The effect of vacuum mixing and pre-heating the femoral component on the mechanical properties of the cement mantle

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We investigated the effect of pre-heating a femoral component on the porosity and strength of bone cement, with or without vacuum mixing used for total hip replacement.

Cement mantles were moulded in a manner simulating clinical practice for cemented hip replacement. During polymerisation, the temperature was monitored. Specimens of cement extracted from the mantles underwent bending or fatigue tests, and were examined for porosity.

Pre-heating the stem alone significantly increased the mean temperature values measured within the mantle (+14.2°C) (p < 0.001) and reduced the mean curing time (-1.5 min) (p < 0.001). The addition of vacuum mixing modulated the mean rise in the temperature of polymerisation to 11°C and reduced the mean duration of the process by one minute and 50 seconds (p = 0.01 and p < 0.001, respectively). In all cases, the maximum temperature values measured in the mould simulating the femur were < 50°C. The mixing technique and pre-heating the stem slightly increased the static mechanical strength of bone cement. However, the fatigue life of the cement was improved by both vacuum mixing and pre-heating the stem, but was most marked (+ 280°C) when these methods were combined.

Pre-heating the stem appears to be an effective way of improving the quality of the cement mantle, which might enhance the long-term performance of bone cement, especially when combined with vacuum mixing.

Long-term clinical outcomes show that aseptic loosening is the main cause of failure of cemented hip prostheses. Polymethylmethacrylate bone cement may fail mechanically in the long term and become a cause of aseptic loosening, thereby influencing the long-term survival of the implant. Another important factor is the quality of the stem-cement interface. Investigations on cement mantles retrieved from revision procedures have shown that the porosities found in the bone cement were of critical importance for the development of cracks.

The extent of porosity within the cement mantle is influenced by different factors including the formulation of the cement, the method of mixing, the technique of injection and the surface properties of the implant. Great efforts have been made to optimise cement formulation, to improve mixing and/or injection, and to select the best texture for the surface of the implant. Despite these efforts, some degree of porosity can still be observed in bone cement mantles. It has been suggested that porosity can be reduced by thermally influencing the rate of polymerisation of cement by preheating the stem before its insertion into the medullary canal. This generates an increase in the static strength of bone cement and the strength of the implant-cement interface. A recent paper investigated the influence of pre-heating the stem on the fatigue behaviour of bone cement, which is the most important mechanical characteristic for its long-term performance. In that preliminary study it was found that pre-heating appeared to improve the fatigue strength of cement, although neither a control group nor vacuum mixing were considered.

The aim of this investigation was twofold. Firstly, to verify the effect of pre-heating the stem on porosity and mechanical behaviour, both static and of the fatigue strength, of manually mixed bone cement obtained under curing conditions simulating the surgical situation, compared to cement moulded according to ISO standards. Secondly, to verify whether preheating the stem had any effect when combined with vacuum mixing of bone cement. As the temperature of polymerisation may cause bone necrosis, the effect of pre-heating the stem and the method of mixing on the increase in temperature during polymerisation was also investigated.
Materials and Methods
Surgical Simplex-P (Stryker-Howmedica, Howmedica International, Limerick, Ireland) bone cement was selected for this study.

Two procedures were used for moulding. In the first vacuum-mixed cement dough was poured directly into a mould to obtain a specimen with the desired shape, according to the relevant standard (ISO 5833 for the bending test; ISO 527-2 for the fatigue test). These specimens were used as control. The second procedure required the injection of the bone cement dough into a custom-made mould designed to simulate the in vivo curing condition. The shape and dimensions of the mould, the pseudofemur, were chosen to replicate those of a typical femoral diaphysis. It consisted of a parallelepiped made of high-density polyethylene. This material has a thermal conductivity similar to that of wet and fresh cortical bone, which is in the range of 0.16 W/ml to 0.34 W/mK. The pseudofemur had an inner cavity, open proximally to allow overflow of excess cement, with a square cross-section. The thickness of the wall of the mould ranged from 3.5 mm proximally to 5.0 mm distally, simulating the cortical wall of the femoral metaphysis and diaphysis, respectively. A polished Co-alloy stem, with a square cross-section, simulated the prosthetic stem. This model was used instead of an elliptical cross-section because it resembles the shape of a real femur more closely, in order to obtain a cement mantle with four flat surfaces of constant thickness. The dimensions of the stem and the inner cavity were selected to obtain two different thicknesses of cement mantle; 3.3 mm, selected to extract four strips from the mantle for bending tests (ISO 5833 standard), and 4.0 mm, to extract four double-bell specimens from the mantle for tensile fatigue tests (ISO 527-2 standard).

For both moulding procedures, the cement was mixed at a temperature of 23°C (±1°C) and at a relative humidity in the range of 40% to 60%. Three minutes after starting the mixing, it was injected using the cement gun associated with the mixing kit, into the mould, maintained at 23°C, or into the pseudofemur, maintained at 37°C, depending on the moulding procedure. The latter was completed with the insertion of the stem, at a rate of 30 mm/s to reproduce the clinical procedure.

In order to investigate the effect of pre-heating the stem, cement mantles were moulded in two ways. In the first the stem was inserted at 23°C (room temperature). In the second it was preheated to 45°C. In both the cement was either vacuum mixed with a nominal vacuum level of -0.8 Bar or mixed in air. Vacuum mixing was performed using a commercial mixing system (Optivac, Biomet Cementing Technologies AB, Sjöbo, Sweden). Air mixing used the same mixing system, except that the vacuum pump was not connected to the mixer. A total of 28 cement mantles were moulded, 12 for the bending test (three repetitions for each configuration) and 16 for the fatigue test (four repetitions for each configuration).

The curing process. In order to assess the influence of pre-heating the stem on temperature distribution, three thermocouples were inserted into the cement mantle, and another three into the pseudofemur (Fig. 1).

Two thermocouples were each inserted at the proximal, mid-stem and distal levels and temperature values were collected in the cement mantle and the pseudofemur at each location for each mantle. Data from the thermocouples were registered using an acquisition device (AD-6B11, Analogue Device, Norwood, Massachusetts). The maximum temperature of polymerisation (T_max) and the polymerisation time (t-pol), defined as the time between the start of mixing and the occurrence of T_max, were determined.

Specimen extraction. One hour after mixing the cement, the stem was removed and the cement mantle extracted from the pseudofemur. Each cement mantle was machined using a water-cooled milling machine to obtain a strip or a double-bell specimen from each of the four sides (Fig. 2). These specimens were of the same dimensions as the corresponding control group.

The surface of each specimen, originally located on the external surface of the mantle, was mechanically polished with 800-grit sandpaper (Exakt Apparatebau, Nordestedt, Germany) to adjust the thickness to the desired value (3.3 mm or 4.0 mm). Specimens were stored in a solution of phosphate-buffered saline at 37°C until testing.

Bending test. Two days after curing, the strips of cement underwent bending tests. For each configuration, 12 specimens obtained from three cement mantles were also tested. For comparison, 12 control specimens were tested. Tests
were performed on a material testing machine (Mini Bionix 858, MTS, Minneapolis, Minnesota). The bending strength and elastic modulus were calculated following the ISO 5833 standard recommendations.

Fatigue test. Two weeks after curing, the double-bell specimens underwent fatigue testing. A material testing machine (MiniBionix 858) was used to stress the specimens. The specimens were subjected to a sinusoidal cyclic stress, from 0 MPa up to 15 MPa, at a frequency of 4 Hz. For each configuration, 16 specimens obtained from four cement mantles were tested until failure. Tests were performed in a saline solution maintained at 37°C. For comparison, 16 control specimens were tested. The latter were checked before testing to ensure the absence of macroporosities (pores > 1 mm) in the narrow part of the specimen. Conversely, no exclusion criterion was applied to the samples obtained from the cement mantles, as the effective strength of the bone cement forming the mantle had to be investigated.

Porosity analysis. All specimens tested in bending were examined. The surface, which formed the stem-cement interface, and one of the lateral surfaces, which represented the cement mantle cross-section, of each strip were analysed for porosities. After the bending tests, the broken specimens were glued back together using a rapid adhesive (Loctite Super Attak, Henkel, Dusseldorf, Germany) and sprayed with dye-penetrant (AVIO-B spray, Rotvel, American Gas and Chemical Company, Northvale, New Jersey). The specimen surfaces were scanned with a flatbed scanner having an optical resolution of 2400 DPI (HP ScanJet 5590, Hewlett-Packard, Palo Alto, California). The porosities were assessed by analysing the digital images using image analysis software (Matlab 6.5, The MathWorks Inc., Natick, Massachusetts). Porosity was expressed by a percentage of area.

Statistical analysis. The Shapiro-Wilk and Bartlett’s tests were used to verify the normality and homoscedasticity assumptions, respectively, for all the data from the curing process, bending tests and surface analysis. If both the assumptions were verified, then the data were analysed using a one-way analysis of variance (ANOVA) and post hoc analysis (Scheffe’s test). Conversely, if at least one condition was not verified, the differences among all groups were compared using a non-parametric method (Kruskal-Wallis test) and a non-parametric multiple comparison (NPMC) test.

The fatigue data were analysed using the two-parameter Weibull distribution. For each group, the Weibull mean life was calculated with 95% confidence intervals (CI), which represents an estimate of the mean time to failure. The mean life ratio between each pair was analysed following the procedure proposed by Kececioglu. A p-value < 0.05 was considered to be statistically significant.

Results
Curing process. Considering the number of moulding repetitions, 84 temperature-time graphs were measured at each location, in the cement mantle or in the pseudofemur. The collected data are summarised in Table I.

Both the temperature of the stem and the method of mixing affected the curing process (ANOVA, p < 0.001 each for the comparison among the four mean values of T_max and t_pol), although the former had a greater effect than the latter.
Considering the 23°C air mixing moulding condition as reference, raised stem temperature led to an increase in the mean Tmax (Scheffe’s test, p < 0.001) and a decrease in the mean tpol (Scheffe’s test, p < 0.001) within the bone cement. The mean Tmax increased by 30% (61.7°C vs 47.5°C), whereas the whole curing process was shortened on average by 16% (7 min 40 s vs 9 min 10 s).

Although, both the mean Tmax and tpol decreased when the cement was vacuum mixed (43.1°C vs 47.5°C and 8 min 40 s vs 9 min 10 s), these differences were not statistically significant (Scheffe’s test p = 0.65 for T_max and p = 0.62 for tpol).

When pre-heating of the stem was combined with vacuum mixing, an increase in the mean T_max was observed within the bone cement (Scheffe’s test p = 0.01), together with a shorter mean tpol (Scheffe’s test p < 0.001). The mean Tmax increased by 23% within the bone cement (58.5°C vs 47.5°C), and the whole curing process was shortened on average by 20% (7 min 20 s vs 9 min 10 s).

The above effects on Tmax were smaller when the readings were acquired from thermocouples placed within the pseudofemur, with the stem pre-heated, and when pre-heating was combined with vacuum mixing providing a maximum increase in the mean value of 5°C. However, in general the maximum temperature was lower than 45°C, except for seven values (four equal to 46°C, two to 47°C and one to 48°C).

### Bending strength

The bending behaviour of the specimens of bone cement from each group is shown in Figure 3.

Stem pre-heating and vacuum mixing affected both the mean bending modulus (ANOVA, p < 0.001) and the mean bending strength (ANOVA, p = 0.003). Post hoc analysis showed a significant difference comparing the mean bending modulus of the control group with the two groups moulded with the stem inserted at 23°C (control vs 23°C air mixing; Scheffe’s test, p = 0.003 and control vs 23°C vacuum mixing; Scheffe’s test, p = 0.005). Similar findings were found for the mean bending strength, although a sig-

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**Table I. Mean values of Tmax and tpol calculated for the four configurations**

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Tmax within the bone cement (°C)</th>
<th>Mean Tmax within the pseudofemur (°C)</th>
<th>Mean Tpol (min:s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air mixing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23°C</td>
<td>47.5 (44.4 to 50.6)</td>
<td>38.5 (37.9 to 39.1)</td>
<td>9.10 (8.40 to 9.40)</td>
</tr>
<tr>
<td>45°C</td>
<td>61.7 (57.0 to 66.4)</td>
<td>43.5 (42.5 to 44.5)</td>
<td>7.40 (7.10 to 8.10)</td>
</tr>
<tr>
<td>Vacuum mixing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23°C</td>
<td>43.1 (40.4 to 45.8)</td>
<td>38.6 (38.2 to 39)</td>
<td>8.40 (8.10 to 9.10)</td>
</tr>
<tr>
<td>45°C</td>
<td>58.5 (53.4 to 63.6)</td>
<td>43.3 (42.5 to 44.1)</td>
<td>7.20 (7.10 to 7.40)</td>
</tr>
</tbody>
</table>

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**Fig. 3**

Static bending properties of bone cement for the different groups (the mean value of each group is reported; the error bar represents the standard error) (AM, air mixing; VM, vacuum mixing).
nificant difference was found only between controls and the 23°C air mixing group (Scheffe’s test, p = 0.008).

The fatigue life of each group is presented in Table II.

The statistical analysis of mean fatigue life showed significant differences between the following pairs: control vs 23°C air mixing, control vs 23°C vacuum mixing, control vs 45°C air mixing (p < 0.01 for all three comparisons), 45°C vacuum mixing vs 23°C air mixing (p = 0.01), and 45°C vacuum vs 23°C air mixing (p = 0.05).

**Porosity.** The data were split into two groups: cross-section or stem-cement interface, depending on the surface analysed (Fig. 4).

Both pre-heating the stem and the method of mixing had a significant influence on the overall porosity (Kruskal-Wallis test, p < 0.001 for both surfaces). Taking the 23°C air mixing moulding as a reference, on the cross-section samples the median porosity was reduced by 32% using vacuum mixing, although this reduction was statistically non-significant (NPMC test, p = 0.085), and by 71% with pre-heating the stem (NPMC test, p < 0.001). A similar reduction (76%) was found when the two techniques were combined (NPMC test, p < 0.001). These reductions were even more marked on the median porosity observed on the specimens at the stem-cement interface; 38% using vacuum mixing, which again did not reach statistical significance (NPMC test, p = 0.064), 83% on pre-heating of the stem (NPMC test, p < 0.001), and 84% when both techniques were combined (NPMC test, p < 0.001).

**Discussion**

We recognise the limitations of this investigation. The experimental procedure used to simulate the clinical setting was based on several simplifications with a plastic facsimile to present the proximal femur and a flat cement-pseudofemur interface of a simple geometrical shape for the whole stem-cement-pseudofemur system. All these simplifications were necessary to ensure repeatability in the tests and allow the extraction of flat specimens from moulded cement mantles for mechanical testing. Additionally, only one configuration was considered: a metallic stem made of Co-alloy with a polished surface, using one brand of bone cement, one mixing device, one temperature for stem pre-heating, and a limited range thickness of the cement mantle of 3.3 mm or 4.0 mm. Last, four strips or four double-bell specimens were extracted from each cement mantle. The statistical analysis used ignored the lack of independence among these four specimens, as independence would only have been achievable if we had restricted the extraction to one specimen from each mantle. Therefore, a bias may have been introduced into the results. These constraints were necessary for the practical management of the investigation with the limited resources available.

Despite these limitations, this study demonstrates that pre-heating the stem and vacuum mixing improved the quality of the mantle made from the selected brand of cement.

The reduction in the time for the cement to cure when pre-heating the stem confirms the accelerating effect of heat on polymerisation.23,34 This is limited to the phase after insertion of the stem into the injected cement. Such a reduction might reduce the risk of release of the monomer into the circulatory system, as the content of residual concentration of the monomer decreases as polymerisation proceeds. However, further investigation is required to quantify the residual concentration of monomer at different times, considering the specific cement-brand/mixing-system/pre-heating-temperature configuration. The acceleration in polymerisation increases the maximum temperature within the cement, near the cement-bone interface.24 The greater temperature increase found in this study than that previously reported24 may be explained by the difference in the location of the thermocouples within the cement mantle. Despite the increase within the mantle, pre-heating the stem had only a slight effect on the mean maximum temperature value, with the increase ranging from 1°C to 5°C within the pseudofemur near the interface with the cement. This might be the result of the poor thermal conductivity of the polymethylmethacrylate. Our findings are in agreement with those of Bishop et al.21 who identified small differences in the maximum temperature value measured half-way through the femoral cortex for the same stem temperatures selected in our study. Although the effect of pre-heating the stem on the maximum temperature value measured in the mould simulating the femur was modest, it should be noted that some maximum values reached the critical range of 45°C to 48°C, albeit for less than two minutes. It has been demonstrated that heat shock at 48°C for ten minutes induces an irreversible response in osteoblasts, whereas exposure at 45°C or below for the same duration induces transient and reversible responses.26 Those temperature values have also been measured in vivo without pre-heating the stem,35 with the peak value depending on the thickness of the local mantle, the presence of moisture at the interface and the brand of cement.36-38 Therefore, it cannot be concluded that pre-heating the stem would not increase the risk of tissue damage. However, the limited duration of exposure to the critical temperature values makes it unlikely that significant thermal damage to the bone would occur when pre-heating is limited to 45°C and the mantle thickness is < 4 mm.

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**Table II. Fatigue life estimated for the five groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>Weibull mean life (number of cycles)</th>
<th>95% confidence interval (number of cycles)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air mixing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23°C</td>
<td>2.3 x 10⁴</td>
<td>1.8 x 10⁴ to 2.9 x 10⁴</td>
</tr>
<tr>
<td>45°C</td>
<td>4.0 x 10⁴</td>
<td>2.9 x 10⁴ to 5.6 x 10⁴</td>
</tr>
<tr>
<td>Vacuum mixing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23°C</td>
<td>3.3 x 10⁴</td>
<td>2.6 x 10⁴ to 4.3 x 10⁴</td>
</tr>
<tr>
<td>45°C</td>
<td>6.4 x 10⁴</td>
<td>4.8 x 10⁴ to 8.7 x 10⁴</td>
</tr>
<tr>
<td>Control</td>
<td>9.7 x 10⁴</td>
<td>7.3 x 10⁴ to 1.3 x 10⁵</td>
</tr>
</tbody>
</table>
Vacuum mixing had a smaller and different effect on the curing process which was accelerated but with reduction in the maximum temperature within the cement mantle, as previously reported.\(^3\) When the stem was pre-heated in conjunction with vacuum mixing the maximum temperature within the mantle decreased slightly and the curing process was further shortened. This suggests a synergistic effect of the two techniques on the curing process.

Pre-heating the stem and vacuum mixing have a positive effect on the porosity of the cement, but they act in different ways. Vacuum mixing reduces the porosity produced during mixing, but cannot eliminate porosities generated during injection of the cement and insertion of the stem.\(^{18-20}\) Conversely, pre-heating has no effect on the preparation of the cement, but does affect polymerisation once the dough is inside the medullary canal. It has been demonstrated that increasing the temperature of the stem above 43°C initiates polymerisation at the stem-cement interface.\(^{21}\) The reversed curing from the stem towards the bone eliminates the porosities induced by shrinkage at the stem-cement interface.\(^{17,24}\) Our study confirms that the highest reduction in porosity at the stem-cement interface can be obtained when the stem is pre-heated and that vacuum mixing used alone is less effective.

The reduction in porosity has a positive effect on the mechanical behaviour of specimens of bone cement moulded \textit{in vitro}, a small effect on static behaviour, but a greater effect on fatigue behaviour.\(^{14,28,40}\) No significant improvement was found in this study on the bending behaviour of bone cement with reduced porosity. This is similar to the findings of Fognani et al,\(^{23}\) who identified no significant increase in bending strength when the stem was pre-heated at 45°C. Conversely, the pores act as stress concentrators and therefore promote fatigue crack nucleation.\(^{8,41,42}\) This explains the present findings on fatigue behaviour. Both vacuum mixing, properly used, and pre-heating the stem reduce cement porosity and hence increase its fatigue strength. The maximum increase was obtained when the two techniques were combined.

Nevertheless, the relevance of the reduction in porosity within the cement remains disputed.\(^{43}\) The alternative view is that as local stress raisers govern crack formation, this may affect the long-term behaviour of the cement mantle.\(^{44-46}\) Different parameters such as the design of the prosthesis, the surface morphology of the implant, the cement quality, the thickness of the mantle, cement-implant and cement-bone interface strength and integrity, affect the stress level within the mantle.\(^{9,10,44,46-48}\) The proposed technique improves the quality of the cement in the mantle. Therefore, it should be a step towards reducing the highest stresses within the mantle, which would be advantageous to the long-term performance of cemented prostheses.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.
References


