Robotic bone preparation does not increase cement penetration into the proximal femur

A matched-pair cadaver study comparing hand-broaching versus robotic bone preparation

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ABSTRACT **In a cadaver study, we prepared 20 matched pairs of human femora using chipped-tooth broaches and robotic milling with the same geometry. For robotic bone preparation the CASPAR robotic system with a rotating milling head was used. Cancellous bone was irrigated with 1 liter of pulsed lavage and the specimens were embedded in specially-designed pots. After vacuum mixing, bone cement was introduced in a retrograde manner and subjected to a standard pressure protocol with a constant force of 3,000 N. Radiographs were taken and horizontal sections were obtained at predefined levels, using a diamond saw. Microradiographs of the bone slices were taken, digitized and analyzed to assess cement penetration into cancellous bone. No femoral fractures or fissures occurred with either preparation technique. The microradiographic evaluation showed no morphometric differences between chipped-tooth broaches and robotic milling as regards cement penetration into cancellous bone. Therefore, in the presence of pulsed lavage, we conclude that robotic bone preparation does not increase cement penetration into cancellous bone of the proximal end of the femur.**

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Modern cementing techniques with the introduction of an intramedullary plug permitting cement containment and insertion of cement under pressure have been shown to reduce aseptic loosening in several clinical studies (Harris et al. 1982, Harris and McGann 1986, Russotti et al. 1988, Mulroy and Harris 1990, Barrack et al. 1992, Schmalzried and Harris 1993, Britton et al. 1996). The results of the Swedish Hip Register (Malchau et al. 1993, Malchau and Herberts 2000) confirmed this correlation. Modern cementing techniques aim to improve the interdigitation between bone and cement thus creating a more durable interface. With increased depth of cement penetration, the strength of the cement-bone interface is enhanced (Halawa et al. 1978, Krause et al. 1982, Panjabi et al. 1986, MacDonald et al. 1993, Mann et al. 1997). Pressurization and pulsatile lavage of cancellous bone have proved to be the main factors for improvement in cement penetration and, in consequence, greater shear strength (Markolf and Amstutz 1976, Halawa et al. 1978, Lee and Ling 1981, Krause et al. 1982, Noble and Swarts 1983, Askew et al. 1984, Panjabi et al. 1986, Bannister and Miles 1988, MacDonald et al. 1993, Majkowski et al. 1993, Mann et al. 1997).

However, relatively little is known about the way in which cement penetration is affected by various bone/canal preparation techniques (DiGiovanni et al. 1999). The effect of various broach surface finishes on cement penetration in the presence of jet-lavage has been studied and no substantial difference in cement penetration has been found with either broach finish (Breusch et al. 2000a). Theoretically, broaches partly remove and compact cancellous bone, thus occluding the cancellous spaces with debris and thereby limit-

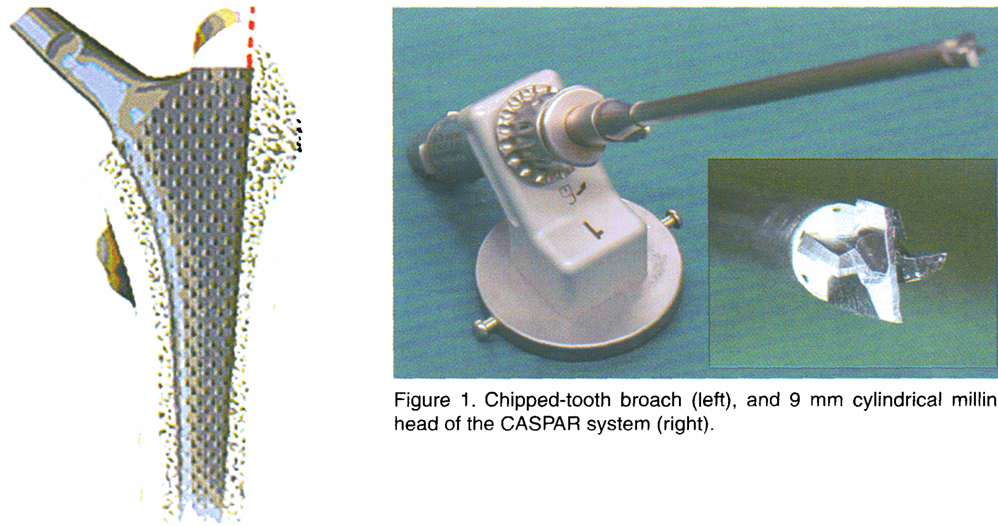

Figure 1. Chipped-tooth broach (left), and 9 mm cylindrical milling head of the CASPAR system (right).

ing the depth of cement penetration. On the other hand, robotic devices for bone preparation (Paul et al. 1992) with rotating cylindrical milling devices only cut and remove cancellous bone under constant low volume irrigation without compression and therefore open cancellous spaces very precisely. In theory, this method of preparation should permit an improved cement penetration. To clarify this question, we studied the effect of robotic bone preparation with a milling device on cement penetration into human bone in a standardized model, using jet-lavage, and compared it to the commonly used chipped-tooth broaches.

Material and methods

20 fresh frozen matched pairs of human cadaver femora (10 pairs) were obtained for this study. Radiographs of all specimens were taken, and the cortical index (CI) was determined to ensure equal femoral configuration. Templates were used to determine the broach size before canal preparation. In each pair, a broach size that would preserve a 3 mm minimum mantle of cancellous bone was chosen.

Palacos R bone cement (Biomet-Merck, Darmstadt, Germany) was used to cement the femur. The bone cement was prechilled at 4 °C before mixing. The mixing protocols followed the manufacturer's recommendations. The Easymix Uno vacuum mixing system (Coripharm GmbH & Co. KG, Dieburg, Germany) was used.

On all specimens, a femoral neck osteotomy with an oscillating saw was performed by a single surgeon (PRA). Care was taken to ensure identical levels of resection of left and right specimens. Each matched femoral pair was randomly allocated to the hand-broaching group on one side and the robotic milling group on the contralateral side. In the hand-broached group, the femoral canal was opened, using a T-handled starting hand reamer and the canal was broached using G2 broaches (Figure 1) (DePuy Orthopedics, Leeds, UK) of the selected size. Care was taken not to malalign the broach. After broaching of the hand group, CT-scans of the specimens were taken and the extent of the broached cavity was measured. In the robotic preparation group, fiducial markers were placed in the greater trochanter and the medial condyle of the femur to permit intraoperative detection of the bone by the robotic system. CT-scans were taken, using a standard femoral implant planning protocol (CASPAR, URS-Ortho). The identical geometry of robotic milling was planned, using the CT-scans of the hand-broached cavities of the corresponding contralateral femora and the standard G2 milling program.

For robotic canal preparation, we used a Computer-assisted Planning and Robotics system (URS-Ortho, Rastatt, Germany). The femora were firmly fixed with a metal clamp to prevent motion during the milling process. To prepare the cavity, we used a 9 mm cylindrical milling device (Figure 1) rotating at 55,000 revolutions per minute under constant low volume saline irrigation.

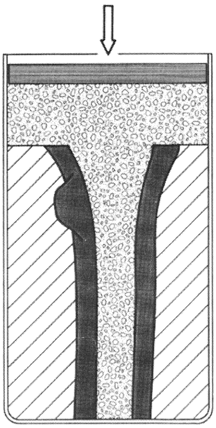

Figure 2. Experimental configuration of a femur embedded in a pot using plaster of Paris. Bone cement is placed in the femoral canal and up the top of the canister. A 3000 N load is applied to the canister lid, pressurizing the femoral canal in a controlled manner permitting standardized cement penetration.

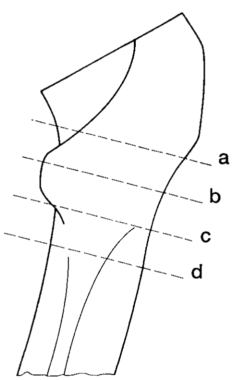

Figure 3. Locations of bone sections from harvested femora (a–d).

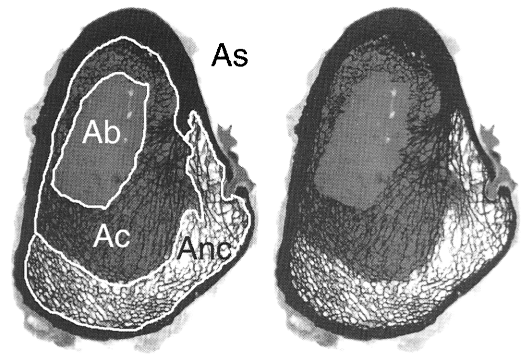

Figure 4. Microradiograph of the femoral cross-section with regional definitions used in image analysis. The definitions of abbreviations are listed below.

As: Entire cross-sectional area of the femur.

Ab: Cement cross-sectional area without cancellous bone (reflecting the broach cavity).

Ac: Cross-sectional area of the region of cancellous bone filled with cement.

Anc: Cross-sectional area of the region of cancellous bone not containing cement.

After canal preparation, the femoral specimens were cut transversely at midshaft level. All bone beds were irrigated, using 1 L jet-lavage (Micro Aire Hi Speed Pulse Lavage, type 4740 with tubing set total hip, Micro Aire Surgical Instruments, Charlottesville, Virginia, USA). The specimens were then placed in specially-designed plastic pots and embedded in plaster of Paris, so that the proximal osteotomy was level with the plaster (Figure 2). After setting of the plaster, the vacuum-mixed bone cement was introduced at 2 minutes in a retrograde manner, using a cement gun. No pressure was applied during the insertion of cement. Hand-mixed Palacos R bone cement was used to fill the remaining space in the pot and served as a reservoir during compression. After manual placement of the lids, the pots were placed in a compression device (Universalprüfmaschine Frank 81816/B). A 3000 N force, corresponding to an intrafemoral pressure of about 370 kPa, was applied at 4 minutes after mixing. This force was maintained for 7 minutes. The force applied had been calculated and chosen according to intrafemoral pressures published previously (Song et al. 1994). After storage of the pots for 48 hours at room temperature, the specimens were retrieved, and radiographs were taken. Standardized horizontal sections were obtained from the proximal femora using a diamond saw (Figure 3). A reference section was first taken at the level of the lesser trochanter. 1 section proximal (+10 mm), and 2 sections distal (–10 mm and –20 mm) to the reference were taken (Figure 3). Microradiographs were obtained using a Faxitron machine (model 43855C, Rhode & Schwarz) (Figure 4). The radiographs were digitized using a scanner and analyzed using image analysis software (Kontron KS 300, Kontron Elektronik GmbH). The entire cross-sectional area of the femur (As), the cement cross-sectional area without cancellous bone (Ab) (reflecting the broach cavity), the cross-sectional area of the region of cancellous bone filled with cement (Ac), and the cross-sectional area of the region of cancellous bone not containing cement (Anc) were determined (Figure 4). The area of cancellous bone in the cement (Abd) also was measured as an indicator of bone quality. From the aforementioned measurements, the following parameters were determined and statistically analyzed:

$$(1)\quad CP\,(\%) = \frac{Ac + Ab}{As} \times 100$$

$$(2)\quad Rcb\,(\%) = \frac{Ac}{Anc} \times 100$$

$$(3)\quad p\,(\%) = \frac{Abd}{Ac} \times 100$$

CP is defined as the cement penetration into cancellous bone, Rcb is the ratio of the region of supported cancellous bone to unsupported cancellous bone, and p is the relative area of trabecular bone in the cement. The distribution of the parameters for the two experimental groups are described by mean and standard deviation for each section area separately.

Statistics

To assess the influence of the preparation method on the parameters, two-way analyses of variance with the preparation method and section level as factors, considering the repeated measures design in both factors, was performed. Cement penetration was chosen as the main parameter and only the evaluation of this parameter can strictly be interpreted as confirmatory. The significance level was fixed at $\alpha = 5\%$. To determine the effect of the preparation method in detail, we calculated two-sided 95% confidence intervals for the mean difference between the robotic and the hand preparation method for each level separately.

Results

No femoral fractures or fissures occurred with either preparation method. There were no differences in the cross-sectional areas, which confirms that horizontal cuts were made from the same location on femoral pairs (Figure 5).

The variance analysis of the cement penetration (CP) revealed no significant effect of the preparation method (Figures 6 and 7) (effect of preparation: $p = 0.07$; effect of section area: $p < 0.0001$; interaction: $p = 0.1$). The method of preparation likewise had no significant effect on the RCB-ratio (effect of preparation: $p = 0.2$; effect of section

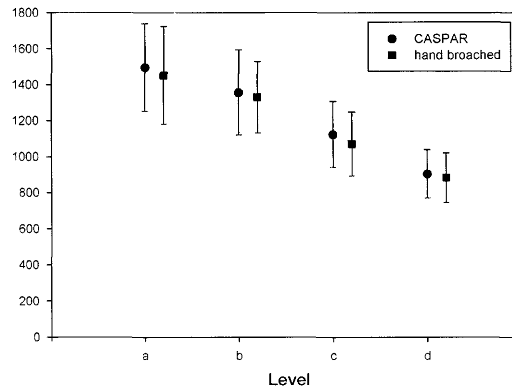

Figure 5. Cross-sectional areas on the a-d levels (CASPAR n = 10, hand broached n = 10).

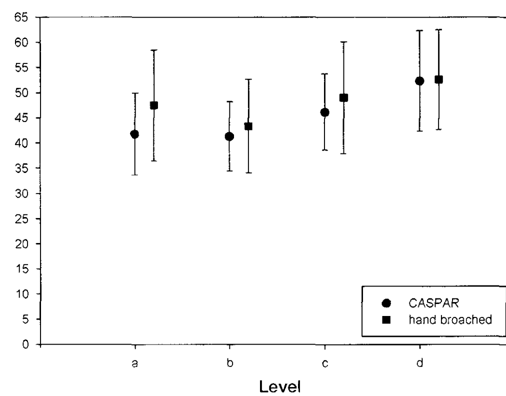

Figure 6. Cement penetration on the a-d levels (CASPAR n = 10, hand broached n = 10).

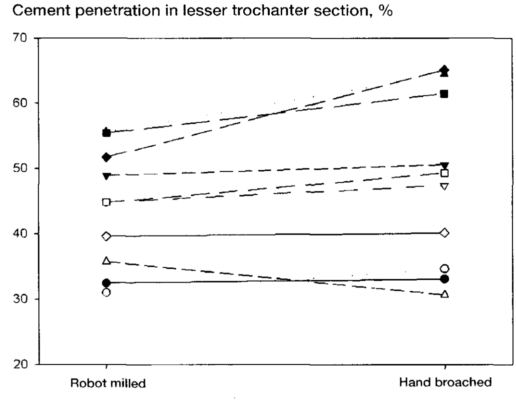

Figure 7. Cement penetration (CP) in matched femoral pairs, bone bed preparation by robot milling or chipped-tooth hand broach taken at the level of the lesser trochanter. There was no significant difference between preparation methods as regards CP.

Differences between CASPAR and broach preparation method regarding the parameters measured

Parameter	Section level	Mean	95%confidence interval
As	1	44.4	–52.7 to 141.5
	2	26.7	–82.3 to 135.7
	3	53.2	–15.4 to 121.8
	4	21.6	–15.6 to 58.8
CP	1	–5.6	–11.0 to –0.2
	2	–2.0	–5.8 to 1.8
	3	–2.9	–7.0 to 1.3
	4	–0.3	–4.4 to 3.9
Rcb	1	–19.7	–49.6 to 10.2
	2	–8.8	–28.8 to 11.1
	3	–50.1	–133.6 to 33.4
	4	–182.7	–449.0 to 83.7
p	1	–4.5	–6.5 to 5.5
	2	1.9	–13.1 to 16.9
	3	1.5	–4.9 to 8.0
	4	–5.6	–12.5 to 1.3

AS Entire cross-sectional area of the femur.
CP Cement penetration into cancellous bone.
Rcb Ratio of the region of supported cancellous bone to unsupported cancellous bone.
p Relative area of trabecular bone in the cement.

area: $p < 0.0001$; interaction: $p = 0.7$) or on the trabecular bone areal density (p) (effect of preparation: $p = 0.8$; effect of section area: $p = 0.1$; interaction: $p = 0.4$).

It is clear from the confidence intervals (Table) that differences between the two preparation methods in favor of the CASPAR method can be excluded for all parameters investigated (AS, CP, RCB and P). If there had been an effect that we did not detect due to the small number of specimens investigated, it would have been in favor of the hand-broached group.

Discussion

Robotic systems were introduced in the early 1990s (Paul et al. 1992) for femoral canal preparation of uncemented hip stems. Various studies have shown the ability of robotic systems to machine accurately cancellous bone after preoperative planning and improve implant fit in the femoral canal (Börner et al. 1997, Bargar et al. 1998, Jerosch et al. 1998, Jerosch et al. 1999).

Primary rotational stability of uncemented stems has been studied in a plastic bone model, using broaches and robotic milling for femoral canal preparation (Thomsen et al. 2002). In that study, 4 stem types were more stable with hand-broaching and 5 stem types were more stable with robotic bone preparation. In recent studies using uncemented femoral components, it has been shown in cadaver and animal experiments that the primary and secondary stability of stems was improved when bone compaction with chipped-tooth broaches was implemented (Green et al. 1999, Chareancholvanich et al. 2002). Therefore in uncemented stems there is no proven advantage of robotic systems as regards implant stability.

However, this technique has now been considered beneficial for cemented THA. The theoretical advantages of cancellous bone milling with preoperative 3D planning include preservation of an even cancellous bone mantle, constant low volume irrigation with removal of debris from the femoral canal and accurate bone cutting leaving cancellous spaces open for cement interdigitation.

The pressures used in our study correspond well to the values given in the literature. In previous studies, intrafemoral pressures were found to vary between 30 kPa and 1080 kPa, depending on the location, stem type or time (Song et al. 1994, McCaskie et al. 1997). Our model eliminates the variable stem insertion thus allowing standardized conditions for comparison of a single factor, here the mode of femoral bone preparation (Breusch et al. 2001).

Regarding cement penetration, it is important to note that in the presence of jet-lavage there was no significant difference between broaches and robotic milling. Even if there might be less compaction and cancellous debris using the robotic system, the jet-lavage system used in our study effectively removed remaining debris from the cancellous spaces. The volume used may appear high, but it is our practice to use copious lavage for canal preparation and again immediately before cement insertion. One might expect different findings in the absence of jet-lavage, but we did not consider such an investigation as appropriate. Jet-lavage should be regarded mandatory for achieving cement interdigitation with cancellous bone in cemented THA (Breusch et al. 2000b). Therefore, in the presence of pulsed lavage, we conclude that robotic bone preparation does not increase cement penetration into cancellous bone of the proximal end of the femur.

Our results also confirm that the mode of femoral bone preparation is not of critical importance as regards cement penetration if jet-lavage is used. More anatomical and clinical studies are required to prove a potential benefit of robotics in hip surgery and justify the high cost of these systems.

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No competing interests declared.

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