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PENETRATION OF ACRYLIC BONE CEMENTS INTO CANCELLOUS BONE

PHILIP C. NOBLE & ERIC SWARTS

Bioengineering Division, Royal Perth Hospital, Perth, Australia

The depth of penetration of five commercial acrylic bone cements into cancellous bone was measured *in vitro*. Under standard, idealized conditions, cement penetration was found to vary significantly with different cements. Penetration was critically influenced by the coarseness of the cancellous bone and increased directly with the effective volume of the "cells" within the osseous matrix. An inverse correlation was determined between the mean cement viscosity during flow into the bone and final penetration depth. The dough time, set time and working time of each acrylic formulation was found to have no significant effect upon the depth of cement penetration.

It is suggested that in addition to the techniques adopted for introduction of cement to the bone, the selection of the bone cement itself may critically influence the incidence of late loosening following total joint replacement.

Key words: bone; bone cements; cement fixation; hip prosthesis; joint prosthesis

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Over the last few years increasing attention has been focused upon the pathophysiology of loosening of total joint replacements (Miller et al. 1978). Several studies have suggested that loosening of the components of arthroplasties is initiated by the occurrence of micromovement at the bone/acrylic interface leading to localized bone resorption and loss of osseous support for the cement mantle (Kaufer et al. 1976). This has led to a new emphasis upon the techniques associated with preparation of the osseous site and introduction of the cement dough (Ling 1980, Oh & Harris 1982). Devices are now commercially available which clean cancellous bone through removal of blood and debris, seal the femoral shaft thus enclosing the cement mass and pressurize the cement mix *in situ* with minimal contamination from blood or water. The fundamental aim of all these new measures is to increase the area of contact between cement and bone, essentially through penetration of the cement into the open cancellous structure (Markolf 1980). This stands in contrast to conventional, manual cement techniques utilizing more viscous bone cement, which generally lead to superficial, incomplete contact between the cement and the irregular osseous surface rather than true mechanical interlocking (Noble & Espley 1982).

Despite the apparent importance of cement penetration upon the long term success of joint replacements, few studies have examined fundamental aspects of the flow of acrylic cement into bone.

This paper reports experiments where the penetration of different commercial cements into cancellous bone has been studied *in vitro* using a standard biological model under controlled conditions. In this way, the interrelation of cement properties and osseous structure with total cement penetration has been determined.

MATERIALS AND METHODS

Cylindical biopsies of cancellous bone measuring approximately 10 mm in diameter by 15 mm in length were drilled from the femoral condyles of cadaveric femora. Five such biopsies were taken parallel to the longitudinal axis of each bone. Each biopsy was cut to 10 mm in length using a diamond saw and chemically macerated to leave a purely osseous structure free of all traces of tissue, fat or debris occupying the intraosseous spaces (Figure 1). In all, 270 such biopsies were prepared. Following maceration, each specimen was examined under a stereomicroscope and only those having sheets of trabecular bone oriented parallel to the longitudinal axis of the specimen were accepted for experimental use. Biopsies in which the intratrabecular spaces appeared occluded were also rejected. To enable the trabecular network to be simply described in quantitative terms, the cancellous structure was visualized as an array of packed, interconnected cylinders of a constant mean diameter. Any one cylinder was assumed to contain internal constrictions at a range of intervals along its length. The trabecular network of any one biopsy could thus be represented by the mean "cell" diameter measured from a section perpendicular to the axis of the specimen (Figure 2) and a mean "cell" length, defined as the average spacing of constrictions in the axial direction along each cancellous tunnel (Figure 3). The mean "cell" diameter was determined by counting the number of exposed, intratrabecular spaces transected by two perpendicular diameters across the end of each specimen.

Sixteen units of each of the following commercial bone cements were purchased from medical suppliers – C.M.W., Surgical Simplex P, Zimmer USA, Palacos and Sulfix 6. At a constant temperature of 22°C, one half unit of each cement formulation was mixed for 1 min in a stainless steel bowl at approximately 120 strokes per minute. Half of the mix was then transferred to a disposable syringe and extruded into four standard chambers of a polyacetal mould into which four numbered bone specimens had previously been placed (Figure 4).

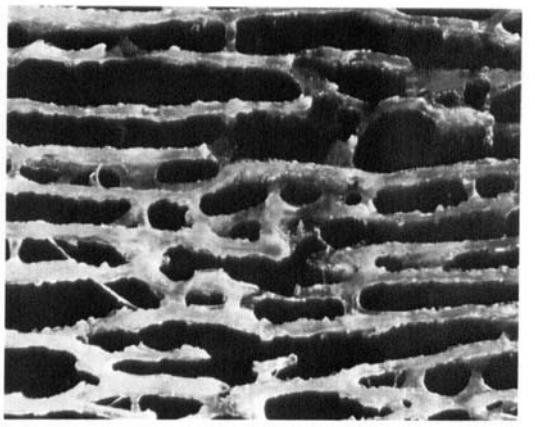

Figure 3. Longitudinal section of cancellous specimen showing typical structure of intertrabecular "cells", ×7.

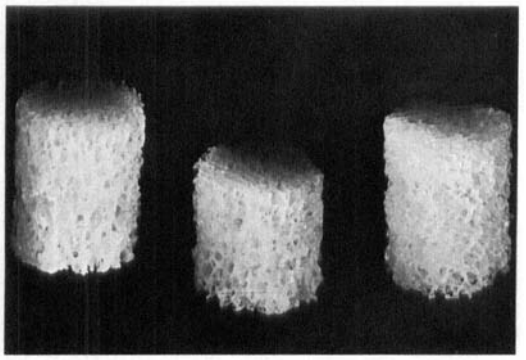

Figure 1. Three typical cancellous bone specimens following chemical maceration, ×1.7.

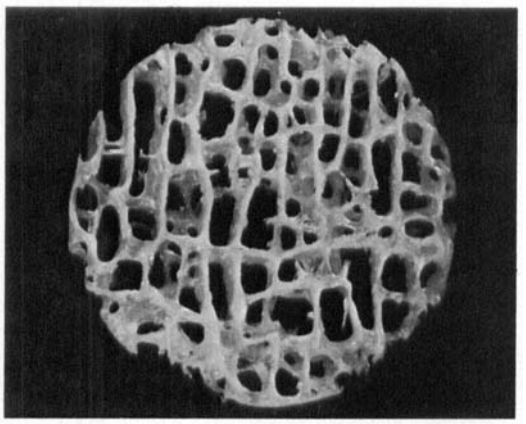

Figure 2. Transverse section of cancellous specimen showing typical structure of intertrabecular "cells", ×5.

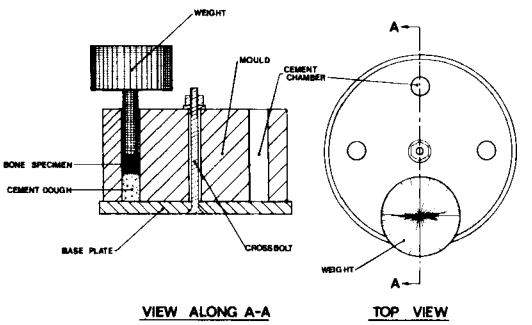

Figure 4. Schematic representation of experimental apparatus with one weight in place.

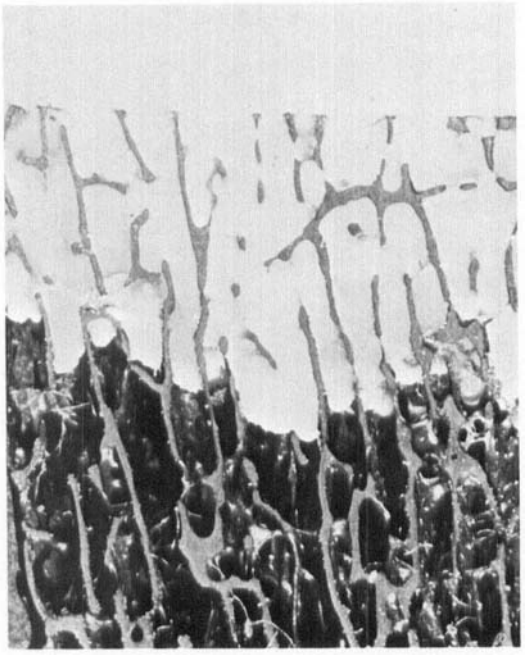

Figure 5. Longitudinal section of bone specimen following cement penetration. Trabeculae have been stained with silver nitrate solution to enhance contrast.

Once each chamber was filled the mould was sealed and inverted. The remaining cement was monitored for the occurrence of the dough stage using the method of ASTM F451-76. Ninety seconds following the dough stage a weight of 2.80 N was placed on each bone specimen and left to descend freely into the bone cement until setting occurred. The weight was sufficient to generate an average pressure of 35 kPa (5 psi) at the bone/acrylic interface which earlier reports have demonstrated to be typical of pressure developed during joint replacement (Markolf & Amstutz 1976). Once the cement had set, each chamber was cleared and the acrylic/bone cylinder sectioned longitudinally to reveal the zone of intraosseous cement intrusion (Figure 5). In each case the mean depth of cement penetration was measured with a stereomicroscope with an electronic microlength measuring accessory. Where any evidence of uneven cement flow or non-uniformity of the cancellous structure was observed, the specimen was rejected. An average of 18 bone specimens was accepted to characterize the depth of cement flow in each of the acrylic formulations. Using the microscope, the mean length of the cancellous "cells" within each specimen was also measured for all "cells" visible within the longitudinal section. The porosity of each specimen was calculated by comparing the true density of the trabecular bone with the apparent density of the cancellous matrix specimen as a whole.

Characterization of cement formulations

The viscosity of each cement formulation during polymerization at 22°C had been measured in previous studies in our laboratory and reported in terms of the resistance of each cement to extrusion from an experimental rheometer under fixed conditions (Noble 1982). In order to convert this data into absolute units of viscosity, the apparatus was calibrated using mixtures of pure methylmethacrylate monomer and prepolymerized powder of varying solid to liquid ratios. Each batch of acrylic dough was divided in two, one half being placed in the extrusion apparatus and the other in a standard container beneath a Brookfield viscometer. Simultaneous measurement of viscosity and extrusion resistance was thus performed with mixtures of approximately 100, 250, 500, 1500, 3000 and 6000 poise. A least squares correlation of Brookfield viscosity against extrusion force led to the expression

$$\eta = 2320\,(F-0.69)$$

where F = extrusion force in kg
η = cement viscosity in poise

This expression enabled the original data to be converted to units of viscosity as presented in Figures 6 and 7. The dough time and set time of each cement formulation were also determined at 22°C using the methods of ASTM F451-76 and represent the average of six experimental values in each case.

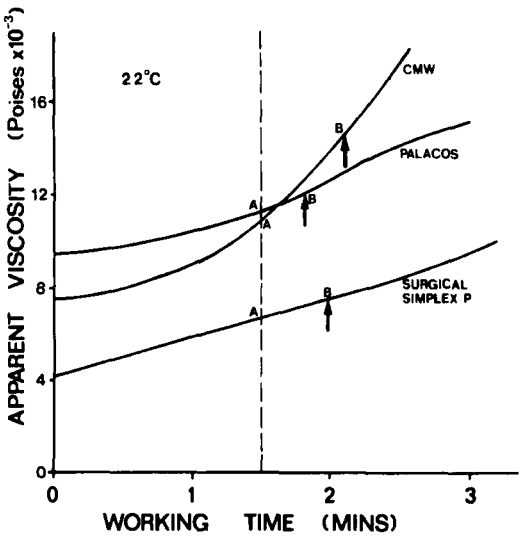

Figure 6. Variation of viscosity of bone cements following the onset of the dough stage. Points marked "A" correspond to cement viscosity at the commencement of cement penetration, "B" to 50 per cent of final penetration.

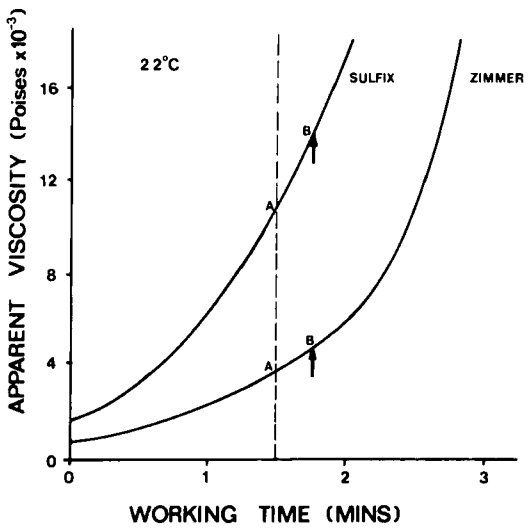

Figure 7. Variation of viscosity of bone cements following the onset of the dough stage. Points marked "A" correspond to cement viscosity at the commencement of cement penetration, "B" to 50 per cent of final penetration.

RESULTS

The mean depth of cement penetration observed for each acrylic formulation is presented in Table 1. Although a different set of bone specimens was used with each cement formulation, statistical analysis demonstrated that no significant differences were present between the average values of parameters characterizing cancellous structure. Average parameters for each set of specimens were: cancellous cell length: 1.93 ± 0.14 mm, cancellous cell diameter: 1.22 ± 0.04 mm, calculated cancellous cell volume: 2.26 ± 0.28 mm^3, porosity: 82 ± 2% (all values ± standard error). Although the bone specimens used with each cement did not differ in osseous structure, the mean depth of penetration varied dramatically from 2.72 mm with C.M.W. cement to 5.40 mm with Surgical Simplex P. Statistical analysis of this data demonstrated two significant levels of cement penetration (at $P < 0.05$). Surgical Simplex P and Zimmer cements were associated with penetration depths which were not statistically distinguishable, with a mean depth of penetration of around 5.2 mm. In contrast, Palacos, Sulfix 6 and C.M.W. cements all displayed mean depths of penetration of around 2.9 mm under the experimental conditions employed.

In order to examine the relationship between

Table 1. Depths of cement penetration observed for each cement formulation (means ± standard errors). Bars link values which are not significantly different at the 5 per cent level

Cement formulation	Mean penetration (mm)		No. of specimens
Surgical Simplex P	5.40±0.33		19
Zimmer	5.01±0.33	P<0.05	14
Palacos	3.01±0.17		21
Sulfix 6	3.00±0.28		22
C.M.W.	2.72±0.17		16

*Table 2. Correlation coefficients for linear regression of cement penetration against variables quantifying osseous structure. All correlations are significant at the 0.01 level except those marked *P>0.05 and **0.01<P<0.05*

Cement formulation	Depth of cement penetration versus				No. of observations
	Cancellous cell length	Cancellous cell diameter	Cancellous cell volume	Porosity	
Surgical Simplex P	0.634	0.714	0.902	0.801	19
Zimmer	0.630	0.598	0.913	0.025(	14
Palacos	0.851	0.635	0.941	0.204*	21
Sulfix 6	0.884	0.798	0.938	0.029*	22
C.M.W.	0.825	0.426**	0.834	0.108*	16
Mean	o.776	0.648	0.909	0.242*	18.4

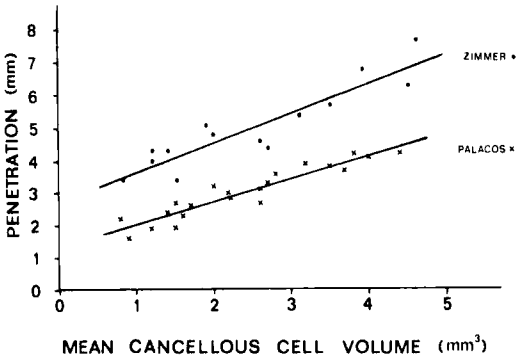

Figure 8. Observed data for cancellous "cell" volume and cement penetration for two bone cements. These results are typical of those observed for all cement formulations.

the structure of cancellous bone and the depth of cement flow, the cement penetration observed with each specimen was correlated against its porosity and cancellous cell length and diameter for each cement formulation. The correlation coefficients in each case appear in Table 2. In all but one instance, the depth of cement penetration was found to depend significantly upon the parameters quantifying osseous microstructure (cancellous cell length and diameter). In only one case did the overall porosity of the bone correlate significantly with penetration depth.

To combine the effects of cancellous "cell length" and "cell diameter," the mean cancellous "cell volume" was calculated using the expression

$$V = \frac{ld^2}{4}$$

where V = mean cancellous cell volume
l = mean channel length between constrictions ("cancellous cell length")
d = mean cancellous cell diameter

This parameter was found to give the strongest correlation with respect to cement penetration for every cement formulation. Over the range of bone specimens employed in this study, the depth of cement penetration was found to vary directly with the cancellous cell volume, leading to linear regression equations. Typical results are presented in Figure 8 with the corresponding lines of best fit. The regression parameters for each bone cement appear in Table 3.

Effect of cement properties

A recent investigation has demonstrated that bone cement flow in cancellous bone continues

Table 3. Regression parameters for each of the bone cements

Cement formulation	Depth of penetration = a (cell volume) + b	
	a ± standard error	b ± standard error
Surgical Simplex P	1.13±0.13	2.70±0.35
Zimmer	0.91±0.12	2.75±0.32
Palacos	0.71±0.06	1.33±0.15
Sulfix 6	0.79±0.07	1.20±0.18
C.M.W.	0.56±0.10	1.48±0.24

Table 4. Experimental data relating to the five cement formulations at 22°C

Cement formulation	Set time (22°C) (seconds)	Time to 50 per cent penetration (seconds) (5 psi) 35 kPa	Viscosity at 50 per cent penetration (poise)	Depth of penetration (mm) (5 psi) 35 kPa
Surgical Simplex P	588	29	7600	5.40
Zimmer	456	16	4900	5.01
Palacos	540	19	12150	3.01
Sulfix 6	510	16	14000	3.00
C.M.W.	396	36	14700	2.72

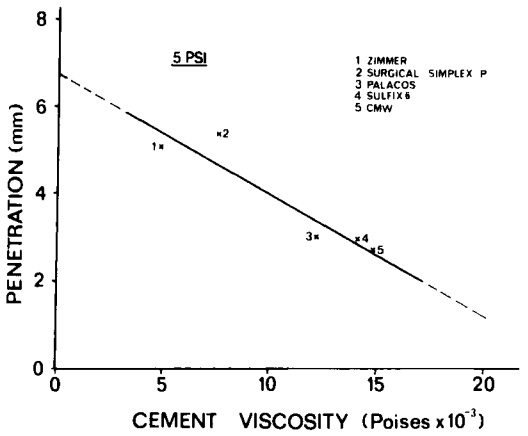

Figure 9. Observed data for mean cement penetration and cement viscosity at 50 per cent of final penetration for the five cement formulations examined in this study.

for approximately 100 s after introduction of cement to bone under a driving pressure of 35 kPa (5 psi) (Noble 1981). The data of Figures 6 and 7 show that during this period all the formulations studied thickened significantly, particularly Zimmer and Sulfix 6 cements. Consequently, a characteristic viscosity was derived for each formulation by taking the viscosity present when 50 per cent of the ultimate penetration depth would have been attained, based upon this work. The duration of cement flow corresponding to 50 per cent penetration has been listed in Table 4 in addition to the corresponding viscosity of each cement. It was assumed that this data could be taken to be indicative of the viscosity of each formulation during the entire intrusion process.

The depth of cement penetration determined for each formulation was found to correlate strongly with the mean viscosity of the mix ($P < 0.005$, $r = 0.931$), a linear relationship being observed over the range of cement properties studied (Figure 9). Correlation of pentration depth against other variables characterizing the rate of polymerization of each cement (set time, dough time, working time) failed to demonstrate any significant statistical relationship.

DISCUSSION

These results have demonstrated that different formulations of bone cement lead to significant differences in osseous penetration under standard, idealized conditions. Indeed, approximately 100 per cent greater depth of penetration was obtained with Surgical Simplex P than C.M.W. cement using virtually identical specimens of typical osseous structure. This suggests that intraoperatively, a significant factors in the relationship between late loosening of total joint replacements and inadequate interdigitation of cement at the bone/acrylic interface may be the selection of the cement itself in addition to the cement technique.

Although considerable differences in cement penetration were observed in similar bone specimens, the dependence of that penetration upon the coarseness of the trabecular structure was also found to vary systematically with each cement, those formulations of lowest working viscosity being, as a first approximation, most dependent upon the bone structure for full realization of their potential for interdigitation. The significant correlation of depth of cement penetration with cancellous cell diameter is not surprising as, in simple fluid flow, the viscous resistance of a fluid varies as the inverse square of the channel diameter. In terms of the idealized model of the cancellous cell structure, a further major obstruction to flow is the presence of periodic constrictions along each cancellous channel, hence the total resistance of any one bone specimen is expected to be a function of the length between constrictions multiplied by the square of the cell diameter – in effect the "volume" of each cancellous cell.

The lack of correlation observed between cement penetration and gross bone porosity is expected to arise because cement is particularly sensitive to the geometry of the trabecular spaces, whereas specimens of similar apparent porosity (i.e. bulk density) may have trabecular cells of different internal geometry, depending upon the thickness of bone separating each space from those immediately adjacent.

On the basis of this study it appears that the single determining factor in the penetration of

cement into bone of a given structure is the viscosity of the mix during its period of initial intrusion into the cancellous network. Given ideal conditions, the thinner the cement, the deeper the flow from the bone/cement interface before viscous resistance brings penetration to an end. Indeed, if it is assumed that 35 kPa is typical of the pressure applied at the surface of the bone by bone cement during total joint replacement procedures, use of Palacos and C.M.W. cements would not be expected to allow cement penetration in excess of 3 mm in many procedures, particularly if fine trabecular bone were present. Sulfix 6 cement would perform similarly if applied late using conventional manual techniques, however early insertion of this cement at around the dough stage using a syringe or surgical gloves treated with paraffin would be associated with penetration equal to or greater than any of the other formulations studied in this work. Sulfix 6, in fact, appeared to be a bone cement not suited to manual insertion in warm operating theatres where the working time is substantially shortened. Both Surgical Simplex P and Zimmer bone cements demonstrated the greatest depth of cement penetration due to their relatively low viscosity throughout most of the period of intrusion (i.e., 45–90 s following the start of cement/bone pressurization). In the case of the Zimmer cement, earlier insertion would have been associated with significantly lower viscosity and thus greater penetration into cancellous bone than was observed in these experiments.

Intraoperatively, substantially less interdigitation of bone cement is expected than was observed in this experimental model. Examination of many bone specimens which had not been adequately macerated prior to cement insertion demonstrated that the flow of cement in bone is particularly sensitive to the availability of empty, vented trabecular spaces. Cement was never observed to displace fat or other interosseous tissue at the intrusion pressure employed in this study. Moreover, unless a clear path was present to allow displaced air to escape from the cancellous structure, penetration was again seriously impaired. Consequently, as in most operative procedures a clean, open cancellous site is not present, the degree of interlocking obtained by intraoperative pressurization of the acrylic is expected to be limited in comparison with our experimental model. The depth of cement intrusion may however be maximized during joint replacement procedures if all available methods are employed to clear trabecular bone of all fat, tissue and osseous debris to a depth of at least 6 mm prior to the introduction of the acrylic cement.

Increased interdigitation of acrylic cement into cancellous bone is expected to lead to greater long term stability of the cement/bone interface as relative micromovement between cement and bone is minimized (Harris 1980, Ling 1980). Histological studies have shown that tissue necrosis occurs to a depth of about 3 mm back from the cancellous surface following joint replacement, and that for a period of up to 2 years postoperatively the osseous bed is remodelled through resorption of necrotic tissue and formation of new bone along the original trabeculae (Willert et al. 1974, Debrunner et al. 1976). It is postulated that during this stage of reconstruction the implant bed is particularly vulnerable to mechanical disruption leading to increased resorption and micromovement (Kaufer et al. 1976). Deep anchorage at the bone/cement interface through penetration of bone cement beyond the necrotic zone is envisaged as assisting in the stabilization of the interface, whilst a new bony architecture is being laid down within the framework of the original trabeculae.

Experimental studies in animals have demonstrated that pressurization of low viscosity bone cements during joint replacement procedures can lead to a significant reduction in component loosening in comparison with conventional manual techniques using "dough" cements of higher viscosity (Miller et al. 1979). It is still unclear, however, whether trabecular bone deeply embedded within acrylic cement can remain viable immediately following joint replacement, or whether the process of osseous necrosis and resorption extends with the bone cement into the trabecular matrix.

Despite its clear potential benefits, the use of low viscosity cements in joint replacement is associated with many practical problems in surgical technique (Harris 1980). Conventional cement technique involving manual delivery of thick ce-

ment dough has relied heavily upon the inherent viscosity of the cement itself to enable the generation of interfacial pressure between cement and bone and to stabilize the position of components within the bone prior to cement setting. As thinner cements may be displaced within the bone so much more readily, the achievement of adequate levels of interfacial pressure becomes more difficult as pressurization depends critically upon complete sealing and containment of the operative site. In practice, this necessitates the use of specialized devices, for example, a distal plug for the femoral canal. In many situations, however, including the proximal femoral shaft, techniques for adequate sealing of all gaps and spaces are not yet generally available.

For this reason, long term studies are still awaited to determine whether conventional or low viscosity cementing techniques offer relative advantages in clinical practice. A recent *in vitro* study (Noble & Espley 1982) has suggested that in the femur both of these methods produced comparable fixation which still remains significantly inferior to the theoretical potential which the experiments of this paper have demonstrated. It thus appears that if the full promise of cement fixation is to be fully realized, the development of a second generation of cement techniques to match the advances in the bone cement itself is essential.

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Correspondence to: Philip C. Noble, M. Eng. Sci., Dept. Orthopaedic Surgery, The Methodist Hospital 6565 Fannin, Houston, Texas 7730, U.S.A; Eric Swarts, Bioengineering Division, Royal Perth Hospital, Perth, 6001, Western Australia.