

# Primary stability of a ROBODOC® implanted anatomical stem versus manual implantation

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## Abstract

**Objective.** To assess the initial stability of anatomical stems implanted in manually broached femoral cavities compared with that assessed in cavities milled with the ROBODOC® system.

**Design.** The bone-prosthesis interface motion was measured in matched pairs of cadaveric femora to assess the initial stability of anatomical stems implanted with two different implantation techniques.

**Background.** The high costs of surgical robots and the increased perioperative efforts associated with their use can only be justified if measurable benefits for patients can be achieved. Increased initial stability of the stem as an early indicator for better bone ongrowth would be such a benefit.

**Methods.** Seven pairs of fresh frozen human cadaveric femora were used. One femur of each pair was randomly assigned to receive the robotic milling method; the other femur underwent manual broaching by an experienced surgeon. Initial micromotions of the anatomical stems were measured during simulated gait cycles with loads of  $\leq 1500$  N, and both groups underwent matched-pair analysis.

**Results.** High motion of the prostheses was found for both implantation techniques

**Conclusions.** The ROBODOC® system did not enhance the primary stability of the anatomical prosthesis compared with the manual broaching method.

## Relevance

The initial stability of a femoral prosthesis may be an indicator of bone ongrowth and improved long-term fixation. Objective outcome measurements are needed to determine the effectiveness of the robotic milling method in achieving initial stability of implanted anatomic femoral stems.

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**Keywords:** Total hip replacement; ROBODOC®; Computer-assisted orthopaedic surgery (CAOS); Primary stability

## 1. Introduction

Robotic systems in orthopaedic surgery are cost intensive and are accompanied by additional perioperative efforts, such as increased planning time, preoperative preparation of the robotic equipment, and increased radiation due to preoperative computed tomographic (CT) scans. In the case of the ROBODOC® system (In-

tegrated Surgical Systems [ISS], Davis, California, USA), a PC-based planning and robotic milling system, the assumed advantages are the ability to plan an operation on the basis of CT scans, to execute those preoperative plans precisely during the operation, and to achieve a more perfect bone interface for the femoral component (Borner et al., 1997; Bargar et al., 1998; Spencer, 1996). The idea of a perfect fit of the stem within the cavity is based on the fact that the shape of the prosthesis is exactly known to the system, which can therefore mill the corresponding cavity precisely. Thus, the bone-prosthesis interface of a robotically prepared

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cavity should be superior to that of a manually broached cavity. A more precise contact at the bone-implant interface should have a positive impact on the primary stability of the stem, resulting in better implant survival.

There is evidence in the literature that the initial stability of the stem has an effect on prosthesis on-growth. In addition to the design of the prosthesis, the preparation of the bone seems to be critical in achieving initial stability (Pilliar et al., 1986). Poor initial stability might lead to bone resorption due to the ongrowth of fibrous tissue (Soballe et al., 1992), thus causing loosening of the implant. The *in vitro* measurement of the initial stability of the femoral stem can therefore be regarded as a parameter with some predictive value for long-term results in total hip arthroplasty (THA). The method of measuring initial three-dimensional micromotions of the stem inside a femur, first described by Bühler et al. (1997), is an established way to evaluate the initial stability of an implant (Speirs et al., 2000).

The aim of this study was to compare the primary stability of an anatomic implant in seven pairs of cadaveric femora in which one femur of each pair was manually broached and the other femur was milled by the ROBODOC<sup>®</sup> system. If the robot-milled cavity creates better bone-implant interfaces, less micromotion and increased initial stability should be expected.

## 2. Methods

### 2.1. Specimens

Seven pairs of fresh frozen human cadaveric femora were acquired for this study (Table 1). The average age of the donors was 66.7 years (range, 40–78 years). Donors with malignant diseases were excluded from this study. Information regarding bone density was obtained

with the use of quantitative CT scans. Prior to implantation of the stem, the femora underwent additional radiographic investigation to exclude bone defects.

### 2.2. Implants

The study was performed with use of the ABG I femoral component (Stryker Howmedica-Osteonics, Rutherford, New Jersey, USA). The ABG I is a collarless anatomic implant with a cylindrical distal shaft (Fig. 1). The proximal segment has an oval shape and a slight bulge on the lateral side. The proximal surface of the ABG is hydroxyapatite coated and has a roughened, fish-scale structure.

Prior to implantation, three shallow, spherical indentations were drilled into the anterior side of the implant for the purpose of seating the measuring tips of the micromotion sensing devices (Fig. 1). The proximal and the distal indentations defined the longitudinal axis of the prosthesis, while the third indentation was prepared medially to the longitudinal axis in the upper half of the implant.

### 2.3. Implantation

One femur of each pair was randomly chosen to receive the robotic milling method and was prepared with use of the ROBODOC<sup>®</sup> system for pin-based procedures; the other femur received manual broaching. For the manual procedures, one surgeon (A.B.) with clinical experience in ABG implantation performed all of the procedures according to a plan made preoperatively with the use of templates on standard radiographs. For the robotic procedures, two titanium screws (pins) were placed ventrally as fiducial markers: one in the greater trochanter, and one in the medial femoral condyle. Computed tomographic scans were then made of the hip

Table 1  
Specimen data of the seven paired femora used in this study

Pair and bone number	Bone density (hounsfield unit $\pm$ std. dev.)		Gender	Bone side	Implantation technique, M: manual, R: robot	Prosthesis size	Age (year)
1, 1	414.7	123	M	Right	R	5	72
1, 2	414.7	123		Left	M	5	
2, 3	474	79.4	M	Right	M	6	67
2, 4	474	79.4		Left	R	6	
3, 5	455	119.7	F	Right	M	3	78
3, 6	455	119.7		Left	R	4	
4, 7	487	82	M	Right	R	6	72
4, 8	487	82		Left	M	5	
5, 9	401	111.3	M	Right	M	6	76
5, 10	401	111.3		Left	R	7	
6, 11	455	119.7	M	Right	R	6	62
6, 12	455	119.7		Left	M	6	
7, 13	548	108.6	F	Right	M	2	40
7, 14	548	108.6		Left	R	4	

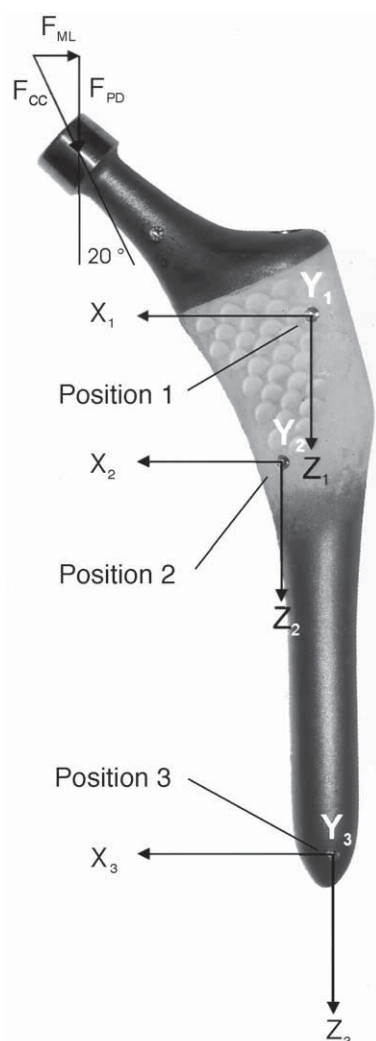


Fig. 1. The ABG I stem with three indentations, used for seating the actuator of the micromotion sensing devices. X = medial–lateral (ML), Y = anterior–posterior (AP), Z = proximal–distal (PD).

and femur, including the two fiducial markers. On the basis of these scans, the surgical plan was made on the Orthodoc (ISS) planning station. The correct-sized stem was chosen from a library of ABG I stems, and the computer program virtually placed the implant in the femur. The resulting milling path for the robot was calculated accordingly by the Orthodoc program, and the data was transferred to the robot onto which the cadaver femur was mounted with a standard clamp. The cutting procedure was performed according to the ROBODOC® standard protocol (25). The correct positioning of all implants in the corresponding femora was ensured with the use of radiographs before testing.

#### 2.4. Specimen preparation and measurement

The specimens were prepared and tested according to the protocol established by Bühler et al. (1997); thus, the technique is only briefly described here. The length of

the entire specimen was adjusted to 35 cm by shortening the distal femoral shaft. This enabled standardized molding of the distal part with low-melting-point alloy in a metal cup. Three 9-mm transverse holes were drilled in the anterior portion of the femoral bone at proximal, middle, and distal locations, corresponding to the indentations previously made on the prosthesis. Micromotion sensors were mounted on the femur with the use of press-fit adapters. If necessary, the adapters were stabilized with bone cement. The reference points on the sensors and the implant were digitized with an optoelectronic camera (Optotrak; Northern Digital, Waterloo, Canada) to allow transfer of the motions to an implant coordinate system with medial–lateral, anterior–posterior, and proximal–distal directions (Fig. 1). The specimens were thawed to room temperature before testing.

The micromotion sensors used in this study were custom-made at the Maurice E. Müller Institute for Surgical Technology and Biomechanics in Bern, Switzerland, and included an optoelectronic tracking device (Bühler et al., 1997; Speirs et al., 2000). A static calibration was performed to determine a maximum error of  $\pm 10 \mu\text{m}$  in the medial plane and  $\pm 15 \mu\text{m}$  in the anterior–posterior direction of the sensor (Fig. 1), within a calibration volume of  $\pm 750 \mu\text{m}$  in each of the axes. The maximum allowed range for each sensor was  $\pm 1000 \mu\text{m}$ . If a reading from any sensor exceeded this value, the sensor was removed to prevent damage. The measurements were aborted if a second sensor exceeded this value.

The motion at each sensor can be characterized as total motion (TM), which is the time-based average micromotion during the loading cycle and which measures the irreversible migration of the implant; and dynamic motion (DM) which is the difference of the measured minimum and maximum value for one loading cycle and represents reversible elastic motions.

#### 2.5. Loading

The fixture holding the implanted femur was rigidly attached to the upper part of a biaxial materials testing machine (Instron, Model 1270, High Wycombe, UK) (Fig. 2). The applied loading pattern simulated the in vivo forces that act on the femoral head during gait (Bergmann et al., 1993). Correspondingly, forces similar to those that act on the femoral head during the single-leg-stance phase of the gait cycle were applied. The axis of the mounted femur was therefore in the frontal plane, adducted  $20^\circ$  from the vertical axis of the test machine, resulting in a cranial–caudal force ( $F_{cc}$ ) that consisted of distally and laterally directed force components (Fig. 1). The sinusoidal  $F_{cc}$  was applied to the head of the implant at 1 Hz, varying between 200 and 1500 N. In addition to  $F_{cc}$ , an anterior–posterior directed sinusoidal

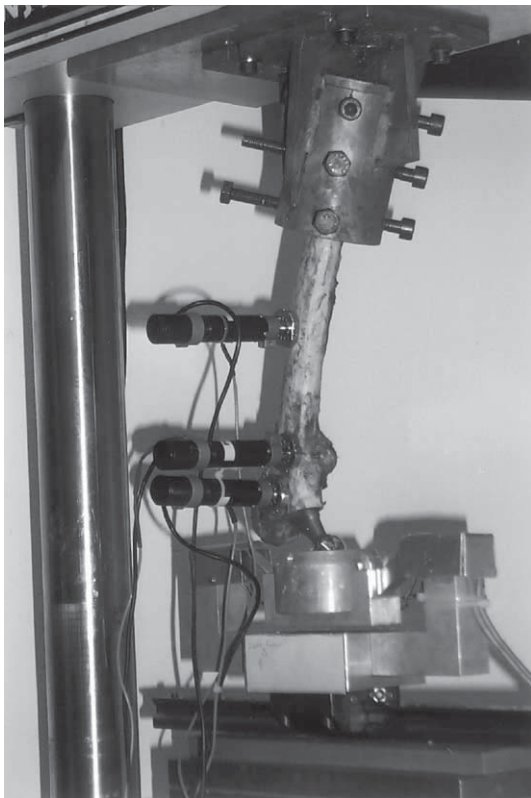


Fig. 2. Cadaveric femur mounted to the testing machine with sensors in place and connected.

force (Fap) was constantly applied at a frequency of 0.5 Hz. The amplitude of Fap was always 10% of the corresponding maximum Fcc and was synchronized so that the maximum anterior force occurred with maximum compression, and the maximum posterior force occurred with minimum compression (200 N).

To standardize the initial settling of the implants prior to installing the sensors and testing, the specimens were preconditioned with an Fcc of 750 N for 100 cycles (here and henceforth: one cycle = one Fap cycle, which is equivalent to one gait cycle). In the first load step, a maximum Fcc of 750 N was applied for 250 cycles. In the second load step, a maximum Fcc of 1500 N was applied for 500 cycles.

### 2.6. Statistics

Nonparametric statistical tests were used. The Wilcoxon matched pairs test, the nonparametric equivalent

of the paired *t*-test, was used to detect differences between the performances due to the two implantation techniques. A *p*-value of 0.05 was specified as the significance level. All statistical analyses were performed using Statistica 5 (StatSoft; Tulsa, OK, USA).

### 3. Results

While testing specimen 1 (pair 1, robotic milling method), the middle and the distal sensor exceeded the limit of 1000  $\mu\text{m}$  after 100 cycles of the second load step. All other specimens were successfully tested. Six complete pairs were therefore available for the statistical analysis of the second load step.

The total motion measured at the individual sensors can be broken down into its components along the three axes of the prosthesis coordinate system to gain insight into the motion patterns (Fig. 1). In the first load step, the magnitude of prosthesis migration at the proximal sensor was about the same order of magnitude as the accuracy of the sensors themselves (10–15  $\mu\text{m}$ ). At the middle and distal sensors, only the total motion of the stems implanted with the ROBODOC<sup>®</sup> system exceeded the magnitude of the sensor accuracy. Magnitudes of total motion at the three sensor locations are provided in Table 2, and the statistical significance levels of the differences are listed in Table 3.

In the second load step, the prostheses implanted with robotic support underwent greater total motion in the anterior–posterior and proximal–distal directions at all three sensors. At the middle and the distal sensors, they also showed greater motion in medial–lateral direction. At the proximal sensor, the manually implanted stems slightly moved, on the average, in a posterior direction, whereas the robotically implanted stems moved in an anterior direction. Magnitudes of total motion at the three sensor locations are provided in Table 2. Most differences in total motion in both load steps were not statistically significant (Table 3).

The pattern for the dynamic motion was similar to that of the total motion (Table 4). In both load steps, the measurements at the proximal and the middle sensor exceeded the accuracy of the sensors themselves only slightly. On the average, less than 25  $\mu\text{m}$  of motion was measured. The prostheses implanted using the ROBODOC<sup>®</sup> system moved more toward posterior at the middle and the distal sensor during the first load step.

Table 2

Magnitude of total motion (in  $\mu\text{m}$ ) at the end of each load step, measured at each of the three sensor location. Total motion is accumulative

Load step	Sensor 1, proximal		Sensor 2, middle		Sensor 3, distal	
	Manual	Robot	Manual	Robot	Manual	Robot
1, <i>n</i> = 7	15	29	7	91	26	148
2, <i>n</i> = 6	58	72	63	216	179	298

Values are given as the mean of *n* specimens.

Table 3

Wilcoxon significance levels for paired comparison of total motion along the indicated axes. Total motion is accumulative

Load step	Proximal sensor			Middle sensor			Distal sensor		
	ML	AP	PD	ML	AP	PD	ML	AP	PD
1, $n = 7$	0.612	0.091	0.612	<b>0.018*</b>	0.128	<b>0.018*</b>	<b>0.018*</b>	0.612	0.735
2, $n = 6$	0.600	<b>0.028*</b>	0.753	0.463	0.600	0.173	0.345	0.173	0.753

ML = medial–lateral; AP = anterior–posterior; PD = proximal–distal.

\*  $p < 0.05$ .

Table 4

Wilcoxon significance levels for paired comparison of dynamic motion along the indicated axes

Load step	Proximal sensor			Middle sensor			Distal sensor		
	ML	AP	PD	ML	AP	PD	ML	AP	PD
1, $n = 7$	0.735	0.499	0.499	0.0910	<b>0.018*</b>	0.063	0.063	<b>0.018*</b>	0.612
2, $n = 6$	0.249	0.753	0.753	0.600	0.173	0.173	0.249	0.173	0.917

ML = medial–lateral; AP = anterior–posterior; PD = proximal–distal.

\*  $p < 0.05$ .

The dynamic motion at the distal end was high, especially for the ABGs implanted with robotic support. The maximum dynamic motion was detected in an anterior–posterior direction; the motion of the manually implanted stems at the end of the second load step was 43  $\mu\text{m}$  on the average, whereas the motion of the stems implanted with ROBODOC<sup>®</sup> amounted to 99  $\mu\text{m}$  on the average. In general, prostheses that were implanted with robot assistance showed similar or greater dynamic motion than the manually implanted stems at all sensor locations for all loads applied, with only two exceptions: the manually implanted stems moved in a more proximal–distal direction at the distal sensor during the first load step (manual: average = 15  $\mu\text{m}$ ; robotic: average = 12  $\mu\text{m}$ ), and in a more medial–lateral direction at the proximal sensor during the second load step (manual: average = 19  $\mu\text{m}$ ; robotic: average = 10  $\mu\text{m}$ ). All these values were close to the limits of accuracy, and no differences were statistically significant.

The torsional stability of a hip prosthesis inside the femur principally can be approximated by examining anterior–posterior motions at the middle sensor relative to those of the other two sensors, which defines the longitudinal axis; however, the ABG I prosthesis used in this study tilted to such an extent that approximating the rotation around the implant axis was not possible.

#### 4. Discussion

We investigated the primary stability of an anatomical stem implanted either manually or with robotic assistance in matched pairs of femora. In general, total motion of the anatomical stem was high and a great deal

of dynamic motion was detected, especially at the distal end of the prosthesis. This was to be expected in a proximal–fixated prosthesis design with an over-reamed distal part. The manually implanted prostheses exhibited less motion than the prostheses that were implanted with use of the ROBODOC<sup>®</sup> system, but no statistically significant differences were found between the two techniques. Robotic machining did not enhance the primary stability of this cementless anatomical femoral component in comparison with conventional manual broaching; neither did it reduce the variability of initial implant stability.

The size of the prosthesis was larger in four of seven cases when the prosthesis was implanted with robotic assistance (Table 1). Conventional and ROBODOC<sup>®</sup> implantations were done independently, following the usual planning sequence of the clinical cases. While performing the conventional operation, the surgeon had to rely on physical feedback mechanisms such as sound and force, whereas the Orthodoc planning station provided a three-dimensional view of the medullary cavity, which afforded the surgeon more precision in choosing the overall best-fitting implant size. Because we intended to evaluate two clinically applied implantation techniques, we tried to achieve optimal performance for each of these techniques independently. Therefore, we allowed different stem sizes to be implanted in the two femora of one cadaver.

We detected micromotion with an in vitro testing method, which provided reliable information to compare two implantation techniques or implant types, but which should be used with caution to predict micromotion in vivo, even though the load pattern used was derived from in vivo loading conditions (Bergmann et al., 1993). In our study, the femur was rigidly fixed,

introducing additional bending moments, whereas in vivo, stability is provided by the muscles and other soft tissues. In addition, in vivo loading never consists of one constant load pattern. Walking, stair climbing, or rising from a chair or a bed all lead to different loading conditions and therefore would result in different micro-motions.

With use of seven cementless stem designs, Thomsen et al. (2002) compared the effectiveness of robotic milling to hand broaching by measuring the primary rotational stability in synthetic femora. Their results were similar to our findings; they reported an increased stability for the ABG implant by hand broaching. Nevertheless, because of their use of plastic bones and due to differences in load application and measurement techniques, comparability to this and other studies is limited. However, compared to the micromotion results of other cementless stems tested in human specimens (Bühler et al., 1997; Gotze et al., 2002), the motion of the anatomic ABG I prosthesis was greater. Those results might not be completely comparable because none of the prostheses reported in the literature had an anatomical design. The total and the dynamic motion of the studied implant were substantially greater at the distal sensor than at the more proximal-lying locations. This result was to be expected in a proximal press-fit stem, which is designed so that the hydroxyapatite coating of the proximal implant surface can support osteointegration. The threshold of micromotion reported for the inhibition of osteointegration is 20–30  $\mu\text{m}$  (Jasty et al., 1997; Pilliar et al., 1986), but it is not clear if the total motion over time or the dynamic motion has the greater influence on bone ongrowth. The total motion of an average ROBODOC<sup>®</sup>-implanted ABG I exceeded these threshold values at the middle sensor at just the first load step. During the second load step, the average total motion exceeded these thresholds, independent of the implantation technique. The measured dynamic motions at the proximal and the middle sensor were generally below the reported thresholds during the two load steps. The dynamic motion observed at the distal end exceeded the limits for bone ongrowth. However, limited osteointegration has been observed with prosthesis motion of up to 150  $\mu\text{m}$ , a value that, on the average, was rarely exceeded during these tests.

Computer-assisted orthopaedic surgery (CAOS) affords an opportunity to utilize computer-based systems to improve the precision and the reproducibility of certain surgical steps (DiGioia et al., 1998a,b). Numerous passive CAOS systems have been developed recently by different manufacturers, but these are mainly navigation systems of different designs that guide the surgeon during a surgery but do not actively perform any procedure. These systems are available for various procedures, such as spine surgery (Foley et al., 2001; Merloz et al., 1998; Nolte et al., 2000), pelvic osteoto-

mies (Haddad et al., 2001; Handels et al., 1999; Langlotz et al., 1997, 1998) and primary THA or total knee arthroplasty (TKA) (DiGioia et al., 1998a,b). With regard to active CAOS machines, meaning robots that actively perform surgical procedures, the picture is completely different. The first surgical orthopaedic robot, ROBODOC<sup>®</sup>, is still the leading robot and currently includes applications for primary THA and TKA and revision hip arthroplasty. Only a few other manufacturers have tried to design their own robots, with varying success (Paul, 1999).

The costs of robotic orthopaedic surgery are high and include the initial cost of the robot as well as maintenance costs. Robotic procedures require some additional time on the part of the surgeon for planning and data transfer and of the operating room staff for non-sterile and sterile preparation. In recent studies reported in the literature, it was shown that the utilization of high-speed cutters—not necessarily robot based, but used for the ROBODOC<sup>®</sup> procedure—added new problems, such as the development of an aerosol cloud (Nogler et al., 2001a,b,c) or heat generation in the femur (Nogler et al., 2001a,b,c). Necessary preoperative CT scans exposed patients to additional radiation, and the fiducial markers that were sometimes required were a source of additional complications (Nogler et al., 2001a,b,c). These costs, perioperative efforts, and complications might be acceptable if patients were to appreciably benefit from the use of such a system. Advantages of the ROBODOC<sup>®</sup> system with regard to precise planning and accuracy of the intraoperative procedure have recently been shown in a prospective randomized study by Honl et al. (2003). Nevertheless they also reported a higher complication rate in the robotic-operated group compared to the conventional one; therefore they recommended further development of this technique.

The scope of this study did not allow us to evaluate the particular effects of the use of the ROBODOC<sup>®</sup> system on quality of planning, the precision of the execution of the preoperative plan, and the reproducibility of results in primary THA. Rather, this study evaluated the immediate postoperative outcome parameter of initial stability in vitro by way of comparing manually implanted stems with stems implanted with the use of the robot. For the ABG I stem, no statistically significant differences were found between robot-assisted implantation of stems and manual implantation of stems by an experienced surgeon, indicating that the use of the ROBODOC<sup>®</sup> system does not improve the single parameter of initial stability for the ABG I stem. The system might have positive effects for other implant designs, and it might improve the outcome for patients through better planning in special cases or guarantee reproducible implant positions. Further research is needed to evaluate these possibilities.

## Contributors

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