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Cement penetration and stiffness of the cement-bone composite in the proximal tibia in a porcine model

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ABSTRACT

Purpose. To assess the stiffness of the cement bone composite and the depth and uniformity of cement penetration into the surface of the tibial component during total knee reconstruction in a porcine model.
Methods. The effectiveness of 3 protocols were compared: 2 commonly used cementing techniques—finger-packing of cement on the cut surface followed by impaction, and coating of the undersurface of the prosthesis with cement followed by impaction—and a new method using a tibial cement-pressurising device. Cement penetration was measured by computed tomography; stiffness was determined by hydraulic penetration testing.
Results. Cement penetration at a depth of 1 mm was significantly greater following coating the undersurface of the prosthesis than following finger-packing (p=0.008). There was no significant difference at deeper levels or between the tibial-pressurising device group and either of the 2 other groups at any level (p>0.3 in all cases). Differences in surface stiffness by tibial plateau region were found in tibiae that had been cemented using finger-packing and in those that had had their undersurface coated, but not in tibiae that had been cemented using the tibial-pressurising device.
Conclusion. The tibial cement-pressurising device eliminated regional differences in stiffness seen with other cementing methods. Elimination of these differences by using this device should reduce micromotion and the incidence of aseptic loosening of tibial base plates in total knee arthroplasty.

Key words: *arthroplasty; bone cements; knee joint; tibia*

INTRODUCTION

A major problem affecting the success of total knee replacement (TKR) is loosening of the tibial component,

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which is believed to be due to micromotion at the cement-bone interface.[1,2] Micromotion is the microscopic rocking of an implant against the cut tibial surface, leading to depression of one side of the implant and elevation of the contralateral side. The degree of fixation at the cement-bone interface, and hence the amount of micromotion, is thought to depend on the penetration of cement into the trabecular bone.[2,3] Deep penetration of cancellous bone by cement has been shown to reduce micromotion and posterior lift-off, and to be important in achieving durable rigid fixation.[2]

Cement penetration into bone is directly proportional to the bone pore diameter and the square root of the pressure applied to the cement; it is also inversely proportional to the time from initial mixing of the cement.[4] Penetration of cement is increased by using high-volume, high-pressure pulsatile lavage to clean the cut surface, by ensuring that the cement viscosity is low,[4–6] and by increasing the duration that pressure is applied to the cement.[4] In contrast, penetration of cement is decreased in sclerotic bone[7]; peripheral penetration is decreased by cement leakage around the edges of the prosthesis.[4,7,8]

Increased cement penetration has been shown to increase tensile and shear strengths of the cement bone interface.[4,6] Although less than 1 to 2 mm of cement penetration results in a weak cement-bone interface, predisposes to micromotion,[7,9] and can lead to radiological evidence of loosening,[4] greater than 5 mm of penetration can lead to heat-induced necrosis of bone, does not increase the strength of the interface, and results in increased loss of bone stock if revision arthroplasty is required.[4,7] Optimal cement penetration thus occurs at a depth of 3 to 5 mm.[4,7] In addition, the use of clamp fixation, which has been described for the proximal tibia,[10] provides a large initial pressure, a lack of variance in force over time, and deep cement penetration, and also allows the surgeon to concurrently cement the other components.

The tensile and shear strengths of the cement-bone interface have been assessed.[4,6] Nevertheless, their relevance to the clinical setting has not been established, because tensile and shear stresses that may pull the tibial component from the bone are not commonly experienced during TKR in situ. It has been postulated that increasing the tensile and shear strengths of the cement-bone interface should decrease micromotion.[4,6] Hence, the stiffness of the cement-bone composite being compressed is likely to be relevant to micromotion and loosening of the tibial component. This concept is supported by evidence of increased subsidence of uncemented tibial components in tibiae with low bone mineral density (although this relationship is eliminated by the use of cement).[11]

Although the stiffness of trabecular bone in normal, osteoarthritic, and rheumatoid knees has previously been examined,[12,13] the stiffness of the cement-bone composite has not. This study sought to investigate cement-bone stiffness in an in vitro porcine model, by using 2 commonly practised cementing techniques and a novel clamp-cement pressuriser that was developed by our group in 2002. This tibial-pressurising device (TPD) allows constant pressure to be applied to the surface of the tibial component during TKR. The TPD is mounted firmly onto the anterior surface of the tibia via fixation pins, and pressure is applied with a removable screw-clamp mechanism that is attached to the main body of the TPD. The fixation pins use the same holes as those used by the tibial cutting guides during bone removal in the preparation of the tibial component.

METHODS

20 cadaveric juvenile porcine tibiae were randomly allocated into 4 groups. The tibiae were cut through at the metaphysis using an oscillating saw, and the metaphyseal bone was analysed in a bone densitometer (DEXA; Lunar Prodigy Bone Densitometer, GE Lunar Corporation, Madison [WI], US) to ensure uniformity of the 4 groups. The cut surface was then prepared with high-pressure, high-volume pulsatile lavage with normal saline. Polymethylmethacrylate cement (Surgical Simplex; Stryker Howmedica Osteonics, Allendale [NJ], US) was prepared according to the manufacturer’s instructions at the ambient temperature of 22°C and applied 3 minutes after mixing. A 10.0 cm x 10.0 cm x 0.5 cm flat, cold-worked piece of stainless steel was used to simulate a prosthesis.

In the first group of tibiae (the finger-packed group), cement was packed into the cut surface with digital pressure. In the second group (the undersurface group), undersurface of the model prosthesis was coated with cement. In these two groups, the model prosthesis was then impacted with a mallet and manual pressure was applied until the cement cured. For the third group (the pressuriser group), cement was applied to the cut tibial surface, the model prosthesis was impacted in the same way as in the first two groups, and pressure was then applied with the TPD. The fourth group (the controls) received no cement or implant.

The specimens were wrapped in saline-soaked towels and frozen at -30°C until analysis. Computed tomography (CT) was performed using a High Speed Advantage CT system (General Electric, Milwaukee [WI], US), which scanned 1-mm slices parallel to the cut surface of the tibia. Imaging conditions were the same for all scans. One researcher analysed the digital CT images to a depth of 5 mm, using special software (IDL Version 4; Research Systems Inc., Boulder [CO], US). On each image, the cortical rim of each slice was outlined manually so that cortical bone and soft tissue could be excluded from the analysis. The penetration of cement into the cancellous metaphyseal bone was calculated as the percentage of pixels within the manually traced area that had a grey-scale reading of greater than 150. This 150 level was chosen as the threshold because scans through metaphyseal trabecular bone that did not contain cement yielded no pixels when the background grey-scale reading was adjusted to greater than 150. To assess the measurement precision, the analysis was repeated 10 times at a depth of 2 mm on one specimen chosen at random (the fourth specimen from the undersurface group).

The tibiae were then thawed and tested for indentation. A 1.5-cm thick slice was cut from the tibial plateau of each specimen, and the cemented surface was placed face-down on a cleaned latex-covered stainless-steel plate and encircled by a 2-cm deep stainless steel cylindrical mould, which was then filled with polymethylmethacrylate cement. After the cement had set, the specimen was inverted and the tibial plateau, which was embedded horizontally in the cement, was examined. A line was drawn across the plateau between points defining the maximum mediolateral width of the specimen. This line was divided into thirds by perpendicular lines creating 6 regions: anteromedial, anterior intercondylar, anterolateral, posterolateral, posterior intercondylar, and posteromedial. Indentation tests were performed to a depth of 0.5 mm at a rate of 2 mm per minute,[12] after the flat end of a cylindrical indenter (diameter, 4 mm) had been fixed to the actuator of a hydraulic materials-testing machine (Instron model 8511; Instron Pty Ltd, High Wycombe, UK). Four tests were performed in each region. We determined stiffness by calculating the slope of the linear region of the loading curve.

Table 1
Cement penetration for each study group, expressed as the percentage of total surface area, by depth of analysis

Group	% of penetration, by depth Mean (SD)				
	1 mm	2 mm	3 mm	4 mm	5 mm
Finger-packed	55 (14)	42 (9)	14 (4)	4 (2)	3 (2)
Undersurface	78 (8)	46 (11)	21 (10)	7 (4)	4 (4)
Pressuriser	64 (6)	43 (19)	15 (8)	6 (4)	5 (5)

Statistical analysis was performed using univariate and repeated measures analysis of variance, as well as Tukey's Honestly Significant Difference post-hoc tests (SPSS 11.5 for Windows, SPSS Inc., Chicago [IL], US).

RESULTS

The mean bone mineral density of the tibiae was 0.88 g/cm^2 (standard deviation [SD], 0.40 g/cm^2), and no statistically significant differences in bone mineral density were seen between the 4 groups (univariate ANOVA, $p=0.317$).

In the assessment of measurement precision, the coefficient of variation (SD as a percentage of the mean) for the determination of the extent of cement penetration was 0.65% (mean, 27.6%; SD, 0.18%). This very low coefficient of variation indicates that the results are precise. Cement penetration data, by depth of analysis are shown in Table 1. Independent ANOVAs were performed for each depth. Cement penetration at 1 mm was significantly greater for a prosthesis with a cement-coated undersurface than for one that had been finger-packed ($p=0.008$). There was no significant difference at deeper levels or between the TPD group and either of the 2 other groups at any level ($p>0.3$ in all cases).

The surface stiffness results are shown in Table 2. The mean overall stiffness of each cemented group was significantly greater than that of the control group ($p<0.001$). Coating the undersurface of the prosthesis with cement produced a greater mean overall stiffness than did the other two cementing techniques ($p<0.001$). Significant differences were found between different regions in the control group ($p<0.001$), finger-packed cement group ($p=0.019$), and undersurface cement group ($p=0.038$). Differences, however, were not found after TPD use ($p=0.621$).

DISCUSSION

Cement penetration of the tibial metaphysis was significantly affected by the method of cement pressurisation. Coating the undersurface of the prosthesis with cement followed by impaction with a mallet produced significantly greater cement penetration at a depth of 1 mm than did finger-packing of the cut tibial surface followed by impaction. No

Table 2
Bone-composite stiffness for each study group, by tibial plateau region

Group	Stiffness, by region[*] Mean (SD) (N/mm)							p value[†]
	AM	AI	AL	PL	PI	PM	Overall	
Control[‡]	623 (199)	591 (319)	1104 (454)	1202 (467)	922 (531)	939 (296)	897 (441)	<0.001
Finger-packed	1438 (422)	1235 (378)	1291 (464)	1416 (337)	1566 (421)	1640 (435)	1431 (427)	0.019
Undersurface	1941 (458)	1771 (383)	2058 (475)	2139 (536)	2228 (521)	2153 (617)	2038 (517)	0.038
Pressuriser	1525 (549)	1316 (528)	1425 (519)	1367 (410)	1425 (291)	1357 (330)	1471 (458)	0.621

[*] AM denotes anteromedial, AI anterior intercondylar, AL anterolateral, PL posterolateral, PI posterior intercondylar, PM posteromedial
[†] Univariate ANOVA
[‡] Non-cemented bone

significant differences were shown between use of the new TPD and use of the other two techniques. The stiffness of the cement-bone composite was also significantly affected by the cementing technique. Coating of the undersurface of the prosthesis with cement followed by impaction produced the most uniform distribution of cement-bone composite stiffness, which was consistent with the cement penetration results.

Regional differences in surface stiffness were found in the control tibiae that were not cemented. The TPD was the only method of cementing that eliminated these regional differences. This greater uniformity of stiffness across the tibial plateau may reduce micromotion and loosening of the tibial component after total knee arthroplasty.

The mean bone mineral density of the tibial metaphysis of a population undergoing TKR has been found to be 0.81 g/cm^2 (range, 0.15–1.33 g/cm^2),[11] which is similar to that found in the porcine tibiae of this study. The mean stiffness of different regions of the cut surface of the tibia from patients undergoing TKR for osteoarthritis shows wide variation, ranging from 586 N/mm (SD, 203 N/mm) to 1786 N/mm (SD, 807 N/mm).[12] The stiffness of the control porcine tibiae in our study fell within this range. These 2 properties support the validity of the porcine model that we used.

When we mounted the tibiae for indentation testing, we needed to hold the cement surrounding the sample with clamps; when there was an uneven base, washers were used for support. It is possible that some settling occurred at the site of these supports during testing. There may also have been some error in the angle of indentation, despite efforts to ensure that it was perpendicular to the area being tested. However, these potential errors would not have favoured any particular study group.

The use of cement increases the stiffness of cancellous bone and should reduce micromotion and the incidence of aseptic loosening of tibial base plates in TKR. The cementing technique should aim at producing consistent stiffness across the cement-bone composite. In this study, penetration was maximised by coating the undersurface of the prosthesis and impacting the cement with a mallet; however, this method also produced regional variations in stiffness. The most uniform stiffness was achieved by the use of the TPD. The TPD also leaves the surgeons' hands free to work on the femur during tibial cement pressurisation.

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