The effects of fluid penetration and interfacial porosity on the fixation of cemented femoral components

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We have investigated the role of the penetration of saline on the shear strength of the cement-stem interface for stems inserted at room temperature and those preheated to 37°C using a variety of commercial bone cements. Immersion in saline for two weeks at 37°C reduced interfacial strength by 56% to 88% after insertion at room temperature and by 28% to 49% after preheating of the stem. The reduction in porosity as a result of preheating ranged from 71% to 100%. Increased porosity correlated with a reduction in shear strength after immersion in saline ($r = 0.839$, $p < 0.01$) indicating that interfacial porosity may act as a fluid conduit.

Debonding of the cement-stem interface, followed by failure of the cement mantle, has been implicated as a cause of aseptic failure in cemented total hip arthroplasty.¹⁻¹⁵ Previous studies have found that debonding of the cement-stem interface is likely to initiate failure of the cement mantle and may provide a pathway for wear debris to migrate distally.^{14,16-18} Clinical studies have shown that polished implants with early signs of debonding of the cement-stem interface have a higher rate of loosening than stems with no debonding.^{9,19} Retrieval studies have also reported that debonding may occur soon after implantation.^{10,20-22} Laboratory studies have shown that the shear strength of the cement-stem interface decreases under physiological conditions by more than 60% after 24 hours and by more than 80% after two months.²³⁻²⁵ The mechanism of this deterioration is unknown, although penetration of fluid into the interface and stress relaxation of the cement have been implicated.

Our aim was to investigate the effect of the penetration of fluid on the strength of the cement-stem interface and the consequence of reducing interfacial porosity.

Materials and Methods

Preparation of specimens. The experimental model was designed to simulate *in vivo* surgical insertion of the stem using comparable materials of similar dimensions and appropriate cementing techniques (Fig. 1).²⁶ Cobalt-chromium cylinders 140 mm long and 126 mm in diameter with rounded ends and a surface

Fig. 1

Diagram of the experimental apparatus.

roughness of 0.889 μm , were used to simulate femoral stems. Sawbones cylinders (Pacific Research Laboratories, Vashon, Washington) 40 pounds per cubic feet, 36 mm in diameter and 75 mm long with a cavity 20 mm in diameter and 60 mm deep were used to simulate femora. The preheated stems were held at 37°C for a minimum of one hour in a temperature-controlled oven (Isotemp Lab Oven 106G; Fisher Scientific, Pittsburgh, Pennsylvania) before use.²⁶ A custom-built centraliser was used during polymerisation to control the stem and to produce a uniform, cement mantle 4 mm thick and 10 mm long, beyond the tip of the stem. In order to determine the maximum polymerisation temperature a thermocouple (Model 5TC-GG-J-20-36; Omega Engineering

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Table I. Details of the results given as the mean (SD)

Cement	Initial stem temperature	Maximum polymerisation temperature (°C, n = 8)	Polymerisation time (min, n = 8)	Shear strength of cement-stem interface			Porosity at the cement-stem interface (% area, n = 8)
				Immediately tested (MPa, n = 80)	After 2 weeks in 37°C saline (MPa, n = 8)	After 2 weeks in 37°C air (MPa, n = 8)	
Depuy 1	Room temperature	49.9 (2.7)	6.9 (0.4)	0.92 (0.19)	0.14 (0.06)	1.20 (0.39)	35.6 (20.8)
	37°C	52.3 (4.3)	5.9 (0.8)	1.68 (0.25)	0.81 (0.23)	1.57 (0.41)	0.8 (0.8)
Depuy 3	Room temperature	50.1 (4.1)	7.5 (0.5)	0.93 (0.12)	0.47 (0.21)	1.07 (0.23)	19.4 (12.7)
	37°C	53.9 (3.3)	6.4 (0.5)	1.27 (0.25)	0.98 (0.24)	1.45 (0.19)	0.1 (0.1)
Osteobond	Room temperature	50.1 (3.2)	7.9 (0.8)	1.18 (0.13)	0.17 (0.06)	1.01 (0.30)	45.8 (4.4)
	37°C	51.8 (3.3)	7.3 (1.0)	1.88 (0.12)	1.36 (0.19)	1.79 (0.18)	0.1 (0.1)
Palacos R	Room temperature	47.5 (3.7)	7.3 (0.5)	0.59 (0.12)	0.14 (0.11)	0.70 (0.30)	50.5 (10.5)
	37°C	50.6 (1.8)	6.6 (0.5)	1.39 (0.47)	1.13 (0.31)	1.60 (0.30)	14.6 (4.9)
Simplex P	Room temperature	47.8 (3.6)	7.6 (0.7)	1.38 (0.18)	0.44 (0.11)	1.46 (0.47)	15.8 (3.2)
	37°C	54.3 (2.8)	6.4 (0.7)	1.84 (0.28)	1.24 (0.22)	1.75 (0.28)	0.1 (0.2)

Inc., Stamford, Connecticut) was placed at the cement-bone interface 5 mm from the bottom of the cement mantle. This had been established previously to be the optimal position for measuring the maximum polymerisation temperature.

The Sawbones cylinders were held in a water bath at 37°C for one hour before and during, polymerisation of cement. Five types of commercially-available bone cement were used: Depuy 1 (CMW 1; Depuy Orthopaedics, Warsaw, Indiana) and Depuy 3 (CMW3; Depuy Orthopaedics); Osteobond (Zimmer, Warsaw, Indiana) Palacos R (Biomet Orthopedics, Warsaw, Indiana); and Simplex P (Stryker-Howmedica-Osteonics, Mahwah, New Jersey). They were mixed for 90 seconds using a vacuum mixing system (Stryker-Howmedica-Osteonics) and then injected in a retrograde manner using a cement gun (Stryker-Howmedica-Osteonics). Two specimens were prepared from each package of bone cement. The stem was inserted three minutes after the initiation of cement mixing. The temperature at the cement-bone interface was measured using a chart recorder (Omegaline 790; Omega Engineering Inc.) for 20 minutes after insertion of the stem. The setting time was defined as the time from insertion of the stem until one minute after the maximum temperature had been reached.²⁷

The shear strength of the cement-stem interface was tested after one of three ageing conditions: immediately after cement polymerisation, after immersion for two weeks in normal saline at 37°C and after storage in air at 37°C for two weeks. For each type of cement, eight specimens were tested for each ageing condition. The polymerisation temperatures were recorded for the eight specimens which had been tested immediately. During the experiment the room temperature ranged from 19°C to 22°C.

Test methods. For static testing, the cement mantle and surrounding material were machined to create rings 20 mm thick with the base located 10 mm proximal to the tip of the stem. The stem distal to this was inserted into an aluminium block with a hole 12.7 mm in diameter. The free end of the stem was loaded in a MTS servohydraulic testing machine (MTS Systems, Eden Prairie, Minnesota) at a rate of 0.3 mm/sec using a self-centering proximal stem holder

to ensure true axial loading with minimal side loads. Compression ('push-out') tests were performed to determine the shear strength of the cement-stem interface. Failure was defined as a marked drop in load or when a displacement of the cement mantle of 1 mm had occurred along the stem.

Distribution of porosity. After mechanical testing, the cement mantle of every specimen which had been tested immediately was carefully removed and cut into longitudinal sections. Eight specimens of each group were prepared for the measurement of porosity. The pores on the interface were highlighted using black ink. The specimens were then photographed using a digital camera (Finepix 4700Z; Fujifilm, Tokyo, Japan) and analysed using Photoshop v. 7.0 (Adobe Systems Inc., San Jose, California) and NIH Image (National Institutes of Health, Bethesda, Maryland) to determine the percentage porosity at the cement-stem interface.

Statistical analysis. In order to analyse the effect of the temperature of the stem on the polymerisation time and temperature at the cement-bone interface, a two-way ANOVA for independent samples was done with one factor being the temperature of the stem and the other the type of cement. For the analysis of porosity a two-way ANOVA for independent samples was done with one factor being the temperature of the stem and the other the type of cement. In order to analyse the effect of the temperature of the stem on shear strength after one of three ageing conditions, a two-way ANOVA for independent samples with a *post hoc* Tukey test was performed for each type of cement, with one factor being the temperature of the stem and the other the ageing condition. Statistical significance was set at $p < 0.05$.

Results

Polymerisation time and temperature at the cement-bone interface. The mean (SD) polymerisation times and maximum temperatures during polymerisation are shown in Table I. The mean polymerisation time of the preheated stems was significantly shortened by 8% to 15% ($p = 7.42 \times 10^{-8}$) and the mean maximum temperature at the cement-bone interface was significantly elevated by 2.4°C to 6.5°C ($p = 1.52 \times 10^{-5}$) compared with the stems at room temper-

Fig. 2

Longitudinal sections of the cement mantle for the different types of cement. There are pores at the cement-stem interface. The column headings are as follows: x40, magnified view of corresponding section at room temperature; RT, at room temperature; 37°C, preheated to 37°C immediately before insertion.

Fig. 3

The effect of saline after ageing for two weeks at 37°C. Each symbol represents the mean of the specimens in the group.

ature. Osteobond bone cement showed no changes in polymerisation time or maximum temperature.

Distribution of porosity. Every specimen in the room temperature group showed extensive porosity at the cement-stem interface (Fig. 2, Table I), although the amount of porosity and the appearance of the pores varied between the types of bone cement. The mean porosity at the cement-stem interface significantly decreased when the stem was preheated ($p = 1.72 \times 10^{-30}$). This reduction in porosity varied from 71.1% to 99.8% depending upon the type of cement. While preheating usually eliminated more than 99% of interfacial porosity, specimens in the Palacos R group with heated stems and the Depuy 1 group with heated stems showed tiny pores at the cement-stem interface and within the cement mantle. In Palacos R specimens these pores were distributed evenly throughout the cement mantle.

Shear strength of the cement-stem interface. For all types of cement, the mean shear strength of the cement-stem interface significantly increased in all preheated stems compared with those at room temperature regardless of the ageing condition (CMW 1, $p = 4.52 \times 10^{-9}$; CMW3, $p = 3.25 \times 10^{-8}$; Osteobond, $p = 7.97 \times 10^{-21}$; Palacos R, $p = 2.32 \times 10^{-13}$; Simplex P, $p = 1.04 \times 10^{-7}$; Table I). After two weeks of immersion in isotonic saline at 37°C, the mean shear strength was significantly lower than that immediately after polymerisation (CMW 1, $p = 5.96 \times 10^{-9}$; CMW3, $p = 2.58 \times 10^{-5}$; Osteobond, $p = 5.10 \times 10^{-9}$; Palacos R, $p = 0.00396$; Simplex P, $p = 9.11 \times 10^{-9}$; Table I). The shear strength was the same or only slightly higher after ageing in air at 37°C than immediately after polymerisation (CMW 1, $p = 0.644$; CMW3, $p = 0.0852$; Osteobond, $p = 0.109$; Palacos R, $p = 0.273$; Simplex P, $p = 0.997$).

The difference in the mean shear strength after two weeks of immersion in saline at 37°C and after two weeks of ageing in air at 37°C was statistically significant for all types of cement (CMW 1, $p = 5.15 \times 10^{-9}$; CMW3, $p = 2.44 \times 10^{-8}$; Osteobond, $p = 5.10 \times 10^{-9}$; Palacos R, $p = 3.33 \times 10^{-5}$; Simplex P, $p = 1.03 \times 10^{-8}$). There was a positive correlation between the mean loss of shear strength because of immersion in saline (calculated using air-aged specimens as a baseline) and the mean area percentage of interfacial porosity ($r = 0.839$, $r^2 = 0.704$, $y = 34.5 + 2.48x$, $p = 0.00239$; Fig. 3).

Discussion

The cement-stem interfacial shear strength decreased dramatically after immersion for only two weeks in saline at 37°C, a finding consistent with previous reports,²³⁻²⁵ whereas it stayed the same or was slightly increased in specimens aged for the same period in air at 37°C. Since specimens in both the wet-ageing and dry-ageing groups were kept at the same temperature (37°C), polymerisation shrinkage and stress relaxation of the cement mantles should have occurred to the same extent.²⁸⁻³⁰ In a study of the effects of ageing on bulk cement, Jaffe, Rose and Radin³¹ immersed specimens in bovine serum at 37°C for

two years and found no appreciable deterioration either in static properties or in compression fatigue behaviour. Thus, our results suggest that the decrease in shear strength which we observed in wet ageing arose from the penetration of saline into the interface rather than from stress relaxation or degradation of the cement itself. It is important to note that this penetration of fluid occurred without cyclic loading or fluid pressurisation.

While preheating of the stem eliminated most interfacial porosity of the cement-stem interface, interfacial porosity was still observed in the Palacos R 37°C group and Depuy 1 37°C group. The source of these pores was not clear. They appeared evenly on the interface and within the cement mantle. Both cements are high-viscosity types and therefore these pores probably came from microscopic air bubbles trapped during mixing of the cement which the vacuum-mixing system could not eliminate.

A significant correlation was found between the amount of interfacial porosity and the reduction in shear strength after ageing in 37°C saline. Preheating the stem eliminates interfacial porosity, resulting in a seal which prevents penetration of fluid. Other important effects of preheating stems such as an increase in shear strength of the cement-stem interface, a slightly-shortened polymerisation time and slightly-elevated polymerisation temperature at the cement-bone interface,^{26,32} occurred in our specimens of bone cement.

As previously reported, the increase in temperature during polymerisation at the cement-bone interface with stems preheated to 37°C is probably too low to produce thermal necrosis of adjacent host bone.^{26,32,33} Bishop et al³² reported no increase in polymerisation temperature with Palacos R bone cement using cadaver femora and stems preheated to 44°C.

Several investigators have suggested that interfacial porosity results from the formation of air bubbles during insertion of the stem.^{34,35} Our findings indicate that the major cause of the formation of interfacial porosity is more likely to be polymerisation shrinkage which is approximately 2% to 7% by volume.^{26,32,36,37}

Increased shear strength of the cement-stem interface is expected when matte/porous-coated stems are used since these types of stem are designed to provide high bonding strength at the cement-stem interface. Strong bonding at the interface minimises stress in the cement mantle and prevents its failure.^{1,15,38,39} For polished, tapered stems, increased shear strength may not be as important. However, it is known that polished surfaces may provide higher friction of forces than matte surfaces.^{40,41} A strengthened cement-stem interface and the use of a polished stem may not be mutually exclusive. The effects of reduced interfacial porosity are not only increased shear strength but better sealing of the cement-stem interface and the reduction of interfacial porosity which could initiate cement cracks. Better sealing of the cement-stem interface may prevent migration of wear debris and thus may lower the risk of

osteolysis for both matte and polished stems.^{14,16-18} Thus, preheating of the stem may be useful for both matte and polished stems.

Finally, it should be noted that the size, shape, and appearance of the interfacial pores varied according to the type of bone cement. The cause of this variation was unclear. It may have been due to differences in additives such as radiopaque agents, catalyst inhibitors, cement particles of distribution size, the chemical composition and differences in the ratio of monomer to polymer.

Although we tried to simulate the clinical situation and materials, there are several limitations of our study. Only one type of material, shape, surface finish and mixing device was used. Bone cement was stored at room temperature before use, but some surgeons prefer to chill it, especially for high-viscosity bone cement such as Palacos R and Depuy 1 (CMW 1). Micropores of less than 50 µm in diameter were not accounted for because of the resolution of the imaging techniques.

Our results show, however, that the rapid reduction in shear strength at the cement-stem interface during immersion in fluid is likely to be due to the penetration of fluid into the interface. A porosity-free cement-stem interface appears to provide a better seal against this penetration of fluid. Preheating stems to 37°C before insertion eradicates all or nearly all of the pores and results in a greater interface shear strength than that seen in stems inserted without preheating.

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