

Safety and clinical performance of kyphoplasty and SpineJack[®] procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study

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Abstract

Summary Clinical performance and safety of two percutaneous vertebral cement augmentation (VA) procedures (SpineJack[®] and Kyphx Xpander[®] balloon) were compared in patients with osteoporotic compression fractures. Both techniques were safe, efficient, and led to a rapid and marked improvement in clinical signs; nevertheless, SpineJack showed better restoration of vertebral heights and angles, maintained over time.

Introduction In patients with osteoporotic vertebral compression fractures (VCFs), both SpineJack[®] (SJ) and balloon kyphoplasty (BKP) led to a rapid and marked improvement in clinical signs. This pilot, monocentric, investigator-initiated, prospective study aimed to compare two percutaneous vertebral augmentation procedures in the painful osteoporotic VCF treatment.

Methods Thirty patients were randomized to receive SJ ($n=15$) or BKP ($n=15$). Analgesic consumption, back pain intensity (visual analog scale (VAS)), and Oswestry Disability

Index (ODI) scores were recorded preoperatively, at 5 days and 1, 3, 6, and 12 months post-surgery. Quality of life (EQ-VAS score) was evaluated at 1, 3, 6, and 12 months. Spine X-rays were taken 48 h prior to procedure and 5 days and 6 and 12 months after.

Results SpineJack[®] led to a significantly shorter intervention period (23 vs 32 min; $p<0.001$), a strong, rapid, and long-lasting decline in pain (94 vs 82 % at 12 months) and in functional disability (94 vs 90 % at 12 months), a greater and sustainable mean correction of anterior (12 ± 13 vs 0 ± 7 % for BKP, $p=0.003$) and central height (12 ± 10 vs 2 ± 6 % for BKP, $p=0.001$) at 12 months, and a larger restoration of the vertebral body angle still evident 12 months after implantation ($-4.4^\circ\pm5.8^\circ$ vs $0.2^\circ\pm3.0^\circ$ for BKP; $p=0.012$).

Conclusions This pilot study showed that both techniques were safe and efficient for the osteoporotic VCF treatment. Radiological results indicate that the SpineJack[®] procedure has a higher potential for vertebral body height restoration and maintenance over time.

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Keywords Back pain · Balloon kyphoplasty · Osteoporosis · SpineJack · Vertebral augmentation · Vertebral compression fracture

Introduction

Osteoporosis is an important and common skeletal disorder worldwide, characterized by bone mineral loss and compromised bone strength. It is a silent disease until fractures occur, either spontaneously or from low-energy trauma. The lifetime risk of osteoporotic fracture is one in two after age 50 for women and one in four for men. Fractures of the vertebral body (VB), called vertebral compression fractures (VCFs), are the most common osteoporotic fractures presenting

typically with sudden onset back pain. In Europe, new cases of osteoporotic VCFs are estimated at around 1.4 million each year [1]. Once a vertebral fracture has occurred, the risk for additional fracture increases up to fivefold [2]. VCFs are associated with increased morbidity such as restrictive pulmonary disease, chronic back pain, loss of independence, reduced quality of life, and considerable negative economic impact [1, 3]. Moreover, patients with VCFs have an increased mortality [4].

Currently available therapy for VCFs includes medical management and surgical treatments, as vertebral cement augmentation (VA). Medical management consists of bed rest followed by early mobilization and analgesic medications. Medical therapy is limited in that it addresses pain but does not directly address the underlying fracture. Substantial evidence suggests that conservative therapy for VCFs (e.g., pain medications, bed rest) leads to increased disability due to further bone demineralization, deconditioning, and intolerable side effects from narcotic analgesics [5]. Surgical treatment of VCFs, i.e., spine stabilization using rods and screws, is limited by easy pullout of bone screws due to underlying bone disease [6].

Balloon kyphoplasty (BKP) and vertebroplasty (VP) are two minimally invasive VA procedures attempting to stabilize the spine and reduce vertebral compression. Both techniques reduce pain and disability and are generally safe [7] but should be reserved for those patients in which analgesic treatment failed. BKP differs from VP in that it is also designed to restore diminished vertebral height and correct kyphotic deformity. Recent studies comparing these two percutaneous procedures demonstrate advantages of BKP over VP in terms of sagittal balance improvement, cement leakage, improved quality of life, mortality rates, and cost savings [7–9]. Thus, we considered BKP as the comparison group in the present study. Nevertheless, some authors demonstrated that with BKP, part of the restored height is lost when deflating the balloon prior to the cement injection [10, 11]. Although balloon kyphoplasty enables better height restoration and kyphotic angle reduction, it should be considered the higher costs and the lack of impact on the functional scores, while its long-term benefit is not known. Moreover, benefits and risk of both procedures, especially regarding leakage and adjacent fractures after cement augmentation, are controversial, and more studies are required [12].

The novel VCF reduction system called SpineJack® (SJ) is a recent technology that has been shown in biomechanical studies to be superior to BKP in terms of height restoration and height maintenance [13, 14]. This implant concept is based on the “in situ fracture reduction” principle whereby an intra-vertebral body implant is expanded in situ to restore the height of the vertebral body mechanically. Afterwards, conventional polymethylmethacrylate (PMMA) bone cement is injected at low pressure to stabilize the restored vertebra.

The objective of this pilot study was to compare the clinical performance and safety of two percutaneous VA procedures (the SpineJack® device and the KyphX Xpander® Inflatable Bone Tamp) in the treatment of patients with painful osteoporotic VCFs in order to provide information on possible differences in outcomes that could be studied in a larger pivotal study.

Methods

Study design and patients

This prospective, monocentric, investigator-initiated, comparative, randomized, pilot study was approved by the local ethics committee (*Comité Ético de Investigación Clínica, Área de Salud Valladolid-Este-CEIC-VA—ESTE-HCUV-*). All subjects gave their informed consent before being enrolled into the study and underwent VCF reduction procedure within 5 days after consent form signature. All of them met the following inclusion criteria: male or female aged between 21 and 75 years, one or two painful VCF(s) with at least one meeting the following criteria: fracture due to diagnosed or presumed underlying osteoporosis; VCFs between T7 and L3; aged <3 months; with a loss of height in the anterior, mid, or posterior third of the VB from estimated pre-fracture configuration of at least 15 % but not more than 40 %; with hyperintense signal on STIR or T2 sequence MRI; patient who failed conservative medical therapy, defined as either having a VAS back pain score of ≥ 5 at 6 weeks after initiation of fracture care or a VAS back pain score of ≥ 7 at 2 weeks after initiation of fracture care; target VB(s) suitable for SpineJack procedure and balloon kyphoplasty (e.g., appropriate pedicle diameter, no cortical bone protruding into the spinal canal) according to the investigator; Oswestry Disability Index (ODI) score ≥ 30 %; patient willing and able to comply with study requirements; patient signing informed consent form; and if women are post-menopausal, surgically sterile women, or agreeing to remain on contraceptives for the duration of their study participation for women with childbearing potential. Subjects with the following criteria will be excluded: target VCFs due to underlying or suspected tumor; due to high-energy trauma or fall from significant height; segmental kyphosis of target VB $> 30^\circ$; any prior surgical intervention on target VB or adjacent level; pre-existing or clinically unstable neurologic deficit; any physical exam evidence of myelopathy or radiculopathy; patient not able to walk without assistance prior to fractures; any radiographic evidence of pedicle fracture or inter-spinous process widening; spondylolisthesis $>$ grade I at target VB(s); history of spine surgery, including prior vertebral augmentation, in last year; any underlying systemic bone disease other than osteoporosis (e.g., osteomalacia, osteogenesis imperfect, etc.); irreversible coagulopathy and/or

taking warfarin (coumadin) or other anticoagulant on regular basis; pregnancy and nursing; pain due to any other condition that required daily narcotic medication; disabling back pain due to causes other than acute fracture; history of intolerance or allergic reaction to titanium or acrylic compounds; active systemic or local infection at baseline; body mass index >40; severe cardiopulmonary disease (e.g., stage IV heart failure, severe chronic obstructive pulmonary disease); any other medical illness or condition that, in the investigator's opinion, was likely to impair long-term follow-up (e.g., cancer) or greatly increased the risk of surgery (including but not limited to patients with contraindications for general anesthesia); any evidence of substance abuse; participation in any other investigational study; ongoing long-term steroid therapy (steroid dose ≥ 30 mg/day for >3 months); patient known to be involved in medical litigation including Workmen's Compensation; and any contraindication for MRI. All patients were known osteoporotic subjects who underwent surgery whatever the extent of bone loss, without bone mineral density (BMD) measurement at inclusion as DEXA scans are not performed in routine practice. All patients received medication for osteoporosis: denosumab 60 mg/ml subcutaneously, every 6 months, plus 1000 ng of calcium, plus 800 UI of vitamin D. After enrolment, patients were randomized and assigned to one treatment group (SJ procedure or BKP) with computer-generated block randomization system (SAS software) and sealed sequential envelopes, according to a 1:1 allocation ratio. As investigators could not be blinded owing to the nature of studied treatments, the allocated procedure was disclosed prior to surgery. Patients remained blinded until the end of follow-up.

After surgery, patients had to attend five clinic visits, at the following time points: 5 days and then 1, 3, 6, and 12 months. At each visit, adverse events (AEs), concomitant diseases, analgesic consumption, back pain intensity on a 100-mm VAS, ODI score [15], and ambulatory status were recorded. A neurologic examination was performed on day 5. Quality of life was evaluated at baseline and 1, 3, 6, and 12 months after procedure, using the EQ-5D questionnaire [16]. Lateral and antero-posterior standing X-rays were taken within 48 h prior to procedure and 5 days after. Lateral spine X-rays were taken at 6 and 12 months. MRI was performed at 5 days and at 6 months. Quantitative radiographic analysis was done on X-ray by ACES Ing.-GmbH, Filderstadt, Germany, an independent, qualified core lab using their 510(k) approval FXA™ software [17].

Vertebral augmentation procedures

All procedures were conducted under general anesthesia, except spinal anesthesia used for two cases. For both procedures, the vertebral body was accessed through a standard posterior

transpedicular approach, and the incision required was identical.

The patient being in a prone position, the SpineJack® Ø 5 mm/KE001 (VEXIM SA, Balma, France) was inserted into the fractured VB in unexpanded format. After insertion into the VB, the implant was expanded using a specially designed tool (part of the expansion kit), which locks into the device and pulls the axial ends of the implant toward each other. Longitudinal compression of the device causes the implant to open in the inferior-superior direction only due to the machined grooves. A simple mechanism locks the implant into the desired expanded position as determined and controlled by the physician. Once the implant has achieved the desired expansion, the device was left in place inside the restored vertebra and PMMA bone cement was injected into and around the implant. Regular fluoroscopic controls throughout the implant insertion and expansion, as well during cement injection, ensured correct procedure. Postoperative rehabilitation was per standard of care at the treating institution. Bilateral SJ placement was typically performed and was required in this study.

The control treatment arm used BKP with the 20/3 KyphX Xpander® Inflatable Bone Tamp 20 mm and the KyphX® HV-R™ Bone Cement (Medtronic, Sunnyvale, CA, USA). The procedure was carried out according to the Instructions for Use via a bilateral approach using two balloons. A BKP curette (KyphX® Latitude™ Curette, Medtronic, Sunnyvale, CA, USA) was used to create space if hard bone was encountered during access or inflation.

Both devices were implanted in accordance with their specific Instructions for Use.

Outcome measures

Clinical improvement was assessed using changes in back pain intensity (VAS score), analgesic intake, ODI score, ambulatory status, and EQ-VAS score. Radiographic outcomes included vertebral body height restoration (assessed by changes in anterior/middle/posterior VB height), changes in VB kyphotic angle, Cobb angle, and Gardner angle. Safety was assessed by the proportion of patients requiring secondary surgical intervention on the index level, the proportion of patients with one or more subsequent radiographic vertebral fractures, and the proportion of VCFs with cement extravasation. All AEs were reported and evaluated by investigators for device and procedure relationship. AEs were systematically classified into preferred terms and system organ class according to the Medical Dictionary for Regulatory Activities (MedDRA) by using the verbatim language reported by investigators. All device deficiencies and malfunctions had to be documented.

Statistical analysis

All statistical analyses were performed at the 0.05 global significance level using two-sided tests. Testing for baseline differences between both groups was performed using Student's *t* test or Wilcoxon's test for quantitative parameters and chi-squared test or Fisher's exact test for qualitative parameters. Efficacy endpoints were analyzed on ITT population (i.e., all successfully implanted subjects). Within-group tests were used to assess evolution of efficacy parameters at each follow-up visit compared to baseline. Wilcoxon's test or Student's *t* test for pairwise comparisons were used, depending on the normality of the distribution. Between-group comparison was done using Student's *t* test or Wilcoxon's test for quantitative parameters and chi-squared test or Fisher's exact test for qualitative parameters.

Results

From March to December 2013, a total of 123 patients were evaluated for the procedure, 58 patients fulfilled selection criteria, 28 declined to participate and, finally, 30 patients were enrolled, included, and randomized: 15 in the SJ group and 15 in the BKP group. Twenty-nine patients completed the study as one patient from the SJ group withdrew prematurely from the study 34 days after surgery because of remote relocation from the investigation site. The mean patient follow-up was 11.2 ± 2.9 months in the SJ group and 11.8 ± 0.7 months in the BKP group.

Patients (80.0 % female) were aged 68.1 ± 5.3 years (range 56 to 75 years) with a mean weight of 69.4 ± 10.7 kg and a mean BMI of 26.6 ± 3.7 kg/m². All patients failed conservative medical therapy, with a VAS back pain score ≥ 7 2 weeks after initiation of fracture care for 26 patients and a score ≥ 5 6 weeks after initiation of fracture care for 4 patients. No clinically relevant differences were observed between both groups for baseline characteristics. Detailed information on gender, age, BMI, and medical history is shown in Table 1.

Sixteen vertebral fractures were treated with the SJ (one patient had 2 fractures), and 17 fractures were treated with BKP (two patients had 2 fractures). Thoracolumbar vertebrae were the most frequently treated (T11, T12, L1). The mean operation time was significantly shorter with the SJ procedure than with BKP technique (23 ± 4 vs 32 ± 8 min; $p < 0.001$). The quantity of cement injected did not differ significantly between procedures with a median value of 5 cc for both groups. Mean length of hospital stay after procedure did not differ between procedures with a median duration of 1 day for all patients.

Clinical results

Evolution of pain

At discharge, there was a significant pain relief as a result of the procedure in both groups of patients ($p < 0.001$) without significant differences between groups ($p = 0.457$). This improvement was sustained over the 12-month follow-up period reaching 90 % at 6 months and 94 % at 12 months in the SJ group versus 81 % and 82 % in the BKP group, respectively. Mean absolute changes from baseline in VAS scores over the 12-month study period are shown in Table 2.

Evolution of analgesic consumption

Before surgery, all patients were taking paracetamol/ acetylsalicylic acid/NSAID. Nearly half patients in each group ($n = 7$, 46.7 %) were prescribed central analgesics, and one patient from the SpineJack® group needed morphine. The decrease in pain allowed an important reduction in analgesic intake as soon as the fifth day after surgery in both groups, with no patient requiring central agents or morphine. One month after surgery, only five patients in each group (33.3 %) were taken analgesics (paracetamol only, except one patient from the BKP group who needed a central agent).

Evolution of ambulatory status

Throughout the 1-year follow-up period, no patients showed worsening of ambulatory status and no patients needed any walking aid.

Evolution of functional capacity

A marked improvement in disability was observed in both groups as soon as the fifth day post-surgery ($p < 0.001$), with no significant differences between them ($p = 0.692$). A sustained progressive improvement was noted over the 12-month follow-up period, with a decrease in ODI score reaching 94 % at both 6 and 12 months in the SJ group versus 90 % at both time points in the BKP group. Mean changes in ODI scores versus baseline over the 12-month study period are shown in Table 2.

Evolution of quality of life

In both groups of patients, a clear improvement in quality of life was observed 1 month after surgery with a mean EQ-VAS score that was double the baseline value. A slightly further improvement was observed till the end of the 12-month follow-up period in the SJ group. Although no significant difference was found between groups, mean changes from baseline

Table 1 Patient characteristics

| Characteristics | Value | | <i>p</i> Value |
|---|--|--------------|----------------|
| | SpineJack® | BKP | |
| Number of patients | 15 | 15 | |
| Age (mean ± SD) | 67.9 ± 4.5 | 68.3 ± 6.1 | 0.662 |
| Gender, <i>n</i> (%) | | | 0.651 |
| Female | 11 (73.3 %) | 13 (86.7 %) | |
| Male | 4 (26.7 %) | 2 (13.3 %) | |
| BMI (mean ± SD) | 25.77 ± 3.34 | 27.39 ± 3.87 | 0.232 |
| Medical history: | | | |
| Smoker status, <i>n</i> (%) | No | 13 (86.7 %) | 14 (93.3 %) |
| | Yes | 2 (13.3 %) | 1 (6.7 %) |
| Time since symptoms' appearance days) (mean ± SD) | 26.9 ± 13.2 | 29.6 ± 21.5 | 0.917 |
| Neurological exam, <i>n</i> (%) | No | 0 (0.0 %) | 0 (0.0 %) |
| | Yes | 15 (100.0 %) | 15 (100.0 %) |
| Ambulatory status, <i>n</i> (%) | | | |
| | Able to walk without assistance | 15 (100 %) | 15 (100 %) |
| | Able to work with aid such as cane or walker | 0 (0.0 %) | 0 (0.0 %) |
| | Must use wheelchair | 0 (0.0 %) | 0 (0.0 %) |
| | Bedridden | 0 (0.0 %) | 0 (0.0 %) |
| Pregnancy test, <i>n</i> (%) | | | |
| | Not performed, patient of non-childbearing potential | 11 (100 %) | 13 (100 %) |
| | Performed, negative | 0 (0.0 %) | 0 (0.0 %) |
| | Performed, positive | 0 (0.0 %) | 0 (0.0 %) |
| | Not performed, other reason | 0 (0.0 %) | 0 (0.0 %) |
| | NA | 4 | 2 |

were higher in the SJ group compared to BKP group at each time points (Table 2).

Radiological results

Five days after surgery, mean anterior and central height restoration around 4 ± 3.5 mm was obtained with the SJ procedure. This restoration slightly decreased to around 3 ± 3 mm at 6 and 12 months. With BKP, height restoration was

significantly far less marked at 5 days for both anterior (1.1 ± 1.9 mm; $p=0.029$) and central (1.4 ± 1.8 mm; $p=0.013$) parts and then decreased progressively over time with statistically significant between-group differences at each time point ($p<0.03$). These changes, expressed as body height ratio differences, correspond to a 16 % correction obtained with the SJ procedure at 5 days post-surgery and to a 12 % correction at 6 and 12 months for both anterior and central parts. Corrections obtained with BKP were significantly lower for both anterior

Table 2 Absolute changes from baseline in clinical results

| | VAS | | ODI | | EQ-VAS | |
|------------------------|--------------|--------------|--------------|--------------|-------------|-------------|
| | SpineJack® | BKP | SpineJack® | BKP | SpineJack® | BKP |
| 5 days post-surgery | -57.5 ± 22.9 | -63.9 ± 23.1 | -48.6 ± 21.4 | -45.8 ± 17.1 | | |
| 1 month post-surgery | -67.7 ± 15.5 | -64.2 ± 26.0 | -59.2 ± 18.5 | -47.8 ± 20.8 | 43.6 ± 18.1 | 38.8 ± 25.7 |
| 3 months post-surgery | -72.5 ± 12.4 | -64.5 ± 28.5 | -59.8 ± 13.9 | -50.2 ± 19.2 | 44.8 ± 21.0 | 34.5 ± 21.4 |
| 6 months post-surgery | -72.8 ± 10.7 | -68.2 ± 21.3 | -61.2 ± 15.8 | -53.7 ± 19.6 | 47.0 ± 19.2 | 40.1 ± 26.8 |
| 12 months post-surgery | -75.8 ± 15.0 | -68.9 ± 20.8 | -61.6 ± 17.0 | -53.9 ± 19.4 | 48.2 ± 22.7 | 40.1 ± 28.3 |

Data are mean ± standard deviation

(4, 2, and 0 %, respectively) and central parts (6, 3, and 2 %, respectively) (Fig. 1, panels a and b). Anterior/central/posterior height ratio differences (in %) by visit compared to baseline are presented in Fig. 1. Non-significant small changes were observed for the posterior part with both procedures (Fig. 1, panel c).

Vertebral kyphotic angle correction versus baseline is shown in Fig. 2. In the SJ group, correction was higher versus baseline at each time point despite a slight decrease of this correction at 6 and 12 months ($p < 0.05$); no difference was observed in the BKP group at any time point.

Between groups, this correction was significantly higher in the SJ compared to BKP group: $-6.1^\circ \pm 6.1^\circ$ vs $-1.1^\circ \pm 2.8^\circ$ at 5 days ($p = 0.009$), $-3.9^\circ \pm 4.7^\circ$ vs $-0.2^\circ \pm 2.8^\circ$ at 6 months ($p = 0.026$), and $-4.4^\circ \pm 5.8^\circ$ vs $0.2^\circ \pm 3.0^\circ$ at 12 months ($p = 0.012$).

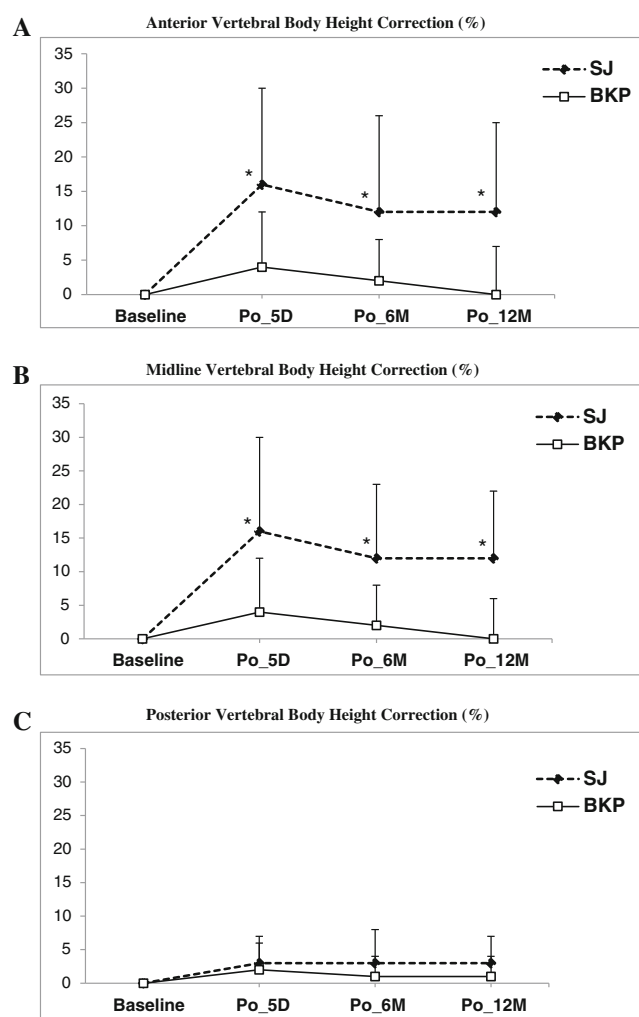


Fig. 1 Anterior/midline/posterior height ratio correction difference versus baseline at 5 days (Po_5D), 6 months (Po_6M), and 12 months (Po_12M) post-surgery, with both procedures balloon kyphoplasty (BKP) and SpineJack (SP). * $p < 0.05$

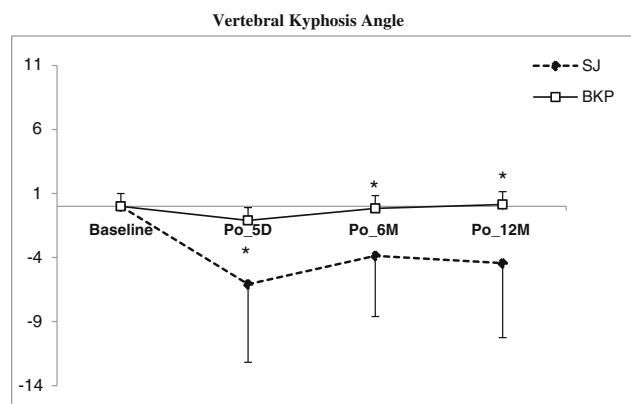


Fig. 2 Degree changes in vertebral kyphotic angle versus baseline at 5 days (Po_5D), 6 months (Po_6M), and 12 months (Po_12M) post-surgery, with both procedures balloon kyphoplasty (BKP) and SpineJack (SP). * $p < 0.05$

Cobb angle correction versus baseline is shown in Fig. 3. In the SJ group, correction was higher versus baseline at 5 days and 6 months ($p < 0.05$); however at 12 months, no significant difference was observed. In the BKP group, no statistically differences were observed at each time point. Significant between-group differences were observed at 5 days ($-3.2^\circ \pm 4.3^\circ$ vs $-0.1^\circ \pm 3.3^\circ$, $p = 0.036$) and 6 months ($-3.0^\circ \pm 5.5^\circ$ vs $2.0^\circ \pm 4.1^\circ$, $p = 0.008$); at 12 months, the correction was $-2.5^\circ \pm 4.2^\circ$ with the SJ while there was nearly no change ($0.3^\circ \pm 4.1^\circ$) with BKP, without statistically significant between-group difference (Fig. 3).

Following a significant decrease in Gardner angle at 5 days post-surgery with the SJ procedure ($-4.4^\circ \pm 6.1^\circ$), a correction loss was observed at 6 months ($-2.0^\circ \pm 4.5^\circ$), but this loss was less marked at 12 months ($-1.0^\circ \pm 4.3^\circ$). With BKP, no correction was obtained 5 days after surgery ($-0.2^\circ \pm 3.5^\circ$), and worsening was observed at 6 and 12 months ($2.2^\circ \pm 4.0^\circ$ and $0.95^\circ \pm 4.26^\circ$, respectively). Significant differences between-group were observed at 5 days and 6 months ($p = 0.038$ and $p = 0.007$, respectively) (Fig. 4).

Safety results

There was neither secondary surgical intervention on the treated vertebrae nor device migration. There were four subsequent fractures concerning three patients (two in the SJ group and one in the BKP group) among the 30 treated patients (10 %). Three out of four fractures were adjacent fractures. One adjacent fracture in the SJ group (at $N+1$ level) was due to a fall at 55 days postoperatively. One out of the 15 patients in the SJ group (6.7 %) presented at L1 level with one asymptomatic cement leakage without any clinical consequences. According to Yeom's classification [18], this cement leakage was C type and located in zone I.

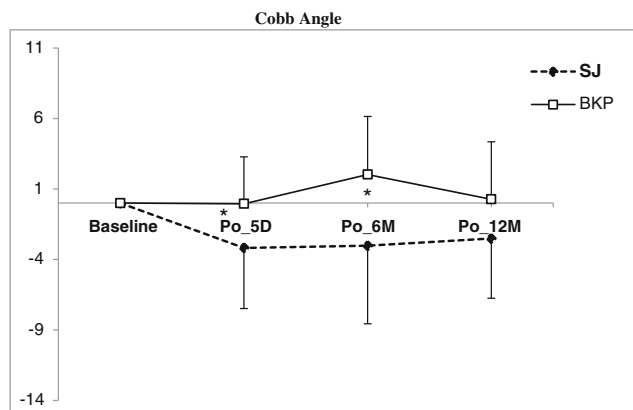


Fig. 3 Degree changes in vertebral Cobb angle versus baseline at 5 days (*Po_5D*), 6 months (*Po_6M*), and 12 months (*Po_12M*) post-surgery, with both procedures balloon kyphoplasty (BKP) and SpineJack (SJ). * $p < 0.05$

Discussion

This pilot, monocentric, prospective, controlled study showed that in osteoporotic patients with acute, painful VCF, both procedures led to a rapid and marked improvement in pain, functional capacity, and quality of life without statistically significant differences between groups.

Although differences in operative techniques resulted in a significantly shorter operative time for vertebral augmentation with SJ (23 ± 4 with the SJ vs 32 ± 8 min with BKP technique; $p < 0.001$), the volume of injected cement and the length of hospital stay were similar between both procedures.

All patients experienced excellent pain relief 5 days after surgery. In these osteoporotic patients who were suffering from severe pain (as defined by Collins et al. by an initial mean score over 75 mm) [19], the mean reduction in VAS was around 60 mm which is twice the 30-mm clinically important difference that corresponds to patients' perception of

adequate pain control [20]. At 6 and 12 months, the relative decrease in pain intensity versus baseline observed in both groups (90 and 94 % in the SJ group or 81 and 82 % in the BKP group, respectively) was thrice the change considered as clinically meaningful. Indeed, Ostelo et al. stated that a 30 % change from baseline may be considered a clinically significant improvement [21].

Improvement in health-related quality of life (HRQoL) is one of the most important goals of orthopedic surgery. The marked pain relief obtained with both procedures as well as the clear and rapid decrease in functional disability (relative decrease in ODI score around 75 % in both groups of patients at 5 days, reaching 94 % in the SJ group and 90 % in the BKP group, at both 6 and 12 months) resulted in a dramatic improvement in quality of life as evidenced by the EQ-VAS score.

Reduction of vertebral height and kyphosis is an important measure of radiographic outcomes after vertebral augmentation procedures.

Similar vertebral body height restoration could be detected at the anterior and middle vertebral location in the SJ group when comparing baseline and 5 days post-surgery. Middle vertebral height ratio increased from 70 to 86 %, corresponding to a 16 % mean correction, while a 6 % mean correction was obtained with BKP ($p = 0.018$). At 6 months post-surgery, the middle height slightly decreased to 84 % for the SJ. For the BKP, this height decreased from 82 % at 5 days to 79 % at 6 months. At 12 months post-surgery, the height was almost constantly maintained in both groups, with 84 % for SJ and 78 % for BKP. These inter-group differences were statistically significant at each time point for the anterior part ($p = 0.03$ at 6 months; $p = 0.003$ at 12 months) as well as for the central part ($p = 0.009$ at 6 months; $p = 0.001$ at 12 months), suggesting a higher efficacy of the SJ procedure. As anticipated in this type of fracture with intact posterior wall, the smallest changes in vertebral body height were found for posterior regions, without significant difference between groups.

At 5 days post-surgery, the SJ produced a spinal correction with a mean magnitude of $-4.4^\circ \pm 6.1^\circ$, $-3.2^\circ \pm 4.3^\circ$, and $-6.1^\circ \pm 6.1^\circ$ for Gardner, Cobb, and vertebral kyphotic angles. BKP caused only a slight change of the vertebral angles with $-0.2^\circ \pm 3.5^\circ$, $-0.1^\circ \pm 3.3^\circ$, and $-1.1^\circ \pm 2.8^\circ$, respectively. All these results indicate that SJ produced a larger restoration of the vertebral kyphotic angle which was still evident 12 months after implantation. In addition, in the SJ group, there was an improvement of the Cobb angle postoperatively and a maintenance with almost no change 12 months after treatment. In the BKP group, the Cobb angle was not improved postoperatively, and there was approximately no change 12 months after treatment.

These radiological results are in line with findings from biomechanical studies in which SJ was superior to BKP in terms of height restoration and height maintenance [13, 14]

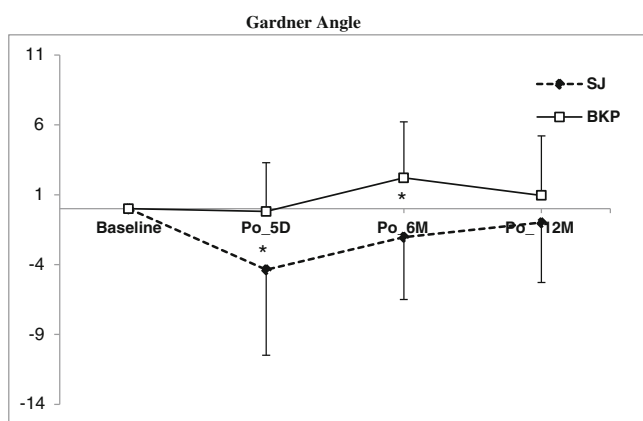


Fig. 4 Degree changes in vertebral Gardner angle versus baseline at 5 days (*Po_5D*), 6 months (*Po_6M*), and 12 months (*Po_12M*) post-surgery, with both procedures balloon kyphoplasty (BKP) and SpineJack (SJ). * $p < 0.05$

Indeed, this novel VCF reduction system is based on a recent technology designed specifically to separate the VB endplates by applying all forces in the craniocaudal direction. Thus, unlike BKP where centrifugal forces are applied laterally, height restoration (HR) may be a result of use of the SJ. Fracture reduction obtained with the SJ may be maintained throughout the VCF reduction procedure by leaving the locked bone tamp in place, while balloon deflation in BKP commonly results in intra-procedural loss of fracture reduction. In BKP, balloon inflation must cease if it touches a lateral VB wall; this might happen before full height restoration is obtained, resulting in premature termination of height restoration effort. This occurrence is not expected with the SJ as this device does not expand laterally. Because of this feature, less antero-posterior fluoroscopy is required when using the SJ.

As for any pilot monocenter study, these results need to be interpreted carefully. Even if randomization gives the highest likelihood of balancing treatment groups for factors influencing the response, we acknowledge several limitations to our study. First, the small number of patients in the cohort limits the potential conclusions on the clinical performance and safety of the tested VA procedure even if significant statistical differences exist. Second, this individual investigator-driven small-sized study may not reflect results that would have been obtained from different physician profiles and associated practice patterns. Third, although results seem to have reached a plateau at 12-month follow-up, long-term follow-up studies will be needed to demonstrate the maintenance of these effects over the time. To make these findings more robust and generalizable, future multicenter studies adequately sized in different settings might address this issue.

However, an interesting feature emerged from the efficacy analysis. It should be noted that results from this pilot study appeared somewhat relevant as we found for BKP similar pain improvement as that achieved in a large-sized trial, the KAST study [22]. This study compared the Kiva® System to BKP in 300 patients with painful osteoporotic VCFs and showed at 12 months post-surgery a mean improvement of 71.8 mm in VAS score with BKP (vs 68.9 mm in our study, with patients showing a similar baseline value around 85 mm) and 70.8 mm for Kiva®. Compared to both devices tested in the KAST study, the SJ led to a slightly better improvement in VAS score with a mean value of 75.8 points.

Unlike for pain, we found quite different results for ODI improvement in the BKP group (changes at 6 and 12 months 53.7 and 53.9, respectively, in our study vs 38.4 and 42.2, respectively, in KAST study) while baseline values were similar (59.9 in our study vs 63.2 in KAST study). These better results we observed on functional capacity could be explained by slightly younger patients in our study (68 vs 75 years) and more recent fractures (age of fractures around 30 days in our study while 45 % of patients had had conservative treatment >6 weeks in KAST study). Differences in radiological results

could also have influenced clinical results, but evolution of vertebral height and angles is not documented in the KAST study.

Clinical results from this pilot prospective randomized study confirmed that both techniques are safe and efficient for the treatment of osteoporotic VCFs. However, radiological results showed important advantages of the SpineJack® compared with the balloon procedure with a higher potential for vertebral body height restoration and maintenance over time. Data from this small-sized monocenter study should be used to design larger and long-term follow-up confirmatory trials.

Compliance with ethical standards

Conflicts of interest David César Noriega has received a speaker honorarium from Vexim and Medtronic. Rubén Hernández Ramajo: none. Israel Sánchez Lite: none. Borja Toribio: none. Raul Corredera: none. Francisco Ardura has received a speaker honorarium from Vexim. Antonio Krüger has received a speaker honorarium from Medtronic, Soteira, Biomed, DFine and Vexim.

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