Clinical Biomechanics 39 (2016) 14–24

Contents lists available at ScienceDirect

Clinical Biomechanics

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

Application of digital volume correlation to study the efficacy of prophylactic vertebral augmentation

Valentina Danesi [a], Gianluca Tozzi [b,*], Luca Cristofolini [a]

[a] Department of Industrial Engineering, Alma Mater Studiorum, Università di Bologna, Italy
[b] School of Engineering, University of Portsmouth, United Kingdom

ARTICLE INFO

Article history:
Received 24 April 2016
Accepted 26 July 2016

Keywords:
Prophylactic vertebral augmentation
Digital volume correlation
Cement-bone interface
Bone fracture
Micro-damage
Full-field three-dimensional strain measurement

ABSTRACT

Background: Prophylactic augmentation is meant to reinforce the vertebral body, but in some cases it is suspected to actually weaken it. Past studies only investigated structural failure and the surface strain distribution. To elucidate the failure mechanism of the augmented vertebra, more information is needed about the internal strain distribution. This study aims to measure, for the first time, the full-field three-dimensional strain distribution inside augmented vertebrae in the elastic regime and to failure.
Methods: Eight porcine vertebrae were prophylactically-augmented using two augmentation materials. They were scanned with a micro-computed tomography scanner (38.8 μm voxel resolution) while undeformed, and loaded at 5%, 10%, and 15% compressions. Internal strains (axial, antero-posterior and lateral-lateral components) were computed using digital volume correlation.
Findings: For both augmentation materials, the highest strains were measured in the regions adjacent to the injected cement mass, whereas the cement-interdigitated-bone was less strained. While this was already visible in the elastic regime (5%), it was a predictor of the localization of failure, which became visible at higher degrees of compression (10% and 15%), when failure propagated across the trabecular bone. Localization of high strains and failure was consistent between specimens, but different between the cement types.
Interpretation: This study indicated the potential of digital volume correlation in measuring the internal strain (elastic regime) and failure in augmented vertebrae. While the cement-interdigitated region becomes stiffer (less strained), the adjacent non-augmented trabecular bone is affected by the stress concentration induced by the cement mass. This approach can help establish better criteria to improve vertebroplasty.

1. Introduction

Vertebral fractures are a severe cause of morbidity and disability (Ferrar et al., 2005; Tancioni et al., 2011), as well as a significant burden for healthcare systems (Goldstein et al., 2015). The cause of the fracture may be pathological, traumatic, or a combination of the two. The main pathological conditions are osteoporosis (WHO, 2007) and metastatic lesions (Sutcliffe et al., 2013), which are associated with metabolic alterations resulting in bone weakening. However, the biomechanics underlying fracture onset and development of post-fracture and prophylactic treatments raises research questions that are still far from being answered.

Recently, prophylactic augmentation (cement injection in a non-fractured vertebra) has been proposed as an alternative to pharmacological treatments (Diamond et al., 2003) to reduce the fracture risk of osteoporotic vertebrae (Chiang et al., 2009; Kayanja et al., 2005; Langdon et al., 2009; Sun and Liebschner, 2004; Tancioni et al., 2011), or to prevent adjacent fractures after augmentation (Aquarius et al., 2014; Kobayashi et al., 2009). This treatment is meant to increase the strength and the structural support of the weak vertebrae, by the injection of an augmentation material into the vertebral body (Aquarius et al., 2014; Chiang et al., 2009; Cristofolini et al., 2016; Oakland et al., 2008; Oakland et al., 2009; Sun and Liebschner, 2004).

Questions have been raised about the efficacy and safety of vertebroplasty in general, because of the associated risks such as cement leakage and subsequent neural damage; tissue necrosis due to residual monomer and to the exothermal reaction; increased risk of fracture in the adjacent vertebrae (Berlemann et al., 2002; Carrodeguas et al., 2004; Lewis, 2006; Tanigawa et al., 2006; Uppin et al., 2003). Prophylactic augmentation exposes the patients to such risks; hence there is a need for a clearer understanding on the cost-benefit trade-off. For this reason, in-depth knowledge of the mechanical behaviour and failure of augmented vertebra is of fundamental importance to understand vertebral biomechanics and improve diagnosis and prophylactic treatments (Oakland et al., 2008).

Furthermore, it is still debated whether prophylactic augmentation actually strengthens the treated vertebra. The increasing interest in the

* Corresponding author at: School of Engineering, Anglesea Building, Anglesea Road, Portsmouth PO1 3DJ, United Kingdom.
E-mail address: gianluca.tozzi@port.ac.uk (G. Tozzi).

http://dx.doi.org/10.1016/j.clinbiomech.2016.07.010
0268-0033/

use of prophylactic augmentation, as a treatment for reduce the risk of fracture, has led to a number of experimental studies (Belkoff et al., 2001; Cristofolini et al., 2016; Heini et al., 2001; Ikeuchi et al., 2001; Kolb et al., 2013; Kruger et al., 2013; Lewis et al., 2008; Lim et al., 2002; Molloy et al., 2005; Rotter et al., 2015; Steens et al., 2007; Tohmeh et al., 1999Wilke et al., 2006). Several in vitro studies showed that the strength of augmented vertebrae was on average greater than that of non-augmented vertebrae (Ikeuchi et al., 2001; Lim et al., 2002). However, there were also cases where single treated specimens were weaker than the untraded controls (Berlemann et al., 2002; Dean et al., 2000). In fact, augmentation has been found to strengthen (Bai et al., 1999; Higgins et al., 2003; Lim et al., 2002), to provide no improvement (Kayanja et al., 2005), or even to weaken at least some specimens (Berlemann et al., 2002; Widmer Soyka et al., 2016), in comparison to untreated controls. It must be noted that most of these studies focused on the overall failure strength of the natural and treated vertebral body, without analysing the strain distribution.

The strain distribution has been partially assessed in the untreated vertebral body (Kayanja et al., 2004) (the most stressed region could not be identified as only one strain-gauge was applied on each vertebra). Recently, the strain distribution was measured for a variety of loading conditions with a large number (8) of strain gauges (Cristofolini et al., 2013). While strain gauges provide point-wise measurements, digital image correlation (DIC) allows for the investigation of full-field strain distribution on the surface of the specimen. In recent years, DIC has been successfully exploited to measure the strain distribution on the surface of untreated vertebrae (Campos-Lopez et al., 2015; Giambini et al., 2013; Grassi and Isaksson, 2015; Palanca et al., 2015a; Palanca et al., 2016). The surface strain distribution was also measured in augmented vertebrae in vitro, using 8 strain gauges (Cristofolini et al., 2016). The measured principal strains were generally aligned as expected: axially/circumferentially for all loading conditions, implying an axial force. It has been shown both experimentally (Cristofolini et al., 2016) and numerically (Widmer Soyka et al., 2016) that the variability of the weakening/strengthening effect depends on the quality of augmentation (amount, localization and distribution of the injected material). Even that study could not draw any conclusive information about the failure mechanisms associated to the internal state of the vertebra.

Numerical predictions through finite element (FE) models allowed the investigation of the internal strain distribution (e.g. (Kinzl et al., 2013; Sun and Liebschner, 2004; Wilcox, 2006)). However, FE models of complex structures such as an augmented vertebra, which include a thin cortical shell, cement-bone interdigitation, tissue anisotropy, inhomogeneity and nonlinearity must be first verified and then validated (Cristofolini et al., 2010; Henninger et al., 2010).

With the recent and rapid progress of high-resolution micro-CT imaging in conjunction with in situ mechanical testing (Buffière et al., 2010; Nazarian and Muller, 2004), digital volume correlation (DVC) emerged as a novel tool for the measurement of 3D deformation fields throughout entire bone volumes (Freddi et al., 2015; Roberts et al., 2014). So far, DVC has been successfully employed to examine full-field internal deformations in trabecular bone (Bay et al., 1999; Brémand, et al., 2008; Dall'Ara et al., 2014; Gillard et al., 2014; Liu and Morgan, 2007; Zauel et al., 2006), cortical bone (Christen et al., 2012; Dall'Ara et al., 2014; Palanca et al., 2015b) and cement-bone interface (Tozzi et al., 2014). Application of DVC to whole untreated vertebra was also exploited to examine yield and post-yield deformations (Hussein et al., 2012; Hussein et al., 2013). DVC is an ideal tool to investigate the internal mechanism leading to failure onset and progression in augmented vertebrae, and could potentially be used to elucidate under which conditions augmentation can reinforce/weaken the vertebral body.

While DVC has been applied to characterize the mechanical performance of untreated vertebral body, so far it has not been applied to augmented vertebral bodies. Recently, for the first time, 3D zero-strain studies demonstrated the suitability of DVC to investigate augmented vertebrae both at organ and tissue level (Tozzi et al., 2015). This study reported that strain uncertainties can be reduced below 300 microstrain if the images are adequately prepared (excluding the non-tissue background), and with an appropriate choice of the computation sub-volume size (i.e. 48 voxels for a 39 μm voxel size image).

The aim of this study was to use DVC, for the first time, to improve the understanding of the failure mechanism inside prophylactically-augmented vertebral bodies. DVC was applied to measure the full-field strain distribution under compression inside the vertebral body augmented with two different cements. The approach enabled focusing on the injected cement, and on the cement-bone interdigitated region, in the immediate post-operative period. The investigation included both the elastic regime (axial, antero-posterior and lateral-lateral components of strain) and the yield/failure internal micro-damage mechanism.

2. Methods

2.1. Specimens and prophylactic augmentation

Four porcine thoracic spine segments (T1–T3) were obtained from animals sacrificed for alimentary purposes. The animals were all female, of the same breed, approximately 9 months old and 100 kg at sacrificeThe single vertebrae were dissected, removing the soft tissues, including the intervertebral discs (Fig. 1). The vertebral bodies measured 20.0–24.0 mm in the cranial-caudal, 18.0–20.5 mm in the antero-posterior, and 26.1–31.3 mm in the lateral-lateral direction. They were treated with two vertebral augmentation materials:

- Four vertebrae (Mendec-1, Mendec-2, Mendec-3, Mendec-4) were prophylactically-augmented with an acrylic cement (Mendec-Spine, Tecres, Verona Italy). Mendec-Spine contains 20.4% $BaSO_4$ pellets with an average size of 300 μm, which grant adequate visibility during micro-CT imaging (Tozzi et al., 2015).
- Four vertebrae (Calcemex-1, Calcemex-2, Calcemex-3, Calcemex-4) were treated with an acrylic-based cement (Calcemex-Spine, Tecres). Calcemex-Spine contains 26% beta-tri-calcium-phosphate (β-TCP), and 6.5% $BaSO_4$ pellets with an average size of 300 μm.

Augmentation was performed using a unilateral approach (Fig. 1) using the proprietary mixing and delivery kit. Injection was stopped at the first visible sign of leakage (injected volume: 1.0–1.5 ml of cement). In order to facilitate a more realistic flow and polymerization of the augmentation material, the vertebrae were placed in saline solution at 42 °C 1 h before and 12 h after augmentation (the physiologic temperature in pigs is 39–41 °C (Reece, 2004; Ye et al., 2007)).

The augmented specimens were tested within 60 days after augmentation. When not in use, the specimens were stored at −28 °C and sealed in plastic bags. Under these conditions the resorbable phase of Calcemex-Spine remains unmodified. In fact, this investigation aimed at replicating the post-operative conditions.

In addition, four vertebrae from those spines were tested in the natural condition (Natural-1, Natural-2, Natural-3 and Natural-4): three of these specimens were part of a different study (Tozzi et al., 2016). These specimens are included in the present paper for comparison, as a blank control; more details about the natural specimens can be found in (Tozzi et al., 2016).

Within each spine segment, two vertebrae were assigned for augmentation with two types of bone cement, and one vertebra was used as the non-augmented control. Sampling was arranged so that the augmented and control samples were well distributed within the spine segment, in order to have at least one T1, one T2 and one T3 per group.

The growth plates were removed from the augmented and natural vertebrae, together with the adjacent endplates (due to the young age