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Vacuum-mixing cement does not decrease overall porosity in cemented femoral stems: AN *IN VITRO* LABORATORY INVESTIGATION

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Abstract

The role of vacuum mixing on the reduction of porosity and on the clinical performance of cemented total hip replacements remains uncertain. We have used paired femoral constructs prepared with either hand-mixed or vacuum-mixed cement in a cadaver model which simulated intra-operative conditions during cementing of the femoral component. After the cement had cured, the distribution of its porosity was determined, as was the strength of the cement-stem and cement-bone interfaces.

The overall fraction of the pore area was similar for both hand-mixed and vacuum-mixed cement (hand 6%; vacuum 5.7%; paired *t*-test, *p* = 0.187). The linear pore fractions at the interfaces were also similar for the two techniques. The pore number-density was much higher for the hand-mixed cement (paired *t*-test, *p* = 0.0013). The strength of the cement-stem interface was greater with the hand-mixed cement (paired *t*-test, *p* = 0.0005), while the strength of the cement-bone interface was not affected by the conditions of mixing (paired *t*-test, *p* = 0.275). The reduction in porosity with vacuum mixing did not affect the porosity of the mantle, but the distribution of the porosity can be affected by the technique of mixing used.

Despite improvements in the design of implants for total hip replacement (THR) and in the surgical techniques, aseptic loosening of cemented femoral components remains a problem. Many believe that the quality of the cement mantle plays an important role in loosening, and much effort has been directed towards the development of techniques to improve the integrity of the mantle and the attachment of cement to bone.¹ Canal lavage, retrograde filling of the canal, cement pressurisation and the use of stem centralisers, have found widespread clinical use.

In preparing the cement before introduction into the canal, systems have been developed to produce a homogenous mix. They can be used under vacuum, with the general understanding based on laboratory testing that vacuum mixing reduces the porosity of the cement.² Numerous laboratory studies have shown significant reduction in the bulk porosity of cement using vacuum-mixing techniques, with resultant improvements in tensile strength and fatigue life.^{3–5} However, the clinical benefits of vacuum-mixing have been difficult to demonstrate, and data from the Swedish Hip Registry⁶ have shown an increased risk of early revision associated with vacuum mixing. This suggests that the bench-top experiments do not adequately represent the conditions which are present *in vivo*.

We have investigated the role of vacuum mixing in the porosity of the cement mantle and fixation of the interface using a model which simulates the thermal, haemodynamic, and

geometric conditions present during intra-operative cementing of a femoral component. Previous work using this system with various vacuum-mixed cements revealed the presence of porosity within mantles and at the cement interfaces,^{7,8} but it is not known whether the magnitude or distribution of porosity would be different for vacuum- *versus* hand-mixed cements. Using the generally accepted role of vacuum mixing on the reduction of porosity, we hypothesised that vacuum-mixed cement would result in lower porosity, both within the cement mantle and at the cement-bone and cement-stem interfaces, and that the strength of the interfaces would be greater for vacuum-mixed compared with hand-mixed cement.

Materials and Methods

We used a matched-pair experimental design in which six pairs of fresh human proximal femora were cemented with femoral components using either vacuum- or hand-mixed cement. The mean age of the specimens was 77 years (58 to 94). They had been obtained from the State University of New York (SUNY) Upstate Anatomical Donor Programme and were maintained at -20°C until use. They were prepared surgically using a broach, followed by vigorous brush lavage, rinsing and distal plugging. The femora were 'potted' distally in a rectangular container and aligned longitudinally in a bath containing a blood analogue solution at 37°C ⁷ to simulate the thermal and haemodynamic conditions during surgery. The blood analogue solution contained physiological saline, a bacteriostatic agent (Roccal; Pharmacia and Upjohn, Kalamazoo, Michigan), calcium chloride and a soluble long-chain polymer (Polyacrylamide; Acros Organics, Geel, Belgium) to give the fluid a viscosity similar to that of human blood. Polymethylmethacrylate (PMMA) bone cement (Simplex P; Stryker Orthopaedics, Mahwah, New Jersey) was mixed in a cement-delivery system (ACM; Stryker Instruments, Kalamazoo, Michigan) for 75 seconds before evacuation into the attached chamber of the cement gun. Following the introduction of the powder and monomer into the mixing chamber, the cements were gently mixed by hand to wet the powder thoroughly. At this point, the cover of the chamber was applied and the mixing handle rotated at a speed of one revolution per second. The hand-mixed cement was prepared without any vacuum being applied, but for the vacuum mix a vacuum of -560 mmHg was applied for the final 45 seconds of the mixing process. The timing of the introduction of the cement into the femoral canal and insertion of the stem into the cement was determined by a Couette flow viscometer (Brookfield Engineering, Middleboro, Massachusetts) using a constant shear rate of 1 per second. The cement was introduced into the femoral canal when its viscosity reached 1000 Pa-s, which corresponded to the surgical 'does not stick to glove' criteria. The canal was then further pressurised using the cement-gun with a proximal seal. Exeter stems (Stryker Orthopaedics) were inserted into the canal when the cement viscosity reached 2000 Pa-s, corresponding to a finger-like cement bolus which did not droop under gravity, at a rate of 400 mm per minute using a mechanical test frame under displacement control. The energy required to insert the stem into the cement, namely the area under the load-displacement curve, and the time of polymerisation of the cement in the bone were recorded. The choice of mix was randomised, with vacuum- and hand-mixed conditions performed in pairs.

The cemented femoral constructs were allowed to cure for one week in the blood analogue solution at room temperature. The specimens were then sectioned transversely, between the collar and the distal tip of the stem with the stem in place, at intervals of 10 mm using an irrigated silicone carbide saw (Isomet; Buehler, Lake Bluff, Illinois). Reflected white-light images of the sectioned specimen surfaces were taken using a tiling procedure which resulted in large, high-resolution ($6\text{ }\mu\text{m/pixel}$) images (Fig 1a). Stereological techniques⁹ were used to determine the area fractions of porosity at the interfaces and in the bulk of the cement, the linear pore fractions at the cement-stem and cement-bone interfaces, and the pore size and number. Porosity was used to define both the gaps at the interfaces and the pores within the bulk cement. At the interfaces, pores could be seen as circular-shaped voids which touched the

interface, or as longer thin gaps. For measurements of area fraction, a rectangular grid was placed over the specimen image and point counts were made for pores which contacted the surface of the stem, were within the bulk of the cement and were in contact with bone. The point counts were normalised to total counts for the cement mantle resulting in area fractions of cement-stem, mid-mantle and cement-bone porosity. Linear pore fractions at the cement-stem interface were made by direct measurement of the total pore length along the interface divided by the perimeter of the stem section. They could not be measured at the cement-bone interface using this technique because of the interdigitation between the cement and bone. In this case, 50 spaced lines were constructed normal to the cement-bone interface as shown in Figure 1b. The lines which crossed the cement-bone interface were counted as either in full contact, no contact or mixed contact in both the contact and gapped regions. An overall cement-bone pore fraction was then calculated as follows:

$$\text{Cement-bone pore fraction} = (\text{no contact count} + (1/2) \text{ mixed contact count}) / \text{total count}$$

The reproducibility of the stereology technique was determined using a representative section with a large number of repeated measurements ($n = 10$).⁹ Confidence intervals (95% CI) were used to describe the variability of a single measurement, and the standard error of the mean (SEM) to describe the error in estimating the sample mean. The linear pore fractions at the cement-stem interface (95% CI 0.70; SEM 0.1) were the most reproducible, followed by the area fraction measurements (95% CI 1.05; SEM 0.15) and the linear pore fractions at the cement-bone interface (95% CI 6.43; SEM 0.91). Nine slices per bone were analysed and were then used to generate one mean value per bone, so that the repeated sampling was representative of the current sample population.

Push-out tests were performed to determine the apparent strength at the cement-stem interface (Fig. 2a). Each transverse section was loaded from distal to proximal using a brass ball located at the centre of the cross-section of the stem. The base of each section was supported by custom-made PMMA support plates which were machined to provide a consistent offset of 1.5 mm between the stem and support. The specimens were loaded with a displacement of 1 mm per minute in laboratory air at room temperature using a mechanical test frame (Instron Corporation, Norwood, Massachusetts). The apparent interface shear strength for each section was calculated as the maximum applied load for each section divided by the nominal area of the section of the stem.

Following the cement-stem interface tests, the resultant void was filled with PMMA cement and small cuboid cement-bone specimens, with a nominal cross-section of 5 mm by 10 mm, were created using a water-irrigated diamond saw. A minimum of 20 pairs of the cement-bone specimens were created for each femoral pair, with the pairing of the specimens based on their axial position in the bone and quadrant. The specimens were mounted in tensile test fixtures and loaded in displacement of 1 mm per minute until complete failure occurred (Fig. 2b). The cement-bone tensile strength was calculated as the peak applied load divided by the cross-sectional area of the specimen.

Statistical analysis

This consisted of paired *t*-tests, with Bonferroni correction¹⁰ for multiple sampling, and lineal-regression analysis to determine the relationships between independent (pore fraction at interface) and dependent variables (strength of interface). A significance level of $p \leq 0.05$ was chosen. For those cases for which a significant regression relationship was found, analysis of covariance (ANCOVA) was used to determine if the dependent-independent relationship was different for the two mixing techniques. A single mean was determined for each outcome measure for each femur.

Results

The insertion time of the stem, which was dictated by the viscometer, was slightly earlier for vacuum-mixed cement, as was the cement polymerisation time (Table I). The energy required to insert the stem was similar for the two mixes (Table I), indicating that the viscosity of the curing cement in the femoral canal during insertion of the stem was similar for both.

Our first hypothesis was found to be false. The overall pore area fraction (Table II) was not greater for the hand-mixed when compared with the vacuum-mixed cement (paired *t*-test, $p = 0.187$). However, there was a greater pore fraction in the mid-mantle with the hand-mixed cement. The linear pore fractions at the cement-stem and cement-bone interface were also similar for the two techniques (Table III). While the overall porosity of the cement was similar for both mixes, the distribution of pore size was very different (Fig. 3, Table II). Vacuum-mixed cement resulted in a lower pore number-density, but a larger mean pore size.

Our second hypothesis was also found to be false since the strengths of the cement-stem and cement-bone interfaces were not greater with the vacuum-mixed cement (Table IV). Indeed, the apparent strength of the cement-stem interface was higher with the hand-mixed cement (Table IV), but this was not found to be a result of differences in linear contact at the cement-stem interface ($r^2 = 0.04$, linear regression, $p = 0.55$) (Fig. 4a). The tensile strength at the cement-bone interface was not higher with the vacuum-mixed cement (paired *t*-test, $p = 0.275$) but there was a strong negative correlation between the cement-bone linear pore fraction and the cement-bone strength ($r^2 = 0.81$, linear regression, $p < 0.0001$), indicating that constructs with better cement-bone contact had stronger interfaces (Fig. 4b). The type of mixing technique did not result in different slopes for the pore fraction-strength relationship (ANCOVA, $p = 0.222$).

Discussion

Our results showed no reduction in the overall porosity of the cement using vacuum-mixing techniques which closely simulated conditions *in vivo*. This may have been a result of shrinkage from polymerisation during curing of the cement in the femoral canal. Polymethylmethacrylate undergoes a volumetric reduction during polymerisation as a low-density monomer is converted to higher density. For the Simplex cement used in our study, shrinkage of 6.7% in volume (4.4% in area) has been measured.¹¹ Gilbert et al¹¹ showed that when cement is cured in a constrained system in which the walls of the container are restricted from moving, porosity develops within the cement in an amount consistent with the shrinkage from polymerisation. In our study, if the cement-stem and cement-bone interfaces had been fully constrained, mid-mantle porosity would have developed up to about 4.4% of the area of the mantle. However, the mid-mantle porosity was lower and shrinkage pores were observed at the interfaces. The higher overall magnitude of porosity (5.7% to 6.0%) in our study as compared with that of isolated cement (4.4%) may have been caused by air trapped at the interfaces during cementing, movement of cement away from the bone because of blood analogue flow and thermal contraction of the cement after polymerisation.

The degree to which cement shrinks may depend on both its type and the technique of mixing. A recent study investigating the polymerisation of six commercially-available cements demonstrated a range of shrinkage between 3.8% and 7.8%, depending on the particular commercial preparation.¹² An investigation of the dynamic volume changes of cement during polymerisation showed an overall reduction of volume during polymerisation of 3.4% for hand-mixed and 6.0% for vacuum-mixed specimens.¹³

To ensure that the vacuum-mixing system was functioning properly in our study, we carried out a small pilot investigation with the cement mixed and extruded through the gun into an

open container with unconstrained walls. Using the same mixing and handling techniques, we found that vacuum-mixed cement in an unconstrained environment had virtually no porosity (0.3% SD 0.4%) while with hand-mixed cement it was much higher (5.8% SD 2.9%). This suggested that the vacuum-mixing chamber and gun were very successful in removing porosity from the cement and further supported the concept that in a constrained system, porosity will develop because of monomer conversion and subsequent shrinkage during polymerisation.

A power analysis was conducted on the primary outcome variable, the overall fraction of pore area, which indicated that with six pairs of femora and a level of significance of 5%, the study should be able to detect with 90% power, a difference of 1 % of porosity. Based on our pilot study, we anticipated a decrease in porosity of nearly 6%, indicating that the study would be able to detect adequately if the conditions of mixing had an effect on overall fraction of pore area in this model.

The most striking difference observed in pore morphology between the two mixing techniques was the presence of significantly larger pores in the mantle with vacuum-mixed cement although with a lower pore number-density, while hand-mixed cement had a more even distribution of smaller pores. This would be expected to be the case if shrinkage polymerisation occurred preferentially at existing pore boundaries. Hand-mixed cement would contain many small pores, which would all expand slightly, but the vacuum mixed would have fewer pores, each of which would be expected to undergo a relatively greater enlargement in size.

With current cement formulations, porosity will be present irrespective of the mixing technique because of the shrinkage from polymerisation. Improvement in the distribution of porosity may reduce the risk of loosening. Some investigators have suggested that preheating the stem would be advantageous because it would reduce the porosity at the cement-stem interface^{14,15} since this area is thought to be an important site for the development of cracks.¹⁶ Another option to reduce porosity would be to cool the bone before the introduction of the cement.¹⁷

Recent debate in the literature on the reduction of porosity has focused on the presence of pores in the mantle and how these may affect the loosening process through fatigue cracking of the cement.¹⁸ In retrieval and laboratory studies of fatigue-loaded cemented femoral components, a strong relationship between pores in the cement mantle and cracking has not been seen with few cracks found to emanate from pores.^{19,20} Computer modelling has shown that it is the high stress intensity near the corners of stems which has the highest propensity for cracking.²¹ These models have shown that the presence of porosity in the mantle has little effect on the growth of cracks from these high stress regions. The importance of removing porosity from the cement mantle is thus unclear.

While small pores which are evenly distributed in the mantle may not induce the formation and growth of cracks under loading, it may be possible that large pores located in regions of high local stress may have an important effect on loosening. Based on theoretical analysis²² and experimental measurement,²³ cracks are predicted to grow faster around large voids. It is perhaps this phenomenon of fracture and loosening from larger voids in regions of high stress in the mantle which could explain the clinical findings of the Swedish Hip Registry⁶ that vacuum mixing had a higher risk of failure in early post-operative periods. However, at present the relationship between defects in the mantle, porosity and clinical loosening is uncertain,^{24,25} probably because of the difficulty of detecting flaws using standard radiography.²⁶

The use of vacuum-mixed cement caused a modest decrease in the apparent strength of the cement-stem interface. Because the stem was polished, any mechanical bond between the stem and cement would be limited. Differences in apparent strength were most likely to have been caused by differences in the residual stresses across the cement-stem interface. These would be expected to diminish over time as a result of cement creep/relaxation and may not have

clinical relevance in terms of fixation of the implant. We found no difference in the cement-bone strength for the two mixing techniques, but there was a strong negative correlation between the linear pore fraction and strength of the interface, but this was not affected by the technique of mixing. The results of strength testing of the cement-bone show grouping of the femoral pairs by donor bone rather than by mixing technique, suggesting that bone morphology probably plays a more important role in the strength of the cement-bone interface.

Although we tried to simulate intra-operative conditions in our laboratory model, these may not have fully captured all clinical conditions. Bleeding into the femoral canal was only grossly simulated by the submersion of the bone into a warm blood analogue and did not mimic actual blood flow. The surgical technique was idealised in that excellent and full exposure of the bone could be obtained to allow ideal conditions for cementing in terms of the introduction of the cement into the canal, pressurisation, and insertion of the stem. These controlled conditions reduced variability in the cementing technique, but could not represent the wide range of surgical techniques used in clinical practice. Also the study only tested a single commercially-available mixing system and cement and stem combination. Finally, there was no biological remodelling between the cement and bone.

We found that vacuum-mixed cement did not result in overall lower porosity of the cement, but the distribution of porosity was different when compared with that of hand-mixed cement. The apparent strength of the cement-stem interface subjected to shear was higher for the hand-mixed cement, but no difference was found in the strength of the cement-bone interface. The most striking difference between mixing techniques was the distribution of porosity in terms of the mean pore size and pore number-density.

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Fig. 1a

Fig. 1b

Figure 1.

a) The pores were designated according to their location indicating the cement-stem (cs), mid-mantle (m), and cement-bone (cb) types, b) The cement-bone linear pore fraction was determined by using a ray-crossing method with intersections between lines drawn normal to the cement-bone interface. Three representative crossing rays are shown indicating full contact, no contact and mixed contact.

Fig. 2a

Fig. 2b

Figure 2.

Diagrams of the test configuration used a) for the tests of the shear strength of the cement-stem and b) for the tensile strength of the cement-bone interface.

Fig. 3a

Fig. 3b

Figure 3. Representative sections illustrating the distribution of porosity for a) hand- and b) vacuum-mixed cement.

Fig. 4a

Fig. 4b

Figure 4.

Graphs showing the interaction between the interface pore fraction and strength for a) the cement-stem interface and b) the cement-bone interface. The arrows indicate results from paired femora. The solid black line represents the linear regression relationship between the cement-bone strength and the linear pore fraction.

Table I

Cementing conditions for hand- and vacuum-mixed cement. The mean and range of values for six pairs of femora are indicated, along with the results of the paired *t*-test with Bonferroni correction¹⁰ for multiple sampling

	Hand mix (range)	Vacuum mix (range)	Corrected p-value
Cement introduction time (min:sec)	5:53 (4:49 to 6:39)	5:38 (4:59 to 6:13)	0.089
Stem insertion time (min:sec)	7:48 (6:26 to 9:00)	7:05 (6:20 to 7:52)	0.030
Cement polymerisation time (min:sec)	12:19 (11:30 to 13:30)	11:44 (10:53 to 12:39)	0.030
Energy to insert stem (Nm)	14.79 (10.14 to 20.33)	14.10 (11.72 to 17.42)	0.568

Table II

The size and density distribution of pores measured using stereological techniques. The mean and range of values for the six pairs of femora are indicated, along with the results of the paired *t*-test with Bonferroni correction¹⁰ for multiple sampling

	Hand mix (range)	Vacuum mix (range)	Corrected p-value
Total pore area (%)	6.0 (5.1 to 7.0)	5.7 (5.1 to 6.5)	0.187
Cement-stem pore area (%)	0.9 (0.5 to 2.1)	1.2 (0.8 to 1.7)	0.187
Cement-bone pore area (%)	3.3 (2.5 to 4.3)	3.7 (2.7 to 4.4)	0.187
Mantle pore area (%)	1.8 (0.6 to 2.4)	0.8 (0.6 to 1.2)	0.036
Mean pore size (mm ²)	0.08 (0.07 to 0.1)	0.23 (0.14 to 0.41)	0.028
Pore number-density (Number/mm ²)	0.68 (0.47 to 0.80)	0.25 (0.15 to 0.34)	0.0013

Table III

Normalised linear pore distribution at the cement-stem and cement-bone interfaces. The mean and range of the values for the six pairs of femora are indicated, along with the results of the paired *t*-test with Bonferroni correction¹⁰ for multiple sampling

	Hand mix (range)	Vacuum mix (range)	Corrected p-value
Cement-bone linear pore fraction (%)	44 (31 to 58)	42 (27 to 58)	0.219
Cement-stem linear pore fraction (%)	20 (15 to 24)	21 (18 to 23)	0.529

Table IV

The measurements of mechanical strength of the interfaces as a function of cement mixing. The mean and range of the values for the six pairs of femora are indicated, along with the results of the paired *t*-test with Bonferroni correction¹⁰ for multiple sampling

	Hand mix (range)	Vacuum mix (range)	Corrected p-value
Cement-stem push-out strength (MPa)	0.43 (0.21 to 0.60)	0.31 (0.06 to 0.36)	0.005
Cement-bone tensile strength (MPa)	3.18 (1.73 to 4.19)	3.03 (2.09 to 4.21)	0.275