Acta Orthop Scand 2002; 73 (4): 379–385

Robotically-milled bone cavities

A comparison with hand-broaching in different types of cementless hip stems

Marc N Thomsen[1], Steffen J Breusch[1], Peter R Aldinger[1], Wolfgang Görtz[1],
Andreas Lahmer[2], Mathias Honl[3], Andreas Birke[4] and Hans Nägerl[5]

[1]Stiftung Orthopädische Universitätsklinik, Schlierbacher Landstr. 200A, DE-69118 Heidelberg. E-mail: Marc.Thomsen@ok.uni-heidelberg.de, [2]BG Unfallklinik, Friedberger Landstr. 430, DE-60389 Frankfurt a. M., [3]AK Barmbek, Rübenkamp 148, DE-22291 Hamburg, [4]Orthopädische Universitätsklinik, Martin Luther Universität, Magdeburger Str. 22, DE-06097 Halle/Saale, [5]IV. Physikalisches Institut, Universität Göttingen, Bunsenstr. 13-15, DE-37073 Göttingen, Germany

Submitted 00-12-21. Accepted 01-09-10

ABSTRACT – We performed an experimental study to compare the effectiveness of robotic bone milling (Robodoc and CASPAR) with hand-broaching as regards primary rotational stability of 7 different cementless stems. Using 48 synthetic femora and a specially-designed apparatus, we compared the implant stability of proximal and distal rotational stem displacement (slip) in relation to the cortex. We also measured stem deformation (twist) and the location of torque transfer from stem to cortex (i.e., fixation pattern).

S-ROM, Antega, and ABG stems were more stable in hand-broached femora. Osteolock stems showed no difference between CASPAR and hand preparation, but rotational stability was better in the Robodoc group. G_2, VerSys ET and Vision 2000 stems gave increased rotational stability in the robotic groups. When placed too laterally, Vision 2000 showed a pattern of more distal fixation.

The findings emphasize the current difficulties in creating a perfect match of robotically-milled cavity and stem geometry to achieve enhanced primary rotational stability. The pattern of fixation seems to depend not only on stem design, but also on canal preparation and stem positioning.

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Cementless femoral stem fixation has become increasingly popular over the last two decades. Numerous stem designs based on different views concerning stem fixation are available. Regardless of stem design, primary stability must be achieved at the time of operation and is regarded as a "conditio sine qua non" for osseointegration (Albrektsson et al. 1981), long-term fixation and clinical success (Callaghan et al. 1992, Morscher 1995, Nourbash and Paprosky 1998). Noble et al. (1988) have emphasized the difficulties of achieving press-fit and showed the influence of stem design and anatomical variations of the proximal femur. Gaps between implant and bone may occur especially when contemporary broaching techniques are used which are subject to surgical error (Sugiyama et al. 1992). As a result, more sophisticated methods of preparing the bone cavity have been developed. Experimental work has led to the clinical introduction of robotic systems for orthopedic surgery (Paul et al. 1992).

Today, almost 100 robots (Robodoc or CASPAR) are in use in Europe, mostly (81) in Germany. The systems cost about 400,000–500,000 €. Moreover, in each case an additional 700–1,000 € is needed for drills, pins and the preparation kit. The orientation of the robot system requires placement of two reference pins (proximal femur and femoral condyle) in a preceding minor operation followed by a postoperative CT-scan. Three-dimensional reconstruction, using a computer workstation, allows for precise preoperative planning (stem size and positioning). During the definitive operation, the robot system takes 30–50 minutes longer for rigid temporary fixation of the femur (to the operating table), referencing and maneuvering of the drill head and the milling process.

Stem types and methods of preparation. Relative standardized rotational angles between the cortex and stem (slips) at the proximal (α_1) and distal (α_{2+4}) level's of the implant, and between the distal and proximal sides of the stem (i.e., stem twist—α_{1-2}) or of the cortex twist (α_5). The data represent the independent measurements of the 3 specimens for each type: mean (range). The p–value reflects the probability that the values of either CASPAR or Robodoc machining are equal to those of the hand preparation (Mann–Whitney U–test)

Stem type		Preparation by			
	Slips and twists	Hand (millidegrees/Nm)	CASPAR (millidegrees/Nm)	Robodoc (millidegrees/Nm)	P–value
ABG	α_1	6.0 (5.8–6.6)		7.8 (7.3–8.3)	0.02
	α_{2+4}	14.6 (13.8–16.4)		15.9 (13.1–18.9)	0.36
	α_{1-2}	3.0 (2.1–3.4)		2.5 (1.2–3.7)	0.36
	α_5	41.3 (40.7–41.8)		40.7 (40.5–42.1)	0.24
Antega	α_1	8.5 (7.8–8.8)		9.6 (8.9–11.1)	0.02
	α_{2+4}	15.7 (14.8–17.6)		23.8 (21.8–27.3)	0.02
	α_{1-2}	8.1 (5.7–8.5)		4.6 (3.7–5.1)	0.02
	α_5	39.2 (38.7–39.6)		40.9 (39.6–41.5)	0.06
G_2	α_1	17.6 (17.1–18.9)	7.6 (6.2–7.6)		0.02
	α_{2+4}	19.8 (19.4–23.3)	24.3 (24.3–25.2)		0.02
	α_{1-2}	14.0 (12.2–15.1)	2.7 (2.4–3.1)		0.02
	α_5	41.3 (41.0–42.2)	40.8 (40.0–41.2)		0.06
Osteolock	α_1	6.1 (5.8–6.5)	5.7 (5.6–6.1)	4.9 (4.9–5.3)	0.06/0.02
	α_{2+4}	16.0 (15.1–17.3)	17.6 (17.2–18.1)	15.2 (15.0–15.9)	0.14/0.25
	α_{1-2}	2.0 (1.6–2.3)	1.6 (1.0–2.3)	2.0 (1.9–2.2)	0.06/0.14
	(5	41.1 (40.9–41.8)	41.7 (41.1–42.3)	40.5 (40.1–41.4)	0.14/0.14
S–ROM	α_1	6.0 (5.7–6.8)		7.4 (7.0–7.4)	0.02
	α_{1b}	2.0 (1.5–3.3)		2.8 (2.1–3.1)	0.25
	α_{2+4}	6.3 (5.2–7.9)		7.2 (6.6–10.1)	0.14
	α_{1-2}	21.7 (19.8–22.9)		20.1 (18.3–20.4)	0.14
	α_5	36.6 (36.3–37.9)		33.5 (33.1–35.1)	0.02
VerSys ET	α_1	12.0 (11.3–13.0)	8.2 (8.1–9.1)		0.02
	α_{2+4}	19.8 (16.9–21.4)	25.4 (24.4–25.9)		0.02
	α_{1-2}	9.8 (8.2–11.6)	4.0 (2.5–4.5)		0.02
	α_5	40.1 (38.4–41.4)	40.9 (40.5–41.5)		0.14
Vision 2000	α_1	12.0 (10.4–13.5)	7.7 (6.0–7.8)		
0.02	α_{2+4}	29.3 (26.0–29.3)	21.8 (20.1–23.1)		0.02
	α_{1-2}	0.5 (0.4–0.5)	2.1 (2.0–2.5)		0.02
	α_5	40.7 (40.0–41.7)	40.2 (40.1–40.9)		0.41
Vision 2000	α_1		5.4 (4.7–6.1)		0.04
(laterally	α_{2+4}		9.9 (9.4–10.6)		0.04
positioned)	α_{1-2}		7.9 (7.3–8.6)		0.04
	α_5		36.3 (35.8–36.6)		0.04

Preoperative planning and exact subsequent intra-operative execution by the robot are considered the most striking advantages (Boerner et al. 1997). Improved stem fit and enhanced primary stability have been proposed by the distributing companies and supporting surgeons. In a cadaver study Alexander et al. (1999) demonstrated superior bone-implant-contact. However, there is no published data to show superior stability with robotic milling.

We studied the effectiveness of computer assisted bone preparation with regard to primary rotational stability of different cementless stems in comparison to hand broaching.

Material and methods

We tested 7 types of cementless femoral components (ABG, Antega, G_2, Osteolock, S-ROM, VerSys ET, Vision 2000) (Table). ABG and Antega were anatomic designs. All other stems were straight and tapered.

To ensure standardized experimental conditions we used 48 synthetic femora (composite bone) from Pacific Research Lab (Vashon Island, WA, USA) with mechanical properties and dimensions closely resembling the human femur and with proven low inter-femur variability (Cristofolini et al. 1996).

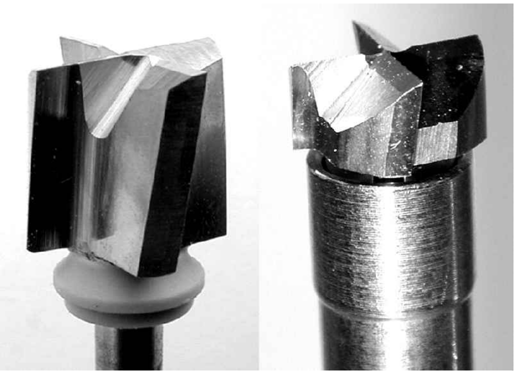

Figure 1. Drill heads of CASPAR (left) and Robodoc (right) having comparable dimensions and design characteristics.

Test protocol

A femoral neck osteotomy was performed at identical levels on all synthetic femora 1 cm above the lesser trochanter. 21 femora (3 per stem design) were prepared by hand broaching by an orthopedic surgeon familiar with the system and in attendance of a company representative. All systems provide undersized broaches/reamers to ensure press-fit fixation.

The femora for the robotic implantation had been CT-scanned prior to planning. The virtual planning and robotic milling for G_2, VerSys ET and Vision 2000 stems were done by the authors clinically using the CASPAR (Computer assisted Surgical Planning and Robotics)-System (URS/orto, Rastatt, Germany). ABG, Antega and S-ROM were planned and milled by surgeons (see acknowledgment), using the Robodoc System (Integrated Surgical Systems Inc. (ISS), Davis, CA, USA). The milling for Osteolock" stems was done with both robotic systems (Table). As regards Vision 2000, 3 additional femora were planned for more lateral stem positioning because this was the clinical method used by one of the participating surgeons.

The geometry of the drill heads from CASPAR and Robodoc was similar (Figure 1). After canal preparation, all specimens were embedded in plaster of Paris at the level of the femoral condyles to produce a rigid attachment of the femur to a support. The stems were then pressed into the femora in a stepwise manner by 25 cycles of 2000 N followed by 25 cycles of 4000 N, using a universal test machine (Frank Universal Testing machine 81816/B, Karl Frank GmbH, Weinheim, Germany). The choice was based on the maximal force acting on the hip joint during walking and jogging, as reported by Bergmann et al. (1993). Antero-posterior and straight lateral radiographs were taken to ensure comparable stem alignment in both groups.

Testing method

The femora with implanted stems were mounted into a specially-designed device for torsion measurements (Thomsen et al. 1999). In principle, relative motion (i.e., stem displacement, defined as “slip”) and deformation of stem and bone (i.e., torsion, defined as “twist”) were measured in millidegrees/Nm (mdeg/Nm). As neither the femur nor the stem can be considered rigid bodies, measurements at several levels (of both the femur and implant) were necessary. Unlike other devices, the apparatus we used permits measurement of movements of a volume element (i.e., spatial dimensions of measurement points) of stem or cortex in 6 degrees of freedom (3 for translation and 3 for rotation), using 6 linearly variable differential transducers (LVDT) with a resolution of 0.1 μm.

The volume elements measured were taken at 5 levels: 2 at the implanted stem (# 1–shoulder, # 2–tip) and 3 at the synthetic cortex (# 3–8 cm below the lesser trochanter, # 4–at the same level as # 2, # 5–20 cm below the lesser trochanter). The external loading system was used on the neck taper. To maintain the press-fit situation achieved during implantation, a continuous co-axial force (F = 70 N) acting along the longitudinal axis of the femur was applied during all measurements.

To produce the variable axially-acting torque, two weights (30 Newton each) were shifted by distance d in an anti-parallel fashion so that the varying axial torque T was given by the equation: $T = 2d \times F_R$. The torque was applied in 6 cycles. Each cycle swept along the interval ± 6 Nm and was carried out by 150 increments. After each increment, the position of the respective volume element was determined in relation to that of the volume element of the lesser trochanter, which was chosen as the reference co-ordinate-system. (N.B.: The S-ROM stems consist of two parts: an inner stem core and an outer sleeve. Therefore, an additional measurement had to be taken from the outer sleeve (# 1b)).

In the following, we refer to the axial rotation angles of the volume elements as α_1–α_5 corresponding to the measurement levels # 1– # 5:

α_1–proximal axial slip between stem and cortex at the "shoulder" (# 1) of the stem;

α_{1b} (S-ROM only)–proximal axial slip between outer sleeve and the cortex;

α_5–axial twist of the cortex between reference and volume element # 5. The level # 5 is far below the apex of the stem, where torque T is fully transferred from the stem to the cortex. (5 depends solely on the location of the center of torque transfer from the stem to the cortex, and is therefore a measure of the distance from level # 5 to the point on the cortex, where the torque transfer is completed. This point is more proximal, the greater α_5 is.

To determine both slip and twist (see above), we calculated the following parameters:

α_{2+4}–axial rotation between the volume elements # 2 and # 4, thus representing the distal axial slip between the stem tip and cortex;

α_{1-2}–axial rotation between the volume elements # 1 and # 2, thus representing the axial twist of the stem (Note: smaller α_{1-2} indicates a more proximal location of torque transfer from the stem to the femur).

Data evaluation protocol

We determined only small hystereses curves from the 6 loading cycles, measured in 150 increments each. The rotational angle α of each volume element and the applied axial torque T were almost proportional to each other. Hence, the axial rotations could be standardized by the average inclination of α/T. Therefore, the values we refer to as α_1–α_5 (in the results section) represent these standardized axial rotations which were calculated with a resolution of 0.2 mdeg/Nm.

We used the Mann-Whitney U-test for the statistical analysis.

Results

Evaluation of the measurement data showed that—except for rotational stem displacement—all other components of stem movement were negligibly small. Therefore, we present rotational data only.

Rotational stability

All stems showed minor rotational displacement and no increasing slip in the testing process (i.e., 6 cycles with 150 increments each). The sets of all three measurements with each stem type resulted in reproducible data with a maximum standard deviation of 0.1–1.2 mdeg/Nm (Table).

Stems with increased stability by hand-broaching

Both anatomic stems (ABG and Antega) gave less proximal slip (α_1) in hand-broached specimens.

For S-ROM stems, hand-broaching resulted in smaller rotational slip (reduction of 18%) between the stem and femur, more marked proximally than distally (α_1 and α_{2+4}). Robotic milling also resulted in a distal shift of the center of torque transfer. All S-ROM inner stem cores showed slips relative to the synthetic femur and to the outer sleeve (α_{1b}).

Stems with increased stability by robotic milling

G_2 and the VerSys ET stems gave smaller proximal slips in the robotically-milled specimens, with a pattern of more proximal fixation than with hand-broaching.

The Osteolock data (Figure 2) showed only small differences between hand-broaching and the two robotically-prepared implants. Only, the three specimens milled by the Robodoc showed a significantly higher value for the proximal slip (α_1).

Vision 2000 stems gave reduced proximal and distal stem slips in robotically-milled specimens. In the stems with more lateral stem positioning, we found increases in the distal torque transfer/distal fixation pattern (indicated by an increase in stem twist = α_{1-2}) and in the overall fixation.

Discussion

The apparent (statistical) weakness of our study is the small number (n 3) of specimens in each group. However, in each implant group we found a high data consistency with minimal standard deviation.

Our model permits standardized measurements of twist of the stem and twist of the femur, i.e., deformation of both. We also determined proximal and distal slips, i.e., relative rotational micromotions of the stem against the femur at the level of the

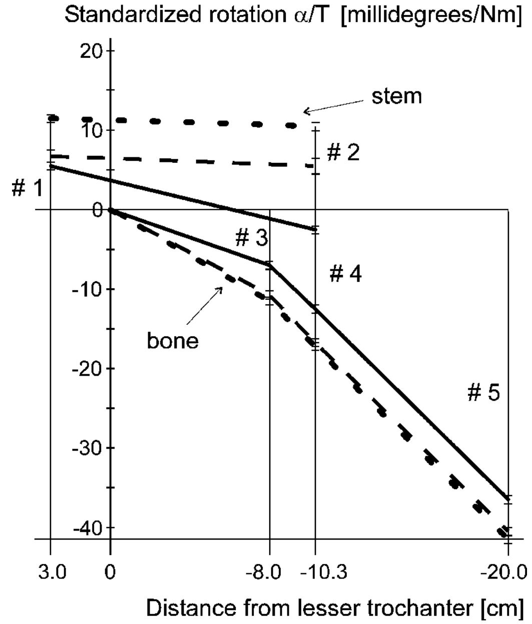

Figure 2. Rotational angle curves of the Vision 2000". The dotted line (....) indicates the results of the 3 hand-broached specimens. The interrupted line (---) shows the results of the CASPAR milling and the straight line those obtained with lateral stem positioning. The standard deviations (I) were minimal, indicating high reproducibility. 0 cm indicates the level of the lesser trochanter, #1–#5 the levels at which measurements were made. The curve of bone twist is marked in the lower section, starting with 0 degrees of rotation.

lesser trochanter and the apex of the stem. Thanks to the 6-dimensional measurements, we could identify typical patterns for all stems evaluated.

ABG, Antega, Osteolock, VerSys ET and the Vision 2000 stems showed a pattern of proximal fixation with little proximal slip. In the Swedish hip register (Malchau et al. 2000), promising short-term results for the ABG Ha stem implanted with hand-broaching have been reported. Interestingly, by positioning the Vision 2000 stem more laterally, the fixation pattern was changed from a proximal to a more distal fixation and torque transfer. However, this did not increase the proximal slip, but it did increase the overall stability and stem twist. Similarly, robotic milling changed the pattern of fixation to an even more proximal one in the G_2 and VerSys ET stems. In hand-broached specimens, due to the change (more distal) in torque transfer, G_2 stems seemed to be subjected to significantly higher levels of implant twist.

The S-ROM stem showed a mixed pattern of proximal, mid-shaft and distal fixation with a high stem twist and reduced stem stiffness; it therefore resembled a deformation pattern closer to (synthetic) femora. Reduced stem stiffness led to reduced proximal bone loss and distal cortical hypertrophy at short-term in a dog model (Sumner and Galante 1992). However, no valid conclusions can be drawn from our data concerning the clinical phenomenon of proximal (radiographically evident) stress shielding, since this represents a bone remodeling response over a longer period.

Early clinical results have been favorable with the S-ROM stem even in dysplastic hips (Cameron et al. 1996). However, we are concerned about the micromotion we measured between the sleeve and inner core of the S-ROM system. It is difficult to believe that no fretting and metal wear occur.

These findings emphasize that the method of preparation, the definition of implant bed dimensions and the implant position significantly affect the pattern of fixation, even with the same type of implant. Furthermore, more distal fixation of a stem may not necessarily lead to reduced proximal stability. An increase in implant deformation occurred in this instance. This observation surprised us, it confirmednot only that femoral implants do not represent rigid bodies which primarily deform bone, but that they also undergo deformation themselves, which seems to depend on the pattern of fixation.

It has been suggested that computer navigation and robotic machining systems improve femoral component alignment and initial press-fit fixation as well as stability of the femoral stem (Boerner et al. 1997, Bargar et al. 1998, Paravic et al. 1999). Although we did not evaluate all benefits of computer-guided stem insertion, some data suggest that stem malpositioning occurs less often with robotic systems (Jerosch et al. 1998, Hasselbach et al. 1999).

However, unlike other reports (Boerner et al. 1997, Bargar et al. 1998), robotic canal preparation did not improve stability in 4 of the 7 implants that we studied. 2 of these were anatomic. We believe that the robot needs more space for maneuvering the drill head around the curved shoulder and it therefore produces gaps between the stem and bone bed. The gaps created by inaccurate bone preparation may cause implant instability and reduce bone ingrowth (Noble et al. 1988). Paravic et al. (1999) compared the accuracy of manual broaching and robotic reaming and found significantly more gaps in the mid-shaft and distal regions between the stem (Osteolock) and bone in the hand-broached group.

In accord with our findings, Alexander et al. (1999) showed that rotational stability of Osteolock stems in robotic-machined human femora was no better than conventional hand-broaching. They suggested that both compaction of the bone bed and critical contact areas in the hand-broached specimens may have caused. They also noted considerable variations in the hand-broached group. This differs from our results which had small standard deviations. The differences between robotic and manual canal preparation might have been more or less marked if paired human femora with genuine cancellous bone had been used.

Some of our findings emphasize the difficulty in creating a perfect robotically-milled cavity since the manufacturers have to make compromises in size and maneuverability of the drill head. Before robotic implantation of a cementless stem, in vitro studies must be done to understand individual patterns of fixation and ensure reproducibility and adequate primary stability. We regard such experimental studies to be of great value to the designing companies and are concerned about the clinical introduction (of robotic milling) without preceding in vitro studies. Considering the substantial additional cost, we find the currentwidespread use of robotic milling devices difficult to justify because it remains to be shown that primary stability will be better or that the ultimate outcome will improve. However, at centers where prospective, comparative studies can be done, the clinical implications of robotic systems should be further evaluated.

The authors thank the State Ministry of Science, Research and Art of Baden-Württemberg, Germany for financial support, DePuy/Johnson & Johnson, Stryker/Howmedica, Zimmer and Aesculap for donation of the implants, Ortomaquet and Integrated Surgical Systems for additional help with the robotic implantation, and Dr. Honl (Hamburg), Dr. Gossé (Hanover), Dr. Birke (Halle) and Dr. Lahmer (Frankfurt) for the robotic planing and milling.

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