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Original Article

New perspective for third generation percutaneous vertebral augmentation procedures: Preliminary results at 12 months

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Abstract

Introduction: The prevalence of osteoporotic vertebral fractures (OVF) increased in the last years. Compression fractures promote a progressive spine kyphosis increase, resulting in a weight shift and anterior column overload, with OVF additional risk (domino effect). The aim of this study is to evaluate the OVF treatment outcome using Spine Jack®, a titanium device for third generation percutaneous vertebral augmentation procedures (PVAPs). **Materials and Methods:** From February 2010, a prospective randomized study was performed examining 300 patients who underwent PVAP due to OVF type A1 according to Magerl/AO spine classification. Patients enrolled in the study were divided in two homogenous groups with regards to age (65-85 years), sex, and general clinical findings. Group A included 150 patients who underwent PVAP using Spine Jack® system; the second, group B (control group), included 150 patients treated by conventional balloon kyphoplasty. Patients underwent a clinical (visual analogue scale and Oswestry disability index) and radiographic follow-up, with post-operative standing plain radiogram of the spine at 1, 6, and 12 months. The radiographic parameters that were taken into account were: Post-operative anterior vertebral body height, pre-operative anterior vertebral body height, cephalic anterior vertebral body height, and caudal anterior vertebral body height. **Results:** Compared to the Spine Jack® group, the kyphoplasty group required a little longer operation time (an average of 40 min–group A vs. 45 min–group B, $P < 0.05$) and a greater amount of polymethylmethacrylate (4.0 mL–group A vs. 5.0 mL–group B, $P < 0.05$;). The post-operative increase in vertebral body height was greater in the Spine Jack® group than in the kyphoplasty group ($P < 0.05$). **Discussion:** PVAP are based on the cement injection into the vertebral body. Vertebroplasty does not allow the vertebral body height recovery. Balloon kyphoplasty allows a temporary height restoration. Spine Jack® has some new features compared to other systems: It is equipped with a mechanical and not a hydraulic opening control; this ensures a gradual and controlled vertebral fracture reduction. **Conclusions:** In our study, we demonstrated that the third generation PVAP with Spine Jack® is able to determine a safe vertebral body height restoration compared to the conventional balloon kyphoplasty.

Key words: Balloon kyphoplasty, mechanical kyphoplasty, osteoporosis, Spine Jack®, vertebral compression fractures, vertebroplasty

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INTRODUCTION

Osteoporotic vertebral fractures (OVF) prevalence in Italy was estimated to be about 61,000 in the 2008, with a 6.3% increase over 7 years.[1] Although, incidence is approximately 189.0 events/100,000 inhabitants, this value doubles for the population between 75 years and 95 years.[2] These fractures often affect the thoraco-lumbar hinge, where mechanical stress

and load are higher, causing chronic pain and physical disability. In more than 70% of cases, type A compression fractures occur, in particular-A1-wedge fractures (according Magerl/AO-spine classification). Compression fractures promote a progressive spine kyphosis increase, resulting in a weight shift and anterior column overload, with a OVF additional risk (domino effect).[3] Therefore, fracture reduction and vertebral height recovery is the only treatment that can be considered curative.[4] The aim of the study is to evaluate the OVF treatment outcome using Spine Jack® [Figure 1], titanium devices for third generation mechanical kyphoplasty.

MATERIALS AND METHODS

From February 2010, a prospective randomized study was performed examining 300 patients who underwent percutaneous vertebral augmentation procedures (PVAPs) due to OVF type A1. Patients enrolled in the study were divided in two homogenous groups with regards to age (65-85 years), sex and general clinical findings. Group A included 150 patients who underwent PVAP using the Spine Jack System®; the second group B (control group), included 150 patients treated by conventional balloon kyphoplasty. Spine Jack®[5,6] is a new device for mechanical kyphoplasty. It is a titanium implant designed to restore vertebral height through a distraction effect via bilateral transpedicular minimally invasive approach, the device is inserted into the vertebral body (from T10 to L5) [Figure 2] and gradually expanded like a little jack [Figure 3]. The distraction exerted by the device allows fracture reduction that occurs by ligamentotaxis on the anterior longitudinal ligament. Spine Jack® is equipped with a mechanical and not a hydraulic opening; this ensures a gradual and controlled vertebral fracture reduction. This feature allows to recover the collapsed vertebra and to provide the primary support 3D to the structure in order to mechanically stabilize the vertebrae in axial compression. Once this step has been completed, bone cement is injected into the restored vertebra in order to secure the vertebral structure, and relieve the patient pain. The presence of two symmetrical devices into the vertebral body allows also a polymethylmethacrylate (PMMA) homogeneous spreading. The device expansion creates a high-viscosity cement preferential flow direction, also reducing the leakage risk. When injected, cement inter-digitation creates a large contact area below the midline: This helps to provide stability to the obtained vertebral body reduction. Although, the technique was developed for osteoporotic fractures, it could be used in traumatic fractures of the thoracolumbar vertebrae.

This technique allows a good reconstruction of the anterior column, restoring vertebral height. Another feature to highlight is the advantage of preventing cement leak into intervertebral disc space, which could increase the risk of adjacent vertebral body fractures in OVF. In fact, the device has a security system: If the load forces concentrated on the devices are too high, the system automatically blocks itself; a further device's expansion doesn't occur, thus reducing the vertebral endplates breakage risk. Furthermore, an excellent reduction of superior endplate may have the potential benefit of better future performance of injured disc.

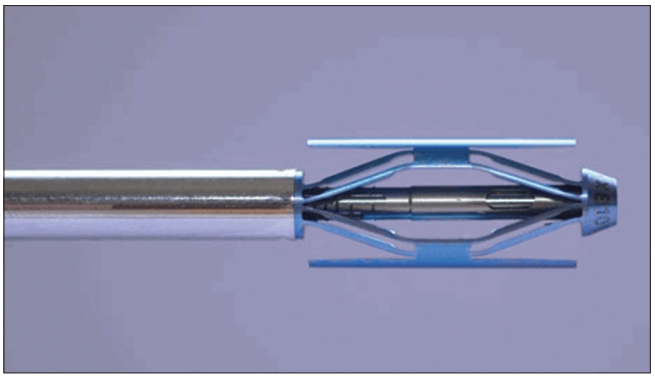

Figure 1: Spine Jack System®

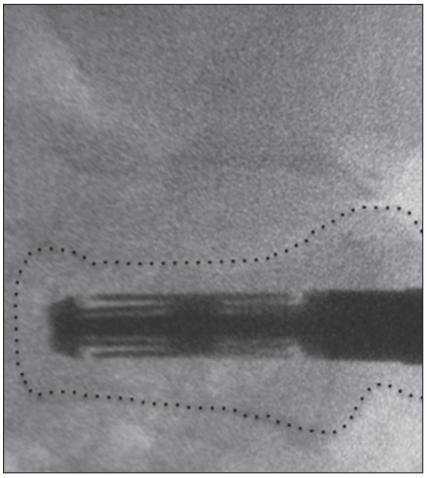

Figure 2: Spine Jack® insertion

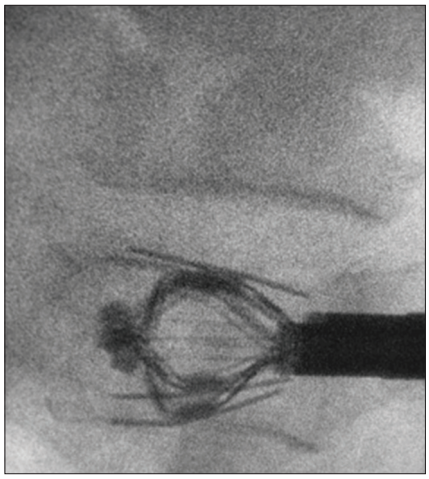

Figure 3: Spine Jack® opening

Patients with radiographic diagnosis of OVF [Figure 4] subsequently underwent computed tomography (CT) and magnetic resonance imaging (MRI) pre-operatively [Figure 5].

The degree of anterior column injury is best assessed using the McCormack and Gaines load sharing classification. The safe indication would be at 3 points and limited to approximately 4-5 points. Patients underwent a clinical follow-up (using VAS and Oswestry disability index [ODI]) and post-operative standing plain radiogram of the spine at 1, 6, and 12 months. The radiographic parameters taken into account were: Post-operative anterior vertebral body height, preoperative anterior vertebral body height, cephalic anterior vertebral body height, and caudal anterior vertebral body height. The fractured vertebral body height restoration was calculated according to the following equation: 2 ×(post-operative anterior vertebral body height-pre-operative anterior vertebral body height)/(cephalic anterior vertebral body height + caudal anterior vertebral body height) × 100%.[7] Vertebral height was measured immediately before and after PVAP, in order to assess vertebral height restoration. A semi-quantitative assessment of vertebral height recovery was performer and three assessment degrees were identified: Grade 0 (no change), grade 1 (below 50%) and grade 2 (greater than 50%). Statistical analysis was performed according to Kaplan-Meier method and $P < 0.05$ was considered statistically significant.

RESULTS

Spine Jack® and kyphoplasty groups did not differ significantly in age, gender distribution, location of OVF, duration between injury and surgery, pre-operative VAS pain score, vertebral body height, or kyphotic wedge angle. Compared to the Spine Jack® group, the kyphoplasty group required a little longer operation time (an average of 40 min vs. 45 min, $P < 0.05$), and a greater amount of PMMA (4.0 vs. 5.0 mL, $P < 0.05$). The post-operative increase in vertebral body height was greater in the Spine Jack® group than in the kyphoplasty group ($P < 0.05$). The 85% of the patients who underwent PVAP using the Spine Jack® system has returned to the assessment degree 2 [Figures 6 and 7], 12% in 1 and 3% in 0. The 58% of the patients who underwent PVAP using balloon kyphplasty returned to the assessment degree 2, 26% in 1 and 16% in 0. There was no statistical difference in VAS pain scores and in the ODI between the treatment groups at any stages from the pre-operative period, through the post-operative period, to the final follow-up. In group A, there were not leakage events, nor device loosening. In the group B, there were 20 not clinical significant leakage events. In both groups, there were not iatrogenic vertebral endplates fractures or fractures

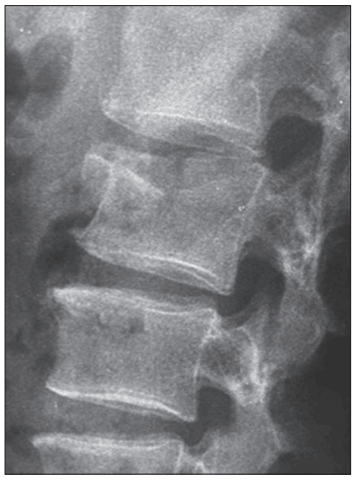

Figure 4: Vertebral fracture in patient with osteoporosis

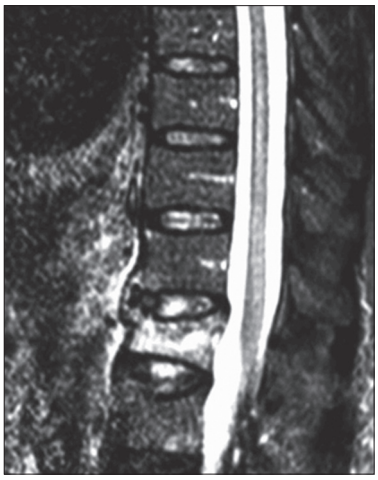

Figure 5: Pre-operative nuclear magnetic resonance

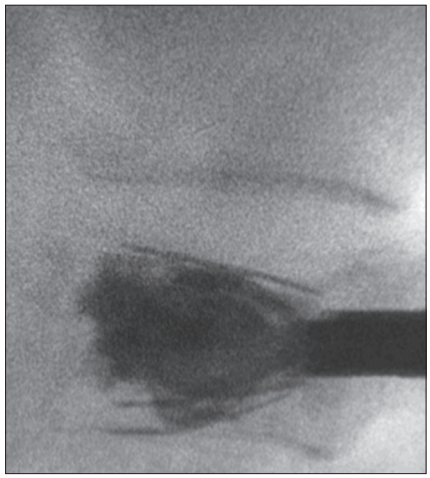

Figure 6: Final intra-operative control

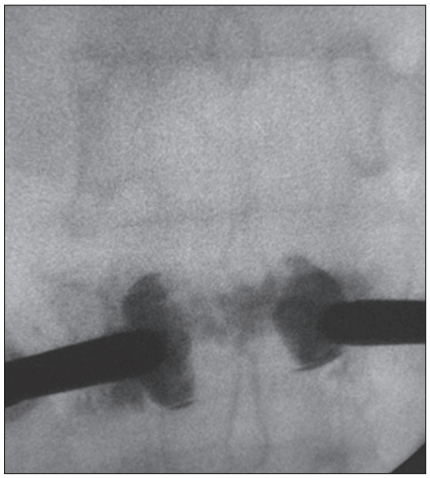

Figure 7: Final intra-operative control

of the vertebra above or below. Neurological defects, radicular symptoms, and pulmonary embolism have never occurred.

DISCUSSION

OVF management

At the moment there is not a single guideline about OVF management.[8,9] Unclear are the timing and the indications for the conservative treatment; besides, the surgical criteria are poorly defined. In the past, a conservative treatment for at least 30 days was considered the proper treatment for the majority of the fractures. If the pain persisted, a surgical solution was needed: Vertebroplasty for OVF with height loss less than 30%, kyphoplasty for OVF with height loss greater than 30%. The conservative treatment avoids surgical risks. However, it forces the patient to a poor quality life and it does not stop the domino effect, with poor results. Vertebral augmentation procedures are fast, performed in general anesthesia and percutaneously. Therefore, a standing radiography is necessary in patients with acute, severe back or low back pain and a risk profile (age >65 years, positive anamnesis for previous vertebral fractures, metabolic diseases, renal failure, and prolonged therapy with the corticosteroids or antiepileptic, body mass index <20). CT scan is performed in order to characterize the fracture personality, in order to obtain more detailed information about fracture type and to distinguish between a simple compression fracture type a more complex lesion. MRI shows any signs of spinal cord and/or dural sac compression, radicular conflict, but also allows to distinguish between new and previous fractures, according to signal intensity in TSE (Turbo Spin Echo) T2 weighted sequences. This is the most important aspect according to which surgical indication and eventually the vertebral height recovery entity are established. The more recent the fracture, the greater is the height recovery possibility.

Minimally invasive surgery

PVAP are based on the cement injection into the vertebral body. These techniques have achieved great success in recent years as they allow an efficient OVF management; stabilizing the vertebra, especially the anterior column, they ensure a rapid pain resolution. The pain in fact, is due to micro-motion fragments at the fracture site. OVF treatment has radically changed in the last three decades. The first generation mini-invasive surgery for treatment of VCF - vertebral compression fracture by percutaneous injection of bone cement (PMMA) was described by Galibert *et al.* in 1987; this surgical procedure goes by the name of vertebroplasty.[10] This technique produced excellent results in terms of pain relief. However, unfortunately, it appears incomplete in several aspects. Infact, the vertebroplasty does not allow the vertebral body height recovery. Therefore, vertebral body remains collapsed and so the spine biomechanic is altered and there is not possibility to stop the domino effect. Additionally, it is necessary to inject a very low viscosity and high pressure cement, with a leakage risk of around 30%. These problems led to the creation of second-generation PVAP. The balloon kyphoplasty[11] is a recent change to percutaneous vertebroplasty, conducted for the first time by Reiley in 1998; this procedure involves the inflation of a balloon catheter in the collapsed vertebral body to restore its height before the stabilization with bone cement. The use of the balloon can create a cavity inside the vertebral body; in this way, the cement can be injected with less pressure and greater viscosity, considerably reducing the risk of leakage.[12-17] Reducing the relevance of cement as the primary stabilizer in vertebral compression fractures may reduce or eliminate concerns about cement leakage.[18-22] Unfortunately, height recovery is temporary. Infact, as soon as the balloon is deflated, there is often a new total or partial vertebral body collapse.[23-28] This has led to new devices creation. They allow the vertebral height recovery. However, they must not be removed from the vertebral body to allow the cementing. Therefore, the conventional balloon can be replaced by equivalent mechanical systems:[4,5] Third generation PVAP. There are also other systems and devices available for PVAP, with similar characteristics to Spine Jack®.

OsseoFix Spinal Fracture Reduction System®: It is intended for the minimally invasive percutaneous treatment of vertebral fractures in the region T10-L5 due to osteoporotic collapse; it facilitates the correction/reduction of OVF using a titanium implant with PMMA cement. The cylindrical titanium implants, once inserted into the vertebral body, restores the height of the vertebral body in question and immediately stabilize a bone fracture; the space created by the installation of titanium stent in the vertebral body (which remains *in situ*) is filled with PMMA.

Staxx® FX Structural System: By unilateral extrapedicular approach, it allows to provide controlled fracture reduction in precise 1 mm increments, maintain vertebral body height restoration with a permanent structural PEEK implant. The system also provides a barrier to posterior extravasation, and it reduces bone cement volume.

Spider Kyphoplasty System®: It is indicated for the treatment of fresh thoracic/lumbar OVF (T7-L5) classified A1 and with special care A2.1 and A2.2 according to Magerl and osteolytic lesions. Once the device is inserted into the vertebra, it creates a cavity in which the filler material (typically bone cement) will be injected. The tool consists of a tube inside, which a pin can slide. Acting on the T-handle of the tool, the pin is allowed to slide inside the tube; in this way the plastic extremity of the tool is compressed. In the terminal part, there is a tube made of nitinol that has some longitudinal cuts.[29] Performing some expansions after having rotated slightly the tool, one can compact the cancellous bone surrounding the treated area in order to get a cavity in which the cement can be injected.

CONCLUSION

In our study, we have demonstrated that the third generation PVAP with Spine Jack® is able to determine a safe vertebral body height restoration compared to the conventional balloon kyphoplasty.[30-32] This is due to the Spine Jack® efficient mechanical characteristic, but above all it is due

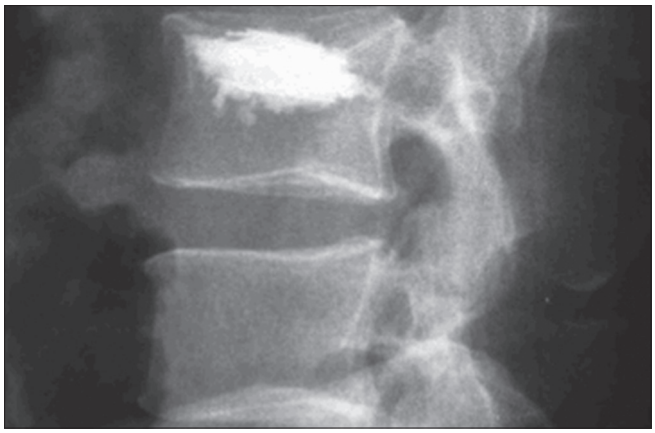

Figure 8: Radiographic post-operative control

to the possibility of leaving the devices into the vertebral body. This avoids vertebral body recollapsing before cement injection[5,6] [Figure 8].

In comparison to traditional kyphoplasty, Spine Jack® has the advantage to restore, according to the "fracture freshness," the vertebral height and the normal spine bio-mechanic and stability. The normal spine bio-mechanic restoration results in an interruption of the domino effect and in a new OVF risk reduction.[33]

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