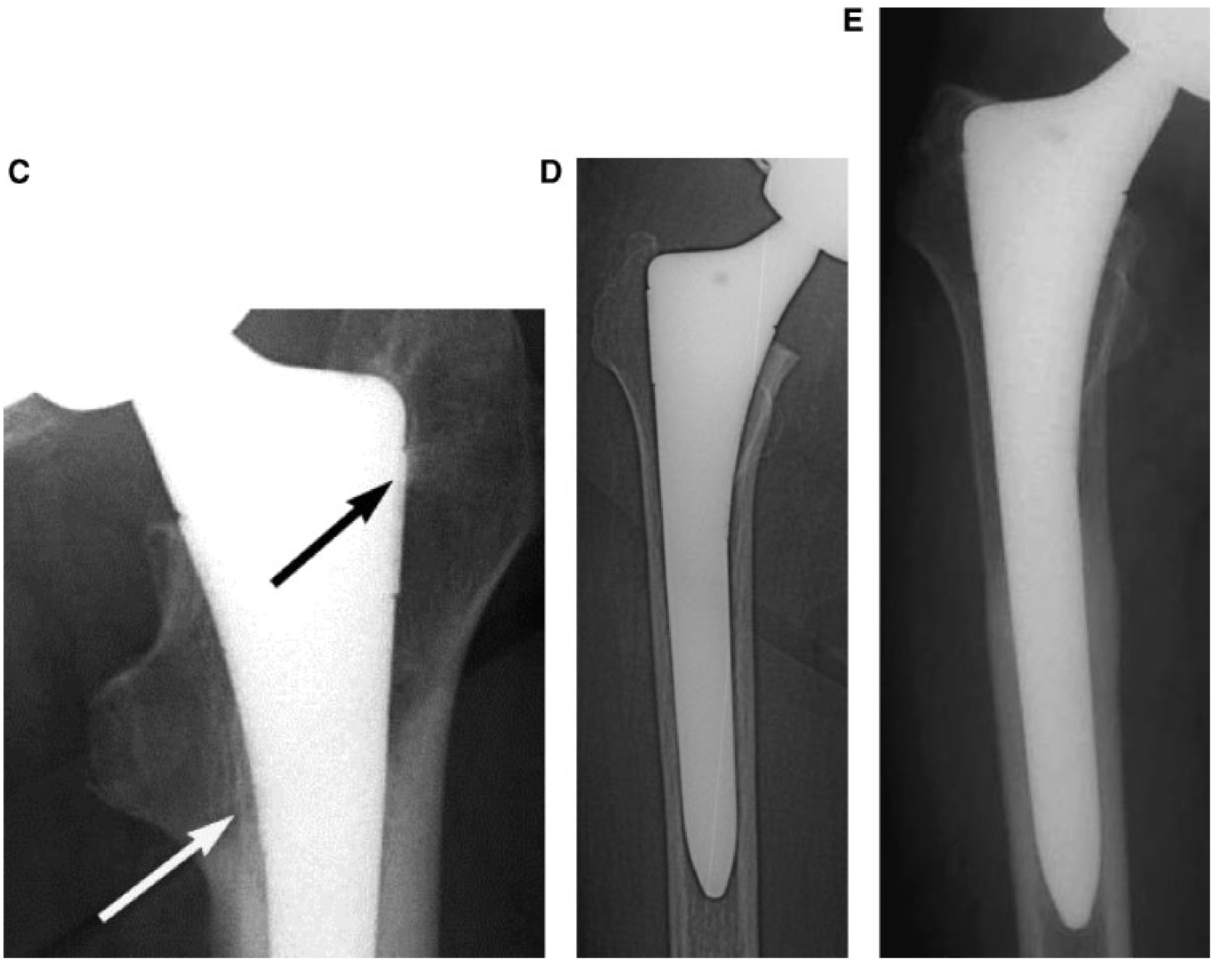

Figure 1. (*Continued*)

Thus, with rasp preparation, vascular injury and decreased blood supply in association with the destruction of trabecular architecture may cause insufficient implant osseointegration.[7] Less destruction of adjacent bony microstructure around the stem using robotic milling might enhance recovery or renewal of periprosthetic bone after surgery. We speculate that BMD ratios in

Table 2. Comparison of Radiographic Results in ROBODOC and Conventional Groups

	ROBODOC ($n = 31$)	Conventional ($n = 27$)	p-Value
Immediate postoperative radiographic assessment			
Stem (varus/valgus) alignment (°)	0.25° ± 0.22°	0.47° ± 0.44°	0.01*
Proximal medial fit assessment of stem (good/fair/poor) (% graded poor)	30/1/0 (0%)	17/4/6 (22.2%)	<0.0001**
Proximal fill assessment of stem (%)	78.3 ± 5.8	75.4 ± 5.6	0.04*
24-month postoperative radiographic assessment			
No. of cases with radiolucent lines	0	0	1
No. of cases with spot welds in proximal zone			
zone 1	26	23	1
zone 7	15	3	0.004**
No. of cases with ectopic ossifications	1 (class 1)	1 (class 1)	1

*$p < 0.05$ with Mann-Whitney U-test.
**$p < 0.05$ with Fisher's exact test.

Table 3. The Initial BMD (Average ± SD) at Postoperative 3 Weeks in the Two Groups

Zone	ROBODOC ($n = 31$)	Conventional ($n = 27$)	p-Value
1	0.87 ± 0.18	0.86 ± 0.17	0.52
2	1.62 ± 0.24	1.63 ± 0.24	0.33
3	1.75 ± 0.23	1.73 ± 0.33	0.42
4	1.60 ± 0.27	1.58 ± 0.30	0.55
5	1.75 ± 0.26	1.76 ± 0.28	0.24
6	1.71 ± 0.25	1.70 ± 0.26	0.26
7	1.12 ± 0.25	1.13 ± 0.26	0.46

the distal zones 4 and 5 of the ROBODOC group were better partly because bony architecture was preserved.

Heat damage by robotic milling may adversely affect bone remodeling, causing subsequent radiolucency on plain radiographs.[25,26] A risk of heat injury throughout the milling procedure in revision THA using the ROBODOC system was reported.[27] However, in our study, radiographs of the ROBODOC group demonstrated proximal bone ingrowth fixation without radiolucent lines, and spot welds in zone 7 indicate a good biologic response. Bone thermal damage may be less evident in a primary THA using the ROBODOC system since there is no need to remove cement or to mill sclerotic bone from previous primary surgery.

We did not compare the time to recovery of walking ability postoperatively between the two groups, although time might influence periprosthetic bone remodeling. One report showed that late weight bearing resulted in a large reduction in BMD around the stem.[28] However, we previously found no significant difference comparing robotic and manual surgery with respect to the time required to regain the ability to walk more than six blocks without a cane.[29] Thus, weight bearing was not considered to be associated with the difference of bone remodeling between the two groups in this study.

Our study has limitations. First, the follow-up period was only two years. In previous reports, long-term BMD changes in periprosthetic femoral bone have been controversial.[22,30] One report

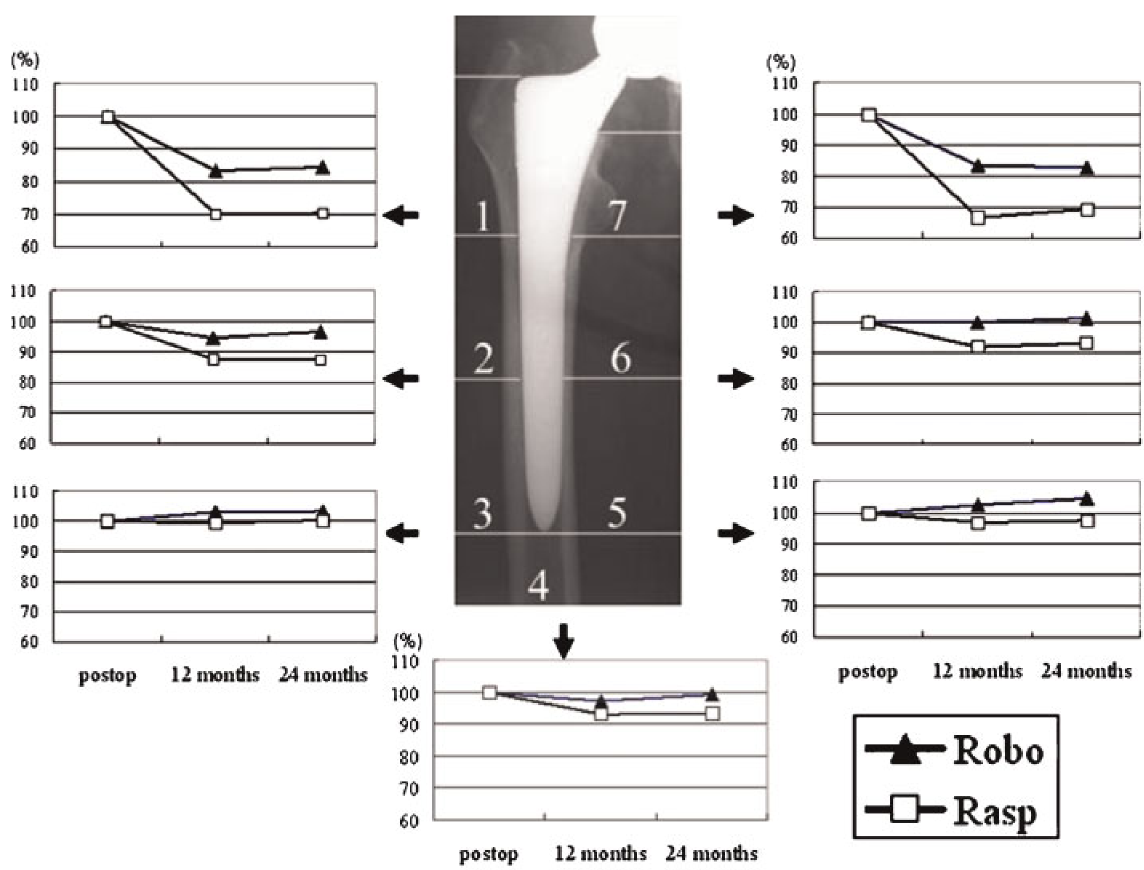

Figure 2. Time-related changes in median BMD ratios in Gruen's zones 1 to 7. ROBODOC surgery (Robo) and conventional manual surgery (Rasp).

Table 4. Comparison of Postoperative BMD Ratios (Average ± SD) between the Two Groups

	12 Months		24 Months	
Zone	ROBODOC ($n=31$)	Conventional ($n=27$)	ROBODOC ($n=31$)	Conventional ($n=27$)
1	83.2 ± 15.4	70.0 ± 15.1	84.5 ± 19.4	70.1 ± 17.3
2	94.6 ± 9.9	87.6 ± 16.8	96.6 ± 11.4	87.5 ± 16.0
3	102.9 ± 12.3	99.4 ± 11.5	103.5 ± 11.2	100.3 ± 11.0
4	97.3 ± 7.5	93.2 ± 8.4	99.2 ± 10.7	93.2 ± 10.2
5	102.6 ± 15.3	96.7 ± 12.0	104.9 ± 14.0	97.6 ± 15.2
6	100.0 ± 13.7	91.8 ± 12.9	101.2 ± 14.7	93.4 ± 16.0
7	83.5 ± 16.5	66.6 ± 14.8	83.0 ± 23.3	69.5 ± 18.2

showed that BMD in zone 7 decreased continuously up to the seventh postoperative year.[30] Another report showed that bone loss in zone 7 2 years postoperatively recovered progressively by 10 years.[22] Further follow-up of our patients is required to determine the long-term effect of robotic milling on BMD change. Second, this study was not randomized; patients enrolled in our study chose robotic milling or manual THA themselves, although the two groups were comparable in terms of preoperative and postoperative factors that can influence bone remodeling. Third, only female patients were enrolled. In our country, patients with hip osteoarthritis are predominantly female.[31] Previous reports showed that the extent of the stress shielding was different between male and female patients,[18,19] so we avoided this effect by enrolling no male patients. Finally, caution is necessary when applying our results to other studies of periprosthetic bone remodeling. Bone remodeling is affected by patient-related factors such as bone chemical markers,[32] BMD of other body parts,[21] menopause, and stem related-factors such as design (e.g., anatomical stem), surface finish and the extent of porous coating.[33] Further trials in a large number of patients stratified by multiple factors are required to examine how these other factors affect the impact of robotic milling impact on periprosthetic bone remodeling.

In conclusion, this study of female osteoarthritic patients evaluated periprosthetic bone remodeling and found that robotic milling reduced postoperative bone loss of the proximal femur after cementless THA using a straight type stem with proximal porous coating and polished distal taper design.

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