

Multi-axial fatigue failure of orthopedic bone cement – experiments with tubular specimens

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Bone cement is subjected to multi-axial cyclic loading when used to fixate orthopedic prostheses for joint arthroplasty. In this study, tubular specimens of poly(methylmethacrylate) (PMMA) bone cement are subjected to internal pressure and cyclic axial loading to ascertain the influence of multi-axial loading on fatigue life. As expected, it was found that the probability of survival of specimens under multi-axial loading was very much reduced relative to specimens loaded uniaxially. Furthermore, the variability of the fatigue life was increased by multi-axial loading. In conclusion, the results point to the importance of characterizing the behavior of bone cements under the multi-axial fatigue experienced *in vivo*, and of the importance of accounting for the multi-axial stress state when predicting implant longevity.

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1. Introduction

Orthopedic joint replacement implants are often fixated into bone using a polymeric thermoplastic called polymethylmethacrylate (PMMA). When mixed with antibiotic and radiopaque additives, this material is called ‘‘bone cement’’. The long-term survival of the joint replacement is dependent on the fatigue strength of this material. For example, hip prostheses have been shown in the Swedish hip register to fail (defined as revision before death) as a consequence of loosening of the components from the bone in some 70% of cases [1]. Several experimental and finite element studies have shown that, under physiological loading conditions, the stress state in the cement is multi-axial [2, 3]. A number of retrieval studies further confirm that damage resulting from the multi-axial nature of the stress occurs in the cement mantle. For example, Topoleski *et al.* [4] conducted a fractographic examination of 12 *ex vivo* cement mantles and showed that secondary cracks propagate perpendicular to the main crack implying that a second tensile stress was involved in damage growth. Furthermore, Jasty *et al.* [5] reported a number of different types of cracks; radial cracks caused by tensile hoop stresses and circumferential cracks caused by bending stresses. Despite the apparent importance of multi-axial stressing of the cement mantle, there is no published data about the multi-axial *fatigue* performance of orthopedic bone cement.

Leever *et al.* [6] investigated the effect of a biaxial stress state on fatigue crack growth in industrial PMMA (i.e. Perspex). Centrally-notched plates of PMMA were subjected to biaxial stress states; the notch was

perpendicular to one of the principal stress directions. They found that a decrease in fatigue crack growth rate occurred with increasing stress bi-axiality, and it was suggested that the decrease was due to crack closure caused by the tensile stress parallel to the propagation direction. One previous paper dealing with bone cement under multi-axial loading is by Silvestre *et al.* [7]. They subjected cylindrical specimens to a combined internal pressure and axial compression, and showed different multi-axial failure loads for two types of acrylic bone cement. Furthermore, they established that bone cement follows the Culomb–Mohr failure criterion such that the stress state at failure is given by $\sigma_1 = A + B\sigma_3$ where σ_1 is the maximum principal stress and σ_3 is the minimum principal stress; A and B being empirical constants.

The aim of this study was to further develop this work by testing the hypothesis that an off-axis load superimposed on a *cyclic* tensile load (i.e. the kind of loading occurring in intramedullary fixation) reduces the fatigue life of PMMA. If this is true, then perhaps a standard test for bone cement should be devised to include multi-axial loading and, furthermore, a multi-axial damage accumulation law might provide even better computer simulations of failure in cemented joint replacements [8].

2. Materials and methods

Bone cement was prepared using Cemex[®] Rx (Tecres, Verona, Italy) acrylic bone cement. The cement was vacuum-mixed using the Optivac[®] system (Scandimed A.B., Sjöbo, Sweden) and was mixed according to the following steps: the cement constituents (PMMA powder

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and a liquid monomer) were added to the Optivac cartridge, the cartridge was sealed and a vacuum applied to the chamber for 10 s to allow complete air evacuation. The cement was then mixed under vacuum for 1 min. After a 30–60 s resting period the cement was injected into the mold.

The mold used to make the specimens consisted of a three-part design: an outer body, an inner body, and a plunger/centralizer (Fig. 1). All components were machined from polyethylene. One end of the inner body was press-fitted into a circular slot in the outer body. The plunger/centralizer fitted over the inner body and between the outer body. Both fits were zero-tolerance fits to ensure centralization of the inner piece. The plunger allowed excess cement to escape via pressure relief holes (Fig. 1).

It can be seen that, when the cement is injected into the mold, the result is a tubular specimen with internal and external tapers (Fig. 2). The region where the cement had extruded out via the pressure relief holes was grinded with 320 SiC grinding paper to ensure a flat surface on the end of the specimen. All specimens were soaked in a bath (Grant Instruments Ltd, Cambridge, England) for 14 days prior to testing to allow polymerization and water absorption to take place. All manufactured specimens

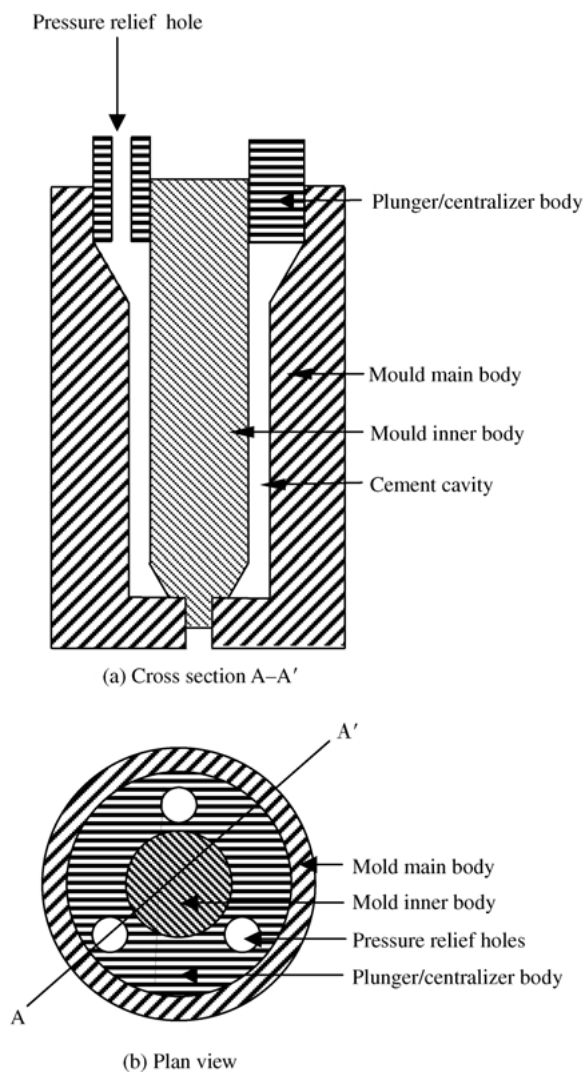


Figure 1 (a) Cross section and (b) plan view of the assembled mold for the multi-axial specimens. The clear section represents the area filled with cement.

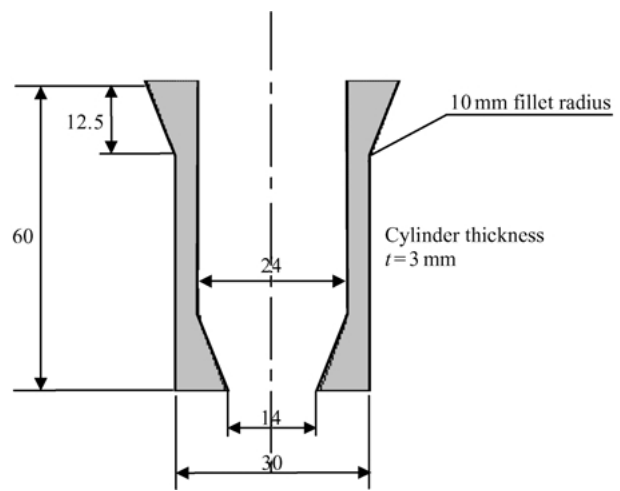


Figure 2 Cross section of a molded multi-axial bone cement specimen. All dimensions are in millimeters.

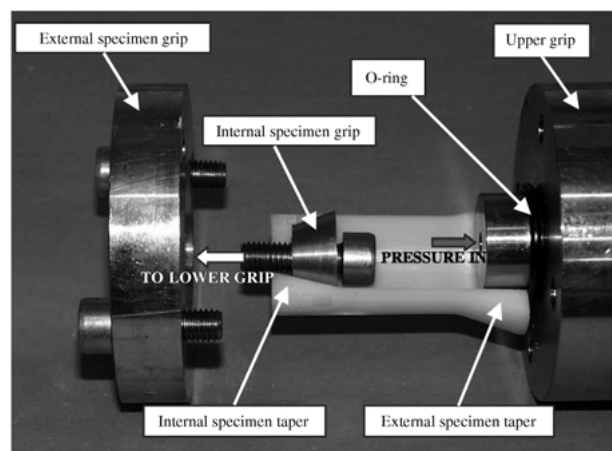


Figure 3 Detail of specimen gripping arrangement.

were tested as to do otherwise would affect the variability in the measured fatigue behavior [9].

The specimen was gripped at the tapers and loaded axially (Fig. 3). An internal pressure was applied simultaneously thereby creating hoop and radial stresses. The specimen was pressurized by an air-activated hydraulic foot pump (Power Team, SPX Corporation, MN, USA) which pumped oil into the cavity. To separate the oil from the specimen and to ensure “burst out” of the oil did not occur, a balloon was fitted over the section of the upper grip that fitted into the specimen. The balloon prevented any “near through-thickness pore” from causing burst out of the oil and loss of pressure. Pressure was maintained in the set-up from a non-return valve to the specimen. The pressure could be read directly from a pressure gauge and released by a pressure relief valve. Pressure within the specimen was contained by o-rings on both ends of the specimen (Fig. 3).

Temperature control within the test rig was achieved by passing a continuous flow of water through the testing tank; a water bath (Grant Instruments Ltd, Cambridge, UK), with a pump attached, was used to heat and pump the water to the test rig; the resulting temperature control was ± 0.1 °C. The temperature was maintained at 37 °C during the test and the loading frequency was 5 Hz.

TABLE I For the multi-axial stress states, comparison of the nominal stress in the wall of the tubular specimens with the actual stress*

Nominal stress ($0-\sigma_a, \sigma_h$)	Actual stress ($0-\sigma_a, \sigma_{h-\min} - \sigma_{h-\max}$)	Cyclic hoop stress
(0-11, 11)	(0-10.9, 10.4-11.0)	0.6
(0-11, 16.5)	(0-10.7, 14.9-16.5)	1.6
(0-15, 15)	(0-14.7, 13.1-15.0)	1.9

*Values in MPa.

2.1. Relationship between loading and multiaxial stress

Five multi-axial stress states were created. The nominal value of these stresses, in MPa and using the notation ($0-\sigma_a, \sigma_h$) where $0-\sigma_a$ denotes the axial stress going from zero to σ_a , and σ_h denotes the hoop stress on the inner surface, was as follows: (0-11,0), (0-11,11), (0-11,16.5), (0-15,0), and (0-15,15). Pressurization of the tubular specimens caused two effects which changed the stress state in the specimen from its nominal value. These two effects arose because:

1. the specimen and grips formed a cylindrical pressure vessel and therefore an additional axial force on the walls is produced on pressurization. This force was measured by setting up the experiment in a testing machine under position control (i.e. the specimen is not allowed to move when clamped); thus the tensile axial force that would act on the specimen due solely to internal pressurization is read as the compressive force by the materials testing machine. The axial force was measured as a function of pressure and a relationship between axial force and internal pressure was determined as $F = aP$ where $a = 0.2074$, and F is the tensile axial force (kN) and P is the internal pressure (MPa).

2. an increase in volume of the pressurized cavity occurs when the load is applied. This increase in volume causes the pressure to vary cyclically 180° out of phase with the axial load. The fluctuation in pressure was noted for all tests by reading the dial of the pressure gauge. The consequences of this effect were as follows:

- a. Consequence for the axial stress in the walls: for each of the multi-axial loading configuration, the cyclic change in axial stress was altered slightly from its nominal value – Table I shows this for each of the multi-axial stress states. It turns out that the cyclic axial stress is not very different from what it should be and therefore the pressurized set of specimens may be compared directly with the unpressurized (control) specimens.

- b. Consequence on the hoop stress in the walls: the effect causes the hoop stress to vary cyclically as shown in Table I.

3. Results

At 11 MPa axial stress, the fatigue life is reduced to 30% of the uniaxial value when a hoop stress of 16.5 MPa is applied. However the p value for this is $p = 0.06$ indicating that the null hypothesis (i.e. that the off-axis stress has no effect) cannot be firmly rejected. At 11 MPa axial stress and 11 MPa hoop stress, a 16% increase in

TABLE II Summary fatigue results for the tubular specimens $n = 6$

	Mean N_f	Standard deviation N_f	p value Mann-Whitney
Axial 11 MPa			
Hoop = 0	545,135	$\pm 635,276$	
Hoop = 11 MPa	646,062	$\pm 437,963$	0.41
Hoop = 16.5 MPa	159,302	$\pm 177,326$	0.06
Axial 15 MPa			
Hoop = 0	68,957	$\pm 89,764$	
Hoop = 15 MPa	28,757	$\pm 53,797$	0.09

p -values are reported for the multi-axial stress states vs. its corresponding control (i.e. zero hoop stress).

fatigue life is found compared to the 11 MPa uniaxial value; however in this case the p value indicates equal likelihood of failure under uniaxial and multi-axial conditions. At 15 MPa axial stress the average fatigue life reduces to 40% of the uniaxial value when an equal hoop stress is applied, but again the null hypothesis cannot be firmly rejected because of the rather high p value of $p = 0.09$, see Table II.

Whilst the results give a firm indication that bone cement fatigue failure is more rapid when there is a multi-axial stress state, the most important result is that there is great variability. This variability dominates over the effect of the multi-axial stress to the extent that no difference in failure life is observed between the uniaxially loaded specimens at an axial stress 11 MPa and the pressurized set with an additional nominal hoop stresses of 11 MPa. To analyze the variability further, a two-parameter Weibull distribution was used. The distribution of fatigue strength for the higher hoop stress levels is consistently more variable than the control specimens and the group tested at the lower hoop stress level, see Fig. 4(a) and (b).

The cumulative Weibull distributions (Fig. 4) further confirm that the reduction in fatigue strength at the high hoop stress values. They show a significant decrease in fatigue strength at 50% probability-of-survival; this represents a decrease in fatigue life of approximately one order of magnitude. While at the low hoop stress (11 MPa) no such difference in fatigue strength exists, see Fig. 4(a).

Typically, failure occurred by fatigue crack growth perpendicular to the axial stress, although at the higher hoop stresses failure sometimes occurred by cracks growing perpendicular to the hoop stress, see Fig. 5.

4. Discussion

This study shows that a tensile stress applied perpendicular to the cyclic stress can reduce the average fatigue life of acrylic bone cement and this is statistically significant at $p < 0.1$ for two of the multi-axial stress states studied. An important observation is that the variation in fatigue strength is greater under multi-axial stresses (Fig. 4).

One explanation for this greater variability under multi-axial stress is that the initiation of failure of orthopedic bone cement depends on the orientation of the pore relative to the stress. Consider the case illustrated in Fig. 6; if the stress in the vertical direction was the only

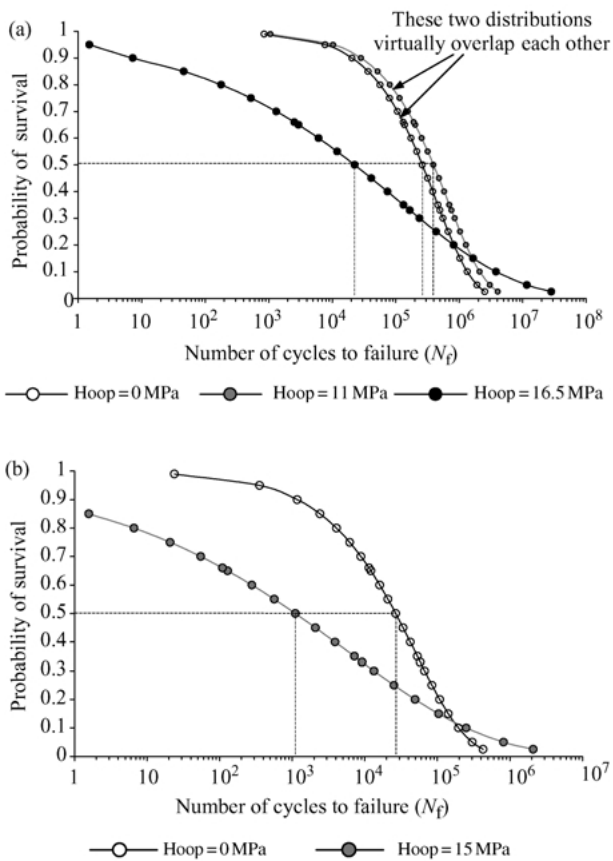


Figure 4 (a) Cumulative Weibull distributions for the fatigue tests with an axial stress of 11 MPa. The distribution of fatigue strength of the specimens with no hoop stress is almost identical to the distribution of fatigue strength of the specimens which had a hoop and axial stress of 11 MPa. While the distribution of fatigue strength of the specimens tested at the higher hoop stress (16.5 MPa) is notably different. (b) Cumulative Weibull distributions for the fatigue tests with an axial stress of 15 MPa. The distribution of fatigue strength of the specimens tested under multi-axial conditions (hoop and axial stress equal to 15 MPa) shows that that the fatigue life at 50% probability of survival is reduced significantly; moreover, the variation in fatigue strength is increased.

stress present the fatigue life of the specimen shown in Fig. 6(a) would be less than the fatigue life of the specimen shown in Fig. 6(b). However, if both stresses σ_1 and σ_2 were present the fatigue life of the specimen shown in Fig. 6(b) would be reduced because σ_2 would now cause the failure. In this way multi-axial stress states could cause greater variation in the fatigue life. This variation is greater than that quantified previously by the authors for uniaxial stress [10]. Consider the differences in the “shape parameter” which is a measure variability of the Weibull distribution – the lower the shape parameter the more variable is the distribution. The shape parameters at the highest hoop stresses are 0.221 ($\sigma_h = 15$ MPa) and 0.234 ($\sigma_h = 16.5$ MPa) compared to an average value of 0.75 for uniaxial fatigue tested vacuum-mixed Cemex Rx bone cement [10].

An noted above, experiments at an axial stress of 11 MPa with zero hoop stress give a 16% higher fatigue life than the experiments where the hoop stress is increased to 11 MPa; although when a comparison is made between the entire distribution of fatigue life, rather than just the average life, it can be seen that there is no difference between the two data sets (Fig. 4(a)). This rather strange result requires an explanation. One

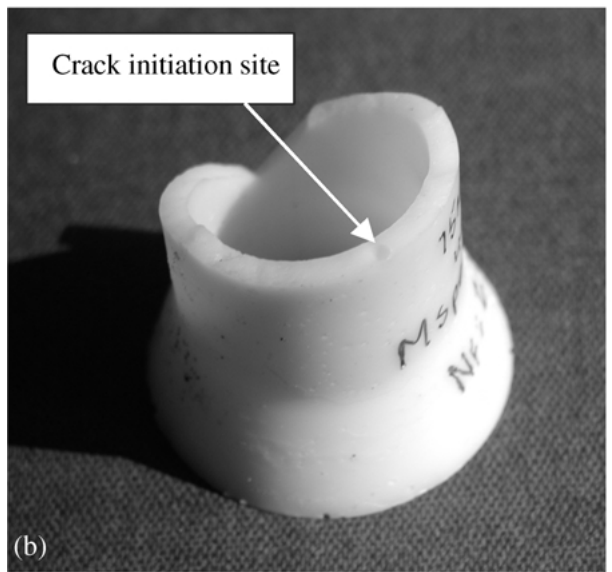
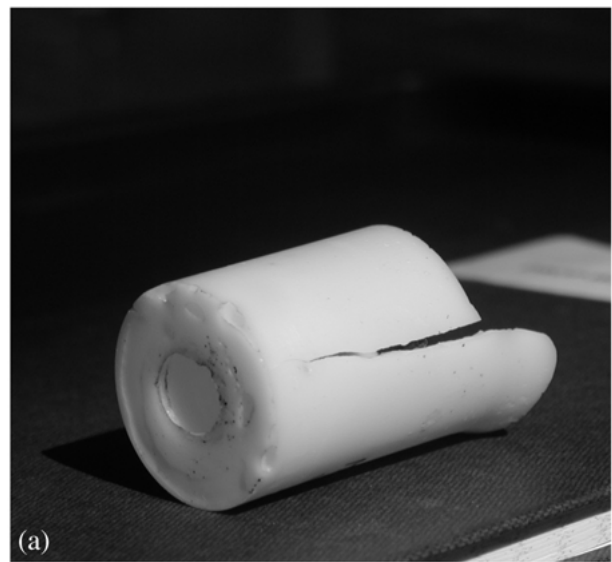


Figure 5 (a) Depicts a specimen that failed due to the hoop stress, (b) shows a specimen that has failed because of the axial fatigue loading. A relatively small pore is visible on the fracture surface and this acted as the fatigue crack initiation site.

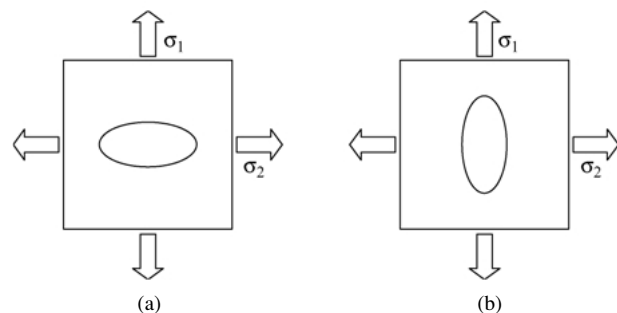


Figure 6 The orientation of pores will effect the orientation of the failure crack (a) σ_1 will cause failure in this case, while in (b) σ_2 will cause failure (if $\sigma_1 = \sigma_2$). More variation in failure under multi-axial stress will occur if pores are oriented randomly.

possible reason could be that, because of the reduced stress amplitude (range) of the hoop stress at this lower hoop stress level (i.e. 0.6 MPa as shown in Table I), the pressure change will not be as great when the specimen extends, thus the stress amplitude of the hoop stress is

lower at low pressures. At higher hoop stress values (15 and 16.5 MPa) the pressure inside the cylinder is greater and any increase in volume of the pressurized cavity will cause the oil in the cavity to have a greater fluctuation in pressure, causing a greater change in hoop stress. At the higher hoop stress, the stress amplitude is greater and the chance that the hoop stress will initiate a fatigue crack is increased, compared to the lower (more constant) hoop stress value (11 MPa). This was observed experimentally; none of the specimens with a hoop stress of 11 MPa failed from the hoop stress, while some specimens at the higher hoop stress values failed from the hoop stress.

Harper and Bonfield [11] carried out tensile and fatigue tests of 10 commercial bone cements and found great variation, particularly in the fatigue strength. It was also noteworthy that the newer bone cements did not perform better than the commonly used cements, and in some cases they performed considerably worse. Similarly, Lewis [12] found significant difference in the fatigue performance of two commercial cements under different conditions. The result of Harper and Bonfield [11] is interesting in the context of the present paper because they found great variation in the fatigue behavior (like us, they did not discard specimens with pores, see Prendergast *et al.* [9]), and furthermore, they were able to find a correlation between clinical outcomes and the fatigue performance. The results of our paper suggest that their finding of variable fatigue behavior of commercial cements would be further emphasized if the cements were to be tested under the multi-axial stress state that occurs *in vivo*.

5. Conclusion

This study has shown that testing of the fatigue behavior of orthopedic bone cement can be done using tubular specimens. The difficulties that arise with this procedure are described and quantified. The results of the tests show that an off-axis stress can greatly affect the fatigue strength of acrylic bone cement. However, the most significant finding was that the variation of fatigue strength is much greater when multi-axial stresses are introduced. This may partly account for the variability in

the loosening behavior of different designs of orthopedic implant.

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