



Basic Science

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 restoration was significantly better in the SpineJack group compared with the balloon kyphoplasty

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

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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. © 2013 Elsevier Inc. All rights reserved.

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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 axial force was centered on the sagittal midline at the end of the anterior fourth of the vertebral body (Fig. 2).

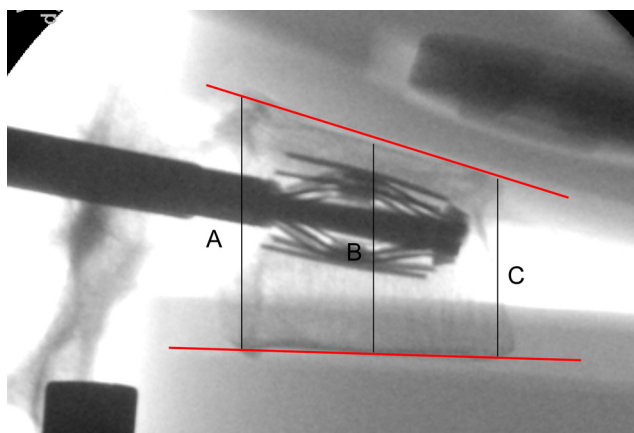


Fig. 1. Height measurements using the six-point method. The height of the posterior (A) and anterior (C) wall of the vertebral body as well as the central height (B) were measured at three time points. The angle between the end plates (red lines) was measured. In addition, the Beck Index (the ratio between C and A) was calculated.

The axial load was increased continuously (load application velocity, 1 mm/min) until the height of the anterior edge of the vertebral body was reduced by 40% of the initial measured values. Anterior heights of the intact vertebral bodies were measured by CT scan. The anterior wall of the vertebral body was marked with optical markers. The distance between these markers was reduced to 60% of the initial height. In forgoing tests, a reexpansion of the vertebral bodies after fracture was observed. The fractured vertebral bodies acted like sponges. To reduce this effect, we maintained the load for 15 minutes.

After 15 minutes the load was decreased manually to 100 N. The vertebral bodies were then fixed in this position on a radiolucent clamp. The clamp is a radiolucent custom-made device and is able to fix the vertebral bodies in a certain position during processing, CT scanning, and transport to make sure no spontaneous changes in height occur. After clamping at the 100-N position, postfracture computed tomography was carried out. Anterior and posterior heights of the vertebral bodies, and their sagittal index (Beck index = Anterior height/Posterior height) as well as the central height of the vertebral body were measured or calculated respectively (Fig. 1). Computed tomographic scans were acquired using a Siemens Somatom Definition scanner. All heights were measured in the midsagittal plane using an Agfa Healthcare Impax EE CD Viewer (Agfa Healthcare, Mortsel, Belgium).

Short description of the techniques used

Balloon kyphoplasty

During the balloon kyphoplasty test, two guidewires were placed through both pedicles using Jamshidi needles. After insertion of two working cannulas, two inflatable bone tamps were advanced into the collapsed vertebral body and they were inflated simultaneously, creating two

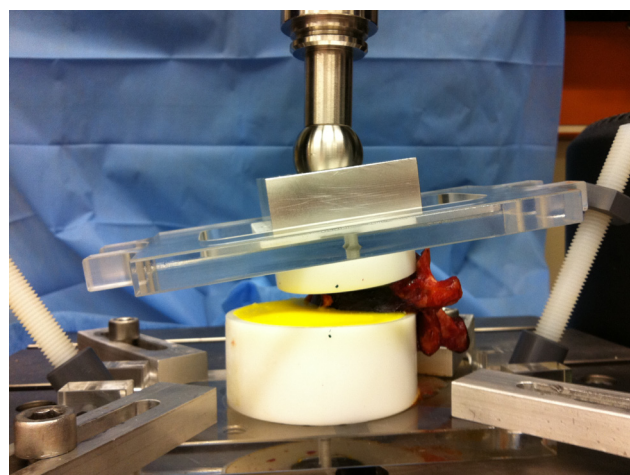


Fig. 2. Creation of wedge compression fractures using a testing machine (Universal testing machine, Instron 5566). The load was transferred by a pivot-mounted pressure plate on the superior vertebral end plate (Instron, Darmstadt, Germany).

cavities and squeezing the surrounding trabeculae to the periphery. The bone tamps were then deflated and withdrawn. The cavity was filled with KyphX HV-R High Viscosity, Radiopaque Bone Cement, according to the manufacturer's recommendations or instructions for use (Kyphon, Medtronic, Sunnyvale, CA, USA).

SpineJack

Access into the vertebrae using the SpineJack device is similar to balloon kyphoplasty. After insertion of the two guidewires, the pedicle and vertebral body are reamed to achieve a space for the insertion of the implant. After reaming, the latter position of the implant is simulated by a template. The position of the template is controlled in two planes by a C-arm. The template is replaced by the implants. The implant is opened in the craniocaudal direction using visualization in two planes with an image intensifier. After positioning and opening the implant, Cohesion (Vexim) bone cement was injected inside the implant and spread into the adjacent trabecular bone.

Instrumentation

All procedures were performed by the same surgeon using an image intensifier. The placement of the K-wires was monitored by (C-arm) fluoroscopy in three planes (anteroposterior, lateral, and craniocaudal) by turning the clamped vertebral bodies under the image intensifier.

As described earlier, the vertebral bodies were fixed in a radiolucent clamp (Fig. 2) after fracture creation and reduction of the axial load to 100 N. After postfracture CT scanning, the clamped vertebral bodies were placed in a custom-made loading frame. This frame allowed fluoroscopic control in two planes as well as constant loading with a preload of 100 N (Fig. 3). The axial force was again centered in the sagittal midline at the end of the anterior

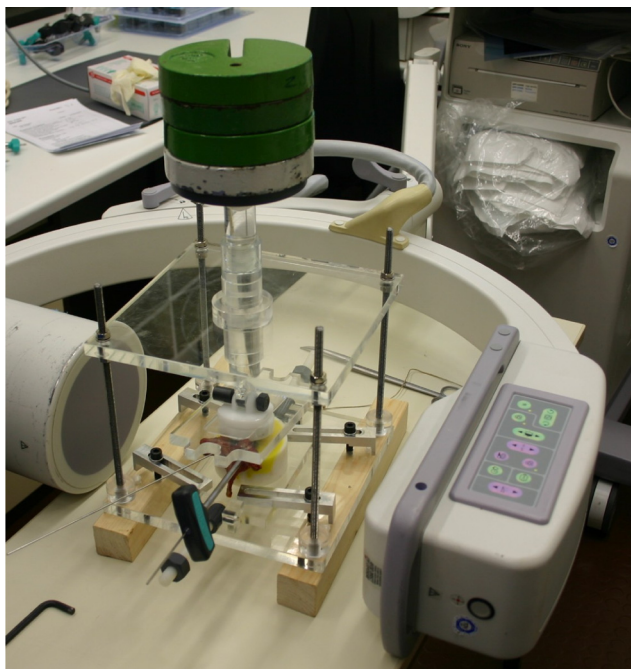


Fig. 3. The procedure was performed in a custom-made loading frame that allowed constant loading of 100 N until the cement hardened completely.

fourth of the vertebral body. After positioning the specimens, the clamp was loosened. The load was maintained during the instrumentation until the cement set completely. All vertebral bodies were treated by the same surgeon. The balloons and implants were inflated or expanded according to clinical judgment. A clear inflation end point (as in the clinical setting) could not be defined.

After the cement had hardened completely, the clamp was closed again and posttreatment CT scans were acquired.

To attain a relevant result, clinical judgment was used to proceed with or stop the cement injection. The aim of cement augmentation in this experimental setting was to fill the vertebral body as much as possible. Cementing was stopped when leakage was observed. The rationale was to fix the specimens as solidly as possible after treatment to avoid changes before the postprocedural CT scan.

Results

For all parameters determined, the results are expressed as mean \pm standard deviation. The test of significance between results from study pairs was conducted by using the Wilcoxon Mann-Whitney *U* test and Student *t* test with significance set at $p < .05$.

Compression fractures could be established in all vertebral bodies. According to the Orthopedic Trauma Association classification they were all A-type fractures [12]. The average force needed to create the fracture was 2,784.2 N (range, 1444.7–4879.6 \pm 937.01 N). The mean anterior height loss was 7.88 \pm 2.40 mm in the balloon kyphoplasty

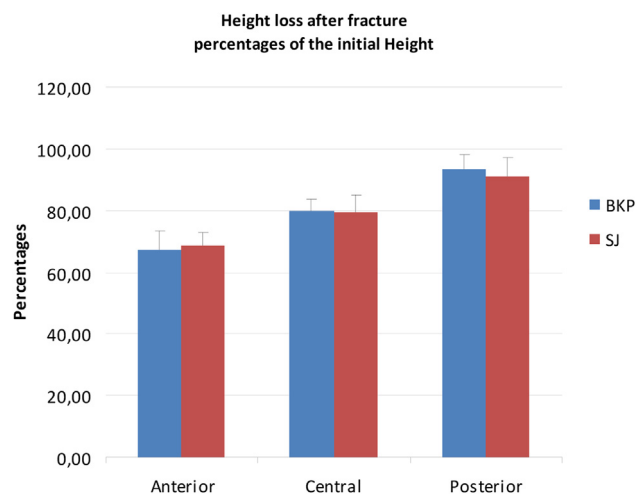


Fig. 4. Anterior, central, and posterior vertebral heights after fracture from the initial unfractured height. There was no significant difference among the groups. BKP, balloon kyphoplasty; SpineJack (SJ; Vexim, Balma, France).

group and 7.34 \pm 1.22 mm in the SpineJack group. The values are also expressed as a percentage of the initial height (Fig. 4 and Table). There was no difference between the two groups ($p = .495$). All surgical procedures could be performed without technical problems. All the equipment worked without technical difficulties. The processing and imaging using the custom-made radiolucent clamps went according to the protocol without technical or systemic difficulties.

The average volume of the inflated bone tamps in the balloon kyphoplasty group was 6.8 \pm 1.51 mL (range, 4.0–9.2 mL). The average maximum pressure used for inflation of the bone tamp was 223.3 \pm 64.4 psi (range, 150–360 psi). The average cement volume used was 8.1 \pm 2.08 mL (range, 4.6–10.8 mL) for the SpineJack group and 6.7 \pm 1.9 mL (range, 4.0–9.0 mL) for the balloon kyphoplasty group.

For anterior height restoration (balloon kyphoplasty, 0.14 \pm 1.48 mm; SpineJack, 3.34 \pm 1.19 mm), central height restoration (balloon kyphoplasty, 0.91 \pm 1.04 mm; SpineJack, 3.24 \pm 1.22 mm), and posterior height restoration (balloon kyphoplasty, 0.37 \pm 0.57 mm; SpineJack, 1.26 \pm 1.05 mm), as well as the Beck index (balloon kyphoplasty, 0.00 \pm 0.06 mm; SpineJack, 0.1 \pm 0.06 mm), the values for the SpineJack group were significantly greater ($p < .05$). The values were also expressed as percentages of the initial vertebral heights after fracture and restoration (Fig. 5 and Table). The initial angle between the end plates was 0.8 \pm 5.7° in the balloon kyphoplasty group and 0.9 \pm 4.9° in the SpineJack group. This angle increased to 12.3 \pm 3.9° in the balloon kyphoplasty group and to 10.2 \pm 4.6° in the SpineJack group. After restoration, the angle decreased to 11.2 \pm 4.3° in the balloon kyphoplasty group and to 7.5 \pm 3.9° in the SpineJack group. Regarding the end plate, the difference between the groups was not significant ($p < .359$).

Table

Overview of the results (the initial height equals 100%)

	BKP		SJ	
	Mean	SD	Mean	SD
Fractured anterior height (%)	67.4	5.8	68.6	4.2
Fractured central height (%)	79.8	3.7	79.5	5.3
Fractured posterior height (%)	93.4	4.6	90.9	6.4
Restored anterior height (%)	68.4	10.0	82.9	5.3
Restored central height (%)	84.1	5.1	95.8	5.2
Restored posterior height (%)	94.9	3.3	96.5	3.3
Initial angle between end plates (°)	0.8	4.7	0.9	4.9
Fractured mean angle between end plates (°)	12.3	3.9	10.2	4.6
Restored mean angle between end plates (°)	11.2	4.3	7.5	3.9

BKP, balloon kyphoplasty; SJ, SpineJack; SD, standard deviation.

Note: All values are expressed as percentages of the initial nonfractured vertebral height. The angle between the end plates was measured in degrees.

Discussion

This article has both a methodological and a scientific aim. Methodologically, the objective was to develop a custom-made loading frame that allowed a constant preload during instrumentation of the vertebral bodies. Scientifically, the focus was on examining the differences in height restoration of two techniques used in vertebral augmentation procedures: balloon kyphoplasty and the SpineJack procedure.

The first aim of this study was to establish this method, and we found it was possible to treat all vertebral bodies without any technical pitfalls. The custom-made loading frame designed for this experiment was set up to work with a constant load of 100 N on the vertebral bodies.

Besides reducing the risk of cement extravasation, one potential benefit of balloon kyphoplasty is realigning the spinal balance in the sagittal plane. However, several studies have shown that these theoretical improvements cannot be transferred to the clinical setting universally. The

average height restoration for percutaneous vertebroplasty is about 5°, and for balloon kyphoplasty it is around 7° [12–15]. Voggenreiter [12] found that 50% of height restoration after balloon kyphoplasty is a result of positioning the patient in a prone position. Another 50% is a result of the balloon kyphoplasty procedure itself. Voggenreiter [12] also found that there is a significant height loss between inflation and deflation of the balloon. These results conform with those of Verlaan et al. [11], who concluded that the end plate fracture reduction that was gained by inflation of the bone tamps could not be maintained after deflation. The reason for the recompression after the balloon is deflated remains unclear. It is obvious that even with a patient in a prone position, forces act on the vertebral body. The precise nature of forces acting on the longitudinal ligaments as well as the forces around the vertebral body during surgery are also unclear. Several authors have tried to measure the loads on intervertebral discs in vivo [16,17]. Sato et al. [17] measured the in vivo intradiscal pressure in healthy individuals. The spinal load calculated on L4–L5 for healthy subjects with an average body weight of 73 kg and an average L4–L5 disc cross-sectional area of 16 cm² was 144 N in the prone position. One reason for the intraoperative height loss after deflation of the balloons has to be the intraoperative forces that act on the vertebral body. There are no studies that investigate the influence of general anesthesia on height reconstruction or maintenance. Based on the existing literature, several cadaveric studies have used a preload during vertebral augmentations [18–21]. In our study, we decided to use a well-established load of 100 N during surgery to simulate the intraoperative compressive forces that act on the vertebral body at deflation of the balloons.

The average force used to inflate the balloons was 223.3±64.4 psi (range, 150–360 psi). After deflation, a reduction of the restored height of the vertebral bodies was noticed (Fig. 6, E and F) in the balloon kyphoplasty group.

One immediately apparent advantage of the SpineJack device is that it acts as a reduction device that does not have to be removed before stabilizing the vertebral body via cement augmentation. However, the surgeon has to position the implant carefully and be sure about the correct positioning, because if the device is positioned and expanded in the wrong position, it cannot be replaced or removed from the vertebral body. The surgeon has to be aware that repositioning after opening is impossible. For this reason, four steps and radiological controls (K-wire placement, positioning of the drill, positioning of the template, and positioning of the nonexpanded SpineJack) reduce the risk of misplacement of the device. Nevertheless, the surgeon has to position the implant carefully. The forces of SpineJack work in a craniocaudal direction. The opening of the device is also controlled by the surgeon. The device is not designed for end plate-to-end plate positioning. The working cannula that is placed in a transpedicular fashion works as an abutment for the upper blade of the SpineJack. The implant has to be

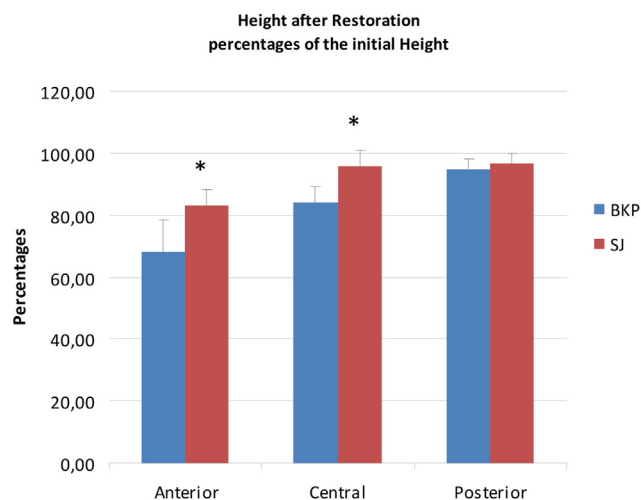


Fig. 5. Anterior, central, and posterior vertebral heights after restoration from the initial unfractured height. For the anterior and central heights, the restoration was significantly better in the SpineJack group. * $p < .05$. BKP, balloon kyphoplasty; SJ, SpineJack.

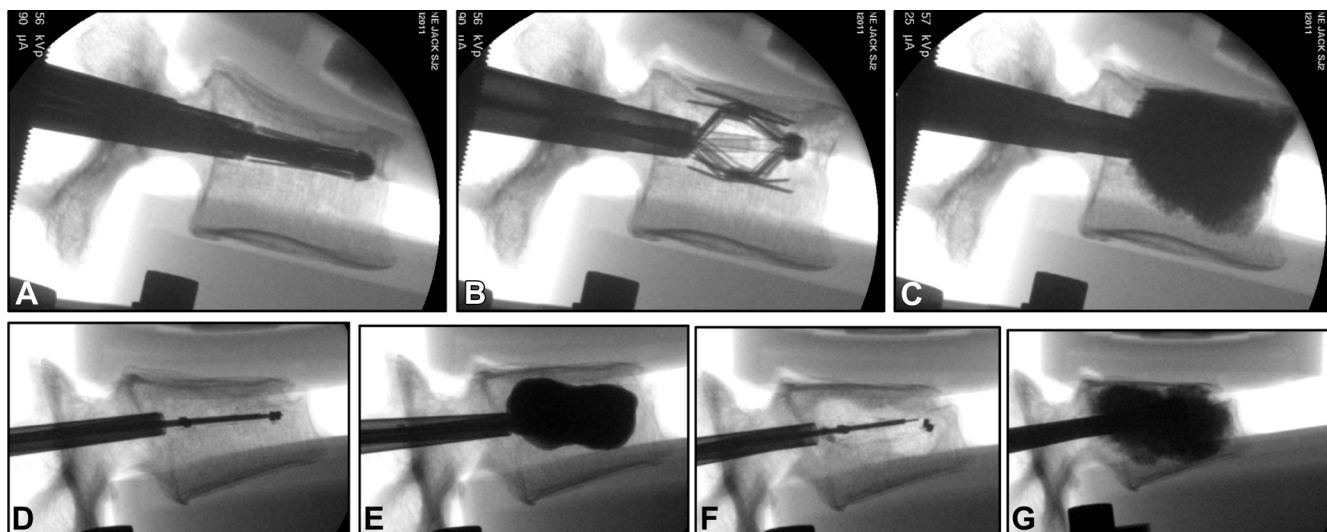


Fig. 6. Intraoperative pictures using the image intensifier in the sagittal plane (representative cases). (A) Positioning of the SpineJack below the upper end plate. (B) Maximum expansion of the SpineJack. Note that the upper blade reduces the upper end plate whereas the working cannula, placed in a transpedicular fashion, works as an abutment. (C) Filling of the vertebral body with cement until leakage is observed. (D) Positioning of the balloons in the kyphoplasty group. (E) Height restoration was noticed during balloon inflation. (F) The height restoration could not be maintained after balloon deflation. (G) Filling of the vertebral body with cement until leakage is observed.

positioned below the upper end plate or above the lower end plate, depending on whether the fracture is a cranial or caudal compression fracture. For this reason, preoperative planning is crucial. In no case was cutting of the blades through the end plates observed.

Contrary to the craniocaudal forces that are used with SpineJack, the balloon in the kyphoplasty group is inflated and expands according to the rules of least resistance. In most cases, the balloon touched the lateral wall of the vertebral body before height restoration in the sagittal plane was observed. The aim of our study was to show the intraoperative scope of the two reduction devices. For this reason, we tried to fill the vertebral bodies with as much cement as possible to fix the intraoperative result and to have reproducible and correct CT measurements after the procedure. The cementing was continued until leakage was observed. The average cement volume used was 8.1 ± 2.08 mL (range, 4.6–10.8 mL) for SpineJack and 6.7 ± 1.9 mL (range, 4.0–9.0 mL) for balloon kyphoplasty ($p < .05$).

The reason for the greater cement volumes in the SpineJack group has to be the improved height restoration and restoration of a greater intravertebral volume that was filled completely according to the study protocol. Future studies with different cement volumes will help to determine whether it is possible to use lesser cement volumes and the influences of different cement volumes during cyclic loading. A number of complications related to the use of polymethylmethacrylat in bone augmentation procedures have been reported in the literature. Progressive collapses are experienced, especially in cases when polymethylmethacrylat conglomerates without contiguous bone interdigitation [22].

Another point of criticism might be that this study was performed on single vertebral bodies only. For a more realistic setting, in future studies the adjacent levels should be preserved to observe the influence of adjacent discs.

Conclusion

A study using cadaveric vertebrae was designed to examine the height restoration of two different augmentation procedures used to treat vertebral compression fractures. The protocols for creating wedge fractures, and the instrumentation under a constant preload of 100 N led to reproducible results and effects.

The study showed that sagittal height restoration was significantly better when using SpineJack than balloon kyphoplasty. The clinical implications include better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to the clinical outcome and the biological healing process. Additional studies with different cement volumes and fillings as well as with one or two motion segments will help us understand this better.

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