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# Bone cement improved by vacuum mixing and chilling

Two mixing methods, hand and vacuum mixing, were compared using high viscosity, high molecular, antibiotic containing polymethylmethacrylate kept at two different temperatures, 4°C and 21°C, prior to mixing. The mechanical properties, i.e., fracture strength, maximum deflection, modulus of elasticity and hardness, were improved by vacuum mixing when compared with hand mixing at both temperatures. The fatigue life was 10 times longer after vacuum mixing. Chilling prior to mixing made the mixing easier and improved the handling characteristics. Vacuum mixing delayed the setting time by 1 minute, but also decreased the peak temperature. Radiographic analysis showed that vacuum mixing mainly reduced the microporosity, but also the macroporosity. The mechanical properties deteriorated slightly after 2 months in Ringer's solution, but the differences between the mixing procedures remained unchanged.

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A good cement filling around a hip prosthesis improves early fixation and reduces early radiographic loosening (Harris et al. 1982, Heyse-Moore & Ling 1982). In tubular bone a good cement filling is best achieved with an injection system. Cement with low viscosity makes the use of delivery systems easier and gives a better penetration of cement into bone (Miller et al. 1979). However, low viscosity cement is sometimes difficult to handle in nontubular bone (Ling 1980). Chilling of high viscosity cement prior to mixing lowers the viscosity so that its application used in tubular bone with an injection system becomes easy (Lidgren et al. 1984b). In an earlier study (Lidgren et al. 1984a), it was shown that vacuum mixing of the cement increased the modulus of elasticity and improved the fracture toughness, especially of high viscosity cement.

We have now analyzed the handling characteristics and mechanical properties of prechilled and room-temperated cement mixed by hand and in a vacuum.

## Materials and methods

The cement used was Refobacin Palacos (Palacos with gentamicin) taken from one batch. The cement monomer and polymer were kept at 4°C and 21°C prior to mixing. The mixing tools were kept at a laboratory temperature of 21°C. Two mixing methods were compared: hand stirring in air and under a vacuum. The mixing by hand was performed in a bowl with a spatula, both of polypropylene. For the mixing in a vacuum, 0.05 bars absolute pressure was continuously applied and the stirring was carried out by hand with a stainless steel spatula in a polypropylene bowl (Lidgren et al. 1984a).

According to the instructions from the manufacturer, the monomer was poured into the bowl before the polymethylmethacrylate (PMMA) powder was added. The mixing time was 60 seconds with about 60 stirrings. A cartridge was then filled with cement, and the cement injected with a gun into a distally plugged cylindrical mold, 120 mm long with a diameter of 11.7 mm. Each sample was divided into two bars, one tested after 48 hours at room temperature and the other was kept for 2 months in room-tem-

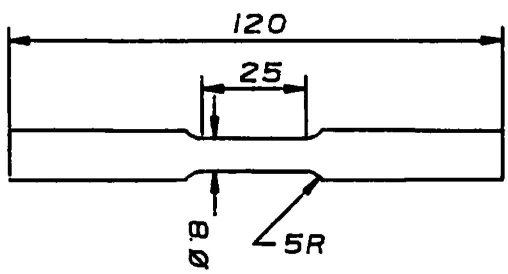



Figure 1. The bar used for the fatigue test. All dimensions in mm.

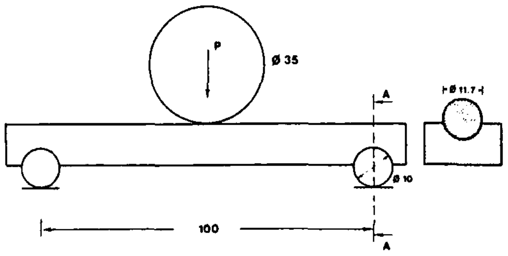



Figure 2. The loading nose, the support radii, and the support span in the bending test.

perated Ringer's solution, which was stirred daily and changed weekly. A radiograph was taken of the specimens. The number of voids larger than 1 mm were measured on the radiograph in the most central 5 cm. The bars intended for fatigue tests were machined to achieve a middle portion that was 25 mm long with a diameter of 8 mm (Figure 1).

The handling and setting characteristics were tested in an operating theater under clinical conditions at 21°C.

The mixing was performed in a 120-cc cartridge with a polypropene nozzle, 200 mm long and with a diameter of 10 mm. A manually driven cement gun was used. The injecting, handling, and setting time were measured. The injecting time was measured from the end of mixing until the cement could no longer be extruded through the pipe. The handling started when the cement did not stick to the gloves and ended when it could no longer be used for implanting a prosthesis (rubber state). The setting time was defined as when the cement has hardened (tested with an osteotome) and not according to ASTM F 451, which defines setting time as the time of maximum temperature.

The temperature in the cement was measured with a digital thermometer and a metal thermocouple with a diameter of 1.5 mm placed in the center of a cylinder (50 mm long and with a diameter of 9 mm) surrounded by the pipe of the cartridge.

Differences between hand and vacuum mixing were evaluated statistically by the Mann-Whitney U test.

## Testing procedures

The following tests were performed on eight groups of different mixing and storage samples. In each group six specimens were tested.

The flexural strength was tested by a standard three point bending test (ASTM E855 method B). A cement bar with circular cross section rested on two supports with a loading nose midway between the supports (Figure 2). The bar was loaded until rupture using an Instron mechanical testing device (Model TT-D), which simultaneously measured the motion of the loading nose relative to the supports. The maximum axial fiber stresses occurred under the loading nose. The rate of crosshead motion of the machine was 2 mm/min. The load- deflection data was used to calculate the maximum flexural strength, the maximum strain, maximum deflection at rupture, and the tangent modulus of elasticity in bending (*Annual book of ASTM standards*, 1980)

The hardness according to the Rockwell L scale was tested with a 5-mm-diameter ball. The strength under impact was tested according to Charpy (ASTM D256, 1981).

The fatigue strength was tested by uniaxial load control, with a set-up of two supports 100 mm apart with a pneumatic cylinder equipped with a cylindrical loading nose that applied a pulsating load between 0 and 67N midway between the supports with a frequency of 2 Hz until rupture. The maximum axial fiber stresses occurred over the area between the loading noses. The specimens were tested dry at 21°C.

## Results

The fracture strength ($P < 0.0001$) and maximum deflection ($P = 0.0001$) increased and modulus of elasticity ($P < 0.0001$) improved with vacuum mixing both at 4°C and 21°C. Also the impact toughness tested by the Charpy method ($P = 0.0007$) and the hardness tested by the Rockwell method ( $P < 0.0001$)

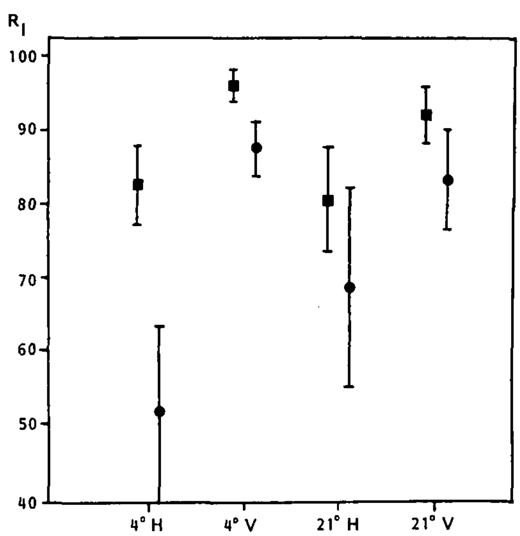



Figure 3. The hardness of the investigated cement according to Rockwell L Scale using a 5 mm ball.

*Table 1. Mechanical properities of bone cement mixed by hand or vacuum. Mean values with standard deviation within brackets.*

| TEMP | | σBmax MPa | EB $10^9$ N/m$^2$ | D mm | CHARPY Kgcm |
|---|---|---|---|---|---|
| 4°H | 48 h | 59.9 (2.29) | 2.10(0.05) | 4.50(0.51) | 6.26(1.12) |
| | 60 d | 52.9 (2.51) | 1.95(0.05) | 4.70(0.39) | 6.10(0.92) |
| 4°V | 48 h | 75.8 (3.95) | 2.54(0.08) | 4.87(0.50) | 8.20(1.13) |
| | 60 d | 67.5 (5.39) | 2.26(0.09) | 5.29(0.70) | 6.19(0.97) |
| 21°H | 48 h | 61.0 (2.11) | 2.16(0.07) | 4.42(0.31) | 6.75(0.78) |
| | 60 d | 54.2 (1.52) | 2.02(0.06) | 4.67(0.40) | 5.29(0.65) |
| 21°V | 48 h | 73.5 (4.13) | 2.44(0.11) | 4.86(0.36) | 9.50(4.19) |
| | 60 d | 66.9 (4.33) | 2.29(0.09) | 5.07(0.37) | 6.40(1.14) |

TEMP = Bone cement kept at 4°C or 21°C prior to mixing
48 h = tested after 48 hours in room temperature
60 d = tested after 60 days in ringer solution
σBmax = Maximum flexural strength
EB = Tangent modulus of elasticity in bending
D = Maximum deflection at the moment of rupture
CHARPY = The strength under impact according to Charpy

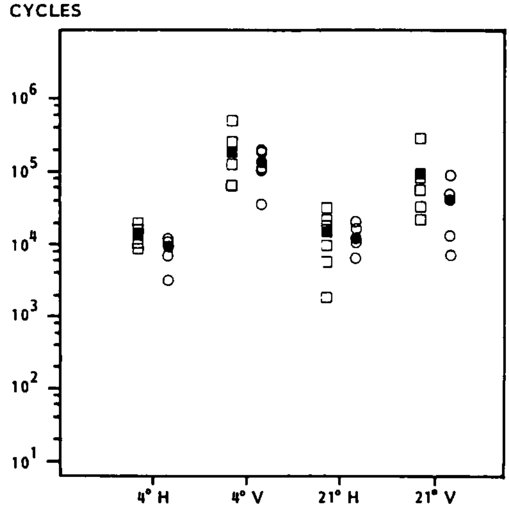



Figure 4. Fatigue life. Pulsating load to 67.7 N. Three-point bending. The mean (filled symbols) and separate values are given after 48 hours in air (□) and after 2 months in Ringer's solution (○).

(Table 1, Figure 3) was increased with vacuum mixing. The fatigue life ($P < 0.0001$) improved 10 times with vacuum mixing at 4°C (Figure 4).

The same tests carried out after 2 months in Ringer solution showed the same differences between the mixing procedures, but a small overall decrease of the mechanical properties. No specimens were excluded. When corrections were made for specimens with air inclusions larger than 1 mm, the differences were not altered. The flow characteristic studies (Table 2) showed an increased handling ($P = 0.0054$) and setting time ($P = 0.0039$) with chilled PMMA and vacuum mixing. The peak temperature ($P = 0.0039$) was lowered by 5°C and delayed ($P = 0.0037$) by the vacuum mixing.

The number of large voids was reduced to one third within the specimens with vacuum mixing (Table 3), and there was a reduction of the microporosity (Figure 9).

## Discussion

It has been shown that the fracture properties of PMMA improve with an increase in molecular weight (Kusy & Simmons 1983). A high viscosity cement, Palacos[R], has a molecular weight of 936,000 compared with 151,000 in Zimmer low viscosity cement. This gives the former a higher fracture toughness (Rimnac & Wright 1985).

*Table 2. Mixing performed in a cartridge by hand and under a vacuum with chilled and room-temperated PMMA. Mean values and range for temperature (°C) and time (mm.ss)*

| | Vacuum | Vacuum | Hand | Hand |
|---|---|---|---|---|
| Temperature prior to mixing | 4° | 21° | 4° | 21° |
| Starting temperature | 13.° | 21.0° | 16.1° | 21.0° |
| Injecting time[a] | 1.00–8.16 | 1.00–8.48 | 1.00–7.31 | 1.00–5.27 |
| | 7.16 | 7.48 | 6.31 | 4.27 |
| Handling time[a] | 2.06–10.39 | 2.21–7.55 | 1.32–8.48 | 1.36–6.57 |
| | 8.33 | 5.34 | 7.16 | 5.19 |
| Setting time[a] | 13.49 | 11.24 | 11.44 | 10.18 |
| Maximum temperature/time | 51.3°/19.35 | 48.3°/17.05 | 54.9°/13.50 | 55.8°/12.40 |

[a]. For definition, see Methods.

*Table 3. Radiographic voids (mean value) larger than 1 mm in 11.7 x 50 mm in the center of the specimens*

| Mixing | Temperature | Voids |
|---|---|---|
| Hand | 21° | 2.5 |
| Vacuum | 21° | 0.9 |
| Hand | 4° | 2.3 |
| Vacuum | 4° | 0.9 |

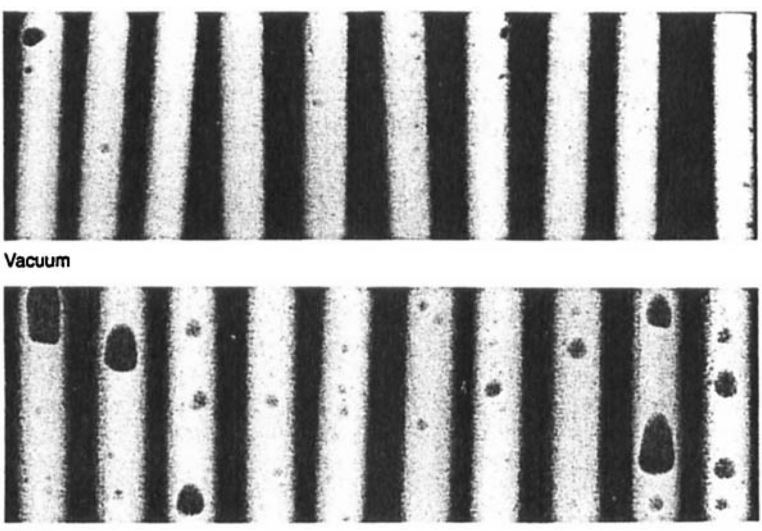
Recently it has been shown that a significant decrease in the peak temperature could be achieved by using a fraction of prepolymerized PMMA particles ranging from 300–500 μm in combination with monomer and methylmethacrylate powder with particles ranging from 5–130 μm (Greer et al. 1985). It thus seems that an improved bone cement could be produced by using a PMMA with optimized particle sizes that sets at a lower temperature. This cement will probably be of a high viscosity type, which makes a good filling of a tubular bone difficult.

Adding antibiotics to PMMA has been shown to reduced the mechanical properties, notably static strength (Klopper & Rijkmans 1982). Increasing the amount of antibiotics makes the cement harder to mix and set without going through a semiliquid phase (Murray 1984). If better initial flow characteristics could be achieved in combination with an improved fatigue life, high molecular antibiotic containing cement could be used with optimal cementation technique and hopefully less prosthetic late failures. For optimum bone intrusion a viscosity of less than 100 Sn/m$^2$ is desirable (Krause et al. 1982).

Some studies have shown a reduction of the air porosity with an improved fatigue life when centrifugation is carried out after mixing the cement (Burke et al. 1984, O'Connor et al. 1985).

These improved mechanical properties with centrifugation have mainly been found for Simplex P bone cement, but not for Palacos, Refobacin Palacos, or Zimmer bone cement (Jasty et al. 1985, Rimnac & Wright 1985). Some concern about centrifugation has been raised as density in the cement at the tip of the centrifuged tube is higher than in the rest of the tube (Skinner & Murray 1985).

Hand-mixed PMMA is only one tenth as stiff as cortical bone and has half the compressive strength (Swanson & Freeman 1977). In the present study we confirmed our earlier results (Lidgren et al. 1984a and b) by showing improved mechanical properties and reduced microporosity and macroporosity by vacuum mixing with both prechilled and room-temperated cement compared with hand mixing. The PMMA decreases its mechanical strength in body fluids (Holm 1980). In our study both the flexural and the fatigue strength decreased slightly after 2 months in Ringer's solution,



Vacuum

Hand

Figure 5. Radiograph showing, without magnification, 10 consecutive PMMA specimens mixed with vacuum and by hand at 21°C. There are fewer large voids (less macroporosity) and the cement is denser (less microporosity) in the vacuum specimens.

but there was still the same difference between the two mixing procedures.

Wixson et al. (1985) reported that in order to avoid boiling the monomer of cement at room temperature, a lower vacuum than 0.2 bars absolute pressure should not be used. They also showed that cement porosity was not reduced after 1.5 minutes of vacuum mixing. We reported earlier (Lidgren et al. 1984b) that only minor improvements in PMMA strength could be achieved with a vacuum lower than 0.05 bars. In the present study, no boiling could be seen by using 0.05 bars.

Chilling of Refobacin Palacos[R] to 4°C prior to vacuum mixing lowered the viscosity and thereby improved the removal of the air bubbles compared with room-temperated cement and resulted in a tenfold increase of the fatigue life. The increase in fatigue life has recently been confirmed in studies by Wixson et al. (1985) using Simplex P bone cement.

Prosthetic survival depends on prosthetic design, positioning, and cement strength, but mainly on the bone cement interface strength. For the interface strength, thermal damage has been regarded as important when a large amount of cement is used or if no heat absorption can occur, for instance, in cemented acetabular cups (Huiskes 1980, Mjöberg et al. 1984). This is a minor problem for the femoral component (Swenson & Schurman 1981). The regeneration capacity of bone is also impaired by the heat (Eriksson & Albrektsson 1984).

We found that mixing under a vacuum gave a delay in the setting time by about 1 minute in comparison with hand mixing. The peak temperature was lowered by 5 degrees, probably by changing the gel effect (Trommsdorff 1963) with maintenance of an almost normal initial polymerization. A 9-mm cement probe does not guarantee adiabatic temperature development, i.e., considerable heat loss through heat conduction occurs. Therefore, the temperatures obtained in this study were lower than seen in the middle of a cement mass of larger size (Huiskes 1980), but may still be of clinical value. A slight delay in end polymerization should result in longer polymer chains and could have contributed slightly to the improved strength. Not only air, but also a small amount of monomer is evaporated by vacuum, but as the air inclusions decrease a better wetting effect of the monomer is to be expected.

The combination of an increased injecting and handling time and reduced peak temperature will probably give a better bone-cement interface strength. Prechilling of the PMMA enhances this by making the mixing and the use of a delivery system easier.

Vacuum mixing and chilling to 4°C prior to mixing of high molecular, high viscosity cement improves significantly the flexural strength, but especially the fatigue life. The better handling characteristics allow the use of a delivery system. A reduction in the peak temperature may result in less bone damage at PMMA setting. The change in the operative technique is minimal and the advantages for prosthetic cement fixation are obvious.

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## References

Standard test methods for flexural properties of plastics and electrical insulating materials (1980) In: *Annual book of ASTM standards.*

Burke, D. W., Gates, E. I. & Harris, W. H. (1984) Centrifugation as a method of improving tensile and fatigue properties of acrylic bone cement. *J. Bone Joint Surg.* **66-A,** 1265-1273.

Eriksson, R. A. & Albrektsson, T. (1984) The effect of heat on bone regeneration. an experimental study in the rabbit using the bone growth chamber. *J. Oral Maxillofac. Surg.* 42, 705–711.

Greer, J. A., O'Connor, D. O., Rey, R. M. & Harris, W. H. (1985) Improved fatigue porosity and thermal properties of a new PMMA bone cement. *31st Annual ORS*, Las Vegas, Nevada. 240.

Harris, W. H., McCarty, J. C. Jr. & O'Neill, D. A. (1982) Femoral component loosening using contemporary techniques of femoral cement fixation. *J. Bone Joint Surg.* **64-A,** 1063–1067.

Heyse-Moore, G. H. & Ling, R. S. M. (1982) Current cement techniques. In: *Progress in cemented total hip surgery and revision.*Symposium, Amsterdam. pp. 71–86. , Holm, N. J. (1980) The relaxation of some acrylic bone cements. *Acta Orthop. Scand.* **51**, 727–731.

Huiskes, R. (1980) Some fundamental aspects of human joint replacement. Analyses of stresses and heat conduction in bone- prosthesis structures. *Acta Orthop. Scand.* Suppl. 185, 164–165.

Jasty, M. Jensen, J. F., Burke, D. W., Harringan, T. P. & Harris, W. H. (1985) Porosity measurement in commercial bone cement preparation and the effect of centrifugation of porosity reduction. *31st Annual ORS*, Las Vegas, Nevada, p. 239.

Klopper, P. J. & Rijkmans, J. (1982) Static load of bone cement after addition of antibiotics In: *Progress in cemented total hip surgery and revision.* Symposium Amsterdam, pp. 69–70.

Krause, W. R., Miller, J. & Philip, N. G. (1982) The viscosity of acrylic bone cements. *J. Biomed. Mater. Res.* **16**, 219–243.

Kusy, R. P. & Simmon, W. F. (1983) *Polymer alloys III* pp. 71–79. Plenum Pub.

Lidgren, L., Drar, H. & Möller, J. (1984a) Strength of polymethylmethacrylate increased by vacuum mixing. *Acta Orthop. Scand.* **55**, 536–541.

Lidgren, L., Möller, J. & Bodelind, B. (1984b) Improved strength of PMMA with vacuum mixing and chilling. Presented at the Swedish Medical Society Meeting in December (Summary in Swedish) pp. 71–79.

Ling, R. S. M. (1980) Prevention of loosening of total hip components. The hip *Proc. 8th Open Sci. Meeting Hip Society* **14**, 292–307.

Miller, J., Burke, D. L., Krause, W., Ahmed, A., Kelleby, L. & Tremblay, G. (1979) Improved fixation of knee arthroplasty components by the injection of acrylic cement into cancellous bone surfaces. *J. Bone Joint Surg.* **61-B,** 515.

Mjöberg, B., Pettersson, H., Rosenqvist, R. & Rydholm, A. (1984) Bone cement, thermal injury and the radiolucent zone. *Acta Orthop. Scand.* **55**, 597–600.

Murray, W. R. (1984) Use of antibiotic-containing bone cement. *Clin. Orthop.* **190**, 89–95.

O'Connor, D. O., Burke, D. W., Davies, J. P. & Harris, W. H. (1985) S-N curve for centrifuged and uncentrifuged PMMA. *31st Annual ORS.* Las Vegas, Nevada, p. 325.

Rimnac, C. M. & Wright, T. M. (1985) The effect of centrifugation on the fracture properties of polymethylmethacrylate bone cement. *31st Annual ORS.* Las Vegas, Nevada, p. 326.

Skinner, H. B. & Murray, W. R. (1985) Density gradients in bone cement after centrifugation. *31st Annual ORS.* Las Vegas, Nevada. 243.

Swanson, S. A. V. & Freeman, M. A. R. (1977) *The scientific basis of joint replacement.* John Wiley & Sons, New York, NY.

Swenson, L. W. & Schurman, D. J. (1981) Finite element temperature analysis of a total hip replacement and measurement of PMMA curing temperatures. *J. Biomed. Mater. Res.* **15**, 83- 89.

Trommsdorff, E. (1963) Polymerisate der Acrylsäure, ihrer Homologe und Derivate. In: *Chemie und Technologie der Kunststoffe.* Vol. II. p. 541. Eds. Houwelink, R. & Staverman, A. J. Akademische Verlagsgesellschaft, Leipzig.

Wixson, R. L., Lautenschlager, E. P. & Novak, M. (1985) Vacuum mixing of methylmethacrylate bone cement. *31st Annual ORS.* Las Vegas, Nevada. 327.