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Spine-Ghost: a new bioactive Cement for Vertebroplasty

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Abstract. An innovative, resorbable and injectable composite cement (Spine-Ghost) to be used for augmentation and restoration of fractured vertebrae was developed. Type III α-calcium sulfate hemihydrate (CSH) was selected as the bioresorbable matrix, while spray-dried mesoporous bioactive particles (SD-MBP, composition 80/20% mol SiO_2/CaO), were added to impart high bioactive properties to the cement; a glass-ceramic containing zirconia was chosen as a second dispersed phase, in order to increase the radiopacity of the material. After mixing with water, an injectable paste was obtained. The developed cement proved to be mechanically compatible with healthy cancellous bone, resorbable and bioactive by soaking in simulated body fluid (SBF), cytocompatible through *in-vitro* cell cultures and it could be injected in *ex-vivo* sheep vertebra. Comparisons with a commercial control were carried out.

Introduction

Vertebral compression fractures (VCF) are one of the most frequent osteoporosis-related diseases, especially in post-menopausal women [1], while, for younger patients, vertebral fractures can be caused either by trauma or cancer. VCF are currently treated through mini-invasive surgical procedures: vertebroplasty (VP), by which a cement is injected into the fractured vertebral body, and kyphoplasty (KP), during which a cavity in the fractured vertebra is created before filling it by injecting the cement, in order to help the restoration of the original vertebral height. Both procedures require an easily injectable material that has also to be highly radiopaque, since both are carried out under fluoroscopic control.

Most of the cements currently used in surgery are based on a polymeric matrix (mainly polymethyl-metacrylate, PMMA), but they have many drawbacks such as mechanical mismatch of the compressive strength, excessive temperature raising during their setting and, being not resorbable, they cannot be replaced by new healthy tissue [2]. Calcium sulfate-based injectable cements, like Cerament by Bone Support, can be a good alternative since they are biocompatible, bioresorbable and show mechanical properties similar to those of cancellous bone [3, 4]. In order to achieve all the requirements of an injectable bone cement for vertebroplasty, composite materials can be developed. In the present work, basing on the main author's patent application PCT/IB2011/052094 [5], we combined type III α-calcium sulfate hemihydrate with mesoporous particles of a bioactive glass and a radiopaque glass-ceramic phase. Moreover, the mesoporous bioactive glass (MBG) was obtained through the spray-drying technique, which allows for a faster and more repeatable process [6].