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Height restoration of osteoporotic vertebral compression fractures using different intravertebral reduction devices: a cadaveric study

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Abstract

BACKGROUND: The treatment of osteoporotic vertebral compression fractures using transpedicular cement augmentation has grown significantly during the past two decades. Balloon kyphoplasty was developed to restore vertebral height and improve sagittal alignment. Several studies have shown these theoretical improvements cannot be transferred universally to the clinical setting.

PURPOSE: The aim of the current study is to evaluate two different procedures used for percutaneous augmentation of vertebral compression fractures with respect to height restoration: balloon kyphoplasty and SpineJack.

MATERIALS AND METHODS: Twenty-four vertebral bodies of two intact, fresh human cadaveric spines (T6–L5; donor age, 70 years and 60 years; T-score −6.8 points and −6.3 points) were scanned using computed tomography (CT) and dissected into single vertebral bodies. Vertebral wedge compression fractures were created by a material testing machine (Universal testing machine, Instron 5566, Darmstadt, Germany). The axial load was increased continuously until the height of the anterior edge of the vertebral body was reduced by 40% of the initial measured values. After 15 minutes, the load was decreased manually to 100 N. After postfracture CT, the clamped vertebral bodies were placed in a custom-made loading frame with a preload of 100 N. Twelve vertebral bodies were treated using SpineJack (SJ; Vexim, Balma, France), the 12 remaining vertebral bodies were treated with balloon kyphoplasty (BKP; Kyphon, Medtronic, Sunnyvale, CA, USA). The load was maintained during the procedure until the cement set completely. Posttreatment CT was performed. Anterior, central, and posterior height as well as the Beck index were measured prefracture and postfracture as well as after treatment.

RESULTS: For anterior height restoration (BKP, 0.14±1.48 mm; SJ, 3.34±1.19 mm), central height restoration (BKP, 0.91±1.04 mm; SJ, 3.24±1.22 mm), and posterior restoration (BKP, 0.37±0.57 mm; SJ, 1.26±1.05), as well as the Beck index (BKP, 0.00±0.06 mm; SJ, 0.10±0.06), the values for the SpineJack group were significantly higher ($p<.05$)

CONCLUSION: The protocols for creating wedge fractures and using the instrumentation under a constant preload of 100 N led to reproducible results and effects. The study showed that height

FDA device/drug status: Approved (Inflatable Bone tamp; Kyphon Medtronic); Investigational (SpineJack, Vexim, SAS CE marked; under clinical investigation).

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restoration was significantly better in the SpineJack group compared with the balloon kyphoplasty group. The clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.

Keywords: Kyphoplasty; Vertebroplasty; Height restoration; Vertebral compression fracture; Cadaver

Introduction

Vertebroplasty and kyphoplasty, the percutaneous injection of various bone cements into affected vertebral bodies, are used commonly to treat painful osteoporotic vertebral fractures. The technique of percutaneous injection was first described by Galibert et al. [1]. Following the introduction of balloon kyphoplasty [2], in which a void in the vertebral body is created using an inflatable balloon before cement augmentation, treatment using both procedures has been increasing significantly.

According to the criteria of evidence-based medicine, there are only two level Ib evidence studies [3,4] that show the benefits of balloon kyphoplasty compared with conservative treatment, especially during the early stage after osteoporotic fracture. However, the study results are limited to clinical benefits such as pain and do not examine kyphotic correction. The level Ia studies comparing vertebroplasty with conservative treatment show inconsistent results and have been discussed in detail elsewhere [5,6]. Several systematic reviews have also reported efficacy with regard to significant pain reduction in 87% of patients undergoing vertebroplasty and in 92% of patients undergoing kyphoplasty [7]. Overall, the complication rate of both procedures is considered to be low [7–9].

Balloon kyphoplasty was designed to improve patient safety during augmentation procedures—in particular, to reduce the rate of cement leakage. Another advantage compared with percutaneous vertebroplasty was supposed to be the possibility of reducing the fracture during balloon inflation. Correction of sagittal alignment, reducing the kyphotic angle, and improvement of the vital capacity of the lungs were supposed to be other advantages.

One procedural disadvantage of balloon kyphoplasty is that the balloons have to be removed after height restoration and before cement injection. This balloon deflation can lead to a significant loss of the previously restored height [10,11]. To circumvent the loss of height restoration, before cement augmentation, a reduction device was designed that would stay inside the vertebral body during cement augmentation.

A theoretical advantage of the SpineJack device is that the force needed to reduce the fracture can be directed in the craniocaudal direction. In balloon kyphoplasty, individual anatomy and the balloon decide where the force is directed.

There is still uncertainty about the clinical importance of height restoration. Reducing fractures in combination with improved sagittal kyphosis is supposed to show better long-term effects. The improved vital capacity of the lungs as well as a reduction of adjacent fractures are advantages of an anatomic reduction of the fractured vertebrae.

Thus, we examined biomechanical behavior and height restoration using the SpineJack device compared with balloon kyphoplasty in osteoporotic vertebral compression fractures.

Materials and methods

Specimens

To analyze the characteristics of the balloon kyphoplasty and SpineJack procedures, it was necessary to create similar conditions for both devices. For this reason, all devices were investigated in the vertebral bodies of two fresh, frozen human cadaveric spines (T6–L5). The donors were two women (age, 70 years and 60 years). Specimens were stored at −20°C. Before surgery a computed tomographic (CT) scan of the spine was performed to identify any pathologies, especially preexisting vertebral fractures or deformities. In addition, bone density was measured for all vertebral bodies separately, which showed substantial osteoporosis (T-score, −6.8 points and −6.3 points). Osteoporosis was defined according to the World Health Organization criteria: BMD (bone mineral density) of more than 2.5 standard deviations below the mean of a young healthy reference population of the same gender (T-score). The spines were dissected into single vertebral bodies and the surrounding soft tissues were removed completely. The laminae and spinal processes were not removed. A total of 24 undamaged vertebral bodies were prepared. The vertebral bodies were assigned to two groups, alternating at every second level. Afterward, the end plates were embedded in Technovit 3040 (cold-curing resin for surface testing and impressions; Heraeus Kulzer, Wehrheim, Germany).

Fracture generation and experimental groups

Vertebral heights were measured at the anterior and posterior walls as well as in the center of the vertebral bodies (Fig. 1). To eliminate inaccurate measurements resulting from projection errors computed tomography was used to measure vertebral heights. Vertebral wedge compression fractures were created by a material testing machine (Universal testing machine, Instron 5566). The load was transferred by a pivot-mounted pressure plate on the superior vertebral end plate. To create wedge compression of the anterior wall of the vertebral body, the main vector of the