

COMPARISON OF ROBOTIC-ASSISTED AND MANUAL IMPLANTATION OF A PRIMARY TOTAL HIP REPLACEMENT

A PROSPECTIVE STUDY

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Background: Robotic-assisted total hip replacement has become a common method of implantation, especially in Europe. It frequently has been postulated that robotic reaming would result in an improved clinical outcome due to the better fit of the prosthesis, but that has never been demonstrated in a prospective study, to our knowledge. The purpose of this study was to compare robotic-assisted implantation of a total hip replacement with conventional manual implantation.

Methods: One hundred and fifty-four patients scheduled for total hip replacement were randomly assigned to undergo either conventional manual implantation of an S-ROM prosthesis (eighty patients) or robotic-assisted implantation of such a prosthesis (seventy-four patients). The five-axis ROBODOC was used for the robotic-assisted procedures. Preoperatively as well as at three, six, twelve, and twenty-four months after surgery, the scores according to the Harris and Merle d'Aubigné systems and the Mayo clinical score were determined. Radiographs made at these intervals were analyzed for evidence of loosening, prosthetic alignment, and heterotopic ossification.

Results: Thirteen (18%) of the seventy-four attempted robotic implantations had to be converted to manual implantations as a result of failure of the system. The duration of the robotic procedures was longer than that of the manual procedures (mean and standard deviation, 107.1 ± 29.1 compared with 82.4 ± 23.4 minutes, $p < 0.001$). Limb-length equality (mean discrepancy, 0.18 ± 0.30 compared with 0.96 ± 0.93 cm, $p < 0.001$) and varus-valgus orientation of the stem (mean angle between the femur and the shaft of the prosthesis, $0.34^\circ \pm 0.67^\circ$ compared with $0.84^\circ \pm 1.23^\circ$, $p < 0.001$) were better after the robotic procedures. At six months, slightly more heterotopic ossification was seen in the group treated with robotic implantation. The group treated with robotic implantation had a better Mayo clinical score at six and twelve months and a better Harris score at twelve months; however, by twenty-four months, no difference was found between the groups with regard to any of the three scores. Dislocation was more frequent in the group treated with robotic implantation: it occurred in eleven of the sixty-one patients in that group compared with three of eighty in the other group ($p < 0.001$). Recurrent dislocation and pronounced limping were indications for revision surgery in eight of the sixty-one patients treated with robotic implantation compared with none of the seventy-eight (excluding two with revision for infection) treated with manual insertion ($p < 0.001$). Rupture of the gluteus medius tendon was observed during all of the revision operations.

Conclusions: The robotic-assisted technology had advantages in terms of preoperative planning and the accuracy of the intraoperative procedure. Disadvantages were the high revision rate; the amount of muscle damage, which we believe was responsible for the higher dislocation rate; and the longer duration of surgery. This technology must be further developed before its widespread usage can be justified.

Level of Evidence: Therapeutic study, Level I-1a (randomized controlled trial [significant difference]). See Instructions to Authors for a complete description of levels of evidence.

Computer-assisted orthopaedic surgery is becoming increasingly popular¹. Two groups of systems—passive and active—are utilized. Passive systems are so-called

navigation systems, which show the surgeon the position of the surgical tools or the implant within a patient fixed reference system. The surgeon navigates within a virtual picture on

TABLE I Data on the Two Groups of Patients

	Robotic	Manual
No. of patients		
Enrolled in study	74	80
Included in study	61	80
Mean age and standard dev. (yr)	71.5 ± 7.1	70.7 ± 8.3
Mean weight and standard dev. (kg)	77.0 ± 15.4	75.3 ± 11.6
Mean height and standard dev. (cm)	170.2 ± 9.3	167.1 ± 8.5
Side (L/R) (no.)	36/25	39/41
Gender (M/F) (no.)	24/37	24/56

a screen while handling the tools or implant. The planning of the operation can be carried out either online or offline. Robotic systems are referred to as active systems. They serve as a delivery tool for a surgical procedure planned offline on a computer prior to the surgery². The surgeon positions the robot by means of a referencing procedure and then supervises the reaming process without the ability to modify (with the exception of interrupting) the procedure online.

In industry, robotics is a well-established method for optimizing processes and increasing quality. The idea of using a robot in the field of orthopaedic surgery, especially for total hip replacement, originated in the United States in the early 1990s. A commercially available industry robot (originally developed for fitting circuit boards) was modified for this application. First, adequate tools had to be constructed and computer hardware as well as software had to be adjusted to

the safety standards for human applications³. Between 1992 and 1993, this robot (ROBODOC; Integrated Surgical Systems, Davis, California) was used with authorization of the United States Food and Drug Administration on patients. In Germany, this robot has been used for more than 4500 total hip replacements, beginning as early as 1994⁴. We are not aware of any published study demonstrating the clinical advantages or disadvantages of this particular procedure in comparison with those of conventional manual implantation of the same type of prosthesis. One of the reasons for this lack of data is that, in most centers, the robotic and manual approaches are used to implant different types of prostheses.

The purpose of this study was to provide objective information regarding the differences in clinical outcome between robotic-assisted and conventional manual implantations of the same type of total hip prosthesis.

Materials and Methods

The criterion for inclusion in the study was a diagnosis of osteoarthritis of the hip joint. One hundred and fifty-four patients (fifty-four men and 100 women) provided informed consent to participate in the study (Table I). The study design was approved by the local ethics committee. The average age at the time of the operation was 70.1 ± 7.8 years. A modular S-ROM prosthesis (DePuy, Leeds, United Kingdom) with a 28-mm-diameter cobalt-chromium head was used in all patients. A spherical cementless press-fit cup (ESKA Implants, Luebeck, Germany) with a polyethylene liner was implanted on the acetabular side. A similar anterolateral approach to the hip joint with the patient in the lateral decubitus position was used for both groups. Cephalosporin, with 2 g given just prior to the incision and two additional 2-g doses given in the immediate postoperative period, was used for prophy-

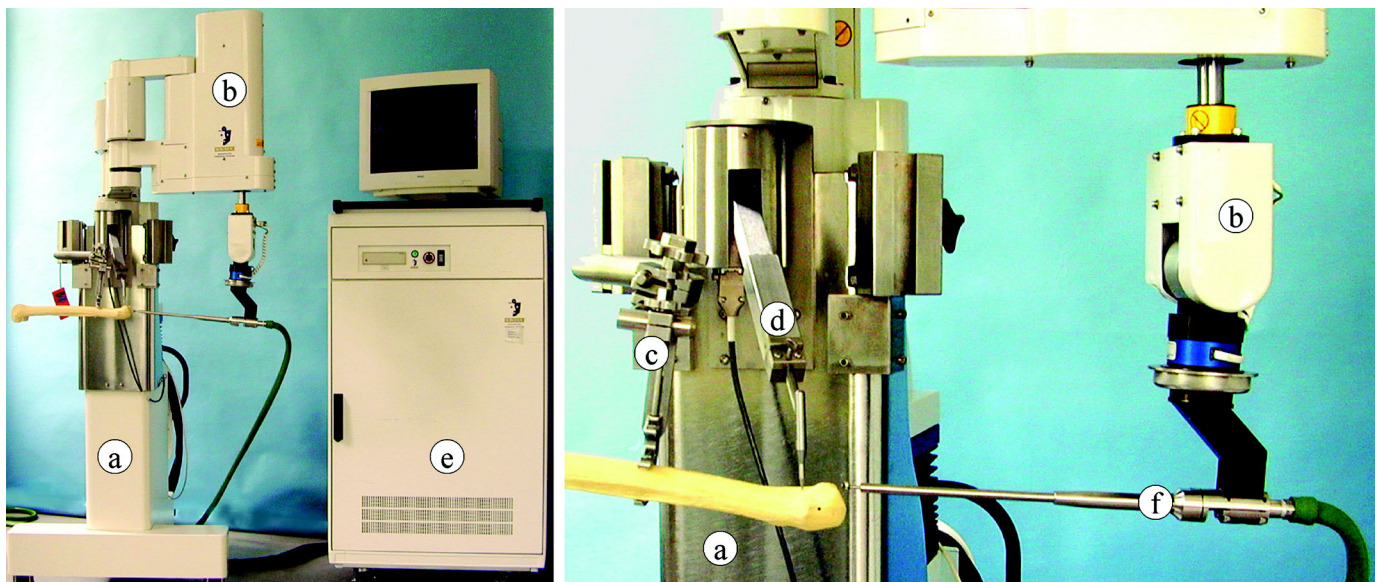


Fig. 1

The ROBODOC surgical robot. a = robot base, b = robot arm with 5° of freedom, c = the femoral fixator, d = the bone-motion detector, e = the control computer, and f = the pneumatic turbine with the reamer bearing sleeve.

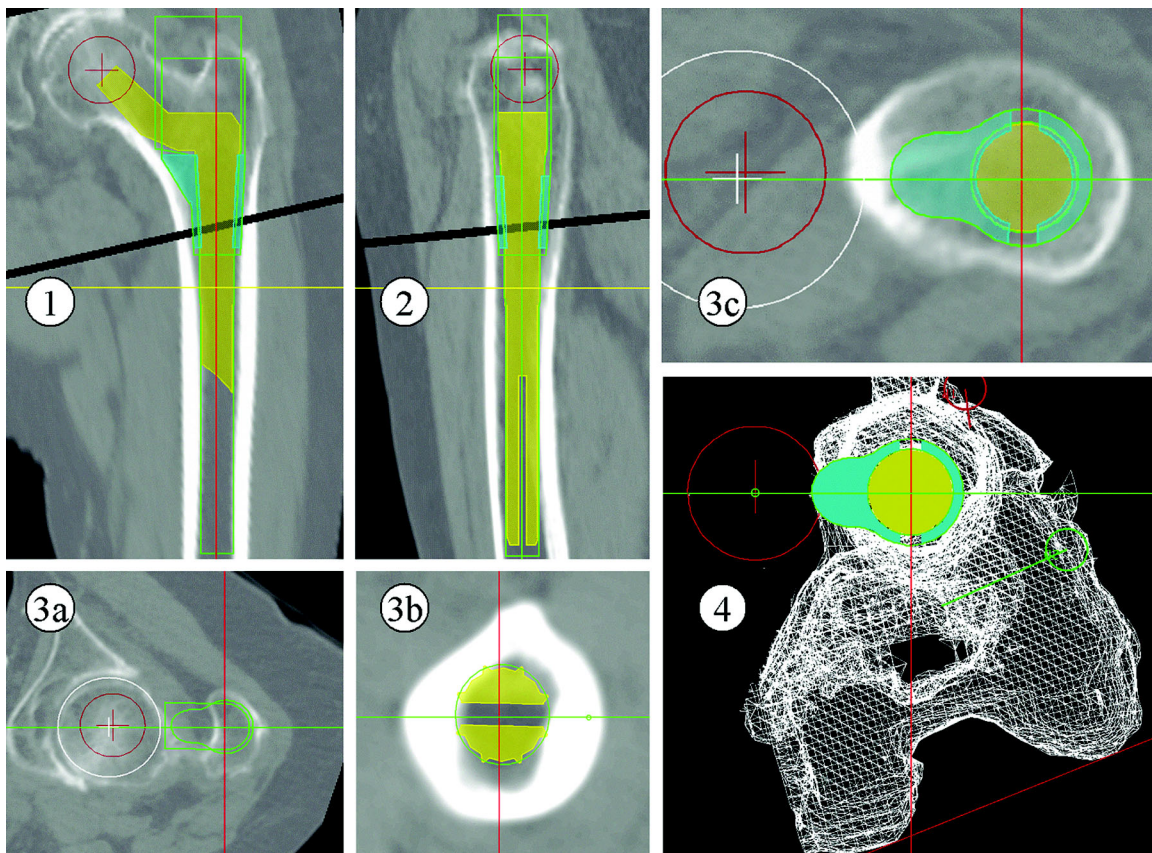


Fig. 2
Preoperative planning of the insertion of the S-ROM prosthesis with the ORTHODOC planning computer. 1 = frontal plane; 2 = sagittal plane; 3a, 3b, and 3c = transverse plane at different heights and magnifications; and 4 = three-dimensional mesh model of the femur with determination of the anteversion of the stem with respect to the knee condyles.

laxis against infection. Indomethacin, 150 mg/day for a period of ten days postoperatively, was given for prophylaxis against heterotopic ossification.

Two surgeons (E.H. and M.H.), both with experience in performing manual as well as robotic implantations of the S-ROM prosthesis, carried out the operations. Each patient was randomly assigned to one of the groups with use of a random-number generator (Matlab, version 6.5; MathWorks, Natick, Massachusetts). The robotic and manual approaches were used in seventy-four and eighty patients, respectively (Table I).

The robotic implantations were performed with ROBODOC along with the ORTHODOC planning computer (Figs. 1 and 2). The patients treated with the robotic implantation had to have two reference pins implanted (the screws in Fig. 3): one in the proximal part of the femur and one in the lateral aspect of the distal part of the femur. After implantation of the pins, which was performed with the patient under local anesthesia on the day before the index surgery, a helical computed tomography scan (Siemens; Munich, Germany) was carried out according to the manufacturer's specified protocol. Then the computed tomography data were transferred to the planning computer and transformed into a three-dimensional reconstruction. After identification of the pins on the scan, the

planning of the implantation of the S-ROM prosthesis in 15° of antetorsion was carried out (Fig. 2). Preoperative limb length, measured clinically as the distance between the medial malleolus and the anterior superior iliac spine, was also taken into account to determine the center of rotation of the total hip replacement. After completion of the planning process, the data were transferred to the controlling computer of the ROBODOC. Before each surgical procedure, the robot was calibrated according to the manufacturer's specifications. After pin-referencing, the reaming process was performed (Fig. 3).

For the procedures to be performed with the conventional manual approach, a preoperative planning sketch was drafted with radiographic templates and with the limb lengths taken into account as well.

In both groups, the acetabular cup was implanted first, with use of a conventional manual technique. The goal was to achieve 40° of lateral tilt and 15° of anteversion of the cup. When the robotic implantation was to be performed, the patient's leg was then placed in the special leg-holder, and the special femoral fixator (Figs. 1 and 3) was applied. The femoral fixator is an external fixation device that rigidly attaches to the robot base and secures the femur so that it cannot move in relation to the robot. Finally, the bone-motion detector (Figs.

1 and 3) was attached to the patient's femur. The bone-motion detector records the relative movement between the robot and the femur. When bone motion exceeds a certain limit, the process is automatically interrupted and the pins have to be referenced again. The positions of the two pins were referenced by the robot arm using a ball-tip probe that had been inserted into the reamer's sleeve⁵. After referencing, the reaming was performed under constant irrigation with physiological saline solution. The specific cutting sleeve was powered by a pneumatic turbine (80,000 revolutions per minute). The S-ROM prosthesis was manually inserted into the femur after the completion of the reaming process.

In the group treated with the conventional manual approach, the implantation of the S-ROM prosthesis was performed according to the manufacturer's recommendations. For the purpose of achieving limb-length equalization, the

distance between a bone screw, inserted in the ilium just above the acetabulum, and the greater trochanter was measured.

Postoperatively, all patients were allowed to bear weight as tolerated. Physiotherapy was carried out for three weeks in the hospital and then for another three weeks in the outpatient department.

All patients were examined clinically and radiographically before the operation as well as at three, six, twelve, and twenty-four months postoperatively. The functional hip scores according to the Harris⁶ and Merle d'Aubigné⁷ systems and the Mayo clinical score⁸ were determined preoperatively and at the identified postoperative intervals. The surgical duration (time from incision to closure) and the procedure duration (preoperative planning time and surgical duration) were calculated for each patient. Knee-related pain and abductor muscle function (as indicated by the Trendelenburg sign and limping)

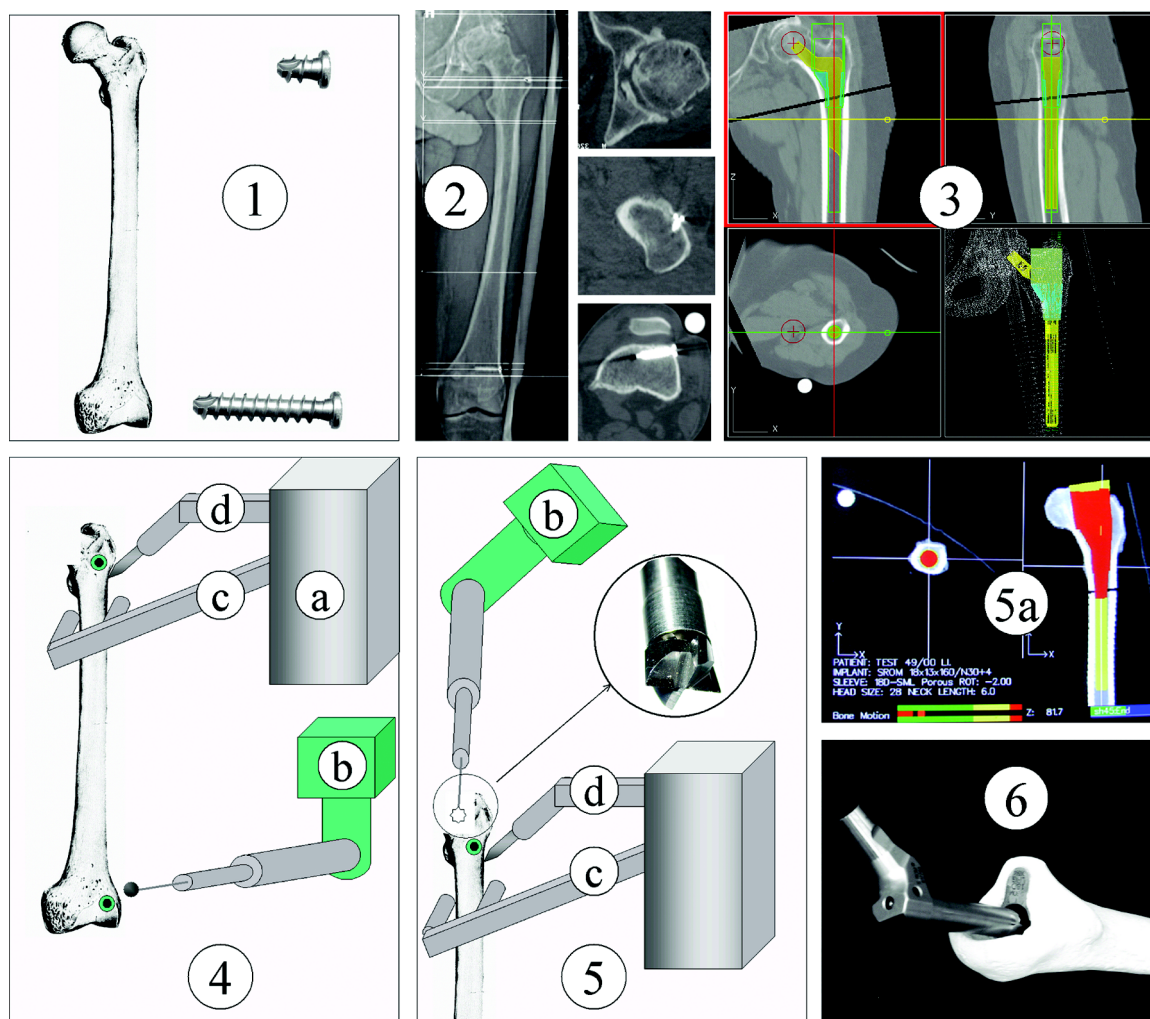


Fig. 3

Flow chart of the robotic procedure: 1 = pin (screw) implantation; 2 = computed tomography data acquisition; 3 = data transfer into a three-dimensional model and pin localization in a virtual sketch; 4 = fixation of the femur with a bone fixator to the robot base, attachment of the bone-motion detector, and referencing of the pin with manual use of the robot arm; 5 = the reaming process, 5a = intraoperative status monitor displaying the position of the reamer and the bone motion, and 6 = insertion of the prosthesis.

TABLE II Hip Scores at the Different Assessment Time Points

	Preop.	3 Mo	6 Mo	12 Mo	24 Mo
No. of patients					
Robotic procedure					
Followed	61 (100%)	58 (95%)	53 (87%)	50 (82%)	51 (84%)
Excluded*	0	0	3 (5%)	9 (13%)	9 (15%)
Not found†	0	3 (5%)	5 (8%)	2 (3%)	1 (2%)
Manual procedure					
Followed	80 (100%)	72 (90%)	76 (95%)	71 (89%)	69 (86%)
Excluded*	0	2 (3%)	2 (3%)	2 (3%)	2 (3%)
Not found†	0	6 (8%)	2 (3%)	7 (9%)	9 (11%)
Merle d'Aubigné score‡ (points)					
Robotic procedure	9.7 ± 2.1	9.7 ± 1.9	13.0 ± 2.8	15.7 ± 2.2	15.7 ± 2.2
Manual procedure	10.1 ± 1.9	10.1 ± 1.8	12.6 ± 3.4	14.4 ± 2.6	14.9 ± 2.1
Mayo score§ (points)					
Robotic procedure	27.7 ± 15.6	45.8 ± 11.6	63.6 ± 15.0	73.1 ± 7.3	73.1 ± 7.3
Manual procedure	28.1 ± 11.5	49.6 ± 12.5	56.0 ± 16.8	62.8 ± 14.3	65.5 ± 9.1
Harris score¶ (points)					
Robotic procedure	44.4 ± 12.9	52.6 ± 12.3	74.4 ± 16.4	85.9 ± 12.0	85.9 ± 12.0
Manual procedure	47.6 ± 11.5	51.7 ± 10.6	68.3 ± 18.7	73.2 ± 16.9	83.6 ± 11.9
P values**					
Merle d'Aubigné score	0.37	0.26	0.04	0.23	0.06
Mayo score	0.39	0.67	0.01	<0.001	0.07
Harris score	0.87	0.08	0.06	<0.001	0.06

*Patients requiring revision surgery were secondarily excluded. †Patients who refused the request to return for clinical examination are considered "not found." (Six of the missing nine patients treated with manual implantation reported that they were doing well during a telephone interview at twenty-four months.) ‡The values are given as the mean and standard deviation. §Only the clinical data of the Mayo score are displayed since the maximum of 20 points possible for radiographic results was achieved in both groups at all times. **For the difference between the scores after the manual and robotic procedures.

were assessed preoperatively as well as at three, six, twelve, and twenty-four months postoperatively. At six months, the limb lengths of the patients were measured. Any major complications (infection, nerve palsy, deep-vein thrombosis, dislocation, and surgical revision) were noted at each visit.

Immediate postoperative radiographs were used to assess the varus-valgus angle of the stem and the difference between the axis of the prosthesis and the axis of the femur with use of the method described by Kramhoft et al.⁹ The anteroposterior radiographs made at the six-month follow-up evaluation were examined for heterotopic ossification, which was classified with the system described by Brooker et al.¹⁰ At six, twelve, and twenty-four months postoperatively, radiographs were analyzed for radiolucent lines and subsidence of the stem.

Statistical Methods

Multifactorial and one-way analyses of variance were performed with the Harris score, Merle d'Aubigné score, Mayo score, limb-length discrepancy, and surgical time as dependent

variables. The independent factors investigated were the surgical method (manual or robotic) and the surgeon (E.H. or M.H.). The age of the patient was taken into account as a covariate. Regression analyses were performed for age, heterotopic ossification, and procedure duration. A chi-square test was performed to compare the distributions of gender between the groups and to identify differences with regard to ossification, limping, the Trendelenburg sign, dislocation, and revision. All statistical tests were performed at a probability level of 95% ($\alpha = 0.05$). SPSS for Windows (version 9.0; SPSS, Chicago, Illinois) was used for the analysis.

Results

With the numbers available, there were no significant differences between the two groups with regard to the distribution of patient age ($p = 0.977$), gender ($p = 0.163$), weight ($p = 0.68$), or height ($p = 0.63$). Similarly, no significant differences in the preoperative hip scores were found (Merle d'Aubigné score, $p = 0.37$; Harris score, $p = 0.87$; and Mayo score, $p = 0.39$) (Table II).

Thirteen of the surgical procedures in which robotic reaming was begun had to be stopped prior to completion of the reaming process, resulting in a failure rate of 18% (thirteen of seventy-four). These patients were subsequently excluded from the study. In nine cases, a so-called "force freeze" occurred, stopping the reaming procedure: the reamer came to a halt in sclerotic bone, and the system automatically shut off and would not resume even after four attempts to restart it. In four cases, software as well as hardware problems prevented the starting of the robotic reaming. The operation had to be continued manually. This occurred without any adverse effect on the patient except for the additional operative time. The exclusion of the thirteen patients left sixty-one patients in the group treated with robotic implantation. Their average age (and standard deviation) was 71.1 ± 7.1 years.

The system shut down during the milling process during sixteen of the sixty-one successful robotic procedures. Usually, the reamer stopped in sclerotic bone areas. In three other cases, bone motion exceeded the critical limit and the pins had to be referenced again.

The average time for implantation of the reference pins, with the patient under local anesthesia, on the day prior to the index surgery was 16.8 ± 4.9 minutes. No complications related to the pin implantation were observed. The preoperative planning for the robotic implantations lasted significantly longer than that for the manual procedures (15.8 ± 3.9 compared with 5.2 ± 2.3 minutes, $p < 0.001$).

The average duration of the index surgery was significantly longer in the group treated with robotic implantation (107.1 ± 29.1 minutes) than it was in the group treated with manual implantation (82.4 ± 23.4 minutes, $p < 0.001$). Most commonly, the longer time was due to additional adjustment and to the duration of the reaming procedure.

There was no notable learning curve with the robotic implantations. The initial duration of the surgery of 122 minutes was reduced by 0.38 minute for each subsequent surgery ($r^2 = 0.04$; $p = 0.112$). The manual procedures were associated with a small but significant learning curve ($r^2 = 0.07$; $p = 0.034$), with the initial duration of the surgery of ninety-six minutes decreasing by 0.37 minute for each subsequent surgery.

No intraoperative complications, such as vascular injury or femoral shaft fracture, were observed in either group. A partial lesion of the femoral nerve was observed in one hip treated with manual implantation, and a partial lesion of the peroneal division of the sciatic nerve was seen in four hips treated with robotic implantation. Thus, the rate of nerve palsy was 7% in the group treated with robotic implantation and 1% in the group treated with manual implantation ($p = 0.04$). At twelve months, the nerve function had returned in all hips.

Prolonged wound-healing (defined as a not totally dry wound fourteen days after the index surgery) was observed in four (7%) of the sixty-one patients treated with robotic implantation and in three (4%) of the eighty treated with manual implantation ($p = 0.29$). No problems with healing of the pin incision wounds were observed. Deep-vein thrombosis

was demonstrated venographically in three (5%) of the sixty-one patients treated with robotic implantation and three (4%) of the eighty treated with manual implantation ($p = 0.38$). Venography was performed only for symptomatic patients.

The immediate postoperative radiographs showed a significantly larger angle between the femur and the shaft of the prosthesis after the manual procedures than after the robotic implantations ($0.84^\circ \pm 1.23^\circ$ compared with $0.34^\circ \pm 0.67^\circ$, $p < 0.001$). This is reflected by the standard deviations from the ideal situation in each group.

The radiographs made at six months showed grade-2 or 3 heterotopic ossification in eight patients (10%) treated with manual implantation and in six (10%) treated with robotic implantation. The difference was not significant, with the numbers available ($p = 0.31$).

The limb lengths were assessed six months postoperatively. The group treated with robotic implantation had significantly less inequality, and had less variance, than the group treated with manual implantation (0.18 ± 0.30 compared with 0.96 ± 0.93 cm, $p < 0.001$).

Three months postoperatively, there were no significant differences in the hip scores between the two groups (Merle d'Aubigné score, $p = 0.26$; Harris score, $p = 0.08$; Mayo score, $p = 0.67$) (Table II). Six months postoperatively, the Mayo score ($p = 0.01$) and the Merle d'Aubigné score ($p = 0.04$) were significantly better in the group treated with robotic implantation, whereas the Harris score ($p = 0.06$) was not significantly different. At twelve months, the Harris and Mayo scores ($p < 0.001$ for both) were significantly better in the group treated with robotic implantation, and the Merle d'Aubigné scores showed a similar but not significant trend ($p = 0.23$). At twenty-four months, there were no significant differences (with the numbers available) in the hip scores between the two groups, although there was a trend for lower scores in the group treated with manual implantation (Table II). The prevalences of the Trendelenburg sign (demonstrated by 8% and 10% of the patients treated with manual and robotic implantation, respectively; $p = 0.60$) and limping (demonstrated by 8% and 11%, respectively; $p = 0.28$) did not differ significantly between the two groups at twenty-four months.

Dislocation of the total hip replacement occurred in eleven (18%) of the sixty-one hips treated with robotic implantation but in only three (4%) of the eighty treated with manual implantation ($p < 0.001$). Recurrent dislocation occurred in five hips treated with robotic implantation and in none treated with manual implantation ($p < 0.001$). All patients with dislocations were seen to have normal anteversion and inclination of the acetabular component as well as normal anteversion of the femoral component on computed tomography scans and at the time of revision surgery.

Two (3%) of the eighty patients treated with manual implantation underwent revision surgery, at four and six weeks, to treat an infection. Nine (15%) of the sixty-one patients treated with robotic implantation had a revision ($p = 0.007$). All revised hips were excluded from the subsequent assessments. The rate of reoperations for a reason other than infection was

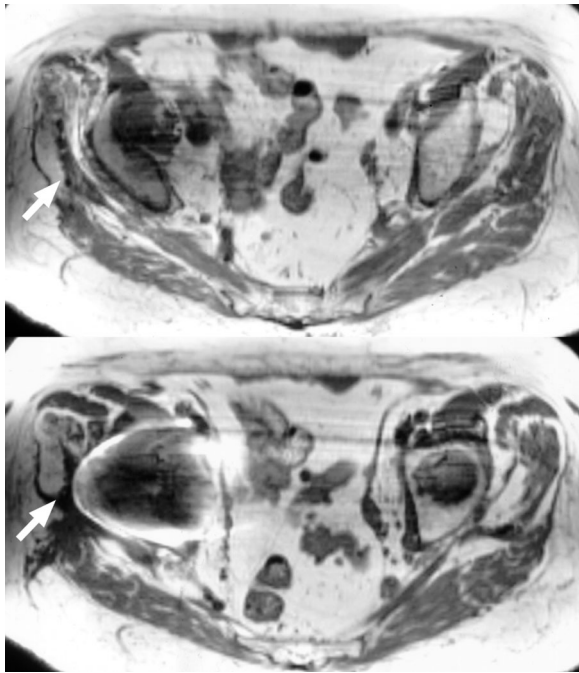


Fig. 4
Magnetic resonance image of the pseudoparalysis of the abductor muscle seven months postoperatively. The fatty degeneration of the gluteus medius muscle (top image) can be seen by comparing it with the muscle on the contralateral side (arrows).

15% (nine of sixty-one) in the group treated with robotic implantation and 0% (of seventy-eight) in the group treated with manual implantation ($p < 0.001$). One hip treated with robotic implantation had to be revised, at eleven months, because of grade-3 heterotopic ossification. Eight patients who required revision after robotic implantation had a pronounced Trendelenburg sign and notable limp, which were associated with recurrent dislocation in five. During all eight revisions, a bursa encompassing the whole greater trochanter was observed. The tendon of the abductor muscles was also found to be detached from its insertion on the femur (Fig. 4).

The radiographs displayed radiolucent lines (a maximum of 1 mm in width) around the sleeve of the prosthesis in two patients treated with manual implantation. These lines were not progressive. No other signs of implant loosening, such as component migration or subsidence, were observed in either group by the time of the two-year follow-up.

Discussion

Primary and revision total hip replacements with the S-ROM prosthesis have had good results for many years^{11,12}. The modularity of that prosthesis can be used optimally in three-dimensional preoperative planning for robotic surgery. The center of rotation of the cup can be included in the planning, so that the preoperatively calculated limb length can be used as a factor in the planning process. Conventional preoperative planning is limited to the two-dimensional views of the radiographic templates. Robotic surgery allows an exact intra-

operative translation of the preoperative planning, whereas there is a certain variability with the manual approach. This is illustrated by the higher accuracy with regard to limb length and varus-valgus alignment of the prosthetic stem in the group treated with robotic implantation. The twenty-four-month hip scores, however, were quite similar, perhaps indicating that the amount of varus-valgus deviation observed in the group treated with manual implantation is not of clinical relevance.

The duration of the surgical procedures done with robotic implantation was about twenty-five minutes longer than that of the manual operations. Other authors have reported similar observations, although they also described a distinct learning curve¹³. The present study was started after the initial learning experience with the robot system had been completed; thus, a significant correlation between operative duration and number of procedures performed was not expected or observed. It was difficult to achieve a surgical duration of less than ninety minutes with the robotic system. The femoral reaming alone takes approximately thirty minutes as a result of the relatively slow velocity of the reamer head, which, according to the manufacturer, is necessary for patient safety. In our experience, however, the reamer frequently came to a standstill in sclerotic bone (in about 30% of the cases). This led to considerable delay and, in several cases, forced the surgeon to finish the operation manually. The prolongation of the surgery did not appear to have any consequences with regard to the occurrence of complications such as infection and thrombosis.

The failure rate of the robotic procedure was 18% (thirteen of seventy-four). One important question is whether aborting the robotic procedure compromises the outcome. Twelve of the thirteen patients in whom the robotic procedure failed were followed, outside of this study, for twenty-four months after the index surgery. No nerve palsy, dislocation, or revision was observed in this small group. The mean Harris score after twenty-four months was 83 ± 8.1 points, which, with the numbers available, was not significantly different from the mean score in the group treated with robotic implantation ($p = 0.346$) or the group treated with manual implantation ($p = 0.125$).

Dislocation has long been reported to be one of the major complications after total hip arthroplasty¹⁴⁻¹⁶. The 4% dislocation rate in the group treated with manual implantation was considered to be in the acceptable range, whereas the 18% dislocation rate in the group treated with robotic implantation was well above it. Dislocations are frequently due to malposition of the cup¹⁶. In our study, the cup angles in the dislocated hips were well within what is considered to be the safe range of $15^\circ \pm 10^\circ$ of anteversion and $40^\circ \pm 10^\circ$ of lateral opening. The robotic procedure provided anatomically exact positioning of the prosthetic stem, as confirmed at the time of revision surgery in nine hips. The same anterolateral approach was used in both treatment groups^{15,17}.

Use of the robotic reamer required that all soft tissue at the reamer's starting point be cut. Furthermore, the reamer

itself cut into some layers of the base of the tendon of the abductor muscles. The part of the muscle attachment that had to be removed to approach the joint was always carefully repaired. Nevertheless, the significantly greater number of dislocations in the group treated with robotic implantation was probably related to insufficiency of the abductor muscles in that group. During the nine revisions following robotic implantations, it was found that the gluteus medius and gluteus maximus muscles did not have any attachment to the greater trochanter. Other authors have not reported problems of this kind or to such a marked degree^{4,13,18}.

The extent of muscle detachment produced by robotic milling depends on the type of prosthesis. A retrospective analysis of the planning sketches for different prostheses revealed that so-called anatomic prostheses have pronounced advantages with respect to this problem (Fig. 5). On the basis of the results of this study, the robot program for the S-ROM prosthesis was modified in order to protect the area of the muscle base of the greater trochanter as much as possible. The new software improves the intraoperative situation, although the clinical results of this modification are not yet available.

The robot provides a very accurate fit of the prosthesis in the bone^{13,18}. A major argument for the robotic approach is the good primary stability of the prosthesis achieved by this close fit. In our study, all patients were allowed to bear weight early. There were no differences with regard to ingrowth, migration, or loosening between the groups treated with manual and robotic implantation. It seems that the better fit that is achieved robotically is not important physiologically. This find-

ing might be related to the fact that the technique of S-ROM implantation with drills and rotating reamers provides, in general, a better fit than that provided by rasps.

The nerve injury rate of 7% (four of sixty-one) in the group treated with robotic implantation is unacceptably high¹⁹. In this group, the femur had to be fixed with the femoral fixator clamp (Fig. 1). The clamp was attached around the femur distal to the lesser trochanter, and the sciatic nerve may have been injured directly. Furthermore, the femur and the sciatic nerve are held in the same position throughout the duration of the referencing and the femoral reaming, which perhaps decreases the blood supply to the nerve. In contrast, during the manual procedure, the position of the femur and the tension of the nerves change several times.

The prevalence of heterotopic ossification in each group in this study was similar to that reported in the literature²⁰⁻²⁴. Thus, the more intensive soft-tissue trauma, prolonged operating time, and very fine bone particles created during robotic reaming did not appear to have any negative consequences.

At six and twelve months, the hip scores in the group treated with robotic implantation were significantly better than those in the group treated with manual implantation; however, the patients with recurrent dislocations (>10% of the group) had been excluded from the group treated with robotic implantation. At twenty-four months, the clinical results were similar in the two groups. In light of these findings, it is difficult to argue that the robotic approach has either a short-term or a long-term advantage.

In the first postoperative year, several patients treated

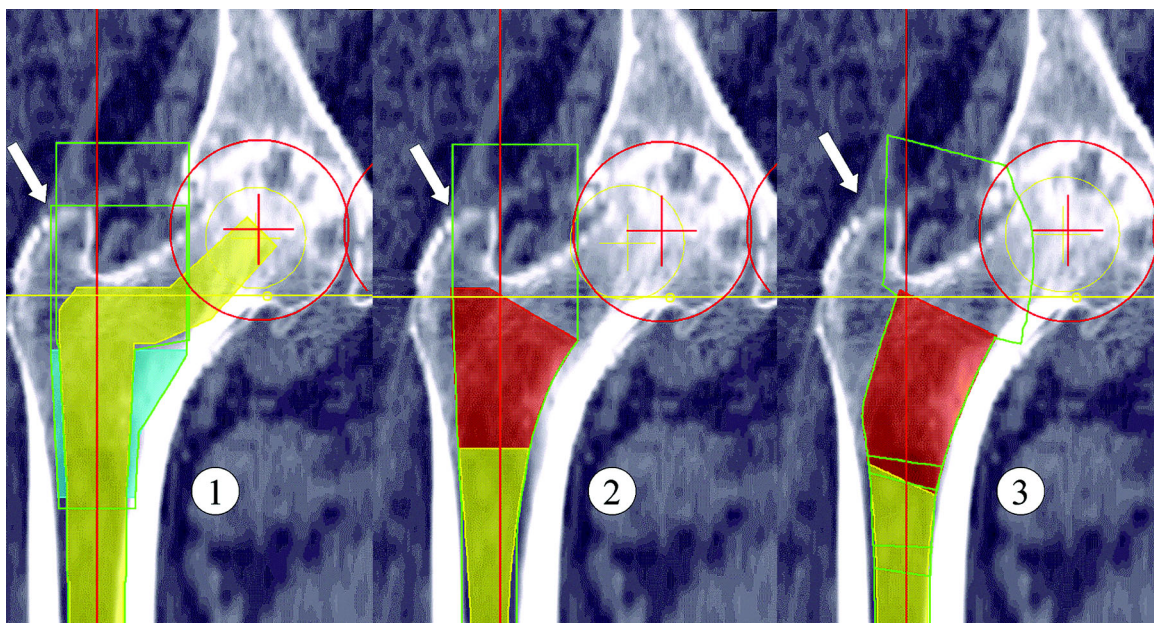


Fig. 5

Comparison of the robotic planning sketches for different prostheses in the same patient. 1 = S-ROM (DePuy, Leeds, United Kingdom), 2 = Osteolock (Howmedica, Rutherford, New Jersey), and 3 = ABG (Howmedica). The arrow indicates the muscle insertion area. The areas framed by the thin green line indicate the structures that will be removed during the reaming process. It can be seen that reaming for the so-called anatomic ABG prosthesis will not encroach as much on the insertion of the abductor muscles on the greater trochanter.

with robotic implantation complained about knee pain that could be related to the pin implantation. Currently, a new technique for pin-free referencing is available. Avoiding a second operation is a clear advantage of this new technique. However, the new approach requires longer preoperative planning (up to forty minutes) as well as more intraoperative adjustment. Furthermore, it has not been determined whether the accuracy of the pin-free referencing process is similar to the high accuracy of the pin-based approach.

Use of the robot currently adds on additional \$700 (U.S.) in cost for each case, beyond the cost of additional operating room time. The additional investment in time and machinery as well as the additional burden for the patient (e.g., a preoperative computed tomography scan) can be justified only by better performance. We have shown that, in its current form, robotic reaming for insertion of the femoral component in total hip replacement is associated with considerable morbidity, as reflected by a rate of neural injury of 7%, a dislocation rate of 18%, and a revision rate within two years after the operation of 15%. This technology must be further developed before its widespread use can be justified. ■

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