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Effects of specimen variables and stress amplitude on the S-N analysis of two PMMA based bone cements

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ABSTRACT

The fatigue performance of bone cement is influenced by the testing parameters. In previous *in vitro* fatigue studies, different testing conditions have been used leading to inconsistencies in the findings between the studies, and consequent uncertainties about the effects of testing specimen specifications and stress parameters. This study evaluates the role of specimen variables (namely; specimen cross-section shape, surface production method and cement composition) in a range of *in vitro* stress amplitudes (±12.5, ±15, ±20, ±30 MPa), using S-N (Wöhler) analysis. The two main findings are: while specimen cross-section configuration and fabrication method (specimen type) played a key role in controlling the fatigue longevity of the same cement, the stress amplitude was seen as the dominant controlling variable to affect the fatigue behaviour of different cements when using the same specimen type. Thus, considering the effect of specimen type, testing at high stress amplitudes should be treated with caution, particularly in tension-compression loading, to ensure fatigue failure occurs due to mechanical rather than thermal effects and thus models the *in vivo* behaviour.

1. Introduction

PMMA based bone cements are used for the fixation of orthopaedic implants, thus their fatigue failure leads to major clinical problems in the form of implant loosening, pain and ultimately clinical failure of the device. The stress levels in the bone cement mantle around a joint replacement range from 3 to 11 MPa [1]. Depending on the patient's age and activity, a hip or a knee replacement faces up to 2 million load cycles yearly [2], therefore these stress levels are required to be transmitted by the mantle of cemented joint replacements for the rest of the patient's life, thus of the order of tens of millions of load cycles. *In vitro*, however, fatigue characterisation of bone cement has been performed using higher stress levels; mostly within the range of 10–30 MPa [3] to shorten testing time and reduce the number of test run-outs.

A review paper by Lewis [4] examined the "intrinsic" and "extrinsic" factors that can affect the measured fatigue performance of bone cement, concluded that there are "only a few areas of agreement" and "many areas of disagreement". The effects of specimen preparation variables (cross section shape and surface production technique) on fatigue behaviour at a specific constant-amplitude stress have been examined in previous studies considering the influence of specimen shape in tension-compression only [5], surface preparation method in tension-tension only [6] or the effects of both configuration and fabrication methods in tension-compression [7,8] and tension-tension loading [8,9]. Due to testing at only one stress amplitude, the fatigue data has been analysed using Weibull relationships in most of these studies [5,7–9] and only one study [8] has compared two testing methods: tension-only of rectangular moulded specimens at a single stress level versus tension-compression at multiple stress levels of circular machined specimens analysing the results using Weibull and Wöhler approaches, respectively. Fatigue testing at various stress amplitudes has been considered in some studies, but using only a single specimen configuration and modification technique within the same study (e.g. [10–12]). It has been suggested that using different fatigue testing methods makes it inappropriate to compare the findings from different studies [13,14]. In addition to using a range of testing conditions, it has been pointed out that many of these studies "have employed inappropriate statistical methods" [3] and "have not addressed the issue of possible interactions between the parameters being investigated" [3]. Additionally, the cement formulation [13], methods of mixing, whether or not a partial vacuum was used to reduce porosity [6,10–12], amount and type of opacifier and/or antibiotic [13,15], all affect the fatigue life and have been discussed extensively [e.g. 15].

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Currently, various standards are available for the fatigue testing of bone cement and have been used to various extents. ASTM F2118 was originally published in 2001, with various subsequent revisions, leading to ASTM F2118-14 being the current version [16]. This standard uses cylindrical dumbbell specimens, with fully reversed fatigue in phosphate buffered saline, either three stress levels are used, or the fatigue life for 5 million load cycles is found. The frequency is required to be constant and if above 5 Hz should be checked to ensure that no frequency effects occur. The suggested stress levels are ±15, ±12.5 and ±10 MPa which can be varied for hip and knee replacement applications or reduced to ±5, ±7 and ±9 MPa for spinal applications with a minimum of 15 speciemns used per load level. The specimens should be manufactured by injecting into a silicone mould which has been produced by moulding the silicone around machined metal blanks. The other major fatigue of bone cement standard is ISO 16402:2008 which was reconfirmed in 2013, and uses four point bending of rectangular bars [17]. The four point bending loads are from 5 N to the force which produces the required maximum stress. The specimens have moulded top and bottom surfaces and their sides may be either moulded or machined. So both standards require that the loaded surfaces are moulded, rather than machined. However, over the years many studies have used machined surfaces, particularly for cylindrical dumbbells, since it is easier to mould cylinders and then machine to shape. Furthermore, being fully reversed tension-compression, ATSM F2118-14 [16] leads to all areas of the cement undergoing the full stress range in both tension and compression, while the 4 point bending in ISO 16402:2008 [17] means that only the upper and lower surfaces are exposed to the maximum stresses and undergo either only tensile or only compressive loading, which may not be what occurs in vivo.

However, as both machined and moulded surfaces and rectangular and circular cross-sections have been used, it is important to examine the influence of specimen preparation method on more than one cement and one stress level [7,9]. This requires the comparison of the fatigue performance of different specimen types at various stress amplitudes and examining whether testing specimen variables, along with changing the stress amplitude, can affect the fatigue behaviour of different specimens and cements and their relative ranking.

Hence the aim of the current study is to compare the fatigue results, with different specimen surface preparation methods and shapes, of two different bone cement formulations with the same viscosity classification (high viscosity) but different filler content. The fatigue life results are compared by the commonly used S-N (Wöhler) analysis (e.g. [8,12,18,19]) as recommended in ASTM F2118-14. Furthermore, it has been reported that fatigue damage accumulation *in vivo* shows that failure progress is affected by the stress amplitude, thus using a single stress amplitude would be a "misleading measure of durability" [20].

2. Materials and methods

2.1. Materials

Two brands of high viscosity bone cements were tested: SmartSet GHV Gentamicin and DePuy CMW1 (both produced and supplied by DePuy CMW, Blackpool, UK). The powder component of SmartSet GHV is a methyl methacrylate/methyl acrylate copolymer and contains 14.37 wt% zirconium dioxide as radiopaque agent and 4.22 wt% Gentamicin as antibiotic filler whereas the CMW1 polymeric powder is solely polymethylmethacrylate and contains 9.1 wt% barium sulphate as a radiopacifier with no antibiotic added. The liquid component is similar for these two cements. A detailed comparison of these cements is available in an earlier study [7].

2.2. Preparation and testing of specimens

The powder and liquid phases were mixed under vacuum using the CEMVAC mixing system (DePuy CMW, Blackpool, UK) as per the manufacturer's instructions, using the recommended mixing, waiting and working time for each cement type, dependant on the room temperature (20 ± 2 °C). Test specimens were manufactured to produce either half-sized ISO 527-2 [21] specimens with rectangular cross sections of 4 mm by 5 mm (designated R), or ASTM F2118 [16] to produce 5 mm diameter circular cross section specimens (designated C), thus similar nominal cross sectional areas of 20 mm^2 and 19.64 mm^2, respectively. However, the gauge lengths are very different at 25 mm and 10 mm, respectively. Fabrication was either by direct moulding (designated DM) or moulding of oversize samples followed by machining to size (designated MM) to give either a moulded surface as would occur *in vivo* or a machined surface as used in many fatigue studies. This resulted in four specimens types: RDM, RMM, CDM and CMM. The specimens were examined for porosity using transmission of a bright light, then soaked in 37 °C saline for between 1 and 6 weeks prior to testing.

Using an MTS – 858 Mini Bionix®II testing machine, the specimens were subjected to fully reversed tension-compression cyclic loading (force-controlled fatigue), at a maximum stress (stress amplitude) of 12.5, 15.0, 20.0 or 30.0 MPa at a frequency of 2 Hz under the flow of saline at 37 °C. The highest stress of 30 MPa was selected assuming that the specimens would not buckle at this stress. According to Euler buckling calculations, if entire length between the grips was at the gauge cross section, compression stress levels of at least 31 or 35 MPa are required to produce buckling for the rectangular and circular specimens, respectively, however, the presence of the specimen shoulders lead to a substantially higher Euler buckling load. The number of cycles to failure were recorded, with run-out set at 5 million load cycles [7–9]. The specimens that were found after testing to have pores with a major diameter of 1 mm or greater in the gauge section were excluded and replaced [22,23].

2.3. Fatigue data analysis

In order to compare the various fatigue testing regimes at a range of *in vitro* stress amplitudes as they have been reported in the literature, S-N or Wöhler curves were used. For each specimen type at each stress amplitude, a minimum of five specimens were tested, with 8 specimens tested at 20 MPa. This sample size is close to that postulated by ASTM E739-91 [24] of a minimum of 6 specimens when performing S-N curves, but less than that required by ASTM2118-14. However, in earlier S-N testing of bone cement, a range of different sample sizes per group have been used, for example, 1–3 specimens [19], 5 specimens [11] or 8 specimens [8]. All the S-N curves were plotted for the stress amplitudes of 12.5, 15, 20 and 30 MPa (independent controlled variable) against the logarithm to base 10 of the cycles to failure (dependent random variable) [8,10,12].

S-N curves with regression line were generated for each specimen type to assist in predicting fatigue lives at lower stress amplitudes based on the assumption that the relationship between the stresses and number of cycles to failure is approximately linear [12]. The fatigue results were compared, using these curves, for different specimen configuration and fabrication methods and the effect of the variation in cement composition. The equations of the S-N lines involve identifying the regression coefficients (slopes) where the analysis of variance between these slopes can be valu-