INTRODUCTION

Spinal surgery in the form of vertebroplasty – the injection of poly(methyl methacrylate) (PMMA) bone cement into a vertebra in order to stabilize a fracture and provide pain relief – has been used since the 1980’s [1]. Although several studies report a high success rate [2], concerns have been raised due to the high polymerization temperature of the PMMA, the risk of leakage of the cement into surrounding tissues and the occurrence of adjacent fractures [3]. The relatively high occurrence of fractures next to augmented vertebrae has been hypothesized to be due to the high stiffness of the PMMA – in particular in comparison to osteoporotic bone - and several studies have been performed in order to produce injectable, low-modulus PMMA bone cement [4-6]. One simple way of reducing the modulus of the PMMA would be to introduce pores into the material. This has been done in previous studies through the addition of an aqueous phase [4, 6], which however has been found to give rise to an excessive amount of particle release in vitro [7]. This is likely due to the immiscibility of the aqueous phase with the monomer, which prevents polymerization of powder entrapped in the aqueous phase [7]. In this study, the addition of an oil phase to the PMMA was evaluated as a means of lowering the modulus of the cement with the aim of avoiding this effect. Castor oil was chosen as it is a polar oil, soluble in the MMA monomer, and is generally considered non-toxic [8-9]. The oil was also expected to improve the handling properties of the cement.

METHODS

Commercially available bone cement for vertebroplasty, Osteopal® V (Heraeus Medical GmbH, Germany) was used as control and as the base material in the study. A recently patented method was used to produce oil-containing cements: castor oil (Sigma-Aldrich, MO) was mixed with the liquid monomer using a vortexer before adding the pre-polymerized powder and mixing the cement manually. Oil-to-monomer ratios of 0.1, 0.3 and 0.5 were used, giving rise to cement containing 0, 2.5, 7.5 and 12 wt% oil in total. The cements were assessed using the methods specified in ASTM F451 [10] for doughing time, setting time and compression strength, although only half a packet of cement was used for each batch. The viscosity during curing was assessed using a parallel plate rheometer (AR2000, TA Instruments Inc, UK), using the time sweep mode at 5Hz with a displacement of 5°104° rad [11]. Statistical analysis was performed using ANOVA with Tamhane’s test for multiple comparisons at a significance level of 0.05.

RESULTS

Doughing time, setting time and maximum curing temperature were measured for 3-5 specimens per group. The doughing times were found to lie between 5 and 6 minutes for the control and the cement containing 2.5wt% oil. The doughing times for the cements containing more oil could not be determined as they did not produce any fibers between the glove and the dough upon probing (used to determine the doughing time). Furthermore, the cement containing 12wt% oil presented phase separation, suggesting a lower amount of oil should be used in order to ensure homogeneity of the cement. The setting times decreased from 18.2(±0.9)min and 20.0(±1.1)min for 0 and 2.5wt% oil, respectively, to 15.3(±1.3)min and 16.4(±1.6)min for 7.5 and 12wt% oil, respectively. The maximum temperature decreased significantly with any addition of oil, from 41.3(±2.1)°C for the control, to 32.4(±4.5)°C, 30.3(±1.8)°C and 28.4(±0.9)°C for the cements containing 2.5, 7.5 and 12wt% oil, respectively.

The compression tests (Figure 1) were performed on 11-18 specimens per group. Both the stiffness and the maximum stress were found to decrease with an increase in the amount of oil added. A statistically significant difference was found between all groups for both parameters. The viscosity measurements, shown in Figure 2, revealed a delay in the viscosity increase with time due to the addition of oil.

DISCUSSION

In this work, castor oil was added to commercially available bone cement, with the aim of creating low stiffness cement, adapted to (osteoporotic) cancellous bone. The addition of oil did indeed produce cements with lower stiffness and strength, closer to the ranges found in the relevant biological tissues. The oil was found to offer additional benefits, such as a reduction in polymerization temperature: commercially available cements commonly present a relatively high temperature which may be detrimental to the surrounding cells [6]. Furthermore, the oil appeared to provide a prolonged handling time, as indicated by the lower viscosity of these cements prior to setting. The full extent of this effect however needs to be confirmed through further injectability testing.

Previous attempts to create injectable porous cement for osteoporotic fractures have not reached clinical use, likely due to an excessive particle release from the cement [7]. Although not yet confirmed for commercial, sterilized cement such as Osteopal® V, a preliminary study in our laboratory (following the method used by Beck et al. [7]), indicated that cement produced from powder and monomer available at Sigma-Aldrich (St Louis, MO) did not give rise to an excessive particle release following the addition of 7.5wt% castor oil (particle release of approximately 0.2% of injected polymer [unpublished data] compared to the 5-14% found in the study by Beck et al. [7]).

Castor oil is frequently used in cosmetics [5] and is also used as a vehicle for intramuscular hormone injections [9]. However, its biological safety for this particular application is yet to be evaluated. In conclusion, the addition of small amounts of castor oil to PMMA bone cement appears to have several beneficial effects for its application to vertebroplasty.

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