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Fatigue of bone cement with simulated stem interface porosity

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Cracks in bone cement have been observed in carefully examined post-mortem preparations of cemented stems. These cracks were probably caused by fatigue, and frequently appeared to initiate at pores. Ubiquitous porosity, occurring preferentially at, or near, the stem, is most likely caused by polymerization shrinkage. Preparation of air-free cement has only a marginal influence on the interface porosity, but pre-heating the stem in order to reverse the direction of polymerization can reduce or eliminate it. To estimate the impact of interface porosity on the fatigue strength of bone cement, test plates for this study were cast in a steel mold without release foils, and with one side of the mold warmer. Sample plates so prepared from chilled, partial vacuum-mixed PALACOS® R, have one face essentially pore-free and the other porous, the extent and morphology of the porosity being very similar to that observed on the stem–cement interface. Four-point bending fatigue strength, determined after 60 d conditioning in Ringer's solution at 37 °C, was only 20 MPa (at 10^6 cycles, with the porous side under tension) compared to 30 MPa for conventionally prepared, pore-free material. This corresponds to a 10–100 fold reduction in cycles to failure in the range of stresses predicted to occur *in vivo*. © *1998 Kluwer Academic Publishers*

1. Introduction

Total hip replacement with bone cement fixation of prosthetic components is a widely accepted surgical procedure with excellent clinical results [1]. Revisions are mostly due to aseptic loosening [2–4], more frequently of the femoral component [5], for which there is solid evidence that it is caused by multiple fatigue fractures of the cement mantle [6]. Crack initiation appears to be localized to pores at the stem–cement interface [6, 7].

Conventional bone cements are based on a mixture of polymethylmethacrylate (PMMA), or its copolymers, and methylmethacrylate (MMA), with additives, such as radio-opacifiers (barium sulphate or zirconium dioxide) and antibiotics, relying usually on a room temperature-curing catalytic system of benzoyl peroxide (contained in the powder) and *N-N*-dimethyl-p-toluidine (contained in the liquid). The polymerization of MMA is exothermic, incomplete and density increasing (monomer density is 0.94 g cm^{-3}, polymer density is 1.18 g cm^{-3}). Cured cement is an inhomogenous material with internal defects caused by additives and admixing of air. Much work has been done to reduce the presence of air bubbles [8–11], and a number of mixing systems aiming to attain this goal are in broad clinical use.

However, polymerization shrinkage of the curing cement, even if completely devoid of air bubbles, can cause "cavitation" depending on the geometry, boundary and initial conditions which control the kinetics of polymerization. The puzzling presence of the interface pores, even with application of air-free cement [12], appears to be explained by the unavoidable cement shrinkage and initiation of polymerization at the normally warmer bone–bone cement interface [13]. The direction of polymerization can be reversed by pre-heating of the stem (to at least 44 °C), which, in simulated implantations, was shown greatly to reduce porosity at the stem–bone cement interface [13].

A number of experimental fatigue studies have compared different cement brands and preparation techniques [14–19]. The International Organization for Standardization (ISO) specifies in the Standard 5833 methods of sample preparation and of testing to determine compression and four-point bending strengths of acrylic resin bone cements [20]. Fatigue testing is not yet required by ISO; published studies have been done in either three [16] or four-point bending [18, 21], or in uniaxial fully reversed tension–compression modes [14, 15, 17, 19]. Fatigue testing under load control leads to earlier failure than displacement control, and is considered more relevant to *in vivo* conditions [21]. Fatigue strength results and their relevance to the clinical situation are very much affected by the method of sample preparation; casting and

polymerization has generally aimed at production of as many defect-free samples as possible, rather than at simulating conditions of cement use in total hip joint replacement.

For this study, in order to estimate the impact of interface pores on the fatigue strength of bone cement, samples were prepared for the four-point-bending fatigue testing using a modified sample-molding technique which could reproduce the morphology and extent of interface porosity in cemented prosthesis.

2. Materials and methods

The bone cement used for the study was PALACOS® R with gentamicin. Both powder and liquid components were chilled to 5 °C and mixed at 20 °C in Optivac, a partial vacuum mixing system from ScandiMed Implant AB, Sjobo, Sweden. Bone cement plates of group A were prepared according to ISO 5833, but the molding frame and the cover plates were made from stainless steel (cover plates were ground and polished). The release from the molds, as prescribed, was facilitated by the use of polyester foils. Plates (90 mm × 65 mm) were cut and milled into five 10 mm wide strips (approximately 3.2 mm thick, 90 mm long) and kept in 37 °C Ringer's solution for a minimum of 60 d before fatigue testing in four-point bending, also performed in 37 °C Ringer's solution with the set-up specified for quasi-static bending according to ISO 5833. The cycle number was limited to 10^6.

For group B, sample plates were prepared in the same molds, using the same bone cement and the same mixing technique, but without release foils and with one of the steel cover plates preheated to 45 °C. In testing, the surface of the samples facing the colder cover plate, and hence scattered with pores, was set under tension.

3. Results

The molding of the samples for group A, using cover foils in order to release the samples from the mold, produced plates of slightly variable thickness, thinner than the molding frame except near the edges. The surfaces were smooth and essentially free of any pores. The use of mold-release foils allows cement polymerization shrinkage (about 5%) simply to reduce the plate thickness.

The molding of the samples for group B produced plates of a very uniform thickness with one side smooth and the other covered by open pores. The area fractional porosity measured at six locations of 7 mm × 14 mm was 24.8% ± 1.6%; close to 18% found on the prosthesis interface in simulated implantation with vacuum-mixed PALACOS® R [13]. The smooth side was the one facing the pre-heated cover plate.

The S–log*N* diagrams according to the Woehler's procedure (Fig. 1) illustrate the following findings for the fatigue strength. In group A, the average quasi-static bending strength was 61.9 ± 1.5 MPa; the regression fit of the data between 10^3 and 10^6 cycles suggested 29.9 MPa at 10^6 cycles. Group B was significantly weaker with the average quasi-static bending strength of 48.6 ± 3.3 MPa (a 21% reduction compared to group A); and 20.6 MPa at 10^6 cycles (a 31% reduction compared to group A). Expressed in terms of cycles to failure, at the level of 35 MPa there is a reduction by a factor of 100 for group B compared to group A, and at 20 MPa by a factor of 10.

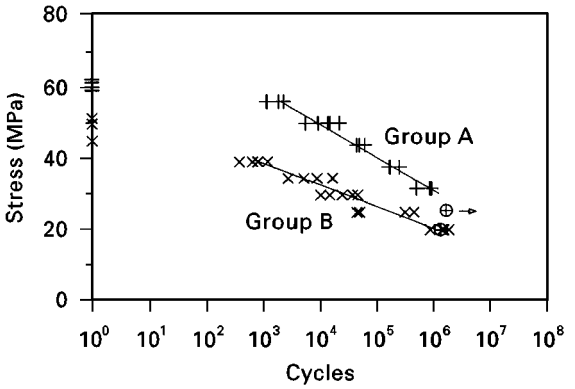

Figure 1 Bending stress versus log cycles to failure according to the Woehler's procedure. Group A (+) are pore-free samples molded with polyester foils. The two encircled samples did not fail up to 10^6 cycles. Group B (×) samples, molded without release foils, had a pore-scattered side set under tension.

4. Discussion

The presence of pores at the prosthesis–bone cement interface leads to a significant increase in risk of cement mantle fatigue failure. The theoretical stress concentration factor at an enclosed spherical cavity is about 2 (for a Poisson's ratio of 0.3) [22]; at an open hemi-spherical cavity it is about 2.2 ([23] calculated by FEM). However, pores in the bone cement are not spherical. A number of "buds" formed by the shrinkage of a newly polymerized matrix over polymer beads protrude from the pore walls; thus the theoretical stress concentration factor is probably significantly higher than for a spherical cavity. On the other hand, in ductile materials, the actual reduction in strength is always lower than that suggested by the theoretical analysis. In this case, the effective stress concentration was 1.3 for quasi-static loading, and about 1.5 at 10^3 and 10^6 cycles, i.e. the fatigue strength of Group A was about 50% higher than of Group B in the cycle range tested.

In all fatigue investigations of bone cements performed by the authors up to now (limited to 10^7 cycles) an endurance limit has never been found and the data could be well fitted by linear regression. Nevertheless, the fatigue data presented here should not be extrapolated on a straight line by more than about a factor of 3 in the number of cycles. There is no rational basis to assume that the lines of the two groups would cross at a point with positive value of stress, i.e. that Group B would become stronger than Group A at any number of cycles. In fact, in this case, the two lines would cross at near zero stress level at about 10^9 cycles. The factor 1.5 in strength

reduction is likely to be maintained throughout the high-cycle fatigue ($> 10^6$).

5. Conclusion

This study has established, using emulated bone cement mantle samples, a significant, 50% increase in the fatigue strength of the cement rendered free of porosity at the stem interface. This may help clarify the clinical findings that reduction of porosity by improved mixing has not led to anticipated improvement in prosthesis survival [1] – even the partial vacuum-mixed bone cement, as used in this study, will produce stem interface pores when polymerization is initiated at the bone interface. The results lend further support for the clinical practice of controlled stem preheating which was shown to reverse the direction of polymerization and thus greatly to reduce the interface porosity [13].

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