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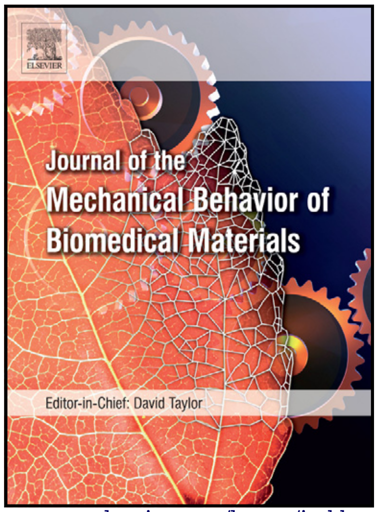

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PII: S1751-6161(15)00265-9
DOI: http://dx.doi.org/10.1016/j.jmbbm.2015.07.024
Reference: JMBBM1554

To appear in: *Journal of the Mechanical Behavior of Biomedical Materials*

Received date: 5 May 2015
Revised date: 21 July 2015
Accepted date: 23 July 2015

Cite this article as: E.M. Sheafi, K.E. Tanner, Influence of test specimen fabrication method and cross-section configuration on tension-tension fatigue life of PMMA bone cement, *Journal of the Mechanical Behavior of Biomedical Materials,* http://dx.doi.org/10.1016/j.jmbbm.2015.07.024

Influence of test specimen fabrication method and cross-section configuration on tension-tension fatigue life of PMMA bone cement

E.M. Sheafi, K.E. Tanner

Biomedical Engineering Division, School of Engineering, University of Glasgow, Glasgow, G12 8QQ, UK

Corresponding Author:
Professor K.E. Tanner
School of Engineering,
James Watt South Building,
University of Glasgow,
Glasgow,
G12 8QQ,
UK
Phone: +44 141 3303733
Fax: +44 141 330 4343
elizabeth.tanner@glasgow.ac.uk

ABSTRACT

Different cyclic loading modes have been used in *in vitro* fatigue studies of PMMA bone cement. It is unclear which loading mode is most appropriate from the perspective of the *in vivo* loading experienced by the cement in a cemented arthroplasty. Also, in different *in vitro* fatigue studies, different test specimen configurations have been used. The present work considers the influence of test specimen fabrication method (direct moulding versus moulding followed by machining) and cross-section shape (rectangular versus circular) on the tension-tension fatigue performance of two bone cement brands (SmartSet GHV and CMW1), under force control conditions. Two trends were consistent: 1) for each of the cements, for molded specimens, a longer fatigue life was obtained with circular cross-sectioned specimens and, 2) for either rectangular or circular CMW1 specimens, a longer fatigue life was obtained using machined specimens. A comparison of the present results to those reported in our previous work on fully-reversed tension-compression loading under force control showed that, regardless of the test specimen fabrication method or cross-section configuration used, the fatigue life was considerably shorter under tension-compression than tension-tension loading. This finding highlights the fact the presence of the compression portion in the loading cycle accelerates fatigue failure.

Keywords:

Fatigue, polymethylmethacrylate, bone cement, stress type, Weibull analysis

1. INTRODUCTION

Fatigue failure of bone cement is a major issue in cemented joint replacements. Approximately three quarters of revision surgery of both cemented and uncemented total joint replacements is due to implant loosening (Malchau et al., 2002). Fatigue failure of the cement mantle is considered to be responsible for the majority of loosened cemented arthroplasties (Jasty et al., 1991, McCormack and Prendergast, 1999, Culleton et al., 1993). Depending on the patient's age and activity, their hips and knees typically encounter between 0.5 to 2 million load cycles per year (Wallbridge and Dowson, 1982) and in cemented joint replacements these are transmitted by the cement mantle. Despite theories stating bone cement surrounding an arthroplasty is subjected to a combination of fatigue loading modes (Krause and Mathis, 1988; Lewis and Nyman, 2000; Lewis et al., 2003; Miller et al., 2011; Dunne et al., 2014), the material is thought to fracture primarily due to the tensile phases of the applied stresses (Gates et al., 1983, Harper and Bonfield, 2000). Dunne et al. (2014) point out that while *in vitro* tension can be a more important factor inducing cement failure than compression, both loading modes occur. Fully reversed tension-compression stress (mean stress = 0) or tension only stress (mean stress > 0) has been adopted in *in vitro* studies of fatigue testing bone cement, to imitate better the *in vivo* fatigue conditions (Tanner et al., 2010). Harper and Bonfield (2000), for example, applied tension-tension fatigue to examine the fatigue properties of various bone cements and reported that "the cements that perform best clinically gave the highest results". Lewis et al. (2003), in contrast, applied fully reversed tension-compression, considering this mode to provide a better model of a material's fatigue behaviour according to Dowling (2007). The selection of a particular stress test, however, depends on the application of the bone cement. Ajaxon and Persson (2014) examined the compressive fatigue properties of a vertebroplasty bone cement and concluded that the mean fatigue limit in compression-compression cyclic loading "was approximately five times that of the compressive loading part of a similar cement tested in full tension–compression". Thus they considered that, for vertebroplasty, "tension-compression fatigue testing may substantially underestimate the performance of cements".

In vitro, it is still not clear which cyclic segment of the fully reversed loading has the greatest influence on the fatigue life of bone cement. For most cements, the compressive strength is higher than tensile, which can lead to the speculation that in reversed loading, the material is more likely to fracture due to the tensile loading segments. Carter et al. (1982) and Gates et al. (1983) compared different loading types (fully reversed tension-compression and zero-tension loading, respectively), and indicated that fatigue failure is mostly controlled by the tensile phase with "little effect" from the compressive phase. However, these two older studies used strain-controlled fatigue, as they considered that the material would tend to encounter such loading conditions *in vivo*.

Testing under stress-control, however, has been applied for most fatigue studies. As suggested by Soltész (1994) it provides more appropriate simulation of the fatigue of bone cement *in vivo* than strain-controlled. As yet, there seem to be no studies considering the effect of loading type on stress-controlled fatigue behaviour of bone cement or of using various specimen types while maintaining the same general testing conditions. Using identical testing procedures to our previous study on the effects of sample type on the fully reversed fatigue behaviour of bone cement (Sheafi and Tanner, 2014), this study examines the fatigue behaviour of bone cement when applying tension only fatigue on various sample types and compares the findings to those for fully reversed tension-compression at the same stress amplitude. Concurrently this study evaluates the role of compression segment in governing the number of cycles to failure, to examine the hypothesis that, in fully reversed tension-compression loading, the fatigue life is mostly controlled by the tension loading segments.

2. MATERIALS AND METHODS

2.1. Materials

Two cements, SmartSet GHV and CMW1 (both supplied by DePuy CMW, Blackpool, UK), were used. The compositions of these two brands are similar, but SmartSet GHV powder contains a methyl methacrylate-methyl acrylate copolymer, ZrO_2 as the opacifier, and an antibiotic (Gentamicin) whereas in CMW1 the powder contains poly (methyl methacrylate) with $BaSO_4$ as the opacifier. The liquid phases of the cements are similar. These are the cements tested in Shaefi and Tanner (2014) and details of their formulations are available there.

2.2. Preparation and fatigue testing of samples

The powder and liquid components of the cements were mixed under vacuum at room temperature using the CEMVAC mixing system (DePuy CMW, Blackpool, UK) as per the manufacturer's instructions. Samples were prepared according to either ISO 527-2 (half-size) or ASTM F2118 to obtain samples with rectangular (R) and circular (C) cross sections, respectively. Fabrication was either by direct moulding (DM) or moulding over size samples and then machining to size (MM) which provided four types of samples: RDM, RMM, CDM and CMM. All samples were assessed for porosity and soaked in 37°C saline for between 1 and 6 weeks prior to testing.

Using an MTS – 858 Mini Bionix®II, the samples were subjected to tension-tension cyclic loading between 2 and 20 MPa (R = 0.1). For each of the four study sets, 10 specimens were tested and those that were found to have macropores (≥1 mm as described by Cristofolini et al. (2002) and Bialoblocka-Juszczyk et al. (2008)) were discarded and the test was run on replacement specimens. Pore size was checked visually. All the other testing conditions and data acquisition procedures were as in our previous study (Sheafi and Tanner, 2014). The cycles to failure, N_f, and cyclic stress-strain data were recorded.

2.3. Fatigue data analysis

Three methods were used analyze the fatigue test results. Preliminary assessment of the statistical significance of variations was made using ANOVA and Student's *t*-test on the logarithms of the number of cycles to failure to obtain normally distributed data. For each of these tests, significance was denoted at $p \geq 0.05$. The second method involved use of the two-parameter Weibull relationship, which is given by:

$$Y = \ln \ln \left[\frac{1}{1 - P(N_f)} \right] \tag{1}$$

where $P(N_f)$, the probability of fracture after N_f cycles is given by:

$$P(N_f) = \frac{i - 0.3}{n + 0.4} \tag{2}$$

where i is the rank of the specimen in the dataset when the N_f results are arranged in ascending order of magnitude (1 = 1, 2, 3, ……..n) and n is the total number of specimens in the dataset. The coefficient b is the Weibull modulus (shape parameter) and Na is the characteristic fatigue life (scale parameter).

The overall fatigue performance index, I, was calculated by:

$$\mathrm{I} = \mathrm{N_a}\sqrt{\mathrm{b}}\mathrm{I} = \mathrm{N_a}\sqrt{\mathrm{b}} \tag{3}$$

For the third method, the instantaneous absorbed energy (area inside the hysteresis cyclic stress-versus strain plot) and the secant modulus (slope of the cyclic stress-strain plot) for certain load cycles were each plotted against N_f (Sheafi and Tanner, 2014; Slane et al., 2014).

3. RESULTS

3.1. Comparison of statistical significance

The initial comparisons of the significance of variations, using either Analysis of Variance (ANOVA) or Student's *t*-test, are shown in Table 1. Contradictory to the previous findings for fully reversed tension-compression loading, when comparing fatigue results for the four sample types in each cement, no significant variations were found within either cement with *p*-values of 0.139 and 0.169 for SmartSet GHV and CMW1, respectively. Also, unlike the fully reversed stress regimes, comparing the fatigue results for the two cements for the same sample type showed significant variations for three sample types (RDM, RMM, and CDM with *p*-values of 0.024, 0.018 and 0.014, respectively). No significant variation was found between the circular machined samples (CMM) of the two cements (*p*-value = 0.073).

3.2. Weibull analysis

The two-parameter Weibull relationships for the fatigue results of the tension-tension loading of different sample types are compared in Figure 2. The values of the Weibull parameters of these functions and the calculated fatigue indices are shown in Table 2. For the SmartSet GHV samples, obvious variations are seen between the four sample types in terms of fatigue lives and data scatter, where the clearest differences in behaviour were associated with the rectangular moulded samples. For CMW1, noticeably less variation in results was seen. Unusually, the machined and moulded samples of this cement showed similar fatigue performance, unlike those obtained from the machined samples of SmartSet GHV.

Considering the effect of sample surface production method only, two major differences between the fatigue performance indices for the same sample shape and material were found. The first was between the RMM and RDM samples made from

CMW1 where the machined samples provided a factor of 2.2 greater fatigue performance compared to the moulded samples. Interestingly, this behaviour is totally the opposite to that reported in the earlier study for fully reversed tension-compression. Secondly, the CDM samples made from SmartSet GHV provided 7.5 times greater fatigue performance compared to the same composition CMM samples, providing a similar trend to the equivalent finding for the tension-compression where a factor of 5.5 difference was seen.

For the same production method and focusing on the influence of sample cross sectional shape for each cement, the circular moulded samples provided 1.5 and 1.7 greater fatigue indices compared to the rectangular moulded for the SmartSet GHV and CMW1 samples respectively, these differences being less than those obtained from similar comparisons of the tension-compression tests. In contrast, the two types of machined samples provided similar fatigue indices for CMW1 and remarkably different fatigue indices for SmartSet GHV (a factor of 4.75 in favour of the rectangular machined samples). Again, these findings differ noticeably from those obtained when the fully reversed tension-compression loading regimes were applied.

Considering the effect of bone cement type, SmartSet GHV provided significantly longer fatigue lives compared to the CMW1 samples, with the exception of the CMM group of the SmartSet GHV cement, which provided the lowest fatigue performance at all. The moulded samples of the SmartSet GHV cement, compared to their CMW1 counterparts, provided 3.5 times greater fatigue life when the circular shape was used and 4 times greater life when the rectangular section samples were tested. When considering the same comparison for the machined samples, the rectangular shape of SmartSet GHV cement provided only 1.7 times greater fatigue lives compared to the equivalent CMW1 samples. Providing a totally different trend, however, the circular machined samples of SmartSet GHV provided only one third of the fatigue performance obtained from the circular machined samples of CMW1.

Table 3 summarises the factors of differences in fatigue performance between the different sample types due to the effect of fatigue loading type by comparing the findings of the current study (tension-tension loading) to those in the previous study (tension-compression loading). It is apparent that, generally, the compression segment in fully reversed tension-compression cyclic loading has a major effect on shortening the fatigue lives of the samples, by a factor between 1.2 and 18. This effect, however, appears to be both sample type and cement composition dependent.

3.3. Hysteresis energy vs. cycles to failure

For each cement, greater similarity was found between the different sample types in terms of the absorbed energy behaviour (Figure 3). Sample type controlled the fatigue life, but with no clear difference between the changes in absorbed energy among the same material samples. During testing, the absorbed energy increased gradually for the SmartSet GHV sample types until a point well before failure where the amount of absorbed energy started to increase more rapidly with at least a 50% increase in the energy absorbed by failure (Figure 4a). In tension-compression loading, the machined samples of this cement, in contrast, showed greater increases in the absorbed energy compared to the moulded counterparts. For the CMW1 samples, similar amounts of energy was absorbed per fatigue cycle throughout the testing period until close to the failure point when the energy absorbed increased by less than 10% (Figure 4b). This indicated similarity in fatigue damage behaviour for all samples of this cement was also observed for the tension-compression loading reported earlier. It is to be noted though, when comparing the absorbed energy findings of the current study with that in the previous investigation, the figures showed approximately 6 times greater absorbed energy per loading cycle from early fatigue cycles for SmartSet GHV with the tension-compression loading compared to that with the tension-only loading. Similarly, CMW1 showed increases in the amount of the absorbed energy per cycle by about a factor of 4 with the fully reversed loading compared to the tension only.

3.4. Secant modulus vs. cycles to failure

Considering each cement composition individually, the trends of the reduction in secant modulus for the four sample types were similar, particularly for the CMW1 samples. As can be seen from Figure 5, the gradual decrease in modulus was more noticeable for the SmartSet GHV samples showing total reductions of approximately 15 to 25% between the 10^{th} cycle and the 5^{th} cycle before failure. This decline was less than 10% for all the CMW1 samples. These overall estimated reduction rates in modulus do not seem to largely differ from those found earlier for the tension-compression stress loading. Stiffness of samples appeared to be affected more by the sample type with, in general, less effect of the loading type when the same cement composition was considered.

DISCUSSION

Under the tension-tension loading used, the results have shown variations in fatigue lives depending on the test variables. In general, the results indicated longer fatigue lives for the SmartSet GHV compared to the CMW1 samples, except for the circular machined samples. While the trend of this exception matches that obtained earlier when tension-compression loading was used, the other sample types have shown dissimilar behaviour to that reported earlier for fully reversed tension-compression where slightly greater fatigue performance indices in favour of CMW1 were found.

Comparing the fatigue indices of the Weibull analysis for the tension-tension loading in the current study with those previously reported for the full tension-compression loading (both loaded at a maximum of 20 MPa, with R = 0.1 and R = -1, respectively) have indicated that stress type can be a key factor in governing the fatigue life of bone cement. SmartSet GHV develops less fatigue damage under tension-tension, compared to the tension-compression, than CMW1. The tension-tension stress-strain hysteresis loops have shown similar, and more slowly progressing, fatigue cracks in SmartSet GHV for all sample types, compared to tension-compression. The trend of crack progress in CMW1 was similar in both loading regimes. For both cements, the greater amount of absorbed energy per loading cycle provided another indicator of the crucial role of tension-compression fatigue in shortening the fatigue life of bon cement. However, creep, seen as movement of the stress-strain curves along the strain axis, was limited in fully reversed loading, but obvious in tension only and greater in

It has been shown that tension only fatigue is not as detrimental as when the fully reversed cyclic loading is applied, with substantially longer fatigue lives associated with the tension only mode. This reveals the important role of applying the compression segments in substantially accelerating fatigue failure of bone cement samples; a finding that contradicts with the statement by Gates et al. (1983) that fatigue failure is primarily driven by the tensile segment during the fully reversed tension-compression with the effect of the compression segment being “small or negligible”. Considering the difference in testing conditions of the current study and those in Carter et al. (1982) and Gates et al. (1983), some interpretations can be made regarding this incompatibility in findings.

Our current and previous studies were performed under stress-controlled conditions unlike Carter et al. (1982) and Gates et al. (1983) who used strain-controlled conditions. The difference in the results is possible since materials, as illustrated by Hertzberg (1996), can provide totally opposite (softening or hardening) deformation depending on the stress or strain controlled loading. Both the current (tension-tension) and the previous (tension-compression) studies showed increases in the strain rates (dependent variable) as the cyclic loading progresses under constant stress limits indicating that the samples softened, which varied depending on both the cement type and sample.

The finding that tension-compression testing regimes provide noticeably longer fatigue lives than tension-only can be attributed to the additional mechanical work applied to the specimen during the compression segment. There seems to be insufficient data reported in previous studies to rely on when describing the relationship between the tension and compression components in the fully reversed loading of bone cement. For other materials, the alternating tension-compression cyclic loading has been found to be more detrimental than the tension only loading, even if the material has higher compressive than tensile strength. The compression portion of the applied tension-compression cycles has been demonstrated to have a significant influence on the “crack tip stress, displacement and plastic deformation field” (Zhang et al., 2010).

Considering the cement composition, it is possible that the inclusions included in the cement, the radiopaque fillers and antibiotic, can respond differently to the type of loading. Similarly, the micropores and defects, especially those on the outer surface of a sample, would react dissimilarly in terms of resisting the initiation of a fatigue crack. According to the microscopic observations of the fracture surfaces of samples tested in the current study (tension-tension loading) and the equivalent ones in the previous study (tension-compression loading), it has been noticed for CMW1 that the cracks have clearer progress paths in tension-tension than in tension-compression unlike SmartSet GHV. Figure 6 shows an optical micrograph of one of these observations when the cracks seemed to develop from a defect at a corner of a fracture surface. Although, according to the fatigue results, the effect of the compression segment in tension-compression loading on controlling the fatigue life of both cements is evident, it seems that the final failure would occur during a tension segment of a fatigue cycle while the compression segments induce the occurrence of this failure.

The stress-strain curves (Figure 3) have showed the cements encounter produce different amounts of creep before failure with the tendency of SmartSet GHV to show approximately three times creep amounts compared to CMW1 which did not reach that extent when the tension-compression was used, presumably due to the compression on the sample repeatedly reversing the tensile creep. This refers to the need of considering the possible contribution of creep into controlling the fatigue life of bone cements differently under different types of loading in future work. Yet, insufficient interpretations can be provided in this study regarding the detailed fatigue crack initiation and propagation mechanisms due to the effect of loading type. The last factor to be considered is that the fully reversed tension-compression will be absorbing more energy per load cycle due the increased stress and strain ranges. In the fully reversed loading initially between 50 and 60 kJm^{-3} was being absorbed rising to up to 150 kJm^{-3} depending on the cement and sample shape whereas the tension testing in this study started from 8-12 kJm^{-3} rising to 18 kJm^{-3}. This absorbed energy could have heated the samples; however they were all tested with a continuous flow of saline which will have kept the sample temperature to 37˚C.

The present study has a number of limitations. First, only two cement brands, one plain formulation (CMW1) and one antibiotic-loaded formulation (SmartSet GHV), were used. With over fifty commercially available brands (Kühn, 2013), the conclusions reached may not have generality to PMMA bone cement as a class of biomaterials. Second, the magnitude of the loading used (2-20 MPa) is much higher than has been postulated to be experienced by the cement mantle in a total joint replacement. Also, the number of specimens tested for each of the study sets (10) is smaller than is recommended in a relevant testing standard (ASTM F2118; fully-reversed tension-compression load cycle under force control (15 specimens)). However, the combination of load magnitude and number of specimens per study set we used allowed the study to be completed in a reasonable amount of time

CONCLUSIONS

The following conclusions are reached:

- For a given cross-sectional configuration, the influence of specimen fabrication method on fatigue performance is complicated.
- For a given specimen fabrication method, the influence of specimen cross-section configuration on fatigue performance depends on the fabrication method: for molded specimen, performance is better than with circular specimens but for machined specimens, the influence is complicated.
- Regardless of the specimen fabrication method or cross-section configuration used, fatigue life under fully-reversed tension-compression loading was

shorter than under tension-tension loading (by a factor that varies from 1.2 to 18.0). This highlights the importance of the compression component in the loading cycle.

ACKNOWLEDGEMENTS

The Libyan Government is thanked for funding the research and DePuy CMW is also acknowledged for providing the bone cement materials and mixing devices.

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LIST OF TABLES

Table 1 Significance of variations in results among various sample types and cement compositions for the tension-tension stress regimes

Comparison status	**statistical hypothesis test**	***p*-value**	**Significance of variations**
SmartSet GHV (RDM vs RMM vs CDM vs CMM)	ANOVA	0.139	non significant
CMW1 (RDM vs RMM vs CDM vs CMM)	ANOVA	0.169	non significant
RDM (SmartSet GHV vs CMW1)	Student's *t*-test	**0.024**	**significant**
RMM (SmartSet GHV vs CMW1)	Student's *t*-test	**0.018**	**significant**
CDM (SmartSet GHV vs CMW1)	Student's *t*-test	**0.014**	**significant**
CMM (SmartSet GHV vs CMW1)	Student's *t*-test	0.073	non significant

Table 2 Summary of the calculated values of the shape and scale parameters (b and Na) and the resultant fatigue performance indices (I).

	SmartSet GHV			CMW1		
Sample type	*b*	*N*a /cycles	*I* /cycles	*b*	*N*a /cycles	*I* /cycles
RDM	0.757	344,552	299,780	1.061	73,130	75,327
RMM	0.465	420,837	286,972	1.000	162,755	162,327
CDM	1.073	442,413	458,296	1.014	133,252	134,182
CMM	0.684	73,130	60,482	0.797	178,872	159,688

Table 3 Comparison of the changes in the fatigue performance index (*I*) due to the change in loading type for different sample types of SmartSet GHV and CMW1 bone cements, showing tension-tension (T.T) vs. tension-compression (T.C). The tension-compression data taken from Sheafi and Tanner (2014).

	SmartSet GHV			**CMW1**		
Sample type	*I* - (T.T)	*I* - (T.C)	Factor of difference	*I* - (T.T)	*I* - (T.C)	Factor of difference
RDM	299,780	37,088	>8	75,327	42,393	>1.8
RMM	286,972	15,709	>18	162,327	19,678	>8
CDM	458,296	75,909	>6	134,182	112,970	>1.2
CMM	60,482	13,346	>4.5	159,688	31,235	>5

I in cycles, T.T = tension-tension loading & T.C = fully reversed tension-compression loading

LIST OF FIGURES