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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.