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CLINICAL RESEARCH

A Comparison between Robotic-assisted and Manual Implantation of Cementless Total Hip Arthroplasty

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Abstract
Background The benefits of robotic techniques for implanting femoral components during THA are still controversial.
Questions/Purposes The purpose of this study was to prospectively compare the results and complications of robotic-assisted and hand-rasping stem implantation techniques.
Method The minimum followup was 5 years (mean, 67 months; range, 60–85 months). One hundred forty-six primary THAs on 130 patients were included in this study. Robot-assisted primary THA was performed on 75 hips and a hand-rasping technique was used on 71 hips.
Results At 2 and 3 years postoperatively, the Japanese Orthopaedic Association (JOA) clinical score was slightly better in the robotic-assisted group. At 5 years followup, however, the differences were not significant. Postoperative limb lengths of the robotic-milling group had significantly less variance than the hand-rasping group. At 2 years postoperatively, there was significantly more stress shielding of the proximal femur in the hand-rasping group; this difference was more significant 5 years postoperatively.
Conclusions Substantially more precise implant positioning seems to have led to less variance in limb-length inequality and less stress shielding of the proximal femur 5 years postoperatively.
Level of Evidence Level II, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

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Each author certifies that his or her institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at the Center of Arthroplasty, Kyowakai Hospital and Department of Orthopedic Surgery, Osaka University Medical School, Osaka, Japan.

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Introduction

Computer-assisted surgery using robotic and image-guided technologies has been used for some time in total joint arthroplasties [7].

The robotic-assisted system (ROBODOC; Integrated Surgical Systems, Davis, CA) was the first active robotic system and was designed to improve outcomes in cementless THA by reducing technical errors [3]. Clinical use of this system began in 1992 [20]. The US Food and Drug Administration authorized a multicenter study starting in 1994. Although the system used in that study required the insertion of three locator pins and the average operative time was more than 240 minutes, the multicenter study showed there was better fit and positioning of the femoral component in the robotic-assisted group [3]. After the study, further system improvement was made, including reduction in the number of locator pins used from three to two, improved milling speed and cutting paths to reduce surgical invasiveness, and robot milling time [3]. In Europe, the first clinical use was in Germany in 1994. Since then, the system sometimes has received harsh criticism and as a result, ROBODOC is not in clinical use in

Europe [22]. However, in August 2008, the ROBODOC system received 510(k) clearance from the US Food and Drug Administration [21].

Some short-term clinical results of this robotic-assisted system have been published [3, 15]. We also reported preliminary results [17]. However, to our knowledge, this is the first prospective study comparing the results of using this robotic-assisted system with the hand-rasping technique in preparation of the proximal femur, with more than 5 years followup. Our research questions were as follows: (1) Does robotic assistance in preparation of the femur result in measurable differences in clinical outcome compared with the hand-rasping technique at 5 years followup? (2) Does use of the robotic-assisted system lead to any difference in complications? (3) Does a difference in the accuracy of restoration of leg length occur when these techniques are compared? (4) Is there a detectable difference in the degree of development of stress shielding and heterotopic ossification seen on radiographs obtained after 5 years of followup?

Patients and Methods

In this prospective cohort study, all patients provided informed consent for participation before surgery. The procedure also was approved by each institutional committee. Beginning in September 2000, from 225 candidates, 143 patients with 162 primary cementless THAs were enrolled at two institutions (Fig. 1). The indications for surgery and being enrolled in this study were patients who had osteoarthritis of the hip with good bone quality (Dorr Type A or B) [8] and of Crowe Class I, II, or III (0%–100% subluxation of the hip) [6] (Fig. 1). Randomization was performed by a person not involved in the study using the randomization list method. Because the robotic-milling procedure needs prior pin implantation, the patients could not be blinded for the surgery. Therefore, we allocated the patients to either group according to the list when they agreed to undergo THA. Minimum followup was 60 months (mean, 67 months; range, 60–85 months). The average age of the patients was 58 years (range, 27–77 years). There were 23 male and 107 female patients included in the study; 10 of the 143 patients enrolled in the study were lost to followup, one died of lung cancer during the followup, and robotic-assisted surgery could not be completed in two, thereby leaving 130 patients in the study. The average body mass index (BMI) was 24 ± 4 kg/m^2. All patients were Japanese. There were no major differences between the two groups regarding distribution of patient age, gender, BMI, or preoperative JOA clinical score [23] (Tables 1, 2). The operative conditions were the same at both institutions. Five surgeons (NN, NS, TN, AK, HM) performed the robotic-assisted and hand-rasping surgeries. All surgeons had more than 10 years' experience using the hand-rasping procedures, but no surgeon had any clinical experience in robotic-milling procedures before this study. Therefore, they trained in doing robotic-milling procedures several times using cadaver bones or plastic bones before performing the surgery.

Because we had no similar previous study, we chose to set the effect size (Cohen's d) of 0.5, which gives a medium level of statistical power in the analysis using Student's t-test [5]. Then we calculated a sample size in the condition of effect size 0.5, power 0.8, and $p < 0.05$. Theoretically, 65 hips in each group were sufficient to determine clinical and radiographic differences. Seventy-five patients (81 hips) were randomized to the robotic-milling group and 68 patients (81 hips) were randomized to the hand-rasping group.

The 75 patients enrolled in the robotic-milling group underwent 81 primary THAs using the robotic-assisted system. The diagnoses were osteoarthritis secondary to hip dysplasia in 78 hips, osteonecrosis in two hips, and rheumatoid arthritis in one hip (Table 1). The 68 patients enrolled in the hand-rasping group underwent 81 primary THAs. Seventy-six of these hips were diagnosed as having osteoarthritis secondary to hip dysplasia, four had

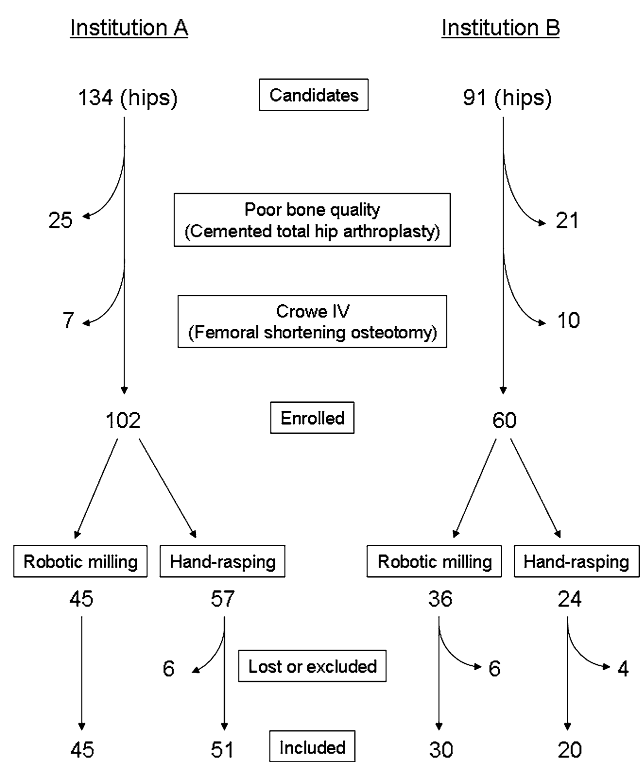

Fig. 1 A detailed flow chart of the candidate patients treated at the two institutions is shown.

Table 1. Patients' background of the two groups

Parameter	Robotic-milling	Hand-rasping	p Value	Effect size
Number of hips				
Enrolled in study	81	81		
Included in study	75 (93%)	71 (88%)		
Number of patients				
Enrolled in study	75	68		
Included in study	69 (92%)	61 (90%)		
Average age (years)	57 ± 10	58 ± 9	0.5 (unpaired t-test)	Cohen's d = 0.11
Diagnosis (number of hips)				
Osteoarthritis	78 (97%)	76 (94%)		
Osteonecrosis	2 (2%)	4 (5%)		
Rheumatoid arthritis	1 (1%)	1 (1%)	0.7 (chi square test)	Cramer's V = 0.07
Average body mass index (kg/m^2)	23 ± 4	24 ± 3	0.3 (unpaired t-test)	Cohen's d = 0.28
Side (right/left) (number)	40/35 (53/47%)	37/34 (52/48%)	1 (chi square test)	Cramer's V = 0.01
Gender (male/female) (number)	13/56 (19/81%)	10/51 (16/84%)	0.8 (chi square test)	Cramer's V = 0.03
Average preoperative JOA score (points)	48 ± 10	51 ± 15	0.2 (Mann-Whitney U test)	r = 0.12

JOA = Japanese Orthopaedic Association.

Table 2. The Japanese Orthopaedic Association (JOA) clinical score

Parameter	Findings	Points
Pain (40 points)	None	40
	Discomfort	35
	Start-up pain or pain after long walk only	30
	Pain on walking without spontaneous pain	20
	Pain on walking and occasional spontaneous pain	10
	Continuous pain	0
ROM (20 points)	(measure at 10°-intervals)	
	Flexion arc ≥ 120°	12
	Flexion arc = a × 10° (a = 0–11)	a
	Abduction arc ≥ 40°	8
	Abduction arc = b × 5° (b = 0–6)	b
Walking (20 points)	Unlimited, without limp	20
	Unlimited, with slight limp	18
	30 minutes or 2 km without cane	15
	10–15 minutes or 500 meters without cane	10
	Indoors only	5
	Unable to walk	0
ADL (20 points)	(with ease: 4, with some support: 2, unable: 0 points for each categories)	
	Sitting on a chair	
	Standing work (30 minutes)	
	Squatting and standing up	
	Stairs	
	Use of public transportation	

ADL = activities of daily living, ROM = range of motion. (Published with permission from the Japanese Orthopaedic Association.)

osteonecrosis, and one had rheumatoid arthritis. In two cases in the robotic-milling group, the robotic-assisted procedure had to be stopped before milling was completed because of a video board problem and locator pin loosening. In these two cases, the operation was converted to the manual method, with no adverse effects. Four patients in the robotic-milling group were lost to followup. Therefore, 69 patients with 75 hips were included in the robotic-milling group (Table 1; Fig. 1). Six patients (eight hips) in the hand-rasping group were lost to followup. One patient (two hips) died of lung cancer during followup. Therefore, 61 patients with 71 hips were included in the hand-rasping group (Table 1; Fig. 1). We used "on treatment analysis" instead of "intention to treat analysis" in this study for the following reasons: (1) our purpose was to find the differences between the two treatment methods; (2) the number of the patients in whom we could not accomplish the robotic procedure was small (two of 81); and (3) there were no differences between the two groups of patients who were included in the study regarding age, gender, BMI, or preoperative JOA score.

The robotic system consists of three units: a robotic arm with a high-speed end-milling device, a control cabinet, and a preoperative planning workstation (ORTHODOC; Integrated Surgical Systems). Additional disposable equipment, such as cutters and drapes, was needed for each surgery, which cost approximately $1500 per patient.

The robotic-assisted THA consists of locator pin implantation, CT scan, preoperative planning using the workstation, robot diagnostics and preparation, exposure and registration of pins, and robotic milling of the femur.

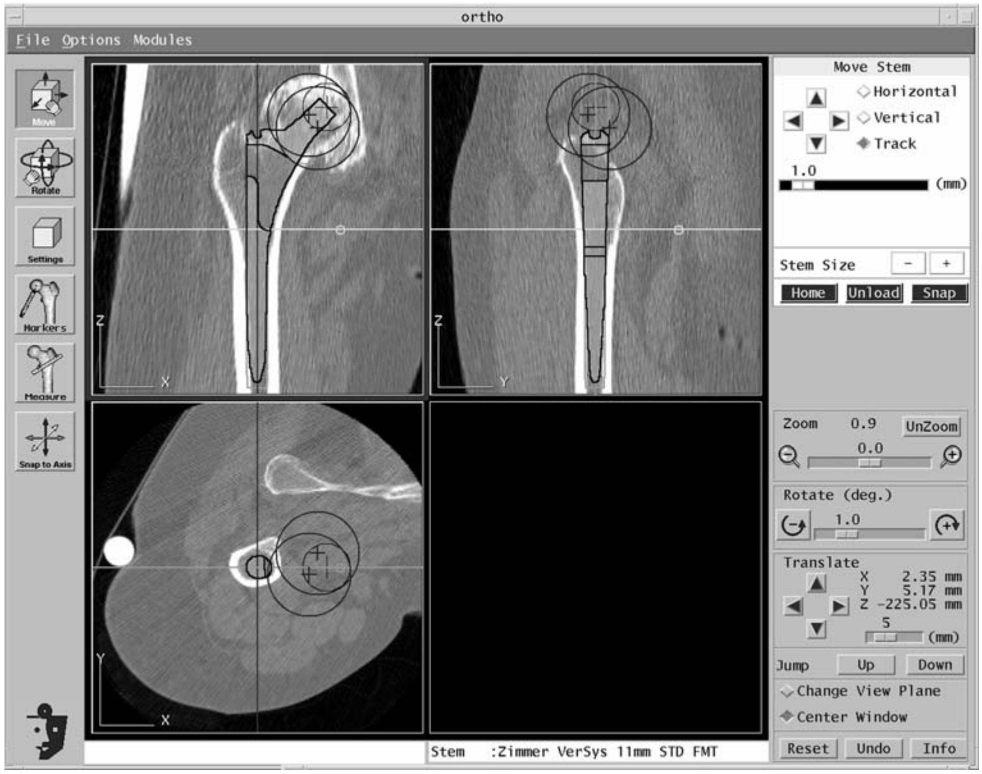

Fig. 2 Preoperative planning was done using the ROBODOC workstation.

For registration of the femur, two locator pins were implanted, one in the greater trochanter and the other in the lateral condyle of the femur. After implantation of the pins, which is performed with the patient under local anesthesia on the day before the index surgery, a CT scan (General Electric, Waukesha, WI) was done according to the manufacturer's specified protocol (1-mm slice thickness; 1–6-mm scan interval; 200-mm field of view; less than 200 total slices). The cost of the CT scan was approximately $50 per patient.

Using the CT image data of each patient on the workstation, the surgeon can construct a three-dimensional (3-D) preoperative plan to select the size of the prosthesis and its position in the femur (Fig. 2). Because the workstation can illustrate cutting paths three-dimensionally, the surgeon can recognize whether abductor tendon injury and/or greater trochanter damage will occur (Fig. 3). When the implant image was positioned optimally on the workstation, this preoperative planning data were recorded on a CD. Preoperative planning time was approximately 30 minutes. Although we were not paid an extra fee for this task, the average cost for Japanese surgeons would be approximately $25. Before each surgical procedure, the surgeon loaded the patient's data on this CD to the robotic-assisted system and performed startup self-diagnostics of the robot. The prosthesis used for this study was the VerSys FM Taper stem (Zimmer, Warsaw, IN). This stem was chosen because a virtual implantation study [18] found it provided a better proximal fit and fill than an anatomic-type femoral component in dysplastic and anatomically normal femora. A 26-mm femoral head was used for all patients in both groups. A Trilogy cup (Zimmer) with a highly cross-linked polyethylene liner (Longevity; Zimmer) was used on the acetabular side for all patients in both groups.

At surgery, the patient was positioned in the lateral decubitus position (Fig. 4). The posterolateral approach was used for both groups. The surgeon exposed the pins and secured the patient's lower extremity with a femoral positioning clamp. The surgeon oriented the robot by guiding its probe into contact with the pins. The robotic-assisted system computer recorded the pin locations and performed registration and verification of the data automatically.

The surgeon then installed a cutter bit and guided the robot arm in front of the bone to begin milling of the femur (Fig. 3C). The gluteus medius and minimus muscles were retracted anteriorly to avoid damage (Fig. 3C). After completion of the robotic milling, the surgeon inserted the implant in the usual fashion. It was easy to determine the osteotomy level of the femoral neck because the robotic milling could show the neck cut line by making a notch in the medial cortex of the proximal femur. After stem implantation, we could measure the height of the stem easily from that line and know the difference from the plan intraoperatively.

In the hand-rasping group, a CT scan was performed preoperatively. These data were transferred to the

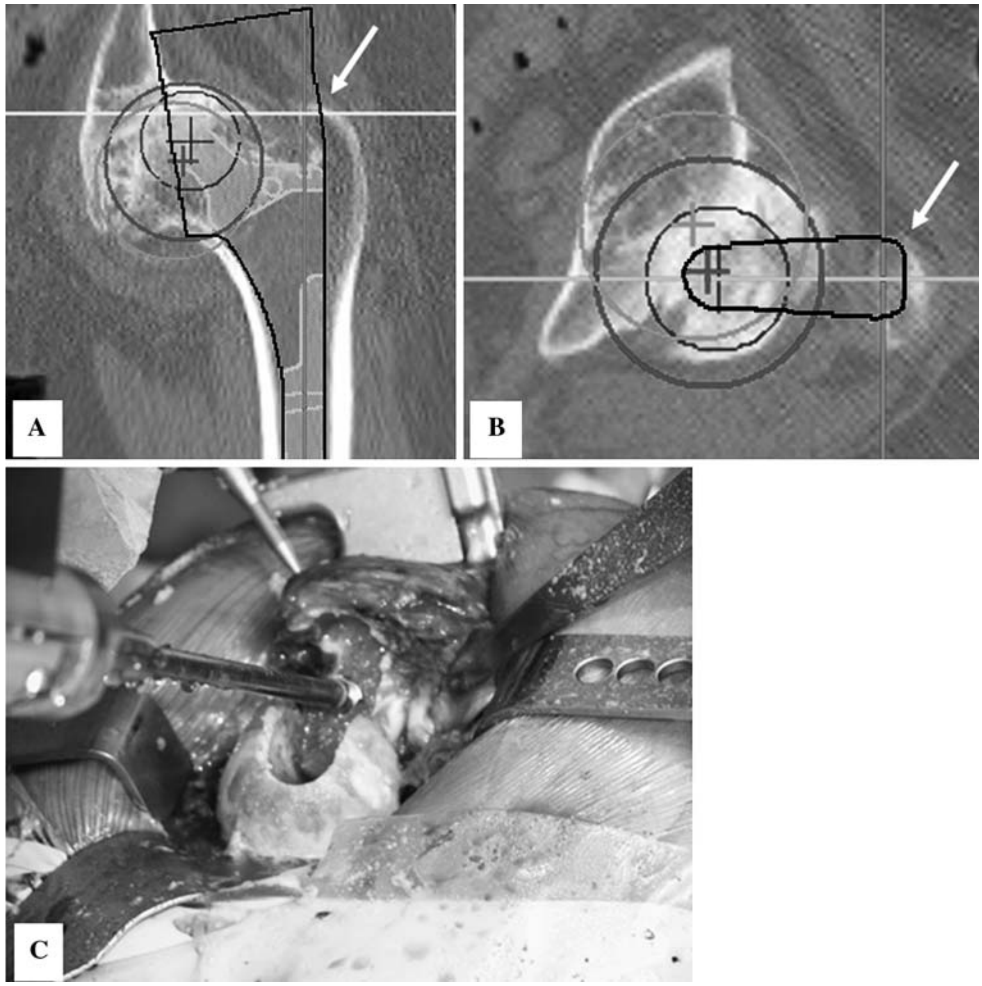

Fig. 3A–C (**A**) Anteroposterior and (**B**) axial views show planning for a patient before insertion of the VerSys FM Taper stem (Zimmer, Warsaw, IN). The arrow indicates the muscle insertion area. The areas framed by the black line indicate the milling path. (**C**) Robotic milling of the proximal femur in the same patient is shown. The gluteus medius and minimus muscles were retracted anteriorly without any damage.

Fig. 4A–B The photographs show the patient in the (**A**) caudal and (**B**) anterior (ventral) views during surgery.

workstation and used to select the position and size of the VerSys FM Taper stem following the same procedure as for the robotic-milling group. The surgeon then performed progressively larger manual handheld rasping until enough axial and rotational stability of the appropriate-sized rasp was felt in the femoral cavity.

In both groups, the same preoperative planning, posterolateral approach, stem, cup, polyethylene liner, and 26-mm head were used, and the acetabular cup was implanted first with the conventional technique. In both groups, the intraoperative procedure of final leg-length adjustment also was the same. We did trial repositioning of the joint and judged soft tissue tension and then determined the neck offset. Full weightbearing was allowed one day after surgery. Rehabilitation processes were the same for both groups at both institutions.

At 1, 2, 3, and 5 years after surgery, hip function was evaluated by the operating surgeon using the JOA clinical score [23] (Table 2). The JOA score has a maximum of 100 points, of which the pain score has a range from 0 to 40 points, the ROM score ranges from 0 to 20 points, the walking ability score ranges from 0 to 20 points, and the activities of daily living score ranges from 0 to 20 points. The best score is 100 points. The JOA score has not been validated as an outcome measure, but it is used universally in Japan [23]. Thigh pain and pin-related knee-related pain also were assessed by the operating surgeon during the hospital stay and at the time of outpatient consultation every 3 months. Radiographs obtained at 1, 2, 3, and 5 years were analyzed for evaluation of limb-length discrepancy [24], implant fixation [10], loosening, stress shielding [9], and heterotopic ossification, which was classified with the system described by Brooker et al. [4]. For limb-length discrepancy, we analyzed the patients whose contralateral hip was normal or already replaced so the discrepancy should become zero postoperatively. Forty-three patients in the robotic-milling group and 42 in the hand-rasping group (Table 3) were analyzed for limb discrepancies. Postoperative AP radiographs of both hips were scanned and limb-length discrepancy was measured using Image J software (National Institutes of Health, Bethesda, MD), using the method described by Williamson and Reckling [24]. The radiographic evaluations were performed by a blinded orthopaedic surgeon (NN).

For statistical analyses, we used the unpaired t-test for comparisons of age, BMI, and surgical time. The Mann-Whitney U test was used for comparisons of JOA scores and limb-length inequality. We used the F-test for comparison of the range of limb-length inequality; chi square test for comparisons of surgical side, gender, and rate of complications; and Mann-Whitney exact test for comparison of nonparametric data such as Engh's grade and Brooker's grade. We also calculated the Pearson product-moment correlation coefficient (r) of the consecutive surgical time of the robotic-milling procedure to know whether there was a learning curve. Differences were considered significant when the p value was less than 0.05. For each statistical analysis, we calculated effect size (Cohen's d for t-test, r for Mann-Whitney U test, and Cramer's V for chi square test). SPSS 9.0 J for Windows (SPSS, Chicago, IL) and online statistical software constructed and maintained by Aoki [2] were used for statistical analyses.

Results

The average duration of the index surgery was longer in the robotic-milling group than in the hand-rasping group ($p = 0.06$) (Table 3). The mean robotic-milling time was 13 minutes (range, 8–40 minutes). The initial surgical time of 140 minutes was reduced by 17 seconds for each subsequent operation ($r^2 = 0.054$), indicating there was a learning curve with this procedure. The mean surgical time in the hand-rasping group was 108 minutes (range, 40–215 minutes).

There was no difference in the JOA score 1 year postoperatively between the two groups (robotic-milling group, 94 ± 5; hand-rasping group, 92 ± 6; Mann-Whitney U test; $p = 0.4$) (Fig. 5; Table 3). Two years postoperatively, the JOA score was higher in the robotic-milling group (96 ± 4, 94 ± 5, respectively; $p = 0.04$). The main

Table 3. Comparison of the postoperative data of the two groups

Parameter	Robotic-milling	Hand-rasping	p Value	Effect size
Surgical time (minutes)	120 ± 27	108 ± 38	0.06 (unpaired t-test)	Cohen's d = 0.37
Dislocation (hips)	4 (5.3%)	1 (1.4%)	0.4 (chi square test)	Cramer's V = 0.11
Thigh pain at 1 year (hips)	1 (1.3%)	4 (5.6%)	0.2 (chi square test)	Cramer's V = 0.12
Knee pain (hips)	2 (2.7%)	0	0.5 (chi square test)	Cramer's V = 0.12
Intraoperative femoral fissure (hips)	0	5 (7.0%)	0.03 (chi square test)	Cramer's V = 0.19
Postoperative JOA score (points)				
1 year	94 ± 5	92 ± 6	0.4 (Mann-Whitney U test)	r = 0.07
2 years	96 ± 4	94 ± 5	0.04 (Mann-Whitney U test)	r = 0.17
3 years	97 ± 4	95 ± 5	0.0003 (Mann-Whitney U test)	r = 0.34
5 years	96 ± 5	95 ± 6	0.05 (Mann-Whitney U test)	r = 0.16
Limb-length inequality (mm)	5 ± 3 (n = 43)	6 ± 6 (n = 42)	0.2 (unpaired t-test)	Cohen's d = 0.27
Range (mm)	0–12	0–29	0.004 (F-test)	

JOA = Japanese Orthopaedic Association.

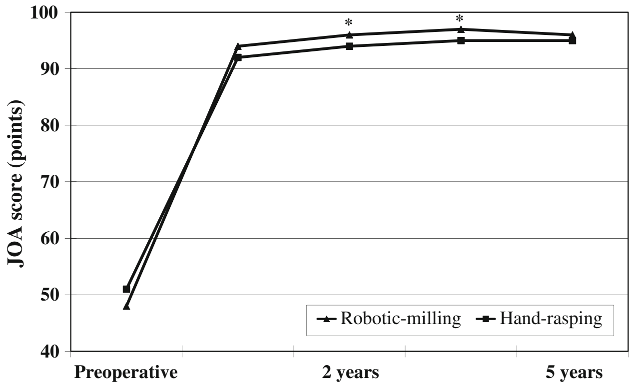

Fig. 5 The graph shows a comparison of the Japanese Orthopaedic Association (JOA) hip scores of each surgery during the preoperative and postoperative periods. * = statistically significant (Mann-Whitney U test).

difference was observed for ROM (18 ± 2, 17 ± 2, respectively; p = 0.01). At 3 years, the higher score persisted in the robotic-milling group (97 ± 4, 95 ± 5, respectively; p = 0.0003). Although the average difference at the 2- and 3-year followups was only 2 points, it meant that there was an average difference in flexion angle of 20° or abduction angle of 10°. At 5 years, the difference in JOA scores no longer was apparent (96 ± 5, 95 ± 6, respectively; p = 0.05).

Overall rates of complications were similar between the two groups (robotic-milling group, 9.3%; hand-rasping group, 14.1%; chi square test; p = 0.4) (Table 3). In the robotic-milling group, thigh pain was reported in one case (1.3%) postoperatively, which disappeared within 1 year. Knee pain, associated with pin insertion, was reported in two cases (2.7%). For both cases, the pain resolved within 1 month (Table 3). In the hand-rasping group, thigh pain was reported in four cases (5.6%) postoperatively, which disappeared within 1 year (Table 3). In one of these cases, thigh pain was associated with stem subsidence as much as 12 mm, although no femoral fracture was found. The subsidence stopped in 1 month and the thigh pain disappeared in 1 year. In the robotic-milling group, there were no serious complications such as intraoperative fractures, nerve palsy, deep vein thrombosis, or infection. In two cases, the technique was abandoned intraoperatively owing to technical problems. Dislocation was seen in four cases (5.3%) (Table 3). There was one dislocation during the postoperative rehabilitation period. Three other dislocations occurred owing to accidental falls at 47, 50, and 52 months postoperatively. All these dislocations were treated successfully and there was no recurrent dislocation. In the hand-rasping group, there were five intraoperative femoral fissures (7.0%), which were treated successfully with wiring, as reported previously [17]. This rate was significantly higher than the rate of the robotic-milling group with a small-sized effect (chi square test; p = 0.03, Cramer's V = 0.19) (Table 3). Dislocation was seen in one case (1.4%). There was no significant difference between the two groups in dislocation rate and the analysis also had a small effect (chi square test; p = 0.4, Cramer's V = 0.11) (Table 3). Periprosthetic fracture was seen in one case (1.4%), which was treated successfully with open reduction and internal fixation.

As far as a difference in limb-length inequality, limb lengths were measured by plain radiographs 2 years postoperatively. Although the average limb lengths were not significantly different (Mann-Whitney U test; p = 0.2), the robotic-milling group had significantly less variance than the hand-rasping group (F-test; p = 0.004) (Table 3).

Plain radiographs obtained at 2, 3, and 5 years showed bone ingrowth fixation for all stems and cups of both groups. There were no signs of mechanical loosening in any implant. Concerning any radiographic difference in stress shielding, there was a significant difference. At 2 years, there was more stress shielding of the proximal femur in the hand-rasping group than in the robotic-milling group (Mann-Whitney exact test; p = 0.03, Cramer's V = 0.18) (Table 4). Notably, this tendency was more prominent at 5 years (Mann-Whitney exact test; p = 0.002, Cramer's V = 0.26) (Table 4).

At 5 years, heterotopic ossification was seen in 20 hips (26.6%) in the robotic-milling group. None was beyond

Table 4. Distribution of stress shielding of the proximal femur according to the classification of Engh et al.

Parameter	None	Grade 1	Grade 2	Grade 3	Grade 4	p Value	Effect size
At 2 years							
Robotic-milling (hips)	29 (39%)	11 (15%)	25 (34%)	8 (11%)	1 (1%)		
Hand-rasping (hips)	20 (28%)	8 (11%)	25 (35%)	13 (18%)	5 (7%)	p = 0.03 (Mann-Whitney exact test)	Cramer's V = 0.18
At 5 years							
Robotic-milling (hips)	20 (27%)	18 (24%)	23 (30%)	11 (15%)	3 (4%)		
Hand-rasping (hips)	5 (7%)	11 (15%)	38 (54%)	12 (17%)	5 (7%)	p = 0.002 (Mann-Whitney exact test)	Cramer's V = 0.26

Table 5. Distribution of heterotopic ossification according to Brooker's grading

Technique	None	G1	G2	G3	p Value	Effect size
Robotic-milling (hips)	55 (73%)	15 (20%)	5 (7%)	0		
Hand-rasping (hips)	60 (85%)	8 (11%)	1 (1%)	2 (3%)	p = 0.1 (Mann-Whitney exact test)	Cramer's V = 0.13

Brooker Grade 2. In the hand-rasping group, heterotopic ossification was seen in 11 hips (15.5%). Although two hips showed Grade 3 heterotopic ossification, the difference was not significant and the analysis had a small effect (Mann-Whitney exact test; p = 0.1, Cramer's V = 0.13) (Table 5).

Discussion

The purpose of this study was to compare the results and complications of robotic-assisted and hand-rasping stem implantation techniques during 5 years followup. For clinical outcome, we assessed the JOA score [23] and complications. For radiologic results, we especially focused on the limb-length inequality, stress shielding, and heterotopic ossification.

Our study has several limitations. First, in the randomization process, the patients could not be blinded for the surgery because the robotic-milling procedure needs prior pin implantation. In addition, we did not use a validated quality-of-life score. The JOA score (Table 2) has been approved and used universally in Japan for almost 40 years. This score is similar to the Harris hip score, in that it can discriminate small differences in pain, ROM, walking ability, and activities of living because the range is 0 to 100 points. However, the score has not been validated as an outcome measure and the interviews were performed by the surgeons. This potentially could lead to bias to better clinical scores for the robotic-milling group.

Robotic-assisted surgery and the hand-rasping operation were prospectively compared in two studies [3, 15] (Table 6). Bargar et al. [3] described the results of the original three-pin system robotic-assisted surgery through a posterior approach that took a longer surgical time (average, 258 minutes) than ours. Honl et al. [15] reported the results using a two-pin system and the S-ROM stem (DePuy, Leeds, UK) through an anterolateral approach. Although different types of prostheses or different surgical approaches were described in these reports, there is some agreement in their results. The clinical scores were similar at short-term followup, the surgical time was longer in the robotic-assisted group, and the radiographic assessment of stem alignment was better in the robotic-assisted group. In our study, the JOA clinical score was slightly but significantly better in the robotic-milling group up to 3 years postoperatively. At 2 and 3 years, the JOA score for the robotic-assisted group was higher than that of the hand-rasped group for ROM. Although the average difference was only 2 points, it meant that the robotic-milling group achieved, on average, a greater flexion angle of 20° or abduction angle of 10°. One possible reason why the robotic-milling group achieved this greater ROM might be that their limb lengths had substantially less variance than those of the hand-rasping group. This might have contributed to faster acquisition of ROM of the surgically treated hip. However the clinical significance of this result is unclear as this superiority seemed to be transient. At 5 years, ROM of the hand-rasping group increased and difference of the JOA score disappeared. During 3 to

Table 6. Previous comparative studies of ROBODOC system

Parameter	Bargar et al. [3]	Honl et al. [15]
Type of study	Prospective, randomized	Prospective, randomized
Number of hips	136 hips (69 ROBODOC/65 manual)	154 hips (74 ROBODOC/80 manual)
Followup	1–2 years	2 years
Prosthesis	AML/Osteoloc	S-ROM
Registration	Three-pin system	Two-pin system
Approach	Posterior	Anterolateral
Clinical score	No difference	No difference
Surgical time	120 minutes longer in the ROBODOC group	25 minutes longer in the ROBODOC group
Radiographic results	Better in the ROBODOC group	Better in the ROBODOC group
Complications	Femoral fracture: ROBODOC 0/manual 3	Dislocation: ROBODOC 11/manual 3 Revision: ROBODOC 8/manual 0

5 years, ROM of the robotic-milling group already seemed to have reached a plateau.

In the current study, the average surgical time was 12 minutes longer for the robotic-milling group. This difference was much smaller than times reported by others [3, 15] (Table 6). This difference in surgical time did not influence the estimated blood loss or infection rate. In addition, our study revealed this procedure had a learning curve. Therefore, we believe the elongated surgical time for the robotic-milling procedure was not a major disadvantage.

The rate of intraoperative femoral fissure was significantly higher in the hand-rasping group. This finding was consistent with that of Barger et al., who concluded robotic milling was safer than hand rasping [3]. In our hand-rasping group, the rate of intraoperative femoral fissures (7.0%) might be somewhat high. One of the reasons might be because we had obtained the 3-D preoperative plan and tried to insert the predicted ideal stem size during the hand-rasping procedure and there might have been a learning curve. Recently, however, the fracture rate of the same stem with manual implantation was reported to be 6% [1].

There have been several reported complications with this system including soft tissue problems, gait abnormalities, and femoral fissures that have limited its use in Europe [22]. In 2003, Honl et al. reported a higher dislocation rate of 18% and subsequent revision rate of 15% in a robotic-assisted group [15]. They attributed this to insufficiency of the abductor muscles, which were cut or injured by the cutter during the robotic-milling procedure and recommended a so-called anatomic prosthesis that will not encroach as much on insertion of the abductor muscles on the greater trochanter [15]. In our series, the dislocation rate of the robotic-milling group was much lower (5.3%; four hips). This rate was not significantly higher than that of hand-rasping group (1.4%; one hip). During the robotic-milling procedure, there was no evidence of abductor tendon detachment or destruction. If we noted that danger, we could stop the robot by pressing the stop button. One possible reason for this difference could be that we used a posterolateral approach for all patients. With this approach, it is possible that we provided better retraction for the gluteus medius and minimus muscles anteriorly and therefore improved access for robotic milling, although using a straight stem (VerSys FM Taper) (Fig. 3). In addition, the preoperative planning workstation can illustrate cutting paths three-dimensionally, and therefore, the surgeon can easily avoid abductor tendon injury or greater trochanter damage by choosing the appropriate implant and/or approach for each patient. Therefore, our results suggest the surgeon using the robotic-assisted system should be able to make the appropriate decisions preoperatively and intraoperatively to ensure the abductor tendon is preserved and the greater trochanter is not damaged. Although not significant, the dislocation rate of the robotic-milling group was higher than that of hand-rasping group. Therefore, we examined ROM of the patients in the robotic-milling group who had dislocations to know whether the better ROM of this group had contributed to dislocation. All but one had lower ROM than average. Therefore, in this series, we could not conclude that dislocation was related to greater ROM.

We had no serious complications such as nerve palsy, deep vein thrombosis, or infection in either group. As reported, robotic milling can reduce the rate of intraoperative pulmonary embolism [12]. Honl et al. [15] reported the nerve injury rate was 7% in their robotic-assisted group. They hypothesized the femoral fixator clamp might have injured the sciatic nerve directly and that the femur and the sciatic nerve were held in the same position throughout the duration of the referencing and femoral reaming, which would decrease blood supply to the nerve [15]. However, with a posterolateral approach, we could identify the sciatic nerve easily and avoid injury while attaching the clamp.

Knee pain associated with pin insertion was seen in two cases (2.6%), which resolved within 1 month. This rate was much lower than that of Nogler et al. [19] who reported 10 of 18 patients had persistent severe pain at the site of pin implantation in the medial femoral condyle with the anterolateral approach. One reason is that, as they stated, the lateral condyle region had fewer neural structures than the medial condyle and therefore the risk of nerve injury probably is smaller in our series. In addition, we routinely inserted the distal pins just proximal to the knee synovium, because we hypothesize that irritation of the knee synovium by pin insertion would be one of the reasons for knee pain.

Stress shielding of the proximal femur,according to the grade presented by Engh et al. [9], was significantly more prominent in the hand-rasping group than the robotic-milling group 2 years after surgery. This result was consistent with a previous comparison dual-energy xray absorptiometry (DEXA) study of 2-year followup data between two groups [13]. This tendency of stress shielding was more prominent 5 years postoperatively on the radiographs. Although 5-year DEXA data were not yet available, we supposed the differences were increasing. The VerSys FM Taper stem was used, which we expected to be a stem with a proximal fixation. However, some reports have suggested that the proximal femoral atrophy was not rare and the rate of proximal fixation was not so high with this stem [16, 25]. Stem design (relatively thick distal part) and grit-blast surface finish from the middle to distal parts might have contributed to this fixation pattern. In robotic milling, the cut path of the VerSys stem was the same design as that of the handheld rasp. It was designed to mill 1 mm undersized at the proximal area and 1 mm oversized at the distal area. Therefore, ideally, both methods optimized the achievement of good proximal fixation of the stem. However, as reported previously, alignment of the stem in the hand-rasping group had significantly more anterior tilt, retroversion, and higher vertical seating than the robotic-milling group, although there was no significant difference for varus/valgus alignment [17]. We hypothesize that precise milling by the robot enabled superior proximal fit and fill of the stem, which led to less stress shielding of the proximal femur for more than 5 years.

Schulz et al. reported heterotopic ossifications after robotic-milling THA were found in 27.8% of patients, although they had no control group [22]. In our series, heterotopic ossification was seen in 20 hips (26.6%) in the robotic-milling group. None was beyond Brooker Grade 2. This rate was not statistically different when compared with that of the hand-rasping group. In addition, with the conventional technique, rates of heterotopic ossification have been reported as 17% to 26% [11, 14]. Therefore, along with the statistical result, it cannot be concluded that the rate of heterotopic ossification was more prominent with robotic-milling procedures.

Robotic-milling THA was associated with slightly better clinical scores until 3 years postoperatively. At 5 years postoperatively, this early difference in the clinical scores no longer was present. Robotic milling led to more precise implant positioning which seems to have led to less variance in limb-length inequality and less stress shielding of the proximal femur 5 years postoperatively.

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