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Augmentation of failed human vertebrae with critical un-contained lytic defect restores their structural competence under functional loading: An experimental study

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ABSTRACT

Background: Lytic spinal lesions reduce vertebral strength and may result in their fracture. Vertebral augmentation is employed clinically to provide mechanical stability and pain relief for vertebrae with lytic lesions. However, little is known about its efficacy in strengthening fractured vertebrae containing lytic metastasis. *Methods:* Eighteen unembalmed human lumbar vertebrae, having simulated uncontained lytic defects and tested

to failure in a prior study, were augmented using a transpedicular approach and re-tested to failure using a wedge fracture model. Axial and moment based strength and stiffness parameters were used to quantify the effect of augmentation on the structural response of the failed vertebrae. Effects of cement volume, bone mineral density and vertebral geometry on the change in structural response were investigated.

Findings: Augmentation increased the failed lytic vertebral strength [compression: 85% (P < 0.001), flexion: 80% (P < 0.001), anterior-posterior shear: 95%, P < 0.001)] and stiffness [(40% (P < 0.05), 53% (P < 0.05), 45% (P < 0.05)]. Cement volume correlated with the compressive strength ($r^2 = 0.47$, P < 0.05) and anterior-posterior shear strength ($r^2 = 0.52$, P < 0.05) and stiffness ($r^2 = 0.45$, P < 0.05). Neither the geometry of the failed vertebrae nor its pre-fracture bone mineral density correlated with the volume of cement.

Interpretation: Vertebral augmentation is effective in bolstering the failed lytic vertebrae compressive and axial structural competence, showing strength estimates up to 50–90% of historical values of osteoporotic vertebrae without lytic defects. This modest increase suggests that lytic vertebrae undergo a high degree of structural damage at failure, with strength only partially restored by vertebral augmentation. The positive effect of cement volume is self-limiting due to extravasation.

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1. Introduction

Vertebral bone is the most common site of metastasis in the skeletal system (Galasko, 1986; Wong et al., 1990). The remarkable and often progressive loss of bone tissue associated with lytic metastatic lesion (LM) (Galasko, 1986; Kanis et al., 1999; White, 2006) significantly reduces the strength of the vertebral bodies (Ebihara et al., 2004; Hipp et al., 1995; Roth et al., 2004; Stechow et al., 2003; Tschirhart et al., 2004; Whyne et al., 2001) exposing the patients to a high risk of catastrophic vertebral failure (Lad et al., 2007; Taneichi et al., 1997; Whealan et al., 2000; Whyne et al., 2003). Clinically, approximately 30% of the affected vertebrae undergoing fracture or subsequently producing hypercalcemia requiring medical treatment (Walls et al., 1995). Although radiation therapy and chemotherapy (Wai et al., 2003) offer pain relief, these treatments do not provide immediate improvement

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to the mechanical stability of the structurally compromised vertebrae (Tschirhart et al., 2004). As the population ages and improved cancer survival rates lead to a larger number of patients presenting with skeletal metastasis, there is a clinical need to offer palliative care for these patients to reduce the morbidity associated with pain and neurological compromise (Harel and Angelov, 2010; Seregni et al., 2011).

Cement-based percutaneous vertebral augmentation (VA) of the failed vertebral body has been used to treat vertebral hemangiomas (Galibert and Deramond, 1990; Gangi et al., 1994) and bone metastases (Cotten et al., 1996; Galibert and Deramond, 1990; Jensen and Dion, 1997; Kaemmerlen et al., 1989) with rapid relief of pain reported in up to 80% of patients as well as improved patient mobility. Cement volume (Tschirhart et al., 2006), location of defect (Tschirhart et al., 2004), cement filling patterns (Ahn et al., 2007) and pressurization (Reidy et al., 2003), are reported to affect efficacy in providing mechanical stabilization for intact vertebrae with fully contained, highly idealized defect patterns. Although VA is commonly employed to provide mechanical stability and pain relief in patients with metastasis, remarkably little is known about the extent to which VA strengthens fractured







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bodies containing such lesions. This information is critical to assess efficacy of VA and to evaluate the effect of the resulted altered loading (Laredo and Hamze, 2004; Uppin et al., 2003; Wang et al., 2012) on the adjacent untreated vertebrae.

In this study, eighteen human lumbar vertebrae were used from a previous study which investigated the effects of uncontained lytic defects on the failure process and residual load carrying capacity of the vertebrae using a wedge fracture model (Alkalay, 2015). The failed vertebrae underwent cement augmentation to investigate the biomechanical effectiveness of VA in restoring the mechanical competence of the failed vertebrae. We hypothesized that VA preferentially increases the failed vertebrae compressive and shear strength and stiffness compared to its flexion/extension and lateral bending based strength and stiffness. With bone density and volume of cement injection being important in the strength osteoporotic vertebrae (Belkoff et al., 2001; Heini et al., 2001; Higgins et al., 2003), we further hypothesized that the volume of cement injected would correlate with the increase in structural competence.

2. Methods

2.1. Specimens

Eighteen unembalmed lumbar vertebrae (L1–L5), obtained from five female donors aged 65–78 years, were recruited from a previous study (Alkalay, 2015) on the effect of lytic defects on the failure of human vertebrae. In that prior study, the lytic vertebra termed, Osteoporotic-lytic (OL), were to tested failure under combined compression and forward bending loads. The failed vertebrae termed, (OL-F), were allowed to recover under a preload of 200 N (simulating recumbence (Wilke et al., 1999) for a period of 30 min). The failed vertebrae were then retested to quantify their residual load carrying capacity (Alkalay, 2015). Prior to the creation of the defect (Fig. 1), each intact spine was imaged using a DXA (Dual X-ray Absorptiometry) scanner (QDR 2000, Hologic Inc., Waltham, MA) and the bone mineral density (BMD) computed for each vertebra along its lateral projection. To simulate a unilateral lytic defect, a high-speed mechanically expanding bur was advanced under fluoroscopic control (MINI 6000, OEC Medical, Salt Lake City, UT) through the pedicle into the body and a cavity occupying 40% of the volume of the body was created using a pre-planned template. A 5.0 mm diameter portal hole was created in the cortex which communicated with this cavity resulting in an uncontained lytic defect, identified as the most detrimental for vertebral collapse in the thoraco-lumbar spine (Taneichi et al., 1997).

2.2. Measurement of vertebral geometry

For each vertebra (OL-F), the vertebral body anterior (H_A) and posterior (H_P) heights were measured at the sagittal mid-line using a mechanical caliper (Mitutoyo, Japan, 0–25 mm, 0.01 accuracy). From these measurements, a vertebral wedge deformity index (WDI) was computed as [$H_A - H_P / H_A$] (Crados et al., 2001). This procedure was repeated once the vertebrae were cement augmented, OL-FA, and following destructive testing of the augmented vertebrae (OL-FAF).

2.3. Vertebral augmentation (OL-FA)

Polymethylmethacrylate cement (Vertebroplastic NH 9-44-20, Codman & Shurtleff, Inc, Raynham, MA) was prepared in accordance with the manufacturer's instruction and poured into several 1.0 cc



Fig. 1. A diagrammatic illustration of the experimental work flow. Recruited from a previous study (Alkalay, 2015), failed vertebral specimens with simulated lytic defect (OL-F) were augmented (OL-FA) and the change in vertebral structural competence quantified under mechanical loading. Changes in vertebral body dimensions with augmentation were similarly assessed.

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