

# Porosity of bone cement reduced by mixing and collecting under vacuum

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Palacos R<sup>®</sup> bone cement was mixed in a commercial vacuum mixing system (MITAB), and in an experimental system allowing evacuating air from the powder before mixing and collecting the cement under partial vacuum. The effect on the porosity of mixing at different pressure levels was tested. The effect of evacuating air from the powder before mixing was also analyzed. The numbers and sizes of the voids in the cement samples were measured in radiographs

and under the microscope. Also, the density of the cement was measured. Vacuum mixed samples had a substantial reduction of voids, as well as an increase in density compared to mixing at atmospheric pressure. After vacuum mixing and collection, a further reduction of the porosity and increased density were seen; all the large voids within the cement were eliminated at 0.05 bar absolute pressure.

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Mechanical loosening of total joint replacement is the most common cause of prosthetic failure. The causes of loosening of the implant originate from failure of the interfaces between cement and bone, prosthesis and cement, or the cement mantle itself (Stauffer 1982, Jasty et al. 1991). Experimentally, a fatigue fracture of bone cement is most likely to occur at the site of the largest voids (Carter et al. 1982).

Topoleski et al. (1990) showed that *in vivo* fracture surfaces are remarkably similar to *in vitro* fatigue fracture surfaces, using fractographic analysis. Vacuum mixing reduces the porosity (Lidgren et al. 1984, Lindén 1989). Wixson et al. (1987) investigated the causes of porosity by taking radiographs during all stages of mixing. They found 5 potential sources of porosity: air initially surrounding the powder, air trapped during the wetting of the powder, air stirred into the cement during spatulation, air trapped during transfer to a cement gun, and monomer boiling. By vacuum mixing, air trapped during wetting of the powder and during spatulation can be reduced, but the other sources of porosity remain. We investigated whether it is possible to reduce the porosity of the bone cement by avoiding the entrapment of air during vacuum mixing and when transferring the cement to the cement gun. We also studied the effect on porosity of a low absolute pressure.

## Material and methods

### *Technique of cement mixing*

Palacos R<sup>®</sup> bone cement (Schering Corp, Germany) from the same batch was used. 1 packet (40 g of powder) and 20 mL liquid monomer, pre-chilled to 4 °C, were mixed using the Mitab commercial vacuum mixing system (Mitab Corp., Sjöbo, Sweden,) and an experimental mixing system. The cement was mixed under partial vacuum at the levels of 0.2 and 0.05 bar absolute pressure; control samples were obtained using the identical mixing technique at atmospheric pressure. 10 packets were mixed at each pressure level and mixing system.

In the Mitab system, the powder was added to the liquid monomer in a mixing box. The chamber was then closed and connected to a vacuum pump. After mixing the cement for 30 seconds under vacuum, the box was taken from the vacuum chamber and a lid with a nozzle was screwed on to it. The cement was collected at the top of the nozzle by a cement gun and injected into a cylindrical polyvinylchloride (PVC) mold with a diameter of 10 mm. The cement was allowed to cure in the mold and nozzle.

In the EMS (experimental mixing system) the mixing took place in 2 steps: In step-I (evacuation of air from powder, Figure 1 step-I), the powder was poured into the mixing box and then the box was put into the vacuum chamber. The air within the powder was evacuated for 10 seconds. Under continued vacuum, the liquid monomer was then injected into the mixing box

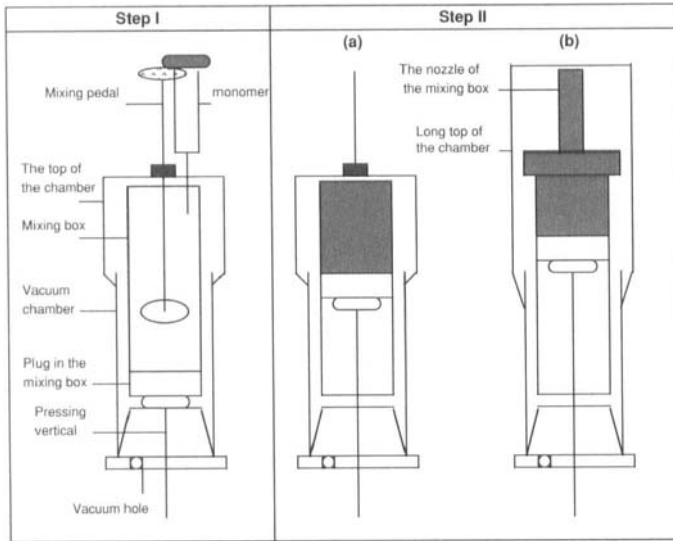


Figure 1. The experimental vacuum mixing system (EMS).

Step I. Evacuation of air from powder under vacuum and vacuum mixing.

Step II. a. Collecting cement to the top of the mixing box under vacuum; b. Collecting cement to the top of the nozzle under vacuum.

and mixed for 30 seconds. In step-II (collecting the cement under vacuum, Figure 1 step-II a, b), the cement was collected to the top of the mixing box by pushing the bottom plug, keeping the same pressure level. The vacuum was then released in order to take away the mixing pedal and change to a top with a nozzle. Thereafter, the box was replaced in a longer vacuum chamber. The vacuum was applied again, and the cement was collected to the top of the nozzle, and then the cement was injected into the PVC molds. The time for mixing and collecting was 2 minutes.

### Specimen analysis

Standardized radiographs of the cement cylinders from the molds and the nozzles were used to count the num-

ber of voids above 1 mm in diameter (Figure 2). They were called macropore, of which the sizes were determined by comparing the radiographs with a radiograph of a standard metal plate with holes of 1-10 mm in diameter. The number of macropores per cubic centimeter was calculated by dividing the total number of macropores with the volume of the cylinder. The average diameter (mm) of the macropores was calculated by dividing the total diameter of voids with the number of voids. A volume percentage of voids was calculated by dividing the total volume of the voids with the volume of the cylinder times 100.

Two 5 mm thick cement slices from the middle part of the cement cylinder from the nozzle were cut by a low-speed water-cooled diamond saw (Isomet, Bueler Corp., Germany). Both surfaces of the slices were

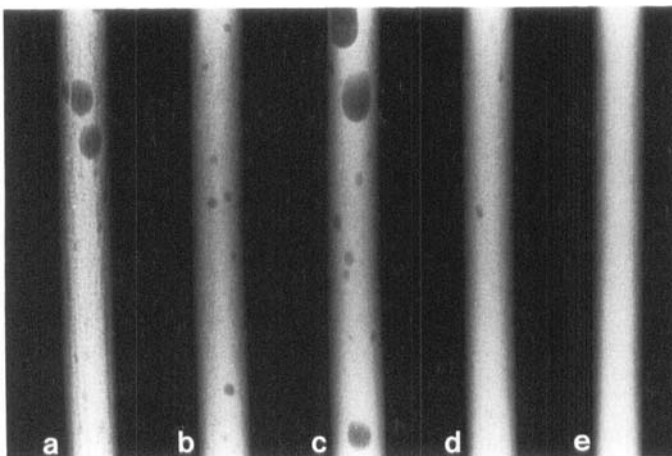


Figure 2. Radiograph of cement cylinders showing the macropores of the cement. a, mixing at atmospheric pressure. b,c, mixing with Mitab mixing system at 0.2 bar and 0.05 bar. d,e, mixing and collecting in EMS step-II at 0.2 bar and 0.05 bar.

Table 1 Number, size and volume of macropores (median, range) at different vacuum levels and different vacuum mixing methods. 10 samples in each subgroup

Method	Pressure (Bar)	No. of voids per cm <sup>3</sup>	Diameter of voids (mm)	Volume % of voids
Mitab system	1	2.3 (1.6-3.0)	1.85 (1.77-1.90)	0.73 (0.51-0.69)
	0.2	1.0 (0.6-1.8)	1.88 (1.18-2.52)	0.34 (0.06-0.95)
	0.05	1.0 (0.2-1.7)	2.02 (1.68-3.14)	0.47 (0.15-1.30)
EMS step-I	0.2	1.1 (0.5-1.2)	2.00 (1.65-2.69)	0.48 (0.12-0.81)
	0.05	0.6 (0.4-1.0)	2.24 (2.27-2.83)	0.31 (0.14-0.90)
EMS step-II	0.2	0.2 (0.1-0.5)	1.50 (1.50-2.50)	0.04 (0.01-0.14)
	0.05	0	0	0

Table 2 Number of micropores and density (median, range) at different vacuum levels and using different vacuum mixing methods. 10 samples in each subgroup

Method	Pressure (Bar)	Number of micropores	Density (g/cm <sup>3</sup> )
Mitab system	1	163 (103-185)	1.151 (1.093-1.213)
	0.2	6.3 (1.5-16)	1.269 (1.259-1.277)
	0.05	2.8 (1.0-5.5)	1.281 (1.265-1.285)
EMS step-I	0.2	4.5 (1.0-8.0)	1.275 (1.260-1.291)
	0.05	1.5 (0-5.0)	1.283 (1.278-1.290)
EMS step-II	0.2	2.0 (0-5.0)	1.283 (1.279-1.286)
	0.05	0.5 (0-3)	1.287 (1.282-1.302)

stained with dark shoe polish, enabling the dark-staining voids to be easily identified. Voids from 0.1 to 1 mm in diameter were called micropores, they were measured under the microscope with incident light (magnification  $\times 5$ ) and the number of micropores was counted on the same area (78.5 mm<sup>2</sup>). The median of the micropores from the 4 surfaces was recorded.

The density of the slices before staining was estimated by using an electronic balance with a density kit (AE 260 Mettler Instrument Corp., Greifensee, Switzerland). The mean of the density of 2 slices from each cylinder was recorded (g/cm<sup>3</sup>).

For statistical analysis the Mann-Whitney U test was used,  $P < 0.05$  was considered to be significant.

## Results

### Macroporosity

The number of voids was reduced to about 50 percent by vacuum mixing, compared to mixing at atmospheric pressure, but there was no difference between 0.2 bar and 0.05 bar pressure level in the Mitab system; however, in the EMS step-I the number of voids was reduced from 1.1 to 0.6 ( $P 0.004$ ). When adding the collecting step under vacuum (EMS step-II), the number of voids was further decreased and, when low-

ering the pressure to 0.05 bar, the macropores were eliminated completely.

Both with the Mitab system and the EMS step-I there was a tendency to enlargement of the voids' diameter at the 0.05 bar level compared to 0.2 bar. However, in the EMS step-II, a reduction was seen at the 0.2 bar level as compared to step-I ( $P 0.01$ ).

Volume percentage of voids was related to the multiplier of the number and diameter of voids. The highest value was found when mixing at atmospheric pressure. There were no differences either within or between the groups of mixing with the Mitab system or EMS step-I. However, in the step-II at 0.2 bar level, due to reduction of the numbers and decreasing diameters of the voids, the volume percentage was reduced by almost 90 percent (Table 1).

### Microporosity

When mixing at atmospheric pressure surface of the slices looked like honeycomb and the number of micropores was more than 20 times higher compared to vacuum mixing (Table 2). Lowering the pressure from 0.2 to 0.05 bar reduced the number, both using the Mitab system ( $P 0.006$ ), and the EMS step-II ( $P 0.048$ ). When comparing the Mitab system with the EMS step-II, a reduction was seen both at 0.2 bar ( $P 0.005$ ) and 0.05 bar ( $P 0.008$ ).

### Density

The density of the bone cement increased on lowering the pressure from 0.2 bar to 0.05 bar in the Mitab system ( $P$  0.007), and in both the EMS step-I ( $P$  0.03) and step-II ( $P$  0.007). When using the EMS step-II, the density was increased compared to the Mitab system ( $P$  0.002), and the step-I ( $P$  0.04) at 0.2 bar and 0.05 bar levels (Table 2).

### Discussion

Previous studies have shown that both vacuum mixing (Lidgren et al. 1987, Wixson et al. 1987, Davies and Harris 1990) and centrifugation (Burke et al. 1984, Davies et al. 1987) reduce the porosity of bone cement and increase its strength and fatigue life (James et al. 1992).

Alkire et al. (1987) used vacuum mixing as a method of reducing the porosity of Zimmer bone cement. A nearly bubble-free product could be achieved at about 0.05 bar. We mixed Palacos R bone cement at 0.05 bar in the Mitab commercial mixing system, but the number and size of macropores were not decreased compared with the 0.2 bar level (pressure recommended by the producer).

Wixson et al. (1987) proposed air initially surrounding the powder before mixing as one potential source of porosity. In our experimental system, evacuation of the air before mixing reduced the number of pores when mixing at 0.05 bar, but at the expense of increasing the diameter of the voids, and the volume percentage was about the same. As evacuation by itself did not reduce the porosity, we added the step of collecting the cement under vacuum and thus avoided the air trapped during transfer to the cement gun. By using this step we found that both the macropores and the micropores were decreased, and the density of bone cement was increased.

Wixson et al. (1987) also recommended that in order to avoid boiling of the monomer at room temperature, "a higher vacuum than 0.2 bar absolute pressure should not be used." Lidgren et al. (1987) showed that using pre-chilled monomer (4 °C) eliminates the risk of boiling at the level of 0.05 bar.

Our results show that mixing and collecting pre-chilled Palacos R® bone cement at 0.2 bar decreased the volume percentage of voids by 90 percent. At 0.05 bar all macropores were removed together with further reduction of micropores, which should increase the fatigue life of the bone cement.

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