Journal of the Mechanical Behavior of Biomedical Materials 83 (2018) 46–51

Contents lists available at ScienceDirect

Journal of the Mechanical Behavior of Biomedical Materials

journal homepage: www.elsevier.com/locate/jmbbm

# Glass -polyalkenoate cement: An alternative material for kyphoplasty in osteoporotic vertebral compression fractures – An ex vivo study☆

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ARTICLE INFO

*Keywords:*
PMMA
Aluminum-free glass-polyalkenoate cement
Kyphoplasty
Vertebral osteoporotic fractures
Stiffness
Adjacent vertebral body fracture

ABSTRACT

Adjacent vertebral body fracture is described as a risk after vertebroplasty and kyphoplasty. It may be true that this phenomenon is caused precisely because of the frequently used polymethylmethacrylate cement (PMMA), which shows a higher level of stiffness than bone material and may ultimately lead to shifting stress levels within the entire spine. The goal of the present study was to evaluate and compare the pressure distribution in the endplate of human vertebrae after kyphoplasty with PMMA and aluminum-free glass-polyalkenoate cement (gpc).

For the present study, 8 fresh frozen human cadaveric vertebral bodies from the thoracolumbar junction were used. All vertebrae were augmented transpedicularly on one side with gpc and on the other side with PMMA. A loading of 600 N, 800 N and 1000 N was applied. In the data processing an individual region of interest (roi) was generated for each vertebra. The following parameters were determined for each roi: maximum force [N], maximum pressure [kPa], mean pressure [kPa], roi area [$cm^2$]. We found significantly higher mean pressure values in the areas of the vertebrae augmented with PMMA, compared to the ones after augmentation with gpc ($p = 0.012$) when applying 1000 N. In the groups with lower forces there were no statistical relevant differences. The pressure distribution shows an advantage for gpc. A material, which does not create load concentration onto the cranial and caudal vertebral surface, could have major advantages concerning the risk of adjacent vertebral fractures. Thus the results of the 1000 N loading protocol suggest gpc being a possible alternative to ordinary PMMA cement, regarding its influence on stiffness in kyphoplasty. These and other general aspects like incorporation should be addressed and elaborated more detailed in further studies.

## 1. Introduction

Kypho - and vertebroplasty were developed to reduce pain and to prevent further collapse of the affected vertebral body with the aim to improve quality of life for patients with osteoporotic vertebral compression fractures (Alvarez et al., 2006; Atik et al., 2006; Cauley, 2013; Diamond et al., 2003; Johnell and Kanis, 2006; Lamy et al., 2014; Rousculp et al., 2007; Voormolen et al., 2007; Watts et al., 2001; Zhao et al., 2016). The majority of osteoporotic vertebral compression fractures occur in the thoracolumbar junction due to the change of the spinal curvature from kyphosis to lordotic and the high sagittal pressure impact on the thoracolumbar spine occurring in upright standing and during active lifting (Abouazza et al., 2016; Rohlmann et al., 2006; Wang et al., 2014). While two prospective randomized studies could not find any advantage of vertebroplasty compared to placebo treatment (Buchbinder et al., 2009; Kallmes et al., 2009), many other investigations and meta - analyses do show an improvement with regard to pain and disability (Alvarez et al., 2006; Diamond et al., 2003; Voormolen et al., 2007; Watts et al., 2001). In biomechanical studies vertebroplasty and kyphoplasty seem to be equivalently effective methods in strengthening osteoporotic vertebrae (Wilke et al., 2006) and showed similar statistically significant and lasting clinical improvement in a clinical trial (Dohm et al., 2014). However it is reported that kyphoplasty had fewer cement leakages, a better mean height restoration of

☆ IRB approval was obtained from the institutional review board (13-011).

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https://doi.org/10.1016/j.jmbbm.2018.03.008
Received 4 November 2017; Received in revised form 27 February 2018; Accepted 5 March 2018
Available online 21 March 2018
1751-6161/ 

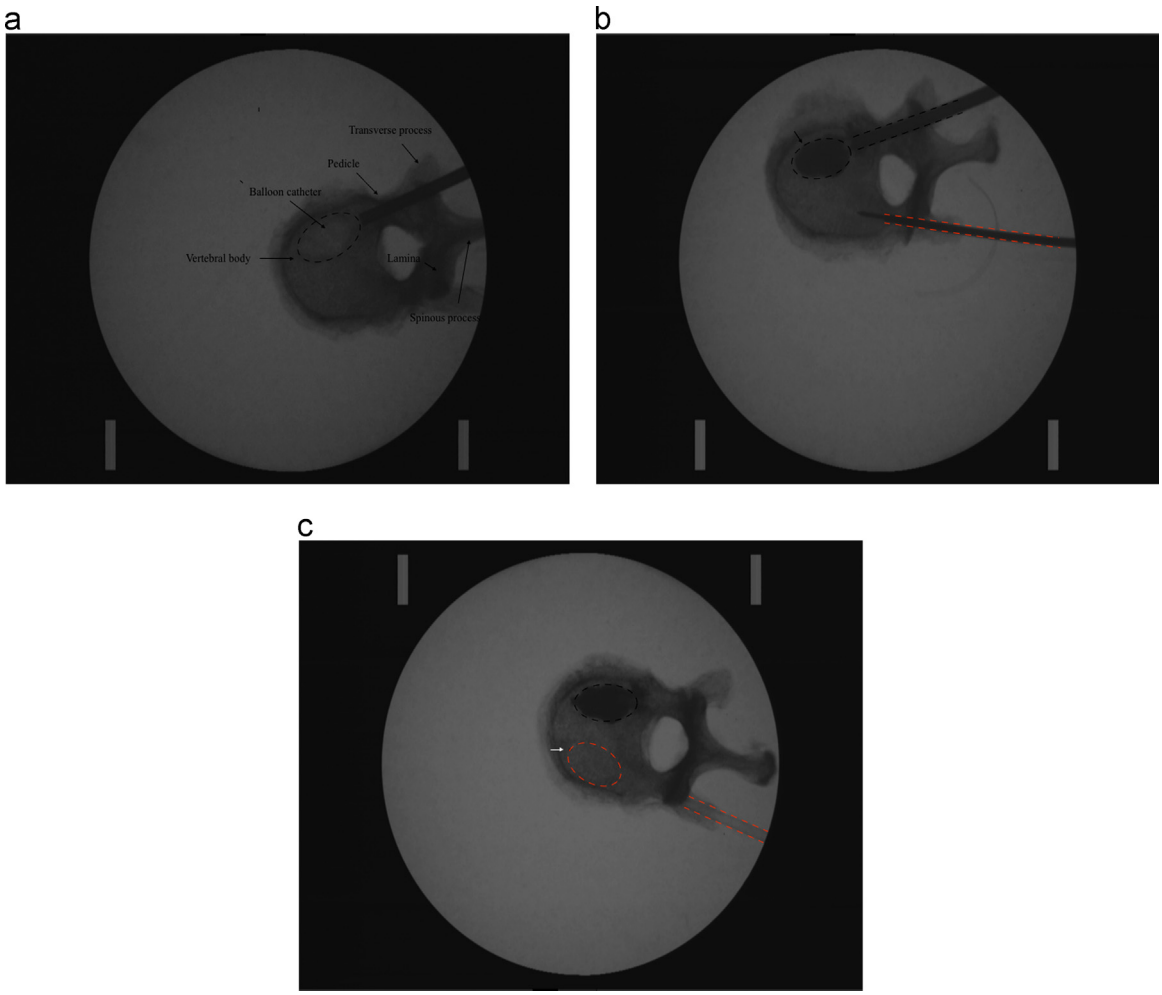


**Fig. 1.** a-c Transpedicularly insertion of the kyphoplasty balloon into the 12th thoracic vertebral body (cranial view (a) and infusion of PMMA (black arrow) (b). After hardening of PMMA the alternate side of the vertebra was augmented with IlluminOss™ (red lines = catheter). Fluoroscopy was used to ensure that the tip of the balloon (white arrow) reached the correct position (c) before augmentation started. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article)

the vertebral body and a trend of longer fracture-free survival (Dohm et al., 2014). Polymethylmethacrylate cement (PMMA) is used in these procedures for stabilization of the vertebral body. PMMA however has some disadvantages like the lack of integration and biological reactivity within the vertebral body or the generation of heat during its hardening process. These disadvantages are associated with intra- and post-operative complications such as the leakage of cement from the treated vertebrae, which is reported in kyphoplasty with an incidence of 9% (Hulme et al., 2006). While this complication tends to be clinically asymptomatic, it entails the risk to cause thermal damage to the surrounding soft tissue including the spinal cord during its hardening process or to evoke vascular, cardiac and pulmonary embolisms (Hulme et al., 2006; Schulz et al., 2012). As a consequence, specific augmentation systems and alternative materials such as calcium phosphate cement have been developed to reduce such adverse effects by allowing for significantly less cement extrusion into spongious bone marrow than PMMA cement (Xin et al., 2016).

Furthermore, once being hardened, PMMA does possess an additional Young's modulus, which is approximately 12 times higher compared to the one found in native bones (Baroud et al., 2003; Campbell and Harrop, 2008). It is assumed that the increased levels of stiffness lead to a shift of stress levels within the entire spine, and a higher prevalence of adjacent vertebral body fractures after kyphoplasty and vertebroplasty (Campbell and Harrop, 2008; Liebschner et al., 2001; Lindsay et al., 2001; Mudano et al., 2009). An alternative material for treatment of vertebral fractures, which is superior to PMMA concerning the aforementioned disadvantages, may thus be of great benefit. In this context aluminum - free glass - polyalkenoate cement (gpc) could be of great interest. It has been used for more than 40 years for the stabilization and fixation of dental implants. The Young's modulus of gpc is similiar compared to the one found in native bone (Baroud et al., 2003; Webb and Spencer, 2007; Wegmann et al., 2013). The IlluminOss™ photodynamic Bone Stabilization System™ (IlluminOss™ Medical Inc., 993 Waterman Avenue, East Providence, RI 02914, USA) was developed to utilize cements similar to gpc for orthopedic and trauma surgery. It is currently licensed with a ce mark and has been used for fracture - stabilization of low - load bearing bones in humans since 2008 (Wegmann et al., 2013). It is in clinical use for fixation of radius, ulna, fibula and clavicle, as well as to stabilize certain femoral, tibial, and pelvic fractures (Stumpf et al., 2015). The aim of the present study was to compare the mean pressure values in the end - plate of human cadaveric vertebrae after kyphoplasty with PMMA and aluminum - free glass - polyalkenoate cement (IlluminOss™).

## 2. Methods

In the present investigation, 8 fresh frozen human cadaveric vertebral bodies from cadavers of voluntary body donors were used. The vertebral bodies stemmed from 5 female and 3 male donors with an average age of 75 years (range 61 – 92 years). Soft tissue structures