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ORIGINAL ARTICLE

Long-term 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 This pilot monocenter study in 30 patients with painful osteoporotic vertebral compression fractures compared two vertebral augmentation procedures. Over a 3-year post-surgery follow-up, pain/disability/quality of life remained significantly improved with both balloon kyphoplasty and SpineJack® techniques, but the latter allowed better vertebral body height restoration/kyphosis correction.

Introduction Patient follow-up rarely exceed 2 years in trials comparing vertebral augmentation procedures for the treatment of painful osteoporotic vertebral compression fractures (VCFs). This pilot, investigator-initiated, prospective study aimed to compare long-term results of SpineJack® (SJ) and balloon kyphoplasty (BKP). Preliminary results showed that SJ resulted in a better restoration of vertebral heights and angles, maintained over 12 months.

Methods Thirty patients were randomized to SJ ($n = 15$) or BKP ($n = 15$). Clinical endpoints were analgesic consumption, back pain intensity (visual analog scale (VAS)), the Oswestry Disability Index (ODI), and quality of life (EQ-VAS score). They were recorded preoperatively, at 5 days (except EQ-VAS), 1, 3, 6, 12, and 36 months post-surgery. Spine X-rays were taken 48 h prior to the procedure and 5 days, 6, 12, and 36 months after.

Results Clinical improvements were observed with both procedures over the 3-year period without significant inter-group differences, but the final mean EQ-$5D_{index}$ score was significantly in favor of the SJ group (0.93 ± 0.11 vs 0.81 ± 0.09; $p = 0.007$). Vertebral height restoration/kyphotic correction was still evident at 36 months with a greater mean correction of anterior ($10 \pm 13\%$ vs $2 \pm 8\%$ for BKP, $p = 0.007$) and central height ($10 \pm 11\%$ vs $3 \pm 7\%$ for BKP, $p = 0.034$) and a larger correction of the vertebral body angle ($-5.0° \pm 5.1°$ vs $0.4° \pm 3.4°$; $p = 0.003$) for SJ group.

Conclusions In this study, both techniques displayed very good long-term clinical efficiency and safety in patients with osteoporotic VCFs. Over the 3-year follow-up, vertebral body height restoration/kyphosis correction was better with the SpineJack® procedure.

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

Introduction

Vertebral compression fractures (VCFs) are one of the most common manifestations of osteoporosis, especially among elderly females [1, 2]. These fractures can lead to severe chronic pain and reduced pulmonary function, with a debilitating impact on patients' activities in daily life. Moreover, loss of height and distorted spine caused by VCFs have a major impact on the emotional wellbeing of many patients [3, 4]. Furthermore, the risk of mortality is twofold higher in patients with VCFs, osteoporotic men being at higher risk than women [5].

The prevalence of osteoporotic VCFs is difficult to estimate because not all fractures come to the attention of clinicians and these are not always recognized on X-rays [6]. Osteoporotic VCFs are a significant health problem with more than 1,400,000 fractures occurring annually in Europe [7]. Patients with one VCF are five times more likely to develop another spinal fragility fracture [8].

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Treating vertebral compression fractures aims to restore mobility, reduce pain, and minimize the incidence of new fractures. Conservative treatment (pain medication, bed rest, and back braces) focuses on alleviating symptoms and supporting the spine but leads to increased disability due to further bone demineralization and intolerable side effects from analgesics [9]. Thus, symptoms and non-surgical management of osteoporotic VCF adversely impact the quality of life (QOL) and represent a considerable health economic burden.

Percutaneous vertebroplasty (VP) and percutaneous balloon kyphoplasty (BKP) without stenting are two minimally invasive vertebral augmentation (VA) procedures recommended as options for treating osteoporotic VCFs only in people who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management [10]. Recent studies comparing both procedures demonstrate the advantages of BKP over VP in terms of sagittal balance improvement, cement leakage, improved mortality rates, and cost savings [11–13]. Thus, BKP appears to be the current standard of care for VCFs, even if recovery of vertebral body (VB) height may be only temporary as there is often a total or partial VB collapse after balloon deflation, prior to cement injection [14].

The third-generation percutaneous VA system called SpineJack® (SJ) has been shown in biomechanical studies to be superior to BKP in terms of sagittal height restoration and height maintenance [15, 16]. Clinical data confirmed these advantages. Indeed, we recently reported the 1-year clinical results of the present study that showed throughout the follow-up period a better VB height restoration with percentages of correction for both anterior and middle parts significantly higher compared to BKP [17]. These results were in line with preliminary results observed at 1 year by Vanni et al. [18].

This pilot study was a prospective, randomized, monocentric study comparing 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. The primary objective here is to report long-term results observed in the extension study, 3 years after initial surgery.

Materials and methods

Patients

From March 2013 through December 2013, patients were randomized to either SJ group ($n = 15$) or BKP group ($n = 15$) as previously described [17]. The allocated procedure was disclosed to the investigator prior to surgery while patients remained blinded until the end of follow-up.

All patients were known osteoporotic subjects who underwent surgery whatever the extent of bone loss, without DMO measurement at inclusion as DEXA scans are not performed in routine practice. Participants had one or two painful VCFs from T7 to L3 due to osteoporosis and aged < 3 months, with a loss of height in the anterior, mid, or posterior third of the VB ≥ 15% but ≤ 40%. They failed conservative medical therapy (VAS back pain score ≥ 5 at 6 weeks after the initiation of fracture care or ≥ 7 at 2 weeks after the initiation of fracture care) and had an Oswestry Disability Index (ODI) score ≥ 30%. All selection criteria have been previously detailed [17].

Participants gave written informed consent before enrollment. The protocol and consent form were approved by the local ethics committee.

Research design

Both devices were implanted in accordance with their specific instructions for use (IFU).

All procedures were conducted under general anesthesia, except spinal anesthesia used for two cases. For both procedures, the VB was accessed through a standard posterior transpedicular approach, and the incision required was identical.

For the patient being in a prone position, the SpineJack® Ø 5 mm/KE001 (VEXIM SA, France) was inserted into the fractured VB in unexpanded format (Online Resource 1, left). 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 towards each other. Longitudinal compression of the device causes the implant to open in the inferior-superior direction only due to the machined grooves (Online Resource 1, right). 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 polymethylmethacrylate (PMMA) high-viscosity 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 (Kyphon Inc., USA). The procedure was carried out according to the IFU via a bilateral approach using two balloons. A BKP curette (KyphX® Latitude™ Curette) was used to create space if hard bone was encountered during access or inflation.

Clinical outcomes at 5 days and 1, 3, 6, 12, and 36 months after surgery included back pain intensity on a 100-mm VAS, analgesic intake, the Oswestry Disability Index (ODI) score [19], ambulatory status, and the EuroQol-5-Domain (EQ-5D) questionnaire [20]—not applied at 5 days. A neurologic examination was performed at 5 days.

Standing lateral spine radiographs were obtained within 48 h prior to procedure, 5 days after, and at 6, 12, and 36 months. Standing antero-posterior spine radiographs were obtained within 48 h prior to procedure and 5 days after. MRI was performed at 5 days and 6 months. Blinded quantitative radiographic analysis was done on X-ray by ACES Ing., GmbH, Filderstadt, Germany, an independent, qualified core lab using their 510(k) validated FXA™ software [21]. Radiographic endpoints included VB height restoration expressed in millimeters and as height ratio differences in percentage (anterior, medial, and posterior VB measurements); kyphosis angle, defined as the angle formed by lines drawn parallel to the caudal and cranial fractured VB endplates; and the local Cobb angle, defined as the angle formed by lines drawn parallel to the superior endplate of the VB above and the inferior endplate of the VB below.

All adverse events (AEs) were reported and evaluated by the investigator for device and procedure relationship. AEs were classified into preferred terms and system organ class according to the Medical Dictionary for Regulatory Activities (MedDRA) [22]. All device deficiencies and malfunctions were documented.

Statistical methods

All statistical analyses were performed at the 0.05 global significance level using two-sided tests. Testing for baseline between-group differences was performed using Student's test or Wilcoxon's test for quantitative parameters and chi-square 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 the evolution of efficacy parameters at each follow-up visit compared to baseline. Wilcoxon's test or Student's test for pairwise comparisons was used, depending on the normality of the distribution. The between-group comparison was done using Student's test or Wilcoxon's test for quantitative parameters and chi-square test or Fisher's exact test for qualitative parameters.

Results

Demographics and baseline characteristics

Among the 30 randomized patients (80.0% female; 68.1 ± 5.3 years old), one patient from the SJ group died because of cardiovascular disease 4.7 months after the 1-month post-surgery visit (information not available for the publication relating 1-year results), and one patient from the BKP group died of stroke 9 months after the 1-year post-surgery visit. Thus, 28 patients completed the 3-year extension study.

No clinically relevant differences were observed between groups for demographics and main preoperative characteristics (Table 1).

Sixteen (16) VCFs were treated with the SJ procedure (one patient had 2 fractures) and 17 fractures were treated with BKP (two patients had 2 fractures). Location, morphological type, and severity of fractures according to the Genant semi-quantitative method [23] are presented in Fig. 1.

Before surgery, all patients were taking paracetamol/acetylsalicylic acid/NSAID. Nearly half patients in each group ($n = 7$, 46.7%) were prescribed central analgesics; one patient from the SJ group needed morphine. One patient from the BKP group was treated with bisphosphonates, two patients in each group received calcium, and vitamin D was given to two patients from the SJ group and one patient from the BKP group. A treatment was applied to manage osteoporosis. Preoperatively, calcium and vitamin D treatment were taken. Postoperatively, denosumab (60 mg/ml subcutaneously) every 6 months, calcium (1000 mg), and vitamin D (800UI) per day were prescribed.

Procedure characteristics

Most patients (93.3%) underwent general anesthesia. The SJ procedure had a shorter mean procedure duration than BKP (23 ± 4 vs 32 ± 8 min; $p < .001$). The median hospitalization duration was 1 day for all patients (Table 1).

Clinical results

The mean patient follow-up was 37.1 ± 10.4 months in the SJ group and 38.0 ± 7.8 months in the BKP group.

Evolution of pain and functional capacity

For each outcome, from discharge until the end of the 3-year follow-up, statistically significant improvements from baseline were observed for each group, without significant differences between groups (Online Resource 2).

As shown in Fig. 2, patients treated with SJ achieved a more marked long-lasting decline in pain compared to patients treated by BKP. One year after surgery, pain intensity was significantly lower in the SJ group (3.3 ± 5.9 vs 15.3 ± 10.9 in the BKP group; $p = 0.037$) representing 94% and 82% improvement, respectively. Three years after surgery, pain intensity increased in both groups with a value significantly higher in the BKP group (25.0 ± 9.0 vs 14.4 ± 7.2 in the SJ group;

Table 1 Demographics, preoperative characteristics, surgical procedure

	SpineJack® procedure ($N = 15$)	Balloon kyphoplasty ($N = 15$)	p value
Female (n, %) Male (n, %)	11 (73.3%) 4 (26.7%)	13 (86.7%) 2 (13.3%)	0.651[a]
Age (years)	67.9 (61–74)	68.3 (56–75)	0.662[b]
BMI (kg/m^2)	25.8 (18.4–31.6)	27.4 (21.1–35.2)	0.232[c]
Back pain on VAS (mm)	80.5 (51–100)	84.3 (60–100)	0.443[c]
ODI	65.4 (40.0–95.6)	59.9 (32.0–93.3)	0.387[c]
EQ-VAS score	41.0 (0.0–78.0)	41.9 (5.0–90.0)	0.915[c]
EQ-5D$_{index}$ score	0.34 (− 0.08–0.59)	0.36 (0.03–0.68)	0.982[b]
Time elapsed since symptom occurrence (days)	26.9 (13–62)	29.6 (6–82)	0.917[b]
Surgical procedure			
Anesthesia (n, %)			
• General anesthesia • Spinal anesthesia	15 (100.0%) –	13 (86.7%) 2 (13.3%)	0.483[a]
Procedure duration (h: min)	0:23 (0:18–0:35)	0:32 (0:23–0:50)	< 0.001[b]
Total cement volume (ml)	4.9 (2.5–7.5)	5.1 (3.5–7.5)	0.566[c]
Length of hospital stay (days)	1.4 (1–3)	1.3 (1–3)	0.936[b]

Data are expressed as number and percentages, or as mean and range

SJ SpineJack®, *BKP* balloon kyphoplasty

[a] p value was assessed using Fisher's test

[b] p value was assessed using Wilcoxon's test

[c] p value was assessed using Student's test

$p = 0.002$), reaching an intensity higher than the one observed at 5 days post-surgery.

At 5 days, 1 year, and 3 years after the procedure, 75%, 97%, and 90% improvements in disability were obtained for SJ, respectively; the corresponding values were 75%, 87%, and 83% for BKP. Three years after surgery, mean ODI scores showed that functional capacity remained significantly better in the SJ group (6.0 ± 3.7 vs 10.5 ± 5.4; $p = 0.027$).

Evolution of analgesic consumptions

Concomitant with pain relief, analgesic consumption decreased with only one in three patients in each group taking paracetamol 1 month after the procedure. Three years after surgery, pain increase reflected in the analgesic intake which was more frequent in the BKP group (50.0%) than in the SJ group (28.6%).

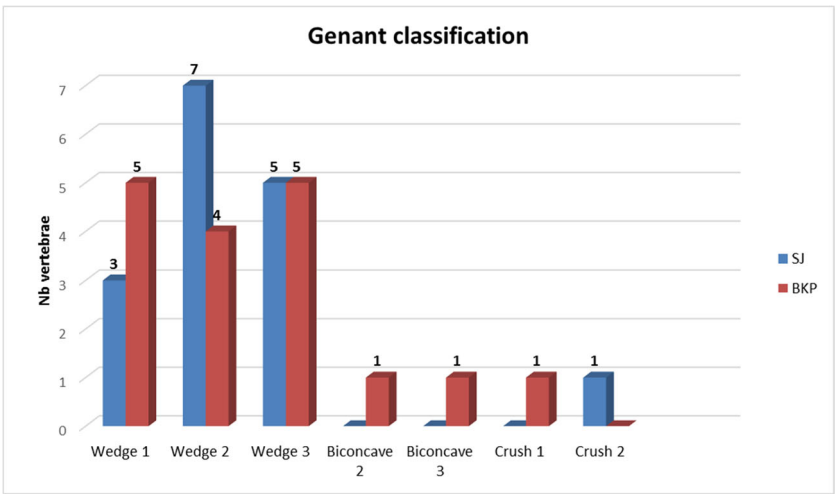
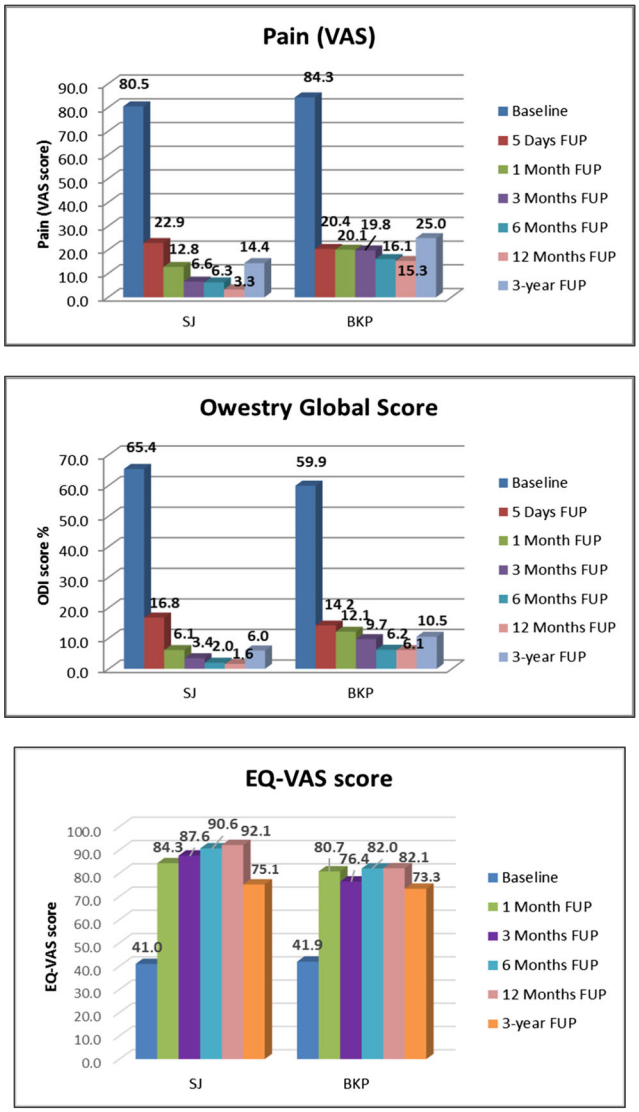


Fig. 1 Distribution of fractures according to Genant's classification. SJ SpineJack®, BKP balloon kyphoplasty

Abbreviations: SJ: SpineJack®; BKP: balloon kyphoplasty



Abbreviations: SJ: SpineJack®; BKP: balloon kyphoplasty

Fig. 2 Mean pain intensity, ODI score, and EQ-VAS score at each visit. SJ SpineJack®, BKP balloon kyphoplasty

Evolution of quality of life

With both procedures, the evolution of EQ-VAS score (Fig. 2) and the EQ-5D$_{index}$ score showed a marked and sustained improvement in QoL from the first month following surgery until the end of the 3-year observation period without significant differences between groups. Despite a slight decrease 3 years after surgery in both groups, the mean EQ-5D$_{index}$ score was significantly in favor of the SJ group (0.93 ± 0.11 vs 0.81 ± 0.09; $p = 0.007$).

Radiographic results

Five days after surgery, the mean anterior and middle height restoration around 4 mm was obtained with the SJ procedure. This restoration slightly decreased to around 3 mm at 12 months and 2.4 mm at 3 years. BKP induced at 5 days a significantly less marked height restoration than did SJ for both anterior (1.1 ± 1.9 mm; $p = 0.03$) and middle (1.4 ± 1.8 mm; $p = 0.01$) parts, and then deteriorated over time reaching -0.3 ± 2.1 mm at 3 years for the anterior part. Between-group differences in favor of SJ were statistically significant at each time point. These changes, expressed as body height ratio differences (Table 2), corresponded to 16%, 12%, and 10% corrections obtained with SJ at 5 days, 12 months, and 3 years after surgery for both anterior and middle parts. Throughout the follow-up period, corrections obtained with BKP were significantly lower for both anterior (4%, 0%, 2%, respectively) and middle parts (6%, 2%, 3%, respectively).

Throughout the study, compared with preoperative condition, average postoperative kyphotic correction was statistically significant with SJ only (Table 3). Between-group differences in mean kyphotic angulation correction were also statistically significant at each time point. The Cobb angle correction was significantly more marked and sustained over the 3-year follow-up period in the SJ group with mean changes of $-3.2° \pm 4.3°$ at 5 days, $-2.5° \pm 4.2°$ at 12 months, and $-2.5° \pm 4.4°$ at 3 years. By contrast, nearly no change occurred with BKP. Evolution of vertebral angles is depicted on Fig. 3.

Safety results

Among the 28 patients included in this study, serious adverse events (SAEs) were reported in 5 patients in SJ group (vein varicosis; head lipoma; cataract; T12 fracture after a fall; patient with significant comorbidities hospitalized four times at 6-month intervals for aorta aneurysm, endoprosthesis thrombosis, iliac thrombosis, and cholecystitis) and 2 patients in BKP group (bradycardia; L4-L5 spinal stenosis). None of these SAEs (including the two deaths mentioned above) were related to the devices or procedures. Two patients reported non-serious AEs after BKP (lumbar pain; neck and shoulder pain).

There was neither secondary surgical intervention on the treated vertebrae, nor device migration.

Within the year following SJ procedure, one patient experienced 55 days postoperatively an adjacent fracture after a fall, and another patient presented two new fractures (one adjacent and one subsequent). Three years after BKP, one adjacent fracture occurred in one patient. In the SJ group, one patient presented at L1 level with an asymptomatic C-type cement leakage located in zone I—according to Yeom's classification [24]—without any clinical consequences.

Table 2 Anterior/midline/posterior height ratio differences by visit compared to baseline (mean ± SD)

	N	Pre op	Day 5	Correction (%)	*N*	6 months	Correction (%)	*N*	12 months	Correction (%)	*N*	3 years	Correction (%)
Anterior vertebral body height ratio (%)													
SJ	16	65 ± 16	80 ± 12	16 ± 14	14	77 ± 13	12 ± 14	15	78 ± 12	12 ± 13	14	75 ± 13	10 ± 13
BKP	17	73 ± 16	78 ± 14	4 ± 8	17	75 ± 13	2 ± 6	17	73 ± 13	0 ± 7	16	72 ± 13	2 ± 8
p inter-group				0.030[a]			0.030[a]			0.003[b]			0.007[b]
Midline vertebral body height ratio (%)													
SJ	16	70 ± 15	86 ± 8	16 ± 14	14	84 ± 9	12 ± 11	15	84 ± 8	12 ± 10	14	81 ± 9	10 ± 11
BKP	17	76 ± 15	82 ± 12	6 ± 8	17	79 ± 12	3 ± 6	17	78 ± 11	2 ± 6	16	79 ± 10	3 ± 7
p inter-group				0.018[b]			0.009[b]			0.001[b]			0.034[b]
Posterior vertebral body height ratio (%)													
SJ	16	93 ± 8	96 ± 7	3 ± 4	14	97 ± 7	3 ± 5	15	96 ± 7	3 ± 4	14	95 ± 7	1 ± 5
BKP	17	94 ± 9	96 ± 9	2 ± 4	17	96 ± 8	1 ± 3	17	95 ± 7	1 ± 3	16	94 ± 6	0 ± 4
p inter-group				0.805[a]			0.505[a]			0.159[a]			0.386[b]

[a] *p* value was assessed using Wilcoxon's test

[b] *p* value was assessed using Student's test

SJ SpineJack®, *BKP* balloon kyphoplasty

Discussion

Adding to the insights gained from the previously published 1-year results in the same patient cohort [17], these long-term results confirmed the higher potential of SJ over BKP in restoring and maintaining VB height.

Throughout the 3-year follow-up, ratings of pain, disability, and QOL remained significantly improved versus baseline without statistically significant differences between groups. Three years after procedure, the mean values of the different clinical outcomes were significantly in favor of the SJ: the increase in pain led to an intensity significantly higher in the BKP group ($p = 0.002$) with a value higher than the 5-day post-surgery value; the mean ODI scores showed a better functional capacity in the SJ group ($p = 0.027$) with a mean EQ-5D$_{index}$ score reflecting a better QOL ($p = 0.007$). The difference between both groups in favor of SJ as to the EQ-5D$_{index}$ score met the 0.08-point minimally clinically important difference as determined by several authors [25, 26].

These osteoporotic patients were suffering at inclusion from severe pain—as defined by an initial mean score over 75 mm [27]—and the dramatic improvement observed with SJ and BKP as soon as the fifth day after surgery (72% and 76%, respectively) was still maintained 3 years later (81% and 70%, respectively). Such changes are well above the 30% change which, according to Ostelo et al., may be considered as a clinically significant improvement [28].

Table 3 Kyphotic correction overtime (°)

		N	Mean ± SD	Median	Range	*p* value intragroup (signed rank)	*p* value intergroup
Day 5	SJ	16	− 6.08 ± 6.10	− 6.45	− 15.6, 4.2	0.002	0.009[a]
	BKP	17	− 1.10 ± 2.76	0.00	− 7.9, 3.0	0.147	
6 months	SJ	14	− 3.86 ± 4.74	− 5.05	− 11.6, 3.7	0.013	0.026[a]
	BKP	17	− 0.16 ± 2.80	0.00	− 8.3, 4.6	1.000	
12 months	SJ	15	− 4.44 ± 5.82	− 4.50	− 15.4, 5.2	0.017	0.012[b]
	BKP	17	0.15 ± 3.02	0.00	− 6.2, 4.1	0.683	
3 years	SJ	14	− 4.97 ± 5.06	− 4.42	− 15.8, 2.1	0.003	0.002[b]
	BKP	16	0.42 ± 3.43	− 0.30	− 4.8, 8.7	0.980	

SJ SpineJack®, *BKP* balloon kyphoplasty

[a] *p* value was assessed using Wilcoxon's test

[b] *p* value was assessed using Student's test

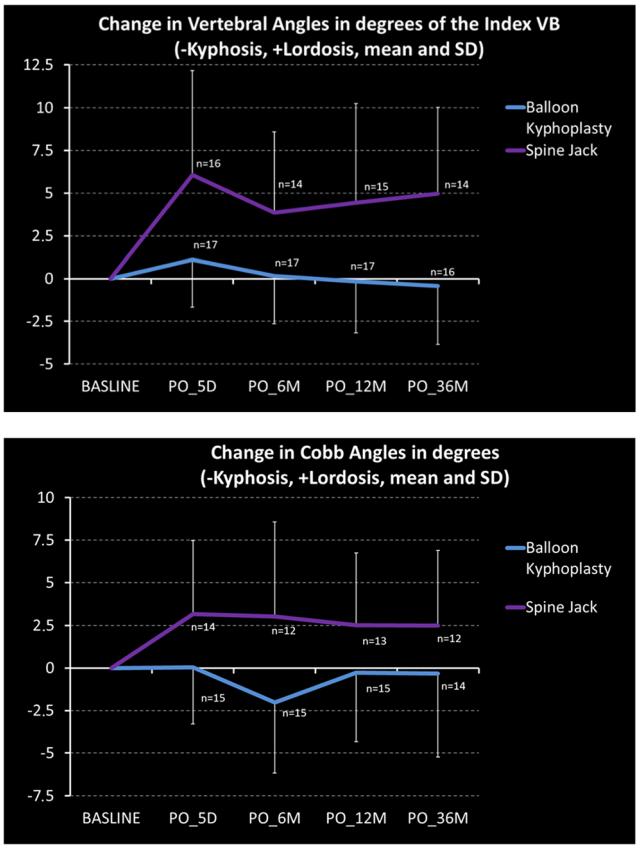


Fig. 3 Evolution of vertebral kyphotic angle and the Cobb angle at each visit (°)

Major randomized controlled trials (RCTs) for kyphoplasty have not always described detailed radiographic results [29] while deformity correction outcomes are of the utmost importance in the assessment of VA procedure efficiency. As stated above, the more satisfactory vertebral anatomy correction was obtained with SJ procedure: 5 days post-surgery, a 16% vertebral height ratio increase was observed for both anterior and middle parts while BKP showed the mean increases of 4% and 6%, respectively. The efficacy of SJ was stable over time without important changes in anterior and middle height at 6 and 12 months and 3 years post-surgery (4%, 4%, and 6% loss versus baseline, respectively), and at each time point, inter-group differences were statistically significant and in favor of SJ (at 12 months, $p = 0.003$ for anterior part and $p = 0.001$ for middle part; at 3 years: $p = 0.007$ for anterior part and $p = 0.034$ for middle part). The smallest changes in VB height ratio were found for posterior regions, without significant difference between groups. Obviously, such a finding could be expected as these areas are not involved in this type of fractures.

Vertebral body kyphosis correction was better in the SJ group compared with the BKP group at all time points through 36 months. Over the study period, postoperative mean changes from baseline showed an average improvement of around 5° in the SJ group while kyphotic angulation correction never exceeded 1° after BKP.

In addition, there was an improvement of the Cobb angle after SJ procedure and a maintenance with almost no change 3 years after treatment. By contrast, nearly no change occurred with BKP. These radiological results are in line with the findings from biomechanical studies in which SJ was superior to BKP in terms of height restoration and height maintenance [15, 16].

Despite the fact that this study was a pilot monocenter study, our data are of interest as they relate to results obtained on multiple clinical and radiographic endpoints after a 3-year follow-up in 93% of the included patients. Indeed, the most recently published meta-analysis [30] mentioned only one study involving BKP with a long-term follow-up over 36 months (mean, 49.4 months). This study investigated new symptomatic osteoporotic VCFs in patients treated by VP or BKP versus conservative treatment without differentiation between results from VP and BKP; neither pain nor QOL was assessed [31]. It seems also important to point out, as we did previously [16], that our results appeared relevant as we found that BKP led to similar pain improvement at 12 months as that achieved in a large-sized study, the KAST study [32].

The good results we obtained on QOL are also in accordance with literature. The large-sized FREE study on 300 patients comparing BKP with non-surgical management during 24 months has explored the link between VB anatomy correction and QOL [29]. The authors showed that patients with greater QOL improvement had more kyphosis correction at the treated vertebrae. Our pilot study supports their conclusions. Indeed, the better results on kyphotic reduction obtained with SJ is matched with significant better results on QOL especially at 3 years ($p = 0.007$) with a between-group difference meeting the 0.08-point minimally clinically important difference (MCID) for $EQ\text{-}5D_{index}$ score [25].

Looking at the literature reporting short- and long-term improvements of kyphotic angle after BKP, we noted that the kyphosis angle changes obtained with BKP in our study ($+0.15° \pm 3.02°$ at 1 year, $+0.42° \pm 3.43°$ at 3 years) were less marked than those reported in the KAVIAR study (mean correction and 95% CI of 1.97° [1.11–2.82] at 12 months and 2.09° [0.90–3.28] at 24 months) [33]. In contrast, we observed for BKP better results on pain and functional capacity than those reported in the KAVIAR study. These discrepancies between both studies could be explained by the differences in study design (monocenter vs multicenter, 15/15 patients vs 191/190 randomized patients).

Similar discrepancies arise from two other studies, with an 8.0° reduction in wedge angle reported 1, 2, and 5 years after

kyphoplasty in the long-term Liu study that compared BKP vs vertebroplasty on two groups of 50 patients each [34]. In the second study [35], a long-term follow-up (mean 49 months) of 87 osteoporotic vertebral fractures in 82 patients treated with BKP showed for kyphotic angle the following mean values: 17.0 ± 3.2 preoperatively, 4.9 ± 1.8 postoperatively, and 5.5 ± 1.6 at the last control. The corresponding values for BKP in our study were 15.8 ± 8.7, 14.7 ± 9.2, and 15.5 ± 7.6, respectively.

Long-term results on new fracture rate obtained with BKP in our pilot study (6.7% at 3 years) also differ from those reported in the literature. The incidence of new symptomatic VCFs was 24% (16% adjacent and 8% non-adjacent) over 5 years in Liu's study [34] and 26.3% at a mean of 2.7 years after surgery in a recent study comparing BKP with conservative treatment [36]. The rate of new radiographic fracture during the year following BKP was high (about 30%) in the FREE study [37] who randomly assigned 300 patients to BKP ($n = 149$) or non-surgical care ($n = 151$). The rate we observed is close to the figure observed on a longitudinal cohort of 726 patients with osteoporotic compression fractures who underwent BKP; 77 patients (10.6%) presented with symptomatic second compression fractures on average 350 days following the initial procedure. Forty-eight of 77 patients (62%) suffered a fracture at a level immediately adjacent to the index level. Adjacent level fractures occurred at a mean time of 256 days following the initial treatment while remote level fractures occurred at a mean time of 489 days following the initial treatment [38].

These discordances between results of our pilot monocenter trial and those from published trials cited above suggest that our findings need to be interpreted carefully and should be proved on a larger sized, multicenter study, with independent radiographic core lab assessments in order to minimize reader bias.

According to the actual knowledge (IFU) including this RCT data, these criteria mean a contraindication for the SJ procedure: vertebra plana, segmental kyphosis > 30°, neurological deficit, pedicle fracture associated, and posterior elements fracture associated.

Long-term results from this pilot prospective randomized study confirmed that both techniques are safe and efficient for the treatment of osteoporotic VCFs. A clear effect on pain relief leading to marked improvements in functional disability and quality of life was maintained throughout the 3-year follow-up period in both groups. However, radiological results indicate that SJ has a higher potential for VB height restoration, kyphotic reduction, and maintenance over time in comparison with BKP.

Compliance with ethical standards

Conflicts of interest None.

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