

Percutaneous vertebroplasty in sheep: testing a novel mesoporous bioactive glass/calcium sulphate cement

Maria Teresa Oliveira¹, José Caeiro Potes¹, Maria Cristina Queiroga¹, José Lopes de Castro¹, Alfredo Pereira¹, João Fragoso², Antonio Manca³, Chiara Vitale-Brovarone⁴, Joana da Costa Reis²

¹ICAAM, ECT, Universidade de Évora, Portugal
teresoliveira@uevora.pt, jacpotes@uevora.pt, crique@uevora.pt, jcastro@uevora.pt, apereira@uevora.pt

²ECT, Universidade de Évora, Portugal
jfragoso@uevora.pt, jmfcr@uevora.pt

³IRT, Radiology Unit, Candiolo Cancer Institute-FPO, IRCCS, Candiolo, Torino, antonio.manca@ircc.it

⁴Politecnico di Torino, Torino, Italy; COREP, Torino, Italy, chiara.vitale@polito.it

ABSTRACT

Polymethylmethacrylate (PMMA) based cements are widely used for vertebroplasty. However, PMMA has disadvantages. The purpose of the present work was to test *in vivo* a new resorbable injectable composite cement – Spine-Ghost. The paste was percutaneously injected in bone defects manually drilled in L4 vertebral bodies of eight mature Merino sheep (Group B). A control group of eight sheep was injected with a known commercial calcium sulphate-based biphasic cement (Group A). After the 6-month implantation period the samples were assessed by micro-CT and histological studies. All sheep completed the 6-month implantation period. Cement resorption and new bone formation were observed in all samples with no signs of infection or inflammation.

Keywords: resorbable cement; percutaneous vertebroplasty; *in vivo* study; sheep.

INTRODUCTION

Synthetic composite biomaterials are widely accepted as valid bone graft alternatives. Presently, most of the cements used in percutaneous bone interventions are based on a polymeric matrix – polymethylmethacrylate (PMMA) –, providing immediate effect and safety. However, PMMA cements present several disadvantages [1]. Calcium sulphate-based injectable ceramic cements, like Cerament™ are effective, well documented bone substitutes since they are biocompatible, resorbable, and osteoconductive, displaying mechanical properties similar to those of cancellous bone, with reduced Young's Modulus [2].

Sheep are considered an appropriate large animal model for biomedical research because of their anatomical similarities to human bones. To date, only a small number of percutaneous vertebroplasty (PVP) pre-clinical studies have been performed in large animals, with several drawbacks, including cement leakage into the vertebral foramen, incomplete defect filling and lack of information on postoperative evolution.

With the goal of reducing long-term post vertebroplasty complications while ensuring immediate pain relief and mechanical stability, a new bioactive injectable cement for percutaneous vertebroplasty was developed – Spine-Ghost [3].

In the present work, the *in vivo* results of Spine-Ghost implantation in a sheep vertebral defect model are reported. The performance was compared to a commercial biphasic cement – Cerament™.

EXPERIMENTAL

Spine-Ghost is composed of type III α -calcium sulphate hemihydrate combined with mesoporous particles of a bioactive glass, and a radiopaque glass-ceramic phase. Prior to the *in vivo* study, the cement went through bioactivity and resorbability, *ex vivo* injection, mechanical and *in vitro* testing [3]. All the tests were carried out using a commercial reference as control.

Procedures were conducted according to European Community guidelines. 16 mature Merino sheep were randomly allocated into 2 groups: control group A, injected with Cerament™; and experimental group B, injected with Spine-Ghost. All underwent PVP under general anaesthesia. Vertebral body defects were created in the cranial hemivertebrae, through modified parapedicular approach developed by the authors [4]. Cements were injected under fluoroscopic guidance using a bone-filler system device (Medtronic Spine LLC, Portugal) and set for 2 hours in the anaesthetized sheep. Post-surgery care was spent in a pen of the veterinary hospital of the University of Évora. Fluorochromes were injected two weeks after surgery and two weeks before sacrifice. During the 6-month implantation period the sheep remained free ranging in the pasture. At the end of the implantation period, the animals were sacrificed, and the vertebrae explanted. Biological response and material integration were assessed by micro-CT and histological studies.

