POROSITY REDUCTION IN BONE CEMENT AT THE CEMENT-STEM INTERFACE

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The fatigue failure of bone cement, leading to loosening of the stem, is likely to be one mode of failure of cemented total hip replacements. There is strong evidence that cracks in the cement are initiated at voids which act as stress risers, particularly at the cement-stem interface. The preferential formation of voids at this site results from shrinkage during polymerisation and the initiation of this process at the warmer cement-bone interface, which causes bone cement to shrink away from the stem. A reversal of the direction of polymerisation would shrink the cement on to the stem and reduce or eliminate the formation of voids at this interface.

We have investigated this by implanting hip prostheses, at room temperature or preheated to 44°C, into human cadaver femora kept at 37°C. Two types of bone cement were either hand-mixed or vacuum-mixed before implantation. We found that the area of porosity at the cement-stem interface was dramatically reduced by preheating the stem and that the preheating temperature of 44°C determined by computer analysis of transient heat transfer was the minimum required to induce initial polymerisation at the cement-stem interface. Temperature measurements taken during these experiments in vitro showed that preheating of the stem caused a negligible increase in the temperature of the bone. Reduction of porosity at the cement-stem interface could significantly increase the life of hip arthroplasties.

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The fixation of prostheses by polymethylmethacrylate cement has been very successful since it was introduced by Charnley in 1960, but many revisions are required and most of them are for aseptic loosening (Fornasier and Cameron 1976; Stauffer 1982; Sutherland et al 1982). Loosening of the femoral component accounts for most cases (Brick and Poss 1988; Jasty et al 1991) and failure of the mantle is believed to start at the cement-stem interface (Jasty et al 1991; James et al 1992) which is significantly weaker than the bulk of the cement under static and fatigue loading (Raab, Ahmed and Provan 1981). A number of studies have indicated that once the cement-stem interface has become loose the stresses become significantly higher in the cement mantle (Freitag and Cannon 1977; Crowninshield and Tolbert 1983; Harrigan and Harris 1991).

The static and fatigue strength of bone cement both decrease with increased porosity (Burke, Gates and Harris 1984; Saha and Pal 1984; James et al 1992) and the cement-stem interface is thought to be similarly affected (Welsh, Pilliar and Macnab 1971; James et al 1993b; Davies, Kawate and Harris 1995). Fatigue is the most likely mode of mechanical failure of the cement mantle (Harris and Davies 1988) and any measure which will reduce the porosity of both the bulk cement and its interface with the prosthesis should be of clinical benefit.

Pores in the cement result primarily from air bubbles which have become entrapped during hand-mixing of the powder and liquid components, but it is also thought that monomer evaporation at the high temperatures of polymerisation may contribute (Debrunner, Wettstein and Hofer 1976). Pores act as stress risers (Timoshenko and Goodier 1934; Freitag and Cannon 1977; Carter, Gates and Harris 1982; Gates, Carter and Harris 1983; Burke et al 1984) and it has been reported that fatigue failure in test specimens occurs almost exclusively through such pores (James et al 1992). Major reduction in porosity has been achieved by centrifugation (Burke et al 1984) and by mixing under vacuum (Lidgren, Bodelind and Möller 1987; Schreurs et al 1988). Other methods include pressurising the cement (Saha and Pal 1984) and the use of an improved hand-mixing technique (Eyerer and Jin 1986).

The fatigue strength of the cement-stem interface can be improved by precoating the stem with a thin layer of polymethylmethacrylate under optimal polymerisation con-

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ditions (Davies, Singer and Harris 1992; Davies and Harris 1993), but pores have still been found at the interface between the precoat layer and the bulk cement (James et al 1993b). Microscopic or macroscopic roughening of the implant surface improves the static strength of the interface, but increases the stresses within the cement mantle, possibly compromising its fatigue strength (Welsh et al 1971; Stone, Wilkinson and Stother 1989).

Early loosening appears to be less critical at the cement-bone interface, where changes are believed to be due to biological rather than mechanical factors (Schmalzried et al 1992). A number of techniques are used to improve the cement-bone interface (Krause et al 1982) which include thorough cleaning of the canal using pressurised liquid and the pressurisation of cement into the cancellous bone interstices (Bourne, Oh and Harris 1984) to ensure the maximum area for load transfer. Noble and Swarts (1983) showed that penetration of more than 5 mm is likely to cause thermal damage to the bone and Jansson, Heimkes and Zimmer (1993) found that from mechanical considerations alone penetration of more than 2.9 mm is possibly superfluous.

The heat of polymerisation of cement may be an important factor in initial bone necrosis (Di Pisa, Sih and Berman 1976), and Lenhartz (1959) has cited the threshold temperature of collagen denaturation (56°C) as one criterion. Moritz and Henriques (1947) found a time-dependent threshold level for cell necrosis reporting that a temperature of 50°C for three minutes kills bone cells. Toksvig-Larsen, Franzen and Ryd (1991) found that the mean maximum temperature was 40°C at the cement-bone interface after the use of lavage and vacuum-mixed cement. They also found that cooling the stem before it was implanted had no effect on the peak cement temperature, but had the adverse effect of increasing the setting time of the cement (De Waal Malefijt, Sloof and Huiskes 1987) and compromising its mechanical properties (Tepic, personal communication, 1995).

Porosity at the cement-stem interface was first described by James et al (1993b) and was thought to be due to rheological effects rather than to the chemical nature of the implant surface or the thermal properties of the system, neither of which appeared to affect the interface porosity. They suggested that interface porosity was caused by entrapment of air during stem insertion because of the inability of cement to wet the stem, and reported that prewetting the prosthesis with monomer reduced the interface porosity (James et al 1991). They later showed that the same effect was possible by insertion of the stem through a diaphragm at the cement surface (James et al 1993a).

We consider that interface porosity may be caused by preferential polymerisation at the warmer of the two cement interfaces. Around a stem implanted at room temperature, the cement at the warmer cement-bone interface will polymerise first, creating a stiff shell towards which cement will shrink. For this reason, cement will shrink away from the prosthetic stem, creating pores at the areas of least adhesion. Conversely, if the cement-stem interface is warmer than the

cement-bone interface, a stiff cement shell will form first around the stem the cement will shrink towards the stem and away from the bone. Reduction of porosity at the cement-stem interface will tend to improve the fatigue life of the cement.

To create a warmer cement-stem interface at the onset of polymerisation the stem must be heated or the bone cooled. The latter leads to retarded polymerisation and weaker cement (Tepic, personal communication, 1995). Moderate heating of the stem before implantation would reverse the direction of polymerisation and dramatically reduce the porosity of the bone cement at the cement-stem interface. In our study, we have modelled the transient temperature distribution in the stem-cement-bone system to find the optimal temperature at which the stem should be implanted. We then implanted hip prostheses preheated to this temperature in laboratory experiments using hand-mixed and vacuum-mixed cements.

MATERIALS AND METHODS

Computer model. In our experiments, polymerisation starts approximately three minutes after stem insertion. During this time, heat is redistributed throughout the stem-cement-bone system and the temperature of the cement interfaces changes. We used an iterative computer model to determine the temperature distribution in the system over time. This theoretical distribution in the stem-cement-bone system just before polymerisation is shown in Figure 1 for varying temperatures of stem implantation. After insertion of a stem at room temperature (23°C), while maintaining the outer surface of the bone at 37°C, the cement-bone

Fig. 1

The theoretical distribution of temperature in the stem-cement-bone system at the onset of polymerisation taking the outside of the bone at 37°C. For a stem implanted at 43°C or higher the cement-stem interface is warmer than the cement-bone interface. For standard clinical implantation with a stem at room temperature (23°C) the cement-bone interface is about 5°C warmer than the cement-stem interface.

Fig. 2a

Fig. 2b

Fig. 2c

Fig. 2d

Cross-sections at the junction of the middle and distal thirds of the prosthesis, implanted in Sulfix 60 bone cement. The black lines in the cement are cross-sections of bony trabeculae.

Figure 2a – Hand-mixed cement implanted with a stem at 23°C. There are a number of pores at and around the cement-stem interface.

Figure 2b – Vacuum-mixed cement implanted with a stem of 23°C. All the pores are due to cement shrinkage, since all others have been removed by the vacuum mixing. The pores are at and around the stem.

Figure 2c – Hand-mixed cement implanted with a stem at 44°C. There are no pores at the cement-stem interface.

Figure 2d – Vacuum-mixed cement implanted with a stem at 44°C. There are very few pores in the cement.

interface is at least 5°C warmer than the cement-stem interface at three minutes, when polymerisation starts. By contrast, the computer model predicts that for a stem implanted at 43°C or higher, the cement-stem interface will be warmer than the cement-bone interface at the onset of polymerisation.

Implant experiments. For our tests *in vitro*, the stems were preheated to 44°C, which is just above the minimum theoretical temperature required for shrinkage on to the stem. One preheated stem and one stem at room temperature were implanted using each of four different cement preparations, giving a total of eight implantations. We tested two com-

monly used cements: Palacos R with Gentamicin antibiotic (Kulzer, Wehrheim, Switzerland) and Sulfix 60 (Sulzer, Winterthur, Germany). The latter is a low-viscosity cement which is thus recommended for vacuum mixing since it allows better escape of bubbles. Each of these cements was prepared both by hand-mixing and by mixing under vacuum. Hand-mixed cement was prepared by a standard clinical technique, and vacuum mixing used the Optivac system (Mitab, Sjöbo, Sweden) in which the monomer and powder are mixed with a plunger in an evacuated syringe. This method is well accepted for clinical use. It yields cement of very low porosity, thus allowing the bubbles which form at

the interface due to shrinkage to be observed without background porosity.

Half of the stems to be implanted were preheated in a water-bath to 44°C and removed and dried with a towel just before use. The cement preparations were mixed at room temperature, except for the vacuum-mixed Palacos R, the components of which were refrigerated to 5°C before mixing to decrease the viscosity and allow more efficient removal of bubbles.

We implanted stainless-steel MS30 femoral components (Protek, Münsingen-Berne, Switzerland), which have a fine-blasted surface finish, into human cadaver femora. The bones were reamed and four holes were drilled into the middle of the cortex for thermistor insertion, equally spaced along the stem length. The bones were then heated in a water-bath at 37°C.

A distal cement plug was inserted and cement introduced into the bone from distal to proximal using a cement gun and delivery nozzle. The femoral stem was implanted into the more viscous Palacos cement at approximately 3.5 minutes after the start of mixing, leaving a further 3 minutes before the onset of polymerisation at 6.5 minutes. Implantation into the less viscous Sulfix 60 was carried out at 4 minutes, again allowing 3 minutes before the onset of polymerisation. The bones were kept submerged in the water-bath during implantation and thereafter for three days, to ensure sufficient polymerisation. Bone cortex temperatures were recorded for up to 12 minutes after stem implantation.

The implanted femoral specimens were sectioned transversely and longitudinally for evaluation. Van Gieson staining was used to provide better visual differentiation between the trabeculae and the cement. The stem sections were removed from the cement and the interface wiped thoroughly with permanent ink to stain the pores. The cement surface was then photographed by a video camera linked to an image analysis system (IMCO 1000 Kontron, Munich, Germany) and the pore area measured within six areas of 7 mm X 14 mm spaced evenly along the length of the cement-stem interface. Electron micrographs were made of the cement surfaces for visual inspection.

RESULTS

Figure 2 shows cross-sections at the distal third of the stem. Implantation of stems at room temperature into both hand-mixed and vacuum-mixed cement (Figs 2a and 2b) caused the pores to be concentrated around the stem. The vacuum-mixed cement has a very low porosity in its main bulk this indicates that the pores around the stem implanted at room temperature were formed by the shrinkage effects of polymerisation. By contrast, none of the samples implanted with the stem at 44°C (Figs 2c and 2d) showed pores at the cement-stem interface. Close inspection of bony trabeculae revealed that in these cases the cement had separated from some of the trabeculae towards the stem.

Longitudinal views of the cement-stem interface are shown in Figure 3. In some samples there are large voids in the cement in the proximal mantle due to imperfect insertion, which are clearly too large to be due to cement shrinkage. The quantitative results are shown in Figure 4 which gives the mean porosities of the six areas of 7 mm X 14 mm measured on one side of each longitudinal section. Vacuum mixing resulted in a less porous cement-stem interface than hand mixing. Heating of the stem to 44°C resulted in a less porous interface for both hand-mixed and vacuum-mixed cements. Both cement types when hand mixed and implanted with a stem at room temperature showed a high density of small pores, which is consistent with the observations of James et al (1993b). A representative example of these surfaces is shown on an electron micrograph (Fig. 5a), to be compared with that of a sample of vacuum-mixed Palacos cement implanted with a preheated stem, which has no pores (Fig. 5b).

The effect of preheating of the stem on the reduction of porosity at the stem-cement interface was tested for significance using a paired *t*-test. The four pairs of implantations using four different cement preparations taken together showed a significant difference in porosity between preheated and room-temperature stems with $p < 0.01$.

The range of temperatures measured in the cortex of the bone during the implantation experiments is shown in Figure 6. Implantation of preheated stems causes a more rapid polymerisation, but the peak temperatures measured in the cortex were similar for all cases, with a maximum difference of 2.2°C. The peak recorded temperatures are given in Table I.

Table I. The peak and mean temperatures measured halfway through the cortex during implantation experiments in vitro

	23°C	44°C
Palacos R		
Hand-mixed	48.9	49.7
Vacuum-mixed	48.7	50.9
Sulfix 60		
Hand-mixed	51.9	51.0
Vacuum-mixed	51.1	50.9
Mean	50.2	50.6

DISCUSSION

The reported survival rates for Charnley-type total hip replacements are near to 100% (Ahnfelt et al 1990), but this figure does not reflect the true long-term performance. A ten-year follow-up of 300 patients implanted with Charnley stems showed a 29.9% incidence of loosening of the femoral component (Stauffer 1982), most of which was due to loosening at the cement-stem interface. In an investigation into the initiation of failure in 16 retrieved femora, Jasty et al (1991) found some debonding of the cement-stem interface in almost all cases, but the cement-bone interface had remained intact in all specimens. They found progressive

Fig. 3a

Fig. 3b

Fig. 3c

Fig. 3d

Longitudinal sections of the cement mantle after implantation of hip prostheses at 23°C and 44°C, into Sulfix 60 and Palacos R bone cements. Some large voids in the proximal sections are due to imperfect implantation. In each pair the result from a stem implanted at 23°C is on the left and at 44°C on the right.

Figure 3a – Hand-mixed Palacos R.

Figure 3b – Vacuum-mixed Palacos R.

Figure 3c – Hand-mixed Sulfix 60.

Figure 3d – Vacuum-mixed Sulfix 60. The distal crack on the right is due to clamping during section preparation.

damage to the cement mantle as the specimens became older and considered this to indicate that failure was due to high-cycle (> 1 million) fatigue fracture mechanisms cracks were commonly found to start at or near the cement-stem interface. Some debonding of the cement-stem interface was seen very soon after the arthroplasty, indicating a quasi-static or low-cycle fatigue loading failure.

Attempts should therefore be made to increase both the static and the fatigue strengths of the cement-stem interface. Davies et al (1995) found that a reduction in porosity at the cement-stem interface by the insertion of the stem through a diaphragm increased the static strength of the interface in torsion. We can find no report of a similar study under fatigue loading, but an increase in static strength indicates a corresponding increase in fatigue life. It seems clear that standard methods of implantation cause a high porosity at

the cement-stem interface, regardless of the bulk porosity. This must reduce the load-bearing capacity of the interface. The pores also act as stress risers and are the site of crack initiation (James et al 1993b).

Preheating the stem to the minimum temperature required to ensure that polymerisation is initiated at the stem significantly reduces the pore area density of the cement at the cement-stem interface. This should increase the static/low-cycle fatigue and high-cycle fatigue strengths of the interface. Other methods have been described to reduce the interface porosity, but it seems that complete avoidance of these bubbles is possible only if the direction of polymerisation is reversed or shrinkage is eliminated.

Cement shrinkage occurs as the monomer increases in density from 0.943 kg/m³ to 1.28 kg/m³ during polymerisation, causing a 35% decrease in volume. Because only 30%

Fig. 4

Surface cement porosity averaged over six areas of 7 mm X 14 mm covering the length of each stem. The vacuum-mixed cement shows lower porosities than hand-mixed cements, but preheating the stem reduces the porosity of both hand-mixed and vacuum-mixed cements. The bars represent the maximum and minimum values for each group.

Fig. 5a

Fig. 5b

Electron micrographs of the surface of the cement at cement-stem interfaces. Figure 5a – Severe porosity in hand-mixed Palacos R implanted with a stem at 23°C. Areas of contact with the stem area are those comparable with the area shown in Figure 5b. Figure 5b – No pores are visible in this sample of vacuum-mixed Palacos R implanted with a stem at 44°C. The surface texture of the area of contact with the stem was the same surface profile as the fine-blasted surface finish.

monomer is added to the powder, however, the overall shrinkage is roughly 5% (Haas, Brauer and Dickson 1975). There are also thermal volume changes due to the heat of polymerisation. Ahmed et al (1982) measured the thermal expansion of hand-mixed bone cement and found it to be $0.47 \times 10^{-4}/^{\circ}\text{C}$. This would give a volume change of approximately 0.2% for a 40°C temperature change, that is from 77°C to 37°C for the cooling of a hot cement mantle to body temperature. Air bubbles in the cement will also expand thermally but because the cement is contained between the implant and the bone this will cause little change in volume because of the compressibility of the gas.

Thus, it appears that interface porosity is caused primarily by shrinkage.

The shrinkage of cement on to a preheated stem implies that the cement will pull away from the bone interface towards the stem. These shrinkage displacements are small compared with the size of the macro interlock in bone trabeculae load-bearing capacity at this interface is likely to be minimally compromised.

Cement shrinkage will induce residual stresses in the cement mantle, but these do not appear to be critical and are likely to decrease over time due to stress relaxation. In any case there should be little difference in such residual

Fig. 6

The ranges of bone temperatures halfway through the cortex during implantations in vitro. The peak temperatures during implantation of preheated stems are similar to those measured during implantation of stems at room temperature.

stresses, whether the stem is heated or not, because the shrinkage remains a constant value for the cement.

The temperature measurements which we made during our implantation experiments in vitro show very little difference in the peak bone temperature half way through the cortex for the two different stem temperatures. In neither case is thermal cell damage likely between this position and the outer surface of the cortex, according to the criteria of Moritz and Henriques (1947). Much higher temperatures (70°C) may be withstood before the regenerative capacity of the bone tissue is permanently damaged (Lundskog 1972). The temperatures at the cement-bone interface itself will be higher than those measured half way through the cortex and may be high enough to cause bone necrosis. A number of studies have concluded, however, that much of the necrosis at the cement interface, and for some depth into the bone, is the result of mechanical damage to the endosteal blood supply caused by reaming, and some possibly due to monomer toxicity, rather than thermal effects (Jefferiss, Lee and Ling 1975; Huiskes 1980; Swenson, Schurman and Piziali 1981). No additional damage due to thermal effects in this area is likely. Dall, Miles and Juby (1986) found that preheating the stem reduced the setting time of the cement. They cemented preheated steel stems into Teflon moulds and measured the temperature at the cement-mould interface. They found that for a stem at 23.5°C the cement-mould interface attained a peak temperature of 50.5°C while for a stem at 45°C the interface reached 55.5°C. They concluded that preheating the stem to this temperature would not be likely to cause thermal damage to the bone according to the criterion of Lenhartz, who measured 56°C as the temperature at which cellular proteins become denatured.

Conclusions. When a stem at room temperature is implanted into bone which is at approximately body tem-

perature, the polymerisation of bone cement will progress from the bone towards the stem. This will induce pore formation in the cement mantle near and at the cement-stem interface. These pores have been shown to decrease the static strength of the cement-stem interface and probably also affect the fatigue strength.

We have shown in vitro that moderate preheating of the stem, using both normal and low-viscosity cements mixed by hand and under vacuum, practically eliminated shrinkage-induced porosity at the cement-stem interface. The small increase in temperature at the cement-bone interface seemed unlikely to produce significant damage to the bone.

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