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The role of microconstituents on the fatigue failure of bone cement

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Abstract

Implant fixation via the use of acrylic bone cement is now a well-established practice in orthopaedics. Excellent long-term clinical results are evidenced in national joint registers based on over 5 decades of clinical experience. Increased life expectancies, patient BMI, together with the need to remain active in later life, are expected to put greater demands on the materials used in load bearing joint arthroplasty. Failure of bone cement and its interfaces with the implant and bone often leads to loosening, requiring revision surgery. This is a particularly invasive procedure, with lower long-term success rates compared to the primary procedure. To reduce the incidence of bone cement failure, it is necessary to understand the origins of failure *in vivo*. In the past, bulk failure of bone cement has been attributed to damage accumulation originating at pores. Advances in imaging technology now mean that we are able to observe cement microconstituents readily and identify crack-initiating defects more precisely as we attempt to understand origins of failure. The role of radiopacifier particles within the bone cement has not been examined extensively to date, and the present study demonstrates that this microconstituent could be in crack formation due in part to its ability to agglomerate and not bond with the surrounding matrix. To verify this hypothesis, explanted bone cement and laboratory tested bone cement are compared and correlations in failure mechanisms are discussed.

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Keywords: Bone cement; defect characterisation; retrieval; radiopacifier; voids; micro computed tomography;

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1. Introduction

Total joint replacement is an established procedure, with good long-term survivorship for the hip and knee joints. Indicated for the treatment of conditions such as end-stage osteoarthritis, hip dysplasia and avascular necrosis [1], the aims of joint replacement surgery are to relieve pain and improve the function and mobility of the affected joint. In developed countries, total joint replacement is one of the most common elective surgeries of the modern era, with many thousands of operations conducted each year in England and Wales alone [1]. Acrylic bone cement is routinely used for fixation of orthopaedic implants and remains the 'gold standard' for elderly patients and those with existing medical conditions who cannot rely on bone in-growth to achieve stable cementless fixation.

Aseptic loosening remains the predominant cause of failure in cemented total hip arthroplasty [1]. Damage accumulation due to initiation and coalescence of micro-cracks within the cement mantle and at its interfaces with the stem and bone has been implicated in the loosening process [2,3]. It has been shown that the microstructure of the cement, including pre-polymerised beads, matrix, radiopacifier particles and voids, is a factor in the development of fatigue cracks [4]. While the impact of porosity on *in vitro* failure has been extensively researched, leading to the development of improved mixing methods, the relative effects of other microstructural features, such as radiopacifier particles, has largely been ignored despite evidence linking particle agglomerates to crack initiation [5]. In order for more robust cement formulations to be developed, that are able to cope with the increased demands of future patient cohorts, it is necessary to gain an understanding of the role of the microconstituents in the failure process. Advances in high-resolution micro computed tomography (μ-CT) capabilities now enable the relative effects of microstructural features on the fatigue performance of bone cements to be characterised. The present work exploits this capability on a commercially available bone cement, and uses scanning electron microscopy on explanted bone cement to identify correlations between *in vitro* and *in vivo* failure mechanisms.

2. Materials and Methods

An explanted cement sample was retrieved from a 51 year old female patient with hip dysplasia, undergoing revision total hip arthroplasty surgery 7 years post surgery. The femoral implant was fixed with antibiotic radiopaque acrylic bone cement (Palacos R + G, Heraeus Medical GmbH, Hanau, Germany). No loosening of the components was reported. Permission for the collection and analysis of the retrieved cement was granted by the NRES Committee South Central – Southampton A.

The retrieved cement specimen dimensions were 10.5 mm (width) x 9.5 mm (breadth) x 21.8 mm (length) with a volume of 0.92 cm^3. The location and orientation of the specimen within the cement mantle were not recorded at the time of retrieval. The cement-stem and cement-bone interfaces were clearly identifiable due to the presence of a smooth profile and biological debris respectively; the specimen was therefore believed to encompass the full thickness of the cement mantle.

Micro-computed tomography imaging of the retrieved cement was conducted using a 225kV HMX-ST system (Nikon Metris, Tring, UK) at a voxel size of 13 μm^3. Internal (non surface-breaking) voids were segmented from the reconstructed volume using a grey value thresholding technique. Due to the irregular shape of the specimen, the boundaries of surface-breaking voids could not be reliably determined; thus only internal voids were included in the defect characterization in this study.

In vitro fracture surfaces were prepared for comparison using Palacos R cement (Heraeus Medical GmbH, Hanau, Germany). The primary distinction between this and the explanted (Palacos R+G) cement was the addition of 2% gentamicin sulphate to Palacos R+G. The cement components were pre-chilled at 4°C prior to mixing under reduced pressure (-70 KPa) using a CemVac integrated mixing and delivery system (Depuy, Leeds, UK), according to the manufacturer's timings. Rectangular bend bars, each measuring 8 x 8 x 45 mm, were fatigue tested to failure under sinusoidal four-point bending at a peak stress of 40 MPa, R-ratio of 0.1 and frequency of 3Hz.

Both *ex vivo* and *in vitro* fracture surfaces were sputter-coated with a thin layer (~15 nm) of gold and imaged using a JEOL JSM6500F FEG-SEM. Low accelerating voltages (5-10kV) were utilised to minimise beam-induced degradation. Very high magnifications were avoided to ensure that morphological features identified on SEM micrographs were not attributable to beam damage.

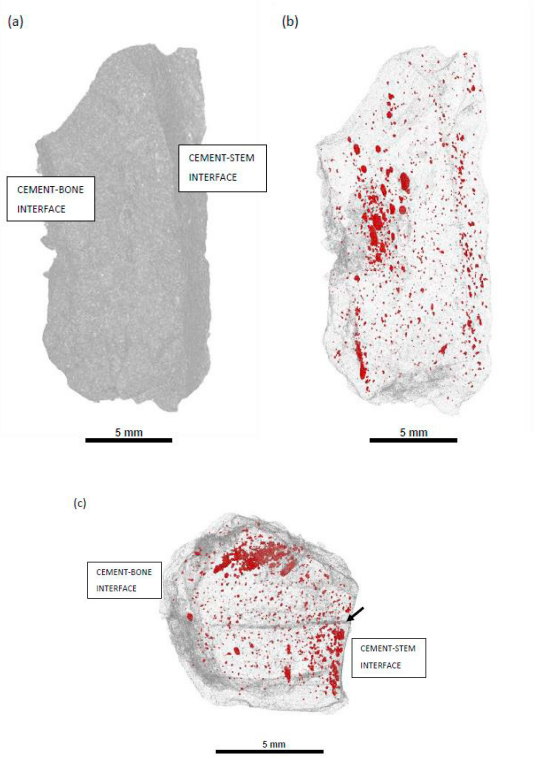

Fig. 1. CT reconstructions of (a) coronal view of retrieved cement specimen; (b) coronal view of distribution of voids (coloured red) within specimen; (c) transverse view of distribution of voids, showing position of pre-existing crack indicated by black arrow.

3. Results

A CT reconstruction of the retrieved cement specimen highlighting the cement-bone and cement-stem interfaces is shown in Figure 1. Interestingly, the cement appeared to contain a crack that bisected the specimen in the coronal plane (Figure 1c).

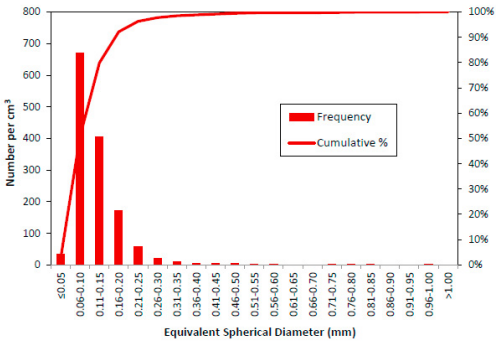

Fig. 2. Size distribution of voids in specimen of retrieved cement.

The size distribution of voids within the retrieved cement specimen is shown in Figure 2. Some directional void clustering was observed along the length of the specimen. Voids were concentrated at the cement-stem interface (Figure 1c), and appeared to be of a relatively consistent size (~0.1 mm diameter) and even distribution along the length of this interface. Significantly larger and more elongated voids (up to 1 mm diameter) were apparent in a cluster mid-way along the length of the specimen, towards the cement-bone interface. The modal void size was 0.06 – 0.10 mm equivalent spherical diameter (ESD), accounting for 48% of the total void population. Only 1% of the voids were larger than 0.40 mm ESD. The largest void was 0.96 mm ESD, accounting for 25% of the total void volume measured in this specimen.

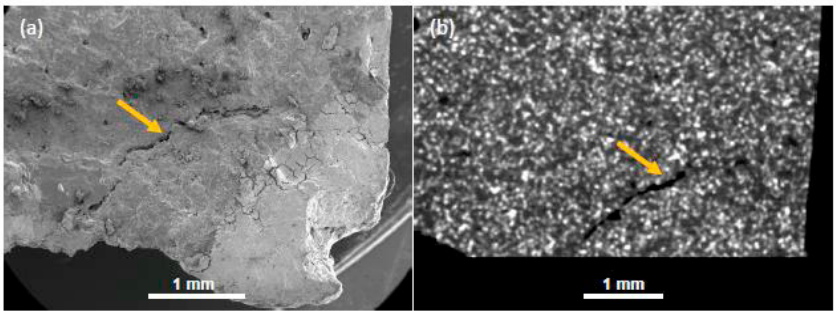

Fig. 3. (a) SEM micrograph (x25) of lower region of the cement fracture surface; (b) of corresponding CT slice through main crack plane. A secondary crack is evident in both images, indicated by yellow arrows.

The fracture within the explanted cement was extracted by immersing the sample in liquid nitrogen and then impacting it to separate the two surfaces. Inspection of the fracture surfaces via CT and SEM revealed evidence of secondary crack formation (Figure 3) that propagated approximately perpendicular to the main crack plane.

Erythrocytes (red blood cells) were visible on the fracture surface, confirming that the main crack occurred either before, or during, retrieval surgery. These cells do not appear to be contained within the surrounding polymer, so are not considered to result from entrapment of blood within the cement during implantation.

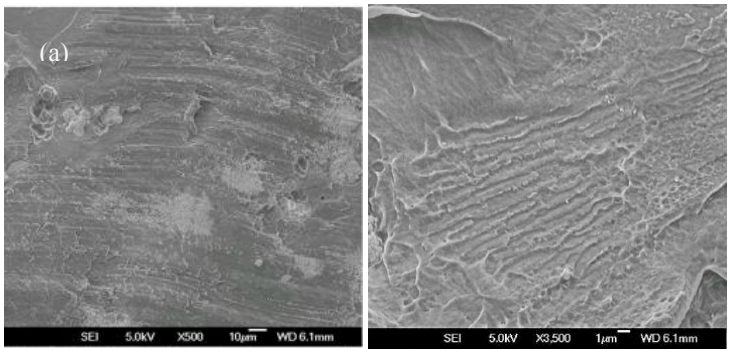

Fig. 4. (a) Fatigue striations and (b) evidence of crazing on the fracture surface.

SEM analysis revealed fatigue striations, of variable spacing but commonly ~1 µm, visible over an area of several square millimetres on the fracture surface in addition to extensive evidence of crazing (Figure 4).

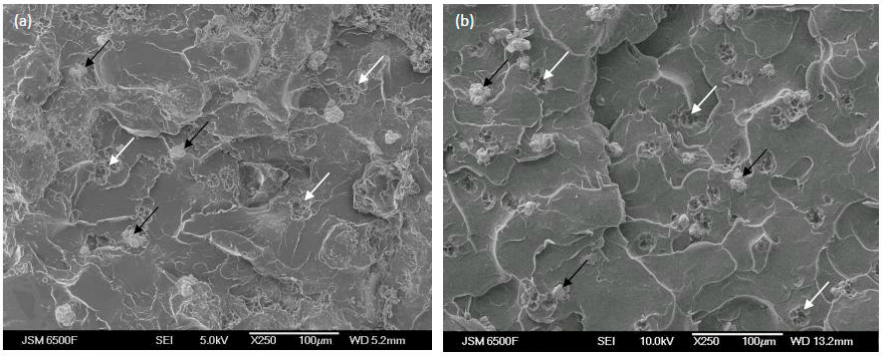

Fig. 5. (a) *ex vivo* and (b) *in vitro* fractures surfaces, highlighting stepped morphology, clusters of ZrO2 particles (black arrows) and ZrO2 pull-out (white arrows).

Comparison of the retrieved cement specimen with *in vitro* fracture surfaces revealed a number of similarities. (Figure 5). Regions of the *ex vivo* surface (Figure 5a) exhibited features that were typical of the early crack growth region near the initiation site of an *in vitro* specimen (Figure 5b). Both surfaces show a stepped morphology, consistent with a tortuous crack path and/or the coalescence of multiple micro-cracks. On both specimens, clusters of zirconium dioxide radiopacifier particles can be seen protruding from the fracture surface, while corresponding recesses in the polymer matrix indicate where these clusters have been pulled out of the polymer matrix during fracture. The process of ZrO2 pull-out was not observed on the final failure regions of either the retrieved specimen or *in vitro* test specimens, and is thus considered to be indicative of slow crack growth.

4. Discussion

The void morphologies identified within the *ex vivo* cement specimen were consistent with voids observed in vacuum-mixed *in vitro* specimens, suggesting similar mechanisms of void formation in both cases. Small, smooth voids may result from entrapment of gases (e.g. air or residual monomer), while larger voids with protruding polymer beads may occur due to shrinkage during polymerisation and/or incomplete filling of the cement mantle.

Previous studies have reported pore fractions, assessed using two-dimensional methods, ranging from 0.1% - 27% in ex vivo cement [3,6] mixed by hand, while others measured 5.7% porosity with a number-density of 0.25 voids per mm2 in vacuum-mixed Simplex P implanted into human cadaveric femora [7]. In the present study, bulk porosity was calculated to be 0.2% of the total specimen volume; this figure is likely to be an underestimate of the total porosity of the cement mantle, due to the exclusion of (potentially very large) surface-breaking voids. Analysis of the void size distributions for *in vitro* and *ex vivo* cement shows that the modal voids occur in the $\leqslant$ 0.05 mm and 0.06 - 0.10 mm ESD intervals respectively. However, the number-density of voids in the *ex vivo* cement was 1.4 per mm3, significantly lower than the 189 voids per mm3 recorded for the *in vitro* Palacos R. In effect, the retrieved cement demonstrates a larger but sparser void population, which may be attributable to more efficient porosity reduction during cement preparation.

The occasional irregular spacing of the striations may be explained by the non-uniform, discontinuous cyclic loading that would be expected to occur during normal patient activity. PMMA exhibits either true striations or discontinuous growth bands (DGBs), depending on load levels and loading history. Fatigue striations in glassy polymers typically form at higher stress levels than discontinuous growth bands, and unlike DGBs their presence does not appear to be dependent on the chemistry and molecular weight of the polymer [8]. Fatigue striations have a narrower inter-band spacing than DGBs, although the spacing of both these features increases further from the crack origin due to increasing ΔK. DGBs were observed in the *in vitro* samples but not in the explanted samples. This may be related to the variation in environmental and loading conditions between the *in vitro* and *ex vivo* specimens, including frequency, temperature, humidity, variable amplitude loading and addition of gentamicin to the cement formulation.

The absence of an identifiable crack origin on the fracture surface, and the evidence of secondary cracking suggests the main crack may have propagated as a result of coalescence of multiple smaller cracks. Damage accumulation due to the initiation and coalescence of cement micro-cracks is cited as a factor in the aseptic loosening of cemented implants, and has been replicated experimentally (McCormack and Prendergast 1999).

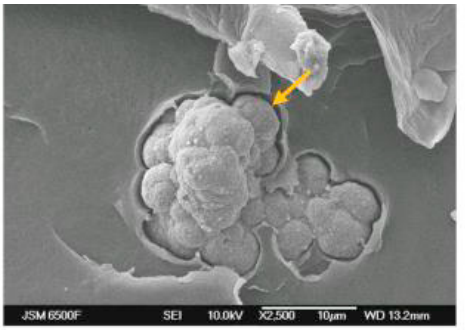

Fig. 6. Limited bonding of radiopacifier to surrounding polymer, with evidence of localised plastic deformation during fracture (yellow arrow).

While the absolute origin of fatigue could not be traced in the explanted sample, this study suggests that the microconstituents, in particular the larger pore sizes in the retrieved sample, play a role. Closer inspection of radiopacifier clusters (Figure 6) indicates limited bonding between the ZrO2 and polymer matrix, with evidence of separation of the interfaces and localized plastic deformation during fracture. This limited bonding suggests that the agglomerations effectively act as pores and therefore may play an additional role early on in the crack growth process.

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