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Abstract

Objectives

Osteoporotic vertebral compression fractures (OVCFs) are an important health issue for which minimally invasive techniques are a feasible treatment. The SpineJack® (Vexim) is an intravertebral expandable system designed to improve the correction of the structural modifications caused by OVCFs. Its ability to stabilize and reduce OVCFs at the acute phase being already well established, we sought to evaluate the feasibility of vertebral augmentation with the SpineJack® in chronic kyphotic OVCFs.

Methods

All consecutive patients treated with the SpineJack® were prospectively included if they met the following criteria: 1) OVCF considered unstable (grade A3 according to Magerl's classification). 2) Local kyphotic angle ≥20°. 3) OVCF older than 6 weeks. 4) Back pain with visual analogue scale (VAS) ≥ 4.

Results

19 consecutive patients (16 women [84.2%] and 3 men [15.8%]; mean age = 73.2±8.2 years) were included. Treatment was performed after a mean delay of 5.8 months ± 2.9 (range: 1.5-12). Median visual analogue scale significantly improved from 7 preoperatively (IQR: 6-9) to 2 (IQR: 1-5) at 6 months ($p<0.01$). Significant kyphosis reduction (i.e ≥ 30%) was obtained in 94.7% of cases. Secondary adjacent level fractures (SALFs) were noted in 21.1% of cases and were correlated to the importance of the kyphosis' reduction.

Conclusions

Vertebral augmentation with the SpineJack® is feasible and seems able to correct major structural deformities in chronic OVCFs. SALFs were noted in a substantial amount of cases. Preventive adjacent vertebroplasty might be useful in patients with several risk factors for SALFs.

Key points:

1. Vertebral augmentation with the SpineJack® is effective to correct major structural deformities such as height loss and kyphosis.

2. Successful reduction is reachable with the SpineJack® in chronic (older than 6 weeks) OVCFs.

3. Aggressive reduction of a major kyphosis might promote SALFs and complementary adjacent vertebroplasties prevent their occurrence.

Keywords: Spinal Fractures; Vertebroplasty; Osteoporotic Fractures; Kyphosis; Back Pain

Abbreviations and Acronyms:

BKP: Balloon Kyphoplasty

CT: Computed Tomography

DSA: Digital Subtraction Angiography

IQR: Interquartile Range

MRI: Magnetic Resonance Imaging

OVCF: Osteoporotic Vertebral Compression Fracture

PMMA: Poly-Methyl-Methacrylate

PVP: Percutaneous Vertebroplasty

RCT: Randomized Control Trial

SALF: Secondary Adjacent Level Fracture

VAS: Visual Analogue Scale

Introduction

Osteoporotic vertebral compression fractures (OVCFs) are a major public health issue, affecting about 1.4 million patients each year world wide [1]. OVCFs may cause debilitating back pain that can affect the quality of life and even lead to increased mortality rates [2–4]. Spinal deformities are also critical consequences of OVCFs, that modify the repartition of the mechanical forces applied to the spine, which can eventually induce iterative fractures and at long term, the secondary degenerative changes are responsible for debilitating pains and even lead to neurological compressions [5]. Moreover, vicious positions promote the risk of fall and result in more severe disabilities in this fragile population, hence the importance of adequate prevention and early management of such deformities.

Despite controversies about the efficacy of routine percutaneous vertebroplasty (PVP) [6–8] in symptomatic OVCFs, PVP remains a commonly used tool in this indication, allegedly providing vertebral stability and thus potentially improving the clinical outcomes [9], especially when performed at the acute phase [10, 11]. However PVP appears insufficient to correct the structural deformities (vertebral height loss and kyphotic angulations) and, in unstable OVCFs (grade A3 in Magerl's classification [12]), might cause bony fragments bulging into the spinal canal.

Numerous percutaneous techniques have then been developed to improve reduction of fractures, mainly by using intravertebral devices such as balloon kyphoplasty (BKP) [13] and more recently the SpineJack® (Vexim) [14]. The effectiveness of the Spinejack® being already established in acute OVCFs [15, 16], the purpose of this study was to evaluate the feasability of vertebral augmentation with the SpineJack® in chronic OVCFs (i.e.: > 6 weeks) with important kyphosis.

Materials and Methods

Device

The SpineJack® is an intravertebral expandable device constituted of a central screw and of two deployable plates (one cranial and one caudal). The diameter of the central screw defines three different sizes: the SpineJack® 5.8, 5.0 and 4.2, which need to be adapted to the pedicles' diameter. Respectively, the maximum craniocaudal expansion that can be obtained is 20, 17 and 12.5 millimetres.

Population

From 2014 to 2016, all consecutive adult patients with symptomatic OVCFs who underwent vertebral augmentation with the SpineJack® were prospectively included. Patients were considered eligible for inclusion if they met the following criteria 1) OVCF involving the lower thoracic and/or lumbar vertebrae, considered unstable (grade A3 according to Magerl's classification). 2) Kyphosis ≥20° at the vertebra's level. 3) OVCF older than 6 weeks. 4) Intractable back pain, with a visual analogue scale (VAS) ≥ 4. Patients were excluded if any of the following was present: 1) Concomitant neoplastic disease. 2) Neurological deficit requiring urgent open surgical decompression. 3) General contraindication to anaesthesia (untreatable coagulation disorder, local or systemic signs of infection, severe cardiopulmonary comorbidities). 4) History of open spine surgery. 5) Pedicles' maximum diameter < 5 mm.

All patients gave written informed consent before treatment and the protocol was approved by the local Ethical Committee.

Preoperative assessment:

Preoperative evaluation included clinical examination performed by the operator and an imaging workup including a Computed Tomography (CT)-scan and a spine Magnetic Resonance Imaging (MRI). Structural deformities were assessed using CT-scan before and after the procedures: Local kyphotic angle was defined as the angle between the upper and lower plates of the fractured vertebra; Anterior, middle and posterior vertebral body heights were recorded in sagittal reconstructions; minimal and maximal vertebral heights were respectively defined as the lowest and the highest of the three heights measures; A modified Beck index was utilized considering the regular Beck Index [17] would not be appropriate to assess irregular fractures. It was calculated as follows: Minimal vertebral height/Maximal vertebral height.

Baseline population characteristics are summarized in **Table 1.**

Procedures

All interventions were performed under general anaesthesia, in a hybrid angiosuite that combines a flat panel C-arm and a dedicated CT-scan (16-row) (Miyabi Emotion 16, Siemens

Healthineers). Using fluoroscopic X-ray guidance, two bevelled bone needles (Thiebaud Biomedical Devices) were directly inserted into the posterior aspect of the vertebral body via a bilateral transpedicular approach. A blunt guidewire was placed inside the vertebral body and through exchanging manoeuvre; a specifically designed drill mounted on a working cannula was advanced into the vertebral body until the desired position of the implant. The drill was then removed, leaving only the cannula in the vertebra. After preparation of both sides, the two SpineJack®, that are mounted on pre-assembled implant expanders, were inserted into the vertebral body and were gradually and simultaneously deployed by turning the expanders' handles clockwise until height restoration and kyphosis reduction were judged satisfactory. Deployment was performed under real time fluoroscopic control in order to ensure correct opening of the device and control a potential posterior wall protrusion. The implants were detached by unscrewing the quick release pin at the tip of handles. Finally, Poly-Methyl-Methacrylate (PMMA) bone cement (Biomet Bone Cement V, Zimmer Biomet) was slowly injected under real time fluoroscopy through the same working cannulae into the vertebral body and around the devices until optimal filling was obtained. At the operator's discretion, a complementary PVP could be performed at adjacent levels during the same procedure (**Figure 1.**). Complementary adjacent PVP were performed in 11 cases (57.9%) (Both vertebrae for 5 patients, upper vertebra only for 2 patients and lower vertebra only for 4 patients).

Follow-up

All patients had postoperative spine and chest control X-Rays in the operating room followed by a spine CT-scan focused on the treated level.

Significant kyphosis correction was defined as an improvement of the kyphosis of at least 30%. Procedure-related complications were systematically assessed and were divided into major (death, permanent neurological deficit or sepsis due to surgical site infection) and minor (transient neurological deficit, transient radicular pain or puncture site hematoma) complications. A systematic clinical follow-up was performed at 1 and 6 month after the intervention, evaluating pain relief and functional improvements. Patients also had an extra consultation with a new imaging workup in case of persistent pain or delayed occurrence of new symptoms.

Statistical analysis:

Data analysis was performed using EPI Info™ software 7.1.5.2 (Centers for Disease Control and Prevention). Results are presented as means ± standard deviations. Comparison of means was performed using a Student-t test or Wilcoxon test, depending on the data distribution. Results were considered statistically significant when p-values<0.05.

Results

Results are summarized in **Table 2.**

Nineteen patients were included in this study (16 women [84.2%] and 3 men [15.8%], mean age: 73.2±8.2 years [range: 50-85]). Percutaneous treatment was performed after a mean delay of 5.8±2.9 months (range: 1.5-12). Synchronous adjacent level fractures were depicted in 36.8% of cases and significant posterior wall bulging (i.e ≥ 5mm) were noted in 5 cases (26.3%).

Two patients (10.5%) were lost to the follow-up. Median VAS score significantly improved from 7 (Interquartile Range [IQR]: 6-9) to 2 (IQR: 1-5) at six month ($p<0.01$) and 57.9% of patients had improvements of their mobility, with 9 patients (47.9%) able to fully ambulate without any technical or human help. Significant kyphosis reduction was obtained in all except one case (94.7%) and the minimal vertebral height significantly improved from 9.9±2.7 mm (range: 6-18) to 15.7±2.4 mm (range: 11-19) postoperatively ($p<0.01$).

On control CT-scan, 3 patients presented minor PMMA cement venous leakages without any clinical consequence and 7 patients had intradiscal leaks (36.8%). One (5.3%) asymptomatic cement pulmonary embolism was depicted. Average volume of cement injected around the devices was 5.9±1.4 ml (range: 4-9). No worsening of posterior wall protrusions were noted.

No major procedure-related complications occurred in the immediate post-operative period. Four patients (21.1%) developed secondary adjacent level fractures (SALFs); one of them also suffered from a non adjacent fracture. All secondary fractures except one were symptomatic and none of them was responsible for any neurological impairment; they occurred between 1 and 9 months after the procedures. In this series, standard PVP was the

treatment of all symptomatic secondary fractures. For the only asymptomatic secondary fracture, a PVP was preventively carried out to ensure stability. In a subgroup analysis (**Table 3.**), the only factor that was found significantly associated with secondary adjacent level fractures was the importance of the kyphosis correction.

Discussion

This original work is the first to take specific interest in the treatment of chronic OVCFs with major structural deformities using vertebral augmentation with the SpineJack®. This method appears to be an efficient tool to correct major kyphotic angulations, even when the treatment is delayed beyond 6 weeks and may help improving pain relief. A possible limit is the high rate of SALFs that was noted in this subset of patients, which appeared to be strongly linked to the importance of the structural correction.

The best treatment option is still controversial for symptomatic OVCFs without neurological deficits. Routine minimally invasive procedures are in the middle of important controversies as some of the earliest randomized control trials (RCTs) found no benefits of PVP over sham procedure in terms of pain and functional improvements [6, 7], which was later confirmed in a large meta-analysis in 2015 [8]. However, in some of the latest randomized data such as in the VAPOUR trial [10], authors concluded that early PVP was beneficial over placebo in acute and painful OVCFs, fuelling even more controversy. Upcoming results of the VERTOS IV trial [18] are awaited and should bring new evidence and clarifications for clinical practice. Meanwhile, PVP remains commonly used in carefully selected patients [9, 19, 20]; its ability to be performed under local anaesthesia alone [21], to provide quick pain relief and vertebral stability might explain its popularity among operators. Nevertheless, PVP seems insufficient to correct major structural deformities and could even be dangerous when associated to posterior wall protrusions. In BKP, the objective is to create a strong intravertebral thrust force in order to restore vertebral height and correct pathological angulations while allowing a better control during cement injection. In the KAVIAR trial [22],

that randomized patients with acute OVCFs in PVP (n=190) versus BKP (n=191), investigators found similar clinical improvements, less cement extravasations for BKP and comparable improvements of kyphosis of approximately 3° for both techniques. These data [23] tend to confirm that during BKP, once the balloon is deflated, the thrust force decreases which prevents the vertebral body from fully reexpanding and subsequently may not provide sustainable height restoration and kyphosis correction. To ensure durable structural correction, various intravertebral devices have been developed: balloon-expandable stenting systems, vesselplasty (Vessel-X®, Spirit Spine) [24] or the KIVA® (Benvenue Medical) device [25]. The SpineJack® is a titanium made intravertebral device designed to homogeneously restore the vertebral height and correct the kyphosis. In cadaveric studies of OVCFs, height restoration was found significantly better with the SpineJack® compared to BKP [14] and required lower cement volumes to achieve vertebral stability [26]. Indeed, the SpineJack® creates a unidirectional craniocaudal thrust force focused on the points of compression whereas BKP causes an exocentric expansion. The lateral forces applied could result in unnecessary damages to the trabecular bone and limit the expansion in the craniocaudal direction. Recent observational studies showed promising results with the SpineJack®, providing simultaneously significant clinical and structural improvements [16, 27]. The series of Lin et al. [28] aimed to compare clinical and technical results of vertebral augmentation with the SpineJack® (n=36) versus standard PVP (n=39) and found that vertebral expansion with the SpineJack® seemed superior to restore vertebral height and angulations without increasing the rate of SALFs. Another series from Noriega et al. [16] compared the SpineJack® to BKP and also found better height restoration and kyphosis correction with the SpineJack®. Percutaneous vertebral augmentations are usually performed at the acute phase (i.e. ≤ 6 weeks), considering that the softness and plasticity of the bone structure in fresh

fractures may facilitate their reduction. In the literature, the positive results with the SpineJack® were mainly retrieved in acute OVCFs and to our knowledge, no study specifically focused on the treatment of symptomatic chronic OVCFs. In this series, treatment was performed after a mean delay of 5.8 months and showed that the ability to correct the structural damages was preserved in chronic OVCFs. In cases of major deformities, a persistent mobility of the vertebral fracture may delay its full consolidation, explaining why intravertebral reduction remains achievable in the chronic phase.

Four patients (21.1%) presented SALFs within 9 months after treatment. SALFs have been described to occur in the aftermath of intravertebral procedures [25], possibly favoured by the modifications of the local constraints induced by the cement and the intravertebral devices. However the responsibility of vertebral augmentation therapies in adjacent fractures is not fully elucidated as recent meta-analysis including PVP and BKP showed no strong association between percutaneous procedures and SALFs [27, 28]. Other series with the SpineJack® reported rates of adjacent fractures from 3 to 11% at one year [16, 27, 28]. Spross et al. [29] have found in a series of 375 patients treated by BKP for a single osteoporotic vertebral fracture that a kyphosis angle>30° was significantly associated with the subsequent occurrence of SALF within 6 months after intervention. Other identified risk factors for SALFs include: fracture at the thoracolumbar junction, large wedge angle and intradiscal cement leakages [30]. Patients from this series usually presented several risk factors which may have increased the rate of SALFs. Interestingly, in the SALF subgroup of our study, drastic improvements of kyphosis were obtained at the end of the procedure (84.5% versus 45.9% in the subgroup without SALF [p=0.007]). As the SpineJack® creates more important and long-lasting forces on the bone compared to BKP or standard PVP, it could also indirectly injure the adjacent vertebrae and weaken the surrounding tissues,

especially when a complete correction of the kyphosis is aimed. It is noteworthy that intradiscal leaks were not correlated to SALFs, possibly by lack of statistical power. The high rate of SALFs in our series might also be explained by the fact that only patients with major structural deformities were included, thus requiring more aggressive reduction. Operators have tried to find ways to prevent such adverse events and preventive adjacent PVP emerged as an efficient tool. In a comparative analysis of OVCFs treated by PVP, with or without preventive PVPs at adjacent levels, authors found an incidence of SALF of 30% within one year in the “nonpreventive group” versus 3% in the “preventive group” (p=0.006) [31]. In our series, preventive adjacent PVP seemed effective as out of the 11 procedures where preventive PVPs were performed, only one SALF occurred. No secondary fracture next to a preventive PVP was retrieved during the follow up. Therefore, we recommend performing PVPs at both adjacent levels in chronic and kyphotic OVCFs, when several risk factors for SALFs are present or when important correction of the kyphosis is aimed with the SpineJack®.

Patients with OVCFs usually present other intercurrent conditions and in this series, they were also eligible for various other treatments such as complementary adjacent PVP, making it difficult to draw definitive conclusions about the clinical efficacy of this treatment, especially in such a small population. The retrospective and monocentric fashion of data collection as well as the short-term follow-up are also significant limitations.

Vertebral augmentation with the SpineJack® is feasible in chronic OVCFs with major kyphosis. The main advantage lies in its ability to correct major kyphosis and restore the loss of vertebral height, even when the treatment is delayed (after 6 weeks). However, we found that an aggressive reduction of these fractures may increase the risk of SALFs, and also that complementary adjacent PVPs might be useful to prevent this adverse event. The SpineJack® being a recent device, few long-term data are available, especially concerning the sustainability of the structural restoration as well as the incidence of secondary fractures and how to predict and prevent them. These results need to be emphasized in larger series and future researches should focus on long term clinical and radiological outcomes.

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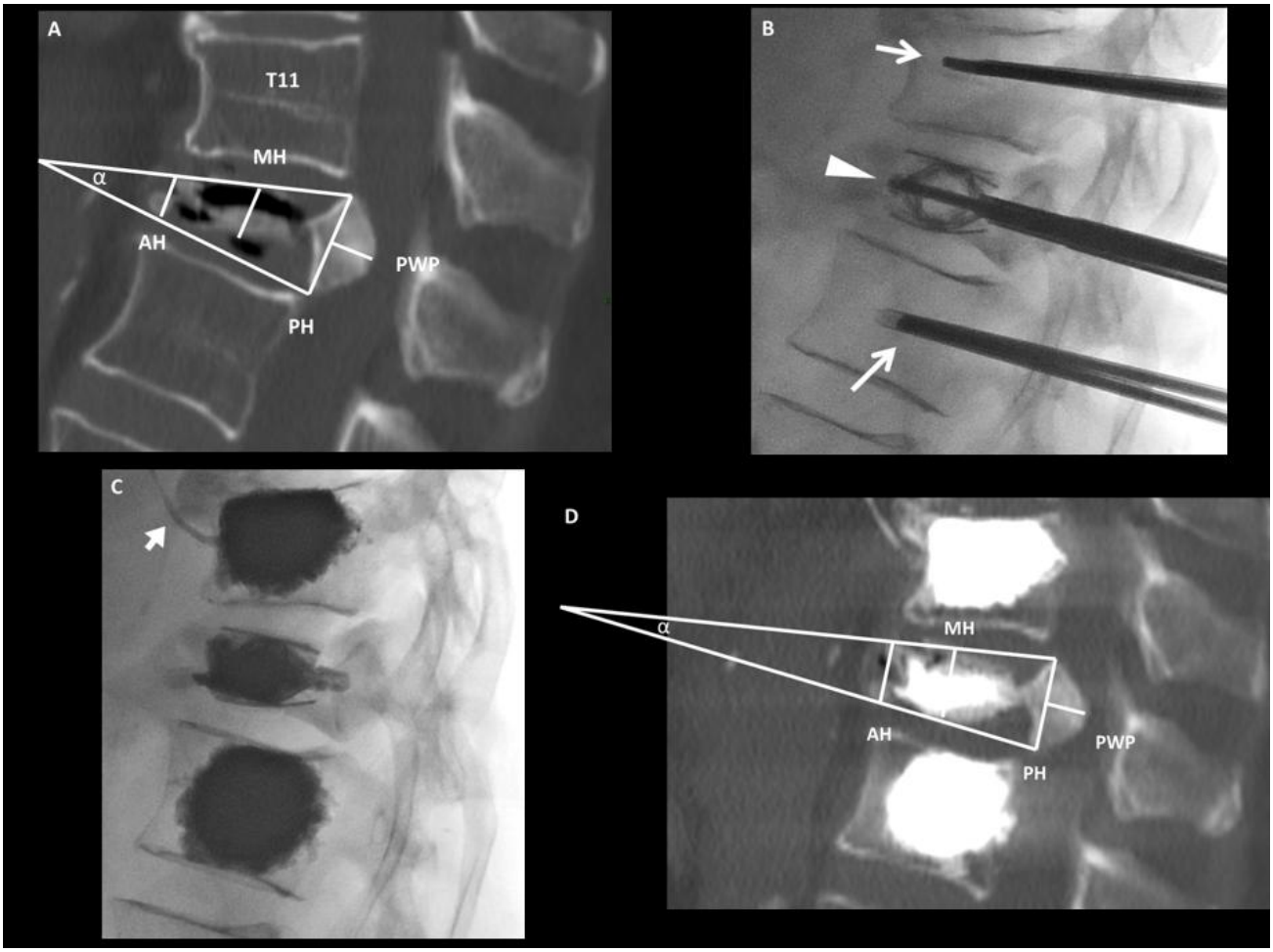
Figure and Tables legend

Figure 1.



82-year-old patient with a symptomatic T12 wedge fracture, graded Magerl A3.2, without any neurological symptom. A) Preoperative CT-scan; sagittal reconstructions: Local kyphotic angulation (α=22°) and vertebral heights were recorded (Anterior height [AH]=9mm, Middle height [MH]=10mm and Posterior height [PH]= 19mm; modified Beck index: 0.47). Note the posterior wall protrusion (PWP=8mm) into the spinal canal. B) Procedure was performed three months after the causative trauma. Perprocedural control X-rays; lateral view: Placement and deployment of two SpineJack® 4.2 into the middle aspect of the targeted vertebral body (Arrowhead). Preventive PVPs were also performed (Arrows) at the adjacent

levels. C) End procedure control X-rays; lateral view: Satsifactory reduction of the fracture is seen. Venous PMMA leak (Arrow) was depicted but remained asymptomatic. D) Post-procedural control CT-san; sagittal reconstructions: Significant correction of the kyphosis (α=13°) and restoration of the vertebral height (AH=13mm, MH=16mm and PH= 21mm; modified Beck Index: 0.62) were obtained without aggravation of the posterior wall protrusion (PWP=8mm).

Table 1. Baseline characteristics of the population

Characteristic	n (%)
Sex	16 Females (84.2%), 3 Males (15.8%)
Treated level **-T11** **-T12** **-L1** **-L2**	 1 (5.3%) 10 (52.6%) 7 (36.8%) 1 (5.3%)
Type of fracture* **-A3.1** **-A3.2** **-A3.3**	 8 (42.1%) 8 (42.1%) 3 (15.8%)
Delay before treatment **- From 1.5 to 3 months** **- More than 3 months**	 7 (36.8%) 12 (63.2%)
Posterior wall protrusion	5 (26.3%)
Simultaneous fractures **-At adjacent levels** **-At non-adjacent levels**	 7 (36.8%) 2 (10.5%)

*According to Magerl's classification [12]

Table 2. Clinical and technical results

Parameter	Preoperative	Postoperative	p-value†
Median VAS* (IQR°)	7 (6-9)	2 (1-5)	**<0.01**
Mean kyphotic angulation¤ (degree ±S.D[1])	24.4 (±4.1)	11.7 (±6.7)	**<0.01**
Mean vertebral heights (mm ±S.D)			
-Anterior aspect	11.2 (±3.1)	16.3 (±2.7)	**<0.01**
-Middle aspect	11.5 (±3.3)	17.2 (±2.7)	**<0.01**
-Posterior aspect	23.4 (±3.4)	24.2 (±3.5)	0.48
Average modified Beck Index[θ]	0.43	0.66	**<0.01**

† in bold when p-value<0.05. * VAS: Visual Analogue Scale. ° IQR: Interquartile Range. ¤ At the fractured vertebra's level. [1] S.D: Standard Deviation. [θ] Minimal vertebral height/Maximum vertebral height.

Table 3. Subgroup analysis of secondary adjacent level fractures (SALFs)

Parameter	**SALF (n=4)**	**No SALF (n=15)**	**p-value†**
Mean age (±S.D[1])	70 (±3.6)	72.3 (± 9.3)	0.514
Average delay to treatment (±S.D)	5.6 (±3.9)	5.9 (±3.1)	0.761
Intradiscal leak§ (n; %)	2; 50%	5; 33.3%	0.450
Mean cement volume (mL ±S.D)	6.8 (±1.7)	5.6 (±0.9)	0.196
Average kyphosis correction (%)	84.3%	45.9%	**0.007**
Average modified Beck index[θ] (%)			
-Preoperative	43.5%	43.3%	0.764
-Postoperative	77%	63.5%	0.05

† In bold when p-value<0.05. [1] S.D: Standard Deviation. § In the secondary adjacent level fracture (SALF) subgroup: defined as a PMMA cement leak in the disc immediately adjacent to the SALF. [θ] Minimal vertebral height/Maximum vertebral height.