

The dimensional accuracy of preparation of femoral cavity in cementless total hip arthroplasty*

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Abstract: Objective: To observe the accuracy of femoral preparation and the position of the cementless prosthesis in femoral cavity, and to compare the results between the computer-assisted surgical group (CASPAR) and the conventional group. Methods: Ten femoral components were implanted either manually or by CASPAR in cadaver femurs. The specimens were cut to 3 mm thick slices. Microradiograms of every slice were sent to a computer for analysis with special software (IDL). The gaps and the medullary cavities between component and bone, the direct bone contact area of the implant surface, the gap width and the percentage of gap and bone contact area were measured in every slice. Results: In the proximal implant coated with HA of the CASPAR group, the average percentage of bone contact reached 93.2% (ranging from 87.6% to 99.7%); the average gap percentage was 2.9% (ranging from 0.3% to 7.8%); the maximum gap width was 0.81 mm and the average gap width was only 0.20 mm. While in the conventional group, the average percentage of bone contact reached 60.1% (ranging from 49.2% to 70.4%); the average gap percentage was 32.8% (ranging from 25.1% to 39.9%); the maximum gap width was 2.97 mm and the average gap width was 0.77 mm. The average gap around the implant in the CASPAR group was only 9% of that in the manual group; the maximum and average gap widths were only about 26% of those in the manual group. On the other hand, the CASPAR group showed 33% higher bone contact than the manual group. Conclusion: With the use of robotics-assisted system, significant progress can be achieved for femoral preparation in total hip arthroplasty.

Key words: Total hip arthroplasty, Femoral cavity preparation, Robotics-assisted surgery

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INTRODUCTION

Cementless total hip arthroplasty (THA) has become an accepted part of the orthopaedic surgeon's choices and is being used with increasing frequency as an attractive alternative to conventional cemented prostheses, especially in young and active patients (Engh *et al.*, 1987; McLaughlin and

Lee, 2000; Mont *et al.*, 1993; Ragab *et al.*, 1999).

Clinical researches revealed that failures of cementless THA arose mainly from the micromotion of the implant and inadequate femoral canal filling and apposition between bone and prosthesis (Amstutz *et al.*, 1991; Bargar, 1989; Dujardin *et al.*, 1996; Walker *et al.*, 2000). The mechanical strength between the bone and prosthesis interface is positively related to bony ingrowth into the implants. The bony ingrowth into the implant is dependent upon the initial stability of the prosthesis and the close apposition to the bone after implan-

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tation. Stability is one of the most important factors for fixation of an implant. Initially, postoperative stability for an implant without cement is dependent upon the 'press-fit', while the permanent stability for an implant is determined by the bone ingrowth into the component. The interface between the implant and bone may play an important role in affecting early implant stabilisation, possibly by influencing tissue healing dynamics. One of the important factors for fixation of an implant is to match the bone and the prosthesis—the femoral component should fit the femur or the femoral cavity should be precisely prepared for the component to be inserted. This facilitates bone ingrowth and proper load transfer through the hip joint.

It is a geometrical challenge for orthopaedic surgeons to prepare the canal cavity for the femoral stem. This is because making and executing a plan requires the exact location for cuts and holes. So, although desired, the precise fit is impossible to be achieved by manual surgeries. In industry, the accuracy and precision in this kind of activity is the province of robotics. The goal of using robotic system is to improve the implant selection and sizing, positioning of the implant within the bone, and the accuracy of preparation of the bone cavity for implantation. The system is called CASPAR (Computer Aided Surgical Planning and Robotics). The current study was therefore conducted to measure the accuracy of CASPAR for preparation of femoral cavity and to compare the outcome with that of conventional techniques in an experimental setting with cadaver femurs.

MATERIALS AND METHODS

Ten fresh human femurs from adult cadavers were randomly separated into two groups. X-rays of all the bones were first taken, and bones were discarded if they had signs of previous trauma, diseases, or serious osteoporosis. The femoral canals were prepared either by using conventional hand-held broaches in the first group (five bones) with the techniques as described by the manufac-

turer, or by using robot-controlled milling (CASPAR) in the second group (five bones). The robotic system consisted of a preoperative planning computer workstation (called PROTON, Ortomaquet, Rastatt, Germany), two robotic arms (one with a high speed device for end milling and the other as a holder to fix the femur). The femoral prosthesis (Osteolock, Stryker Howmedica-Osteonics, NJ) was a collarless, straight, tapered, Ti alloy stem. The proximal third of the stem was coated with a dense 50 μm thick layer of Hydroxyapatite (HA). An additional centralised device (sleeve) can be applied to the tip of the stem if necessary. The design rationale of the limited proximal porous coating was to maximise proximal stress transfer and avoid distal stress shielding. Bony ingrowth occurs mainly in the proximal part coated with HA.

In the first group, the procedure of installing the femoral stem is the same as procedure for using conventional techniques. This procedure included the following three steps: (1) Anteroposterior (AP) and lateral X-ray films of the femur were obtained before surgery; (2) Proper femoral template in both AP and lateral projections were employed to determine implant size; (3) The femoral cavity was reamed and the implant was installed manually using the techniques and advice offered by the manufacturer.

In the second group (robotic group), the procedure is different from the manual group. (1) AP and lateral X-ray film of the femur were obtained before operation. (2) Locator pins were placed in the femur for navigation of the robot during the operation. One pin was inserted into the greater trochanter and the other into the medial epicondyle above the knee. (3) The femur was scanned with a three-dimensional computer tomography (CT), including the proximal femur and two pins. (4) The CT data of the femur were sent to and stored in the planning computer workstation and used for preoperative planning and selection of an implant. The preoperative planning system displays a sagittal, a coronal and a transverse image of the femur. An image of the candidate implant was manipulated and superimposed on the image of the femur in the

desired location for implantation. When the surgeon was satisfied with the selected implant and its orientation, the computer recorded this information (data on position and implant dimensional geometry) relative to the position of the two locator pins. A disc with these data was produced to be loaded into the computer controller of robot CASPAR at the time of the THA for programming the surgical robot to mill out a corresponding cavity. The digital data on the three-dimensional shape of many sizes of this type of prosthesis were supplied by the implant manufactures. (5) The robot then milled the inside of the femur to the size and position of the implant selected preoperatively at the computer workstation based on the data. (6) The implant was inserted by a senior surgeon when the femoral canal was completed.

Thereafter, the specimens containing the prostheses underwent a plasticization procedure in the Anatomic Department of KōIn University. The specimens were prepared for sectioning by construction of a line perpendicular to the exposed flat shoulder of the metal implant. This line represented the long axis of the implant. Transverse guidelines were constructed perpendicular to the long axis of the implant at 3-mm increments, beginning at the shoulder of the implant and extending distally to the tip of the stem. About 50 transverse sections were cut by a diamond blade-sectioning machine for every specimen. These cross sections are approximately 3.0 mm thick (some were eroded by the saw), they allow a direct view of the prosthetic-bone interface of the femoral implant.

Microradiograms were taken for every slice. Every X-ray film was scanned (300 dpi) and the images were stored into a personal computer. The images of the cross sections were viewed under magnification of 300% on the computer screen; and were analysed with a special designed program developed in IDL (Research Systems Inc.). The circumference of the implant was measured automatically. Gaps and medullary cavities were outlined manually on the computer (which recognized the outline made by two individual observers). The gap is defined as the space between bone and implant caused by the operation. The minimal width

of a measurable gap was 0.1 mm in this study. In some areas, it was difficult to determine whether a space between bone and implant is a gap or a cavity. Because of the special design of the femoral implant used in this study, there were only small parts of direct contact between bone and implant in the distal part. The implant has no contact with bone in the segment just above the sleeve. The proximal part coated with HA is the critical part for this type of implant. The analyses focused on the proximal segments and paid less attention to the distal part of the implant in this study.

The circumference of the prosthesis, the length of the gap in the circumference, the area of the gap, and the maximum width of gap were measured in every slice of the specimen. The same measurements were conducted for the cavities in the slices. Some slices had more than one gap, so we added up the length of gaps and the area of gaps. The average gap width was determined by dividing the area by the length of the gap. The percentage of gap around the implant surface was calculated by dividing the length of the circumference occupied by the gaps by the total length of the circumference, and multiplying by 100. The same calculation was done for the cavities. Then the area of direct bone contact (no measurable space between bone and implant) was evaluated by subtracting the gap's area and the cavity's area from the surface of the implant. The percentage of gap, cavity and bone contact in the distal part was derived in the same manner. All these results were obtained from every serial transverse section through the implant.

RESULTS

To facilitate analysis and description of the results, the femoral implant was divided into two parts as viewed on AP and on lateral X-ray films. These were: the proximal part of component coated with HA and the distal part of component without HA. Because the femoral implant used in this study was a type of proximal fixation, the study focused on the proximal part.

Close examination of the proximal part re-

vealed that most of the implant surface was surrounded by bones. The appearance of the gaps at the bone-implant interface looked differently in two groups (Figs.1–4). In the slices of the CASPAR group, there were no gaps or very small gaps as transparent lines around the implant (Figs.1–2). The interface between implant and the adjacent bone showed intact trabecular architecture. No trabecular bone was crushed. Most surfaces of the implant were in close contact with bone. In contrast, the gaps in the manual group were large and irregular (Fig.3). These gaps were created when bone was torn out by the teeth on the broach. “Saw-teeth” were often seen in trabecular bones as the vestiges of the bone torn out by the teeth on the broach. The trabecular bone in some areas around the implant was crushed to high density; in other areas there was no bone contact. Femoral fissures were found in a specimen from the manual group (Fig.4). In part

two, because of the medullary cavity and the design shape of the prosthesis (the diameter of the sleeve was larger than that of the segment of the prosthesis), most of the implant surfaces were surrounded by gaps or cavities.

Table 1 shows details of the findings in the CASPAR group of the proximal part. The average gap percentage in these specimens was 2.9% (range 0.3%–3.4%); the average percentage of cavity in these specimens was 3.9% (range 0–7.4%); the average percentage of bone contact was 93.2%; the maximum gap width in the CASPAR group was 0.81 mm, the mean gap width was 0.20 mm (range 0.04–0.28 mm). The results in the manual group are given in Table 2. The average gap percentage was 32.8% (range 25.1%–39.9%); the average percentage of cavity in these specimens was 7% (range 0–15%); the average percentage of bone contact was 60.1% (range 25.3%–70.4%); the maximum gap

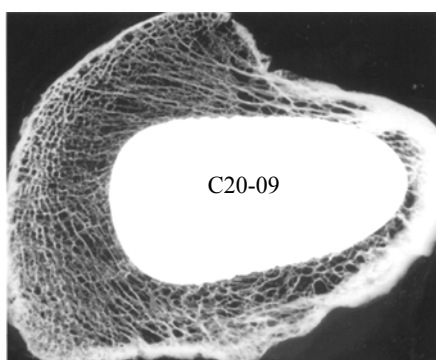


Fig.1 Bone-implant interface of the CASPAR group. The interface between implant and adjacent bone showed intact trabecular architecture. No gap was present in the proximal implant

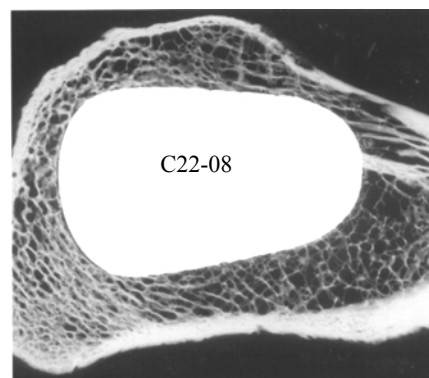


Fig.2 Bone-implant interface of the CASPAR group. Linear gaps were present in the interface

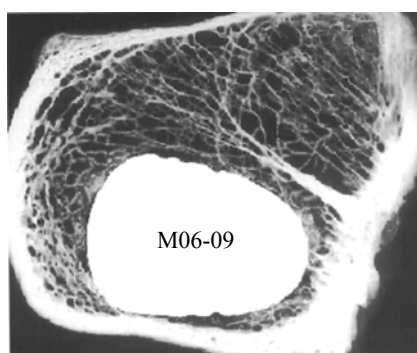


Fig.3 Bone-implant interface of the manual group. Relatively large and irregular gaps were present with adjacent trabecular bone crushed

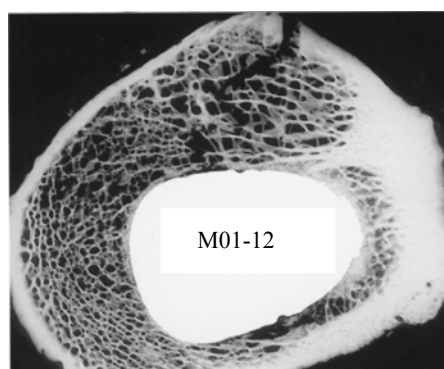


Fig.4 Bone-implant interface of the manual group. Femoral fissures can be detected in the specimens

width in the manual group was 2.97 mm, the average gap width was 0.77 mm (range 0.49–0.95 mm). Comparison of the results of the two groups for the proximal part is presented in Table 3. As summarised in Table 3, the gap in the CASPAR group was only 9% of that in the manual group. The maximum and average gap width were also much smaller in the CASPAR group, the maximum gap width was only about 28%, and the average gap width was only about 26% of that in the manual group (Table 3). Use of SPSS 10.0 (SPSS Inc.) software for statistical analysis showed that there was significant difference in bone contact rate, the maximum gap width and the average gap width between the two groups. No difference was detected in the percentage of cavity around the prosthesis. On the other hand, the CASPAR group showed 30% higher bone contact than the manual group (Table 3).

DISCUSSION

It is commonly acknowledged that a successful cementless component demands: (1) initial stability; (2) close apposition to bone; (3) bony ingrowth; (4) uniformity of stress transfer. For the femoral component, the 'fit' and 'fill' of the femoral canal is a critical factor. Many published studies demonstrated the clinical importance of a close match between the dimensions of the femur and the implant prosthesis (Amstutz *et al.*, 1991; Carlsson *et al.*, 1988; Collier *et al.*, 1988; Kim and Kim, 1992; Martell *et al.*, 1993; Noble *et al.*, 1988). It is only to expected that the implant should match the femur in size, and that a perfect femoral cavity for the implant can be made by robotic operator.

We found that the manual group had relatively large and irregular gaps around the prosthesis. The broaches used in our study were supplied by the

Table 1 The results of 5 specimens of the proximal part in the CASPAR group

Number	Bone contact (%)	Gap (%)	Cavity (%)	Max gap width (mm)	Average gap width (mm)
C13	89.2	3.4	7.4	0.81	0.28
C20	99.7	0.3	0	0.72	0.04
C22	87.6	7.8	4.6	0.78	0.28
C25	93.1	2.6	4.3	0.52	0.22
C28	96.3	0.5	3.2	0.31	0.17
Average	93.2	2.9	3.9	0.63	0.20
±SE	5.0	3.0	2.7	0.21	0.10

Table 2 The results of 5 specimens of the proximal part in the manual group

Number	Bone contact (%)	Gap (%)	Cavity (%)	Max gap width (mm)	Average gap width (mm)
M01	64.7	35.3	0	2.97	0.95
M03	64.1	28.0	7.9	2.08	0.87
M04	70.4	25.1	4.5	2.80	0.90
M05	52.3	39.9	7.8	1.29	0.49
M06	49.2	35.8	15.0	1.93	0.65
Average	60.1	32.8	7.0	2.21	0.77
±SE	9.0	6.1	5.5	0.68	0.19

Table 3 Comparison of the results of the CASPAR and the manual group

Number	Bone contact (%)	Gap (%)	Cavity (%)	Max gap width (mm)	Average gap width (mm)
CASPAR group	93.2±5.0	2.9±3.0	3.9±2.7	0.63±0.21	0.20±0.10
Manual group	60.1±9.0	32.8±6.1	7.0±5.5	2.21±0.68	0.77±0.19
F value	51.72	96.73	1.32	24.6	34.4
P	< 0.001	< 0.001	> 0.05	< 0.001	< 0.001

manufacturer of the femoral stem. The procedure was performed by a senior surgeon familiar with the technique of cementless THA. The procedure for preparing the femoral cavity was based on the guidelines of the manufacturer. The manual broaching and reaming of the canal created many gaps around the prosthesis. In the proximal part, the most important part for cementless femoral stem fixation, examination of the cross sections with bone and prosthesis of the manual group revealed that the average percentage gap around the prosthesis and the average percentage of bone contact were 32.8% and 60.1%, respectively (Table 3). The results of this study showed that the current techniques for preparing the femoral cavity using hand-held broaches and reamers have considerable inherent inaccuracy. Although the femoral stems seemed stable in the femur during the operation, the initially exact contact between bone and prosthesis in many areas was not reached; more than 1/3 of the implant surface coated with HA had no contact with bone. The widths in many of the gaps were larger than 1.0 mm, which means that in these areas, bony ingrowth into the prosthesis across the gaps would be difficult and unreliable. Compared to cortical bone, the cancellous femur bone could be easily torn out by the broach. Another potential problem is the tendency of the broach to bounce and destroy some bones around the cavity when it makes contact with cortical bones or dense trabeculae.

This study revealed that robotic system CASPAR can feasibly be used for accurate preparation of femoral cavity for cementless THA. Most of the surface of our implants showed close contact with the surrounding bones in the proximal part, where the average percentage of bone contact reached 93.2%, or 33% higher than that in the manual group. One of the specimens even reached 99.7% bone contact. The average percentage of gap around the implant was only 2.9%. While in the manual group, the gap percentage was about 32.8%. For some specimens, it could be possible that the initial orientation of the prosthesis implanted by the manual method was slightly different from that of the prepared cavity; and that the actual vertical position of the implant may be a little different from

that of the cavity. The fit of any cementless femoral component requires not only the precision of the cavity preparation but also the accuracy of the insertion of the implant.

The quality of the initial fit of the implant is correlated with the clinical and radiographic outcomes of THA without cement (Engh *et al.*, 1987). It is reasonable that implants with a good fit in the metaphyseal regions are indicative of improved stability and osseous ingrowth into the component. Besides the high percentage of initial stem contact with bone in the CASPAR group, the gap width in the CASPAR group was smaller than that in the conventional group (Table 3). In the proximal part, the average gap width in the CASPAR group was 0.20 mm, while the average gap in manual group was 0.77 mm; the maximum gap width was also much smaller in the CASPAR group, only about 26% of that in the manual group. Compared to the conventional operation, it was also easier for the bone to bridge the gaps in the implant-bone interface in the CASPAR group. Significant progress in surgical quality was achieved with the use of CASPAR. Prosthesis fit is often compromised because it is technically difficult to cut the bone precisely by hand. Bone ingrowth into cementless prosthetic components is difficult because of the gap between the prosthesis and the surrounding bone. Examination of the histological sections and corresponding microradiographs clearly demonstrated that direct contact between bone and prosthesis increased the osseous response to the implants (Bobyn *et al.*, 1981; Cook *et al.*, 1988; Dalton *et al.*, 1995; Lind *et al.*, 1996; Sandborn *et al.*, 1988). Dalton *et al.* (1995) evaluated the mechanical and histological response to femoral intramedullary implants with different gaps in dogs. They made the uniform initial implant-bone interface gaps range from 0 to 2 millimetres and found that mechanical attachment strength, bony ingrowth and gap filling were significantly affected by the interface gap size. Regression analyses suggested that mechanical strength and bony ingrowth increased significantly with decreased initial gap size ($P < 0.001$) and interface gap ($P < 0.001$), respectively. Sandborn *et al.* (1988) evaluated uni-

form gaps of 0.0, 0.25, 0.5, 1.0 and 2.0 millimetres in a study of femoral intramedullary implants in adult dogs. Substantial bony ingrowth was found in the gaps 0.5 mm or less, while in the 2.0 mm gaps, only limited, poorly organised bony ingrowth occurred at 12 weeks. The rate and degree of maturity and mineralization of new bone were better when the gap width is 0.5 mm or less. Although it is generally difficult to extrapolate the results of animal experiments to humans, it is certain that the lesser the gap is, the more is the bony growth into the prosthesis. From the results of our study, the accuracy at which CASPAR could machine the femurs was one order of magnitude greater than the accuracy obtained when manual broaches and reamers were used. It is reasonable to expect that the specimens in the CASPAR group should have more bone ingrowth into the prosthesis and greater mechanical attachment strength of the prosthesis because of the higher bone contact percentage and small linear gap.

In the cross sectional slices of the manual group, the compression from the broach and the prosthesis to surrounding bones was asymmetrical (Fig.3). Trabecular bone in some areas around the prosthesis was crushed to a high density while in other areas direct contact between the implant and bone was not reached. So the implant fit was patchy. The bony ingrowth into the prosthesis was fine in some areas while in other areas the bony ingrowth into the prosthesis was poor because of the gaps. This caused localized contact between bone and prosthesis and produced high local bone stresses instead of uniformity of stress transfer in the weight-bearing state. This might be one of the factors contributing to thigh pain (Barrack *et al.*, 1992). Such cases are more likely to cause thigh pain postoperatively. Significantly, no such phenomenon was observed in the cross sections of the CASPAR group (Figs.1–2). With the almost exact fit of component with metaphyseal and diaphyseal in the CASPAR group, the femoral component will receive uniform stress transfer in loading. Close intramedullary femoral component fit reduces the concentration of contact stress at the implant-bone interface; so the occurrence of thigh pain may de-

crease after cementless THA with the robotics assisted reaming.

Another technique used now to improve the intimate contact between the prosthesis and bone is called 'press-fit', in which the femoral instrumentation used to achieve an intimate fit between bone and prosthesis can be undersized compared with the real prosthesis depending on the hip system used (Amstutz *et al.*, 1991; Otani *et al.*, 1995; Robertson *et al.*, 1988; Robinson and Clark, 1996). This technique appears to help bony ingrowth into the prosthesis and is accepted by many orthopaedic surgeons. However, this may cause an intraoperative fracture—one of the complications that may contribute to failure of cementless THA (Capello *et al.*, 1994; Jasty *et al.*, 1992; Kold *et al.*, 2003; Martell *et al.*, 1993; Schutzer *et al.*, 1995). Kold *et al.*(2003) reported that 8 of 10 femurs with tamping and 2 of 10 femurs with broaching for preparing the femoral cavity had fractures using macroscopic inspection at the preoperative templated size, although none of the fractures could be detected on postoperative AP and lateral radiographs. Jasty *et al.*(1992) pointed out that postoperative radiographs usually are inadequate for showing linear undisplaced fractures, particularly with the femoral component in place. Undetected fractures dramatically decrease the stability of the femoral component. The influence of treated fractures on femoral component function is undefined. Canine studies showed that treated and untreated fractures restrain early bony ingrowth into prosthesis. Schutzer *et al.*(1995) studied the influence of intraoperative femoral fractures and cerclage wiring on bony ingrowth into porous coated femoral components in dogs. Micromotion analysis revealed a significant increase in rotational instability in fractures without fixation by cerclage wires ($P<0.05$) compared with the intact femur. The fractures have a significantly deleterious effect on bony ingrowth even after cerclage wiring.

With the use of robotic system, the intraoperative fractures are rare (Bargar *et al.*, 1998; Jerosch *et al.*, 1999; Paul *et al.*, 1992). Bargar *et al.* reported the result of one ongoing study in the USA, which included 134 hips (69 of robotic system and

65 of control). There were 3 intraoperative femoral fractures (cracks) in the control group and none in the robotic group ($P < 0.01$). In another ongoing study in Germany with robotic system, involving 900 primary THAs and 300 revisions, no fissures or fractures were detected during surgery or on the postoperative radiographs. In our study, we also found that all the implants were easily inserted into the femoral cavity in the CASPAR group with high percentage of bone contact, and without any intraoperative fracture or trabecular bone crush around the implant.

The role of robot assisted preparation of the femoral canal in cementless femoral component fixation is still controversial. Advantages of the robotic system with regard to precise planning and accuracy of the intraoperative procedure had been shown in a study by Honl *et al.* (2003), although there was higher complication rate in the robotic-operated group compared to the conventional one. An additional operation is needed for pin placement for robotic operation, and the operation time is longer than that of conventional operation (Honl *et al.*, 2003; Bargar *et al.*, 1998). Bargar *et al.* (1998) reported the surgical time and blood loss were significantly greater for patients in the robotic system group. Analysis of the increased surgical time for patients in the robotic group showed that intrinsic delays such as application of the fixation, docking, pin finding, and milling. The short-term clinical results of robotic system are not statistically significant different from those of conventional THA. But significant radiographic differences were found between the robotic and manual group. The radiographic result of the robotic group was much better than that of the control one.

Nogler *et al.* (2004) investigated the immediate postoperative stability of an anatomical stem (ABG I) implanted either manually or with robotic assistance in matched pairs of cadaveric femora in vitro. For the stem stability, no statistically significant differences were found between the two groups, although the size of the prosthesis was larger in four of seven pairs (57.1%) when the prosthesis was implanted with robotic assistance. Thomsen *et al.* (2002) reported an increased stability for the anatomic implants (ABG and Antega) by hand

broaching over robotic milling in synthetic femora. It seemed that the anatomic stem is not suitable for preparing the femoral canal by robot, because it needs more space for manipulating the drill head around the curved stem and therefore gaps are produced between the stem and bone bed. We use the straight cementless stem in our study (Osteolock). With use of the same stem, Thomsen *et al.* (2002) compared the primary rotational stability in synthetic femora subjected to robotic milling and hand broaching. They reported increased stability for the implant by one robotic system (Robodoc), but no difference between the Caspar robotic system and hand preparation. Nevertheless, because of their use of synthetic bones and only 3 specimens, comparability of this study is limited.

The practice of robotic system has only short follow-ups, the long-term result is not known. Our study showed clear advantage of CASPAR over the manual operation for preparing the femoral canal in dimensional accuracy. Further research is needed to evaluate the cost-efficiency of the robotic system.

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