Clinical Biomechanics 30 (2015) 720–725

Contents lists available at ScienceDirect

Clinical Biomechanics

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

Minimum cement volume required in vertebral body augmentation—A biomechanical study comparing the permanent SpineJack device and balloon kyphoplasty in traumatic fracture

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ARTICLE INFO

Article history:
Received 15 July 2014
Accepted 28 April 2015

Keywords:
Kyphoplasty
Cement
Spine
Volume
SpineJack
Fracture

ABSTRACT

Background: Minimally invasive treatment of vertebral fractures is basically characterized by cement augmentation. Using the combination of a permanent implant plus cement, it is now conceivable that the amount of cement can be reduced and so this augmentation could be an attractive opportunity for use in traumatic fractures in young and middle-aged patients.
The objective of this study was to determine the smallest volume of cement necessary to stabilize fractured vertebrae comparing the SpineJack system to the gold standard, balloon kyphoplasty.
Methods: 36 fresh frozen human cadaveric vertebral bodies (T11-L3) were utilized. After creating typical compression wedge fractures (AO A1.2.1), the vertebral bodies were reduced by SpineJack (n = 18) or kyphoplasty (n = 18) under preload (100 N). Subsequently, different amounts of bone cement (10%, 16% or 30% of the vertebral body volume) were inserted. Finally, static and dynamic biomechanical tests were performed.
Findings: Following augmentation and fatigue tests, vertebrae treated with SpineJack did not show any significant loss of intraoperative height gain, in contrast to kyphoplasty. In the 10% and 16%-group the height restoration expressed as a percentage of the initial height was significantly increased with the SpineJack (>300%). Intraoperative SpineJack could preserve the maximum height gain (mean 1% height loss) better than kyphoplasty (mean 16% height loss).
Interpretation: In traumatic wedge fractures it is possible to reduce the amount of cement to 10% of the vertebral body volume when SpineJack is used without compromising the reposition height after reduction, in contrast to kyphoplasty that needs a 30% cement volume.

1. Introduction

Vertebroplasty and kyphoplasty are the standard methods for minimally invasive treatment of vertebral compression fractures. A key feature of these methods is stabilizing the fracture by cement augmentation. Disadvantages of this technique are changes in the mechanical properties of cancellous bone and an increased risk of complications due to leakage (Hulme et al., 2006; Taylor et al., 2006, 2007).

Positive side effects of kyphoplasty were an increased restoration of vertebral height and filling of the cavity created with high viscosity cement compared to vertebroplasty. However, in order to stabilize the achieved height reduction, the entire cavity has to be filled with cement. Another problem with kyphoplasty, the loss of vertebral height following fracture reduction with a balloon tamp and its subsequent removal (Voggenreiter, 2005) has been resolved by developing newer alternatives (Furderer et al., 2002). This "third" generation of augmentation system uses specific implants that remain within the vertebra (Rotter et al., 2010). However, these implants also rely on cement injection to stabilize the vertebra permanently (Kruger et al., 2013). Using the combination of a permanent implant plus cement, it is now conceivable that the amount of cement can be reduced and so this augmentation could be an attractive opportunity for use in traumatic fractures in young and middle-aged patients (Wikipedia, 2014).

One ex vivo study following percutaneous vertebroplasty showed that for restoration of vertebral body strength and stiffness, vertebral body cement filling degrees of 16% and 30%, respectively, are required (Molloy et al., 2003). A clinical study on the relationship between the

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http://dx.doi.org/10.1016/j.clinbiomech.2015.04.015
0268-0033/

volumetric analysis of cement in vertebroplasty with clinical outcome and complications showed that a volume larger than 11.65% leads to a significantly increased incidence of leakage and adjacent fractures (Jin et al., 2011).

As mentioned above, to the best of our knowledge there is currently no effective information that allows the surgeon to reduce the amount of cement in the third generation kyphoplasty technique without decreasing vertebral strength and stiffness.

It was the aim of this study to identify the minimum quantity of cement necessary while still sufficiently stabilizing the restored fractured vertebra in the SpineJack (SJ) system (Fig. 1) compared to the gold standard balloon kyphoplasty (BKP).

2. Methods

2.1. Specimens and experimental groups

For equal group sample size 36 vertebrae from eight intact fresh human male cadaveric spines (T11-L3) were used in this study. The average age of the donors was 62 years (51–69 years). Each specimen was screened by computed tomography (CT) scan (Aquilion, Toshiba, Tokyo, Japan) for bone mineral density (BMD) measurements including calculation of vertebra body volume (Aquarius INtuition version 4.6.85.2800, TeraCcon, Frankfurt, Germany). All vertebrae were pooled to create two different groups consisting of each augmentation systems (SJ vs. BKP) and subdivided into three cement groups (10%, 16% and 30% cement filling of the vertebral body volume, $n = 6$).

The SJ system (Vexim SA, Balma, France) consists of an expandable metal implant (titanium alloy) mounted on an expander, of which two are inserted bilaterally into the vertebral body and simultaneously expanded. The unexpanded implant (Ø 5 mm) is delivered in a pre-folded state, and is gradually expanded to its final configuration until fracture reduction is satisfactory and/or the maximum expanded height of 17 mm is reached. After the implant expansion both implants stay in place to maintain the restored height. PMMA cement is then injected through the central part of the implant (Fig. 1).

2.2. Fracture generation and instrumentation

The vertebrae were isolated and all soft tissue was removed. The caudal endplates of the vertebrae were embedded into radiolucent PMMA (Beracryl; Troller Kunststoffe, Fulenbach, Switzerland). Vertebral compression fractures (AO A1.2.1) (Magerl et al., 1994) were performed using a universal material testing machine (MTS; Eden Prairie, MN, USA; 15 kN load cell, measurement error: 0.3%). Load was transferred by the pivot-mounted pressure plate in orthograde projection to the superior vertebral endplate to allow a wedge compression of the anterior wall until a compression of the anterior vertebral edge of more than 40% was reached (2 mm/min; 5 Hz) (Fig. 2).

After generating the vertebral compression fractures, the vertebral body height was redetermined by CT scan including calculation of the vertebral body volume (Table 1).

For augmentation the vertebrae were mounted into a custom made testing device performing reduction tests under a constant axial preload of 100 N. The specific working cannulae of both systems were placed bipedicular under the fluoroscopic imaging guidance of a C-arm (Ziehm Vario 3D, Ziehm imaging, Nuremberg).

Either SJ (Ø 5 mm [diameter] × 25 mm [length]) or an inflatable kyphoplasty bone tamp/balloon (KyphX Xpander® 20/3, Kyphon Europe Zaventem, Belgium) was inserted simultaneously on both sides and expanded by two surgeons simultaneously. The re-alignment was continued until the vertebral body height was restored.

Next, PMMA cement (Cohesion® Bone Cement CM0300, VEXIM SA, Balma, France) was injected synchronously on both sides using filling cannulae by Vexim or Kyphon, respectively, to comply with the manufacturers' recommendations. Each step was performed under

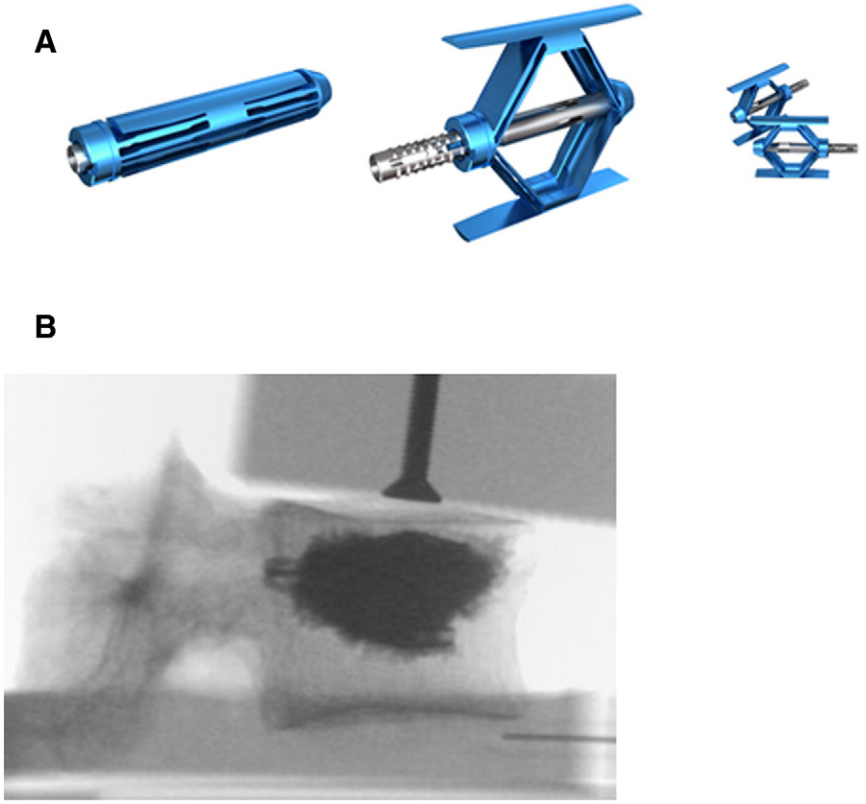

Fig. 1. A; Illustration of the SpineJack implant in the pre-folded and expanded states. B; SJ-representative lateral X-ray image after cement augmentation.