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Spine Jack® System for Percutaneous Stabilization of Osteoporotic Vertebral Compression Fractures: Clinical and Radiological Results

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ABSTRACT

Background Data: Balloon kyphoplasty allows surgeons to directly reduce the fractured vertebral body using inflatable balloons. However, the reduction cannot be maintained following balloon deflation and removal. Therefore, mechanical kyphoplasty techniques were designed to avoid loss of the reduction before cement injection and restore the vertebral body indefinitely.

Study Design: A prospective cohort clinical case study.

Purpose: To assess efficacy and safety of mechanical kyphoplasty using the Spine Jack® system in treatment of osteoporotic vertebral compression fractures (VCFs) of the thoracolumbar spine.

Patients and Methods: During the period from April 2016 to March 2018, seventeen patients who sustained recent osteoporotic VCFs of the thoracolumbar spine, presenting with intractable back pain following one-month trial of conservative treatment, were included. Patients with pathological fractures, those with neurological deficits, or those medically unfit were excluded. The study included 6 males and 11 females with mean age of 60.37 years. Fractures were surgically treated using the Spine Jack® system that was inserted percutaneously through the transpedicular approach. Back pain intensity and degree of functional recovery were assessed using the Visual Analogue Scale (VAS) and the Oswestry Disability Index (ODI), respectively, whereas segmental deformity of the fractured vertebra was evaluated using standing plain X-rays and CT scan, including measurement of the local kyphotic angle and Beck Index.

Results: Patients were followed for at least 6 months (mean 7.4±1.2). At final follow-up, there was significant improvement in mean VAS score (7.3 to 2.9) and mean ODI score (61.4 to 28.7). Postoperative imaging showed significant improvements in mean Beck Index (0.68 to 0.77) and mean local kyphotic angle (21.4° to 14.3°). Cement leakage was noted in 2 patients (11.7%) with no clinical relevance. None of the patients developed neurological deterioration, adjacent fracture, or hardware-related complication during the follow-up.

Conclusion: Percutaneous stabilization of osteoporotic VCFs of the thoracolumbar spine using the Spine Jack® system is effective and safe even with posterior wall involvement, with significantly better outcome in terms of pain relief, functional recovery, and vertebral body restoration. (2019ESJ182)

Keywords: Vertebral compression fractures, Spine Jack®, Mechanical kyphoplasty

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INTRODUCTION

Osteoporosis is a common systemic skeletal disease characterized by reduced bone mass and architectural deterioration of the bone that lead to increased fragility of bone and susceptibility to fracture. Osteoporotic VCFs represent the most common fragility fracture seen in the elderly and are considered by some as the hallmark of osteoporosis.[10] These fractures are often associated with physical activity (lifting an object and binding). However, they can develop spontaneously, whereas, in people with healthy bone, VCFs require a more significant mechanism of trauma like traffic accidents or hard falls to develop.[19] Pain is the usual presentation of osteoporotic VCFs. However, patients can present with a decline in physical performance, back deformity, impaired mobility, and pulmonary dysfunction with subsequent adverse effects on activities of the daily living.[24]

Conservative treatment was considered the standard primary treatment for most osteoporotic VCFs. However, this option may become poorly tolerated in patients with refractory pain or medical comorbidities. In this setting, minimally invasive vertebral augmentation techniques like vertebroplasty and balloon kyphoplasty are well-established alternates for treating painful osteoporotic VCFs.[17] While vertebroplasty is principally applied for fracture stabilization without the aim of direct correction of vertebral deformity, balloon kyphoplasty was evolved for better restoration of vertebral height and realignment.[21] However, loss of the achieved initial reduction after balloon deflation led researchers to look for a technique able to maintain the initial reduction until bone cement can be delivered. Therefore, mechanical kyphoplasty utilizing intravertebral metallic implants has been introduced.[28]

Spine Jack® system is a titanium vertebral augmentation device used for mechanical kyphoplasty. For almost ten years, this device has provided a further option for treatment of osteoporotic VCFs.[18] The purpose of the present study was to evaluate efficacy and safety of Spine Jack® system in minimally invasive percutaneous stabilization of osteoporotic VCFs of the thoracolumbar spine.

PATIENTS & METHODS

The present study was conducted in the period between April 2016 and March 2018 and was comprised of 17 adult patients with mean age of 60.37±3.83 years (range, 53–68). Patients who sustained recent thoracolumbar osteoporotic VCFs (AO/Magerl types A1.2, A1.3, and A3.1)[14] and presenting with intractable back pain refractory to one-month trial of conservative treatment were included. We excluded patients with fractures related to metastatic or hematological disorders, patients with neurological deficits, and medically unfit patients. The study proposal was approved by the medical committee of the authors' hospital, and a written informed consent form was signed by eligible patients before surgery. Fractures were surgically reduced using two expandable titanium implants (Spine Jack®, Vexim, France) inserted percutaneously into the fractured vertebral body through the transpedicular approach, followed by injection of the supplemented high viscosity PMMA bone cement into the deployed implants to keep the reduction.

Postoperatively, patients were allowed for ambulation while wearing a thoracolumbar brace for a few days for support. All patients were followed up for a minimum of 6 months. Clinical evaluation included measurement of pain intensity on the ten-point Visual Analogue Scale (VAS) and measurement of the functional recovery based on the activity level on the Oswestry Disability Index (ODI).[5] Radiological evaluation of the segmental deformity of the fractured vertebra was performed using standing plain radiographs and included measurement of the local kyphotic angle (angle between the base plate and the cover plate of the fractured vertebra) and measurement

of the Beck Index, that is, the ratio between anterior and posterior vertebral heights (AVH/PVH) for wedge/crush type fractures or the ratio between middle and posterior vertebral heights for biconcave fractures (MVH/PVH).[13]

Clinical and radiological evaluations were carried out preoperatively, 2 days postoperatively, at 3 months, and at final follow-up visit. CT scan, including reconstruction images, was used preoperatively to verify a pedicle diameter ≥5.8 mm to accommodate the Spine Jack® instrumentation and during follow-up to look for position of implants or presence of cement leakage. Bone mineral density (BMD) of the thoracolumbar spine was measured in all patients using DEXA (dual energy X-ray absorptiometry) scan, and, according to the WHO classification, T-scores <-2.5 were considered diagnostic for osteoporosis.[12] Preoperative magnetic resonance imaging (MRI) was performed in selected cases to verify the fracture edema correlating with recent fractures. Chi-square test was used for comparisons of binomial variables, while Wilcoxon's signed-rank test was used for preoperative to postoperative comparisons of continuous variables. The difference was considered significant if $P<0.05$.

Surgical Technique

The percutaneous transpedicular approach was used to insert the Spine Jack® implant. Patients underwent operation in prone position over a spinal frame and under general anesthesia. The fracture level was identified and the entry points overlying the pedicles were localized using a biplane fluoroscopic guidance. Two stab skin incisions were made just lateral to the pedicles of the fractured vertebra. Using two cannulated needles, two guide wires were inserted into the pedicles of the fractured vertebra, followed by reaming of the pathway through the pedicle and the vertebral body below the most caudal part of the collapse to attain a space suitable for insertion of the implant. The final position of the implant was simulated by a template and was controlled under fluoroscopy. With the aid of an implant delivery system, the template was replaced with the appropriate implant (available in three sizes) into the vertebral body. Another mechanical working system was used to open the implant gradually in the craniocaudal direction, till achieving the desired reduction. After opening the implant, high viscosity PMMA bone cement was injected inside the implant and spread into the vertebral body to stabilize the reduction.

RESULTS

The study included 6 males (35.2%) and 11 females (64.7%) with mean ages of 58.16±3.49 and 65.87±2.17 years, respectively. Statistical analysis showed a significant difference of the average age according to gender ($P<0.05$). Fractures were predominantly located around the thoracolumbar junction and distributed from T7 to L3. The overall mean duration of fractures was 6.4±0.72 (range, 5–8) weeks. Distribution of fracture according to Magerl classification was as follows: type A1.2 in 7 patients (33.32%), type A1.3 in 9 patients (42.8%), and type A3.1 in 5 patients (23.8%). Fractures were due to minor trauma in 10 patients (58.8%) and due to high-energy trauma in 4 patients (23.5%), but, in 3 patients (17.6%), the exact mechanism was unknown. The average bone mineral density T-score of the thoracolumbar spine was -2.72±0.21 (range, -2.56 to -4.2) in males and -3.93±1.28 (range, -2.9 to -5.1) in females (Table 1). Most patients (76.4%) were operated within 3 days of admission. The procedure was performed on a single vertebral body in 13 patients (76.4%) and on two vertebral bodies in 4 patients (23.4%). A total of 12 lumbar and 9 thoracic vertebrae were stabilized using the Spine Jack® system supplemented with PMMA bone cement as mentioned above. The mean amount of injected cement per level was 4.7 ml (range, 4–7).

All procedures were performed without any technical difficulties or intraoperative complications related to the Spine Jack® system. The mean operative time was 57 ± 4.58 minutes (range,

45–75 min), and the mean hospital stay length was 5.3±1.1 (range, 3–7) days. Postoperatively, patients were followed on outpatient basis, with mean follow-up duration of 7.4±1.2 (range, 6–12) months. Clinical evaluation revealed statistically significant improvement of the average VAS and ODI scores at final follow-up. The mean VAS scores decreased from 7.3±1.2 before surgery to 3.8±0.46 two days after surgery, to 3.3±0.17 at 3 months, and to 2.9±0.83 at final follow-up ($P<0.05$). The mean ODI also improved from 61.4±5.1 before surgery to 39.6±1.1 two days after surgery, to 31.7±1.4 at 3 months, and to 28.7±1.3 at final follow-up, which represented a statistically significant improvement in activity level and quality of life ($P<0.01$). Similarly, radiological evaluation demonstrated statistically significant improvement of the average Beck Index from a preoperative value of 0.68±0.12 to a postoperative value of 0.79±0.06 ($P<0.05$), then changed to 0.78±0.08 at 3 months, and to 0.77±0.05 at final evaluation. The average local kyphotic angle changed from 21.4± 3.7° (range, 18–25°) before surgery to 13.3±1.4° postoperatively ($P<0.05$), to 13.7±1.6° after 3 months, and to 14.3±1.8° at final evaluation (Table 2). Final radiological evaluation revealed minimal loss of the achieved initial reduction. However, the differences between postoperative and final assessments of Beck Index and local kyphotic angle were statistically nonsignificant.

Postoperative CT scans showed reasonable positioning of the implant-cement complex within the vertebral bodies with no changes in the position of the posterior vertebral wall. Cement leakage was seen in 2 cases (11.7%), but was limited to the paravertebral soft tissue, and without any clinical sequelae. During follow-up, none of patients developed complications such as neurological deterioration, adjacent fractures, wound problems, or pulmonary embolism.

Table 1. Preoperative demographic data.

Parameters		Value
Gender	Male	6 (35.2%)
	Female	11 (64.7%)
Age	Male	58.16±1.49 (53–60)
	Female	65.07±2.17 (63–68)
	Overall	60.37±3.83 (53–68)
Mechanism of injury	Minor trauma	10 (58.8%)
	High-energy trauma	4 (23.5%)
	Unknown	3 (17.6%)
Level of fracture	T7-T11	4 (19%)
	T12-L1	13 (61.9%)
	L1-L3	4 (19%)
	Total	21 (100%)
AO/Magerl classification	A.1.2	7 (33.3%)
	A.1.3	9 (42.8%)
	A.3.1	5 (23.8%)
T-score	Male	-2.72±0.21 (-2.5–-4.2)
	Female	-3.93±1.28 (-2.9–-5.1)

Table 2. Mean changes of clinical and radiological parameters.

Parameters	Preoperative	2 days postop	3 months postop	Final	P value
VAS	7.3±1.2	3.8±0.46	3.3±0.17	2.9±0.83	< 0.05#
ODI	61.4±5.1	39.6±1.1	31.7±0.4	28.7±1.3	< 0.01#
Beck Index	0.68±0.12	0.79±0.06	0.78±0.08	0.77±0.05	< 0.05*
Local kyphotic angle	21.4±3.7°	13.3±1.4°	13.7±1.6°	14.3±1.8°	< 0.05*

P #: postoperative compared with final value; **P***: preoperative compared with postoperative value.

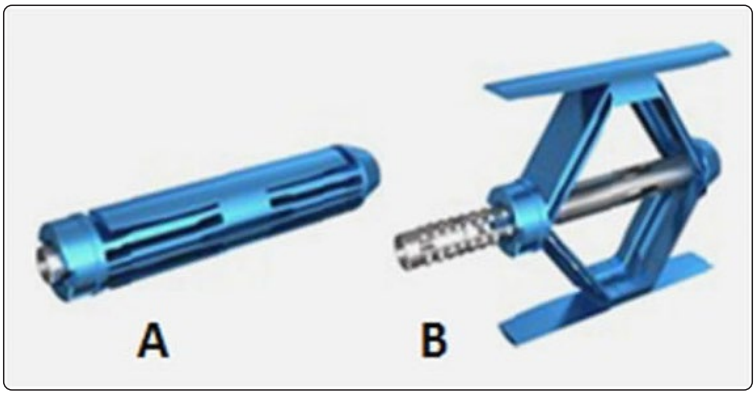

Figure 1. Spine Jack® implant: closed (A) and expanded (B).

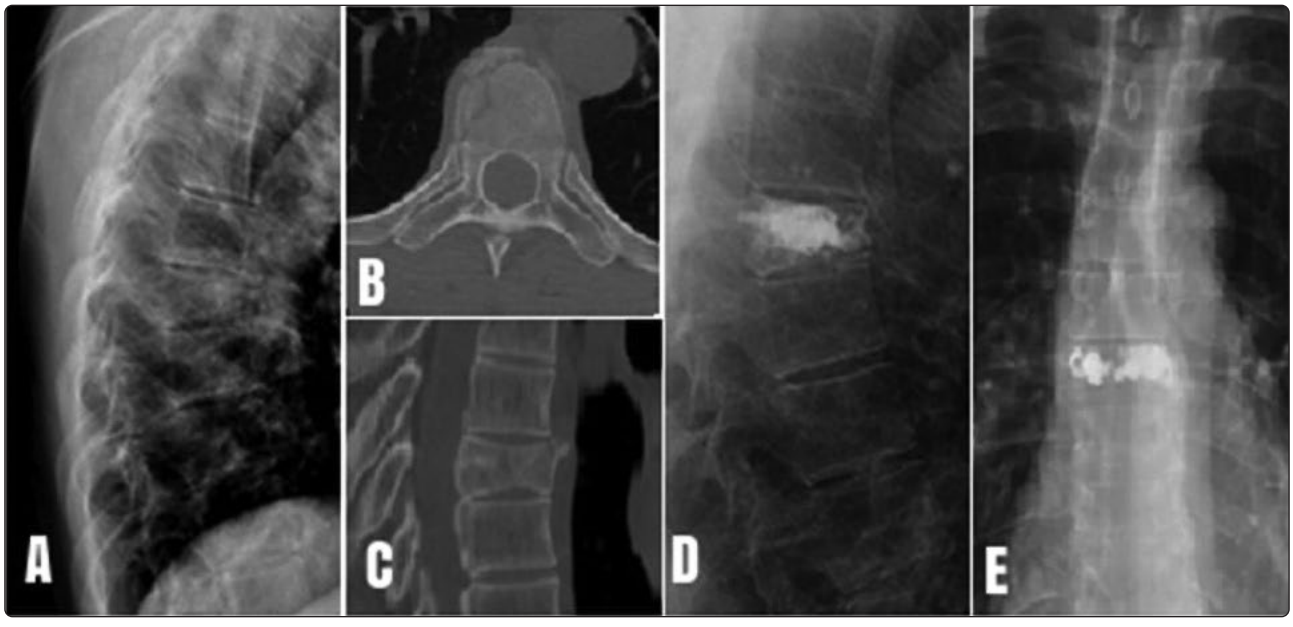

Figure 2: A 53-year-old male presenting with back pain after a trivial fall (VAS 7). Lateral radiograph (A) demonstrated **T** 7 vertebral compression fracture (type A1.3). Axial (B) and sagittal (C) CT scans demonstrate fracture of the upper and lower endplates with kyphotic deformity. Lateral (D) and anteroposterior radiographs (E) after 8 months showing adequate fusion and alignment.

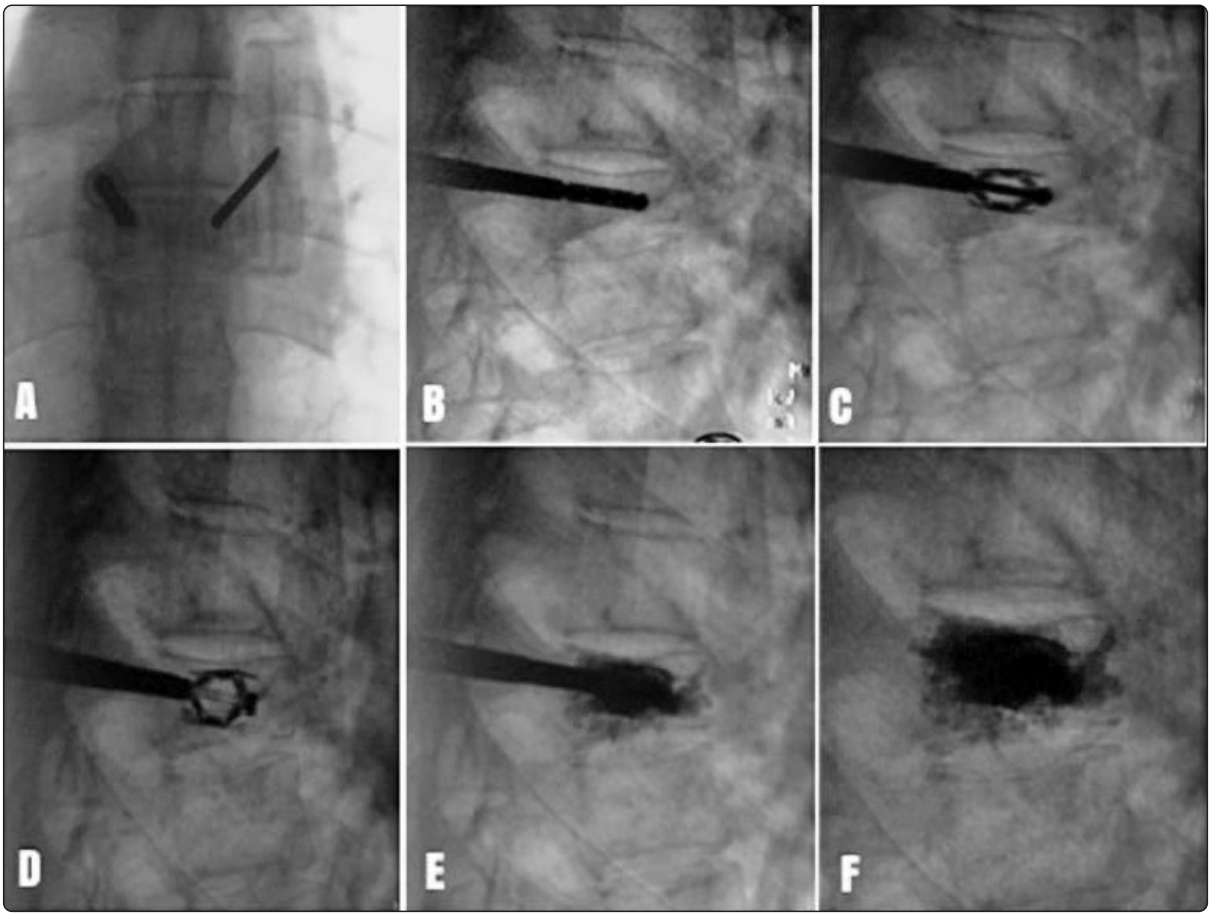

Figure 3. Intraoperative radiographs of the same patient showing localization of pedicles (A), insertion of Spine Jack® implant (B), expansion of the implant (C-D), injection of bone cement after fracture reduction (E), and final lateral view (F).

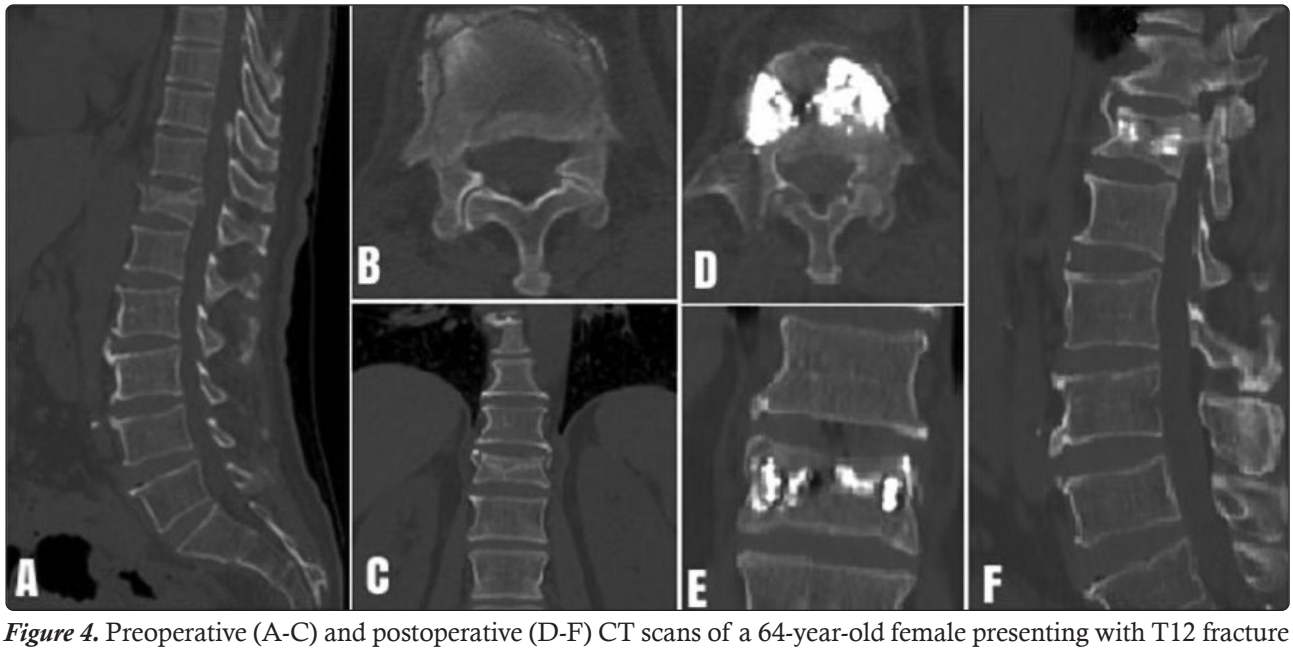

Figure 4. Preoperative (A-C) and postoperative (D-F) CT scans of a 64-year-old female presenting with T12 fracture (type A3.1) following a minor traffic accident.

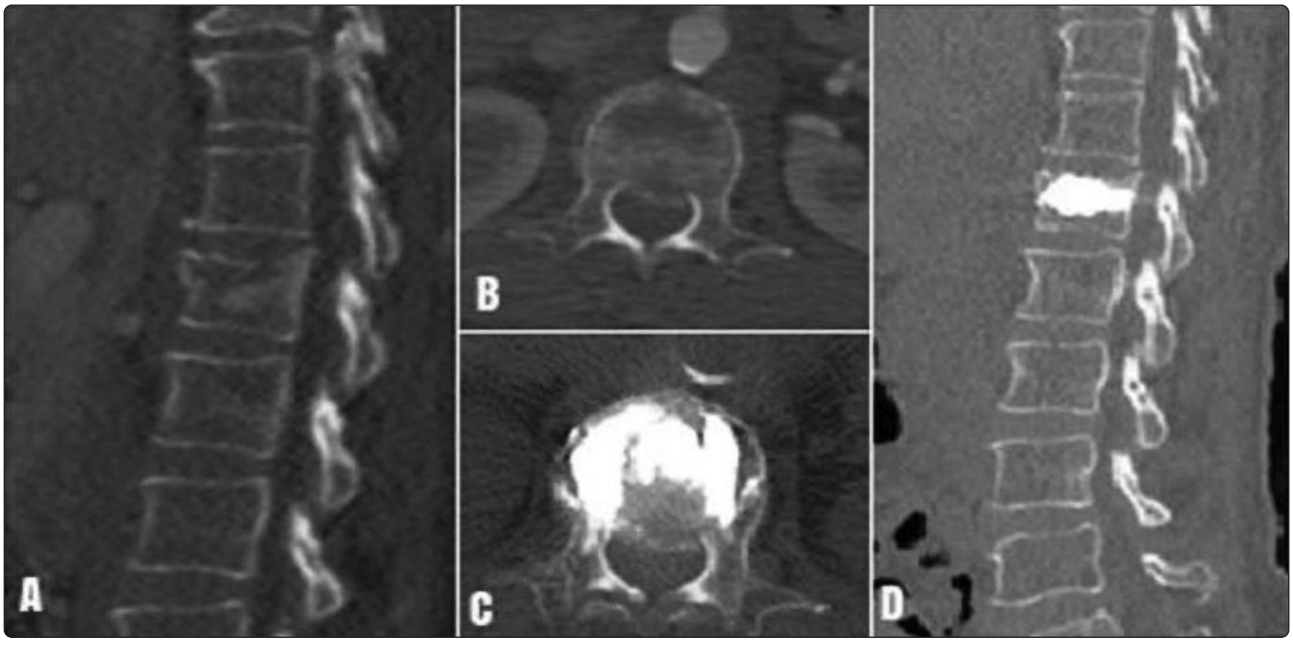

Figure 5. Preoperative (A-B) and postoperative (C-D) CT scans of L1 fracture.

DISCUSSION

Osteoporotic VCFs are considered a leading cause of morbidity and disability in the elderly and linked with a higher mortality rate than in general population.[2] These fractures are more usual in females and affect about 25% of postmenopausal women due to postmenopausal osteoporosis, whereas its prevalence is less frequent in elderly men.[16] Gheita et al. reported that the prevalence of osteoporosis in Egypt was 28.4% in women and 21.9% in men, while 54% of women and 26% of men had osteopenia. Moreover, the prevalence of osteoporosis was higher in rural areas of Upper Egypt and reached 47.8% among postmenopausal women.[6]

Heini et al.[8] reported that the incidence of osteoporotic VCFs is underreported, with nearly one-third of the cases becoming a focus of clinical attention, and most of them (84%) are detected incidentally during workup for back pain. The low rate of clinical diagnosis could be related to the lack of a traumatic event and misinterpretation of symptoms as muscle sprain.[27] In the present study, females represented 64.7% of the study group, with mean age of 65.07±2.17 years versus 58.16±1.49 years in males. Most osteoporotic VCFs (70%) are type A compression fracture, particularly type A1 according to AO/Magerl classification, and often develop at the thoracolumbar junction or the mid-thoracic region where mechanical stress and compression loads are higher, resulting in vertebral body collapse or progression to vertebra plana if untreated.[22] Furthermore, the progressive kyphosis at this location increases the risk for adjacent level fractures (domino effect) secondary to weight shift and anterior column overload.[24] Most fractures (76.1%) in the present study were type A1 fractures and located mainly around the thoracolumbar junction (61.9%). Lumbar location was noted in 57.1% of patients versus 42.8% for thoracic location, which is in agreement with previous publication reported lumbar location as the most common location of osteoporotic VCFs compared to thoracic location.[9]

Treatment of osteoporotic VCFs ranges from conservative treatment to invasive surgical procedures. Conservative treatment entails bed rest for 4–6 weeks, pain medications, antiosteoporosis therapy, and bracing in erect position for additional 6–12 weeks. Although conservative treatment avoids surgical risks and achieves fair results in almost two-thirds of patients, it may become

poorly tolerated in elderly patients with refractory pain or medical problems. Moreover, in patients with kyphotic deformity, conservative treatment cannot stop the domino effect in adjacent levels.[23] In the past, operative treatment was limited to open stabilization procedures. However, these procedures were associated with significant postoperative morbidity and high failure rates especially in the elderly.[29] Therefore, minimally invasive vertebral augmentation procedures (vertebroplasty/kyphoplasty) using PMMA bone cement were introduced and achieved great success over the last few decades, with the advantage of being fast and performed percutaneously.[25] Vertebroplasty can decrease pain effectively and allow early mobilization because it limits the micromotion between fracture fragments that generate pain. However, it does not allow vertebral height recovery or stops the possible domino effect (0–8%) due to the altered spine biomechanics.[15] Because of that, it has been limited to fractures with height loss <30%. Furthermore, the low-viscosity bone cement used in vertebroplasty needs to be injected at a high pressure, increasing the risk of uncontrolled cement leakage (19–70%) beyond the bony confines.[26] Balloon kyphoplasty was then introduced to improve patient safety during augmentation procedure, and involved inflation of balloon catheter inside the collapsed vertebral body to restore the vertebral body height before injecting the high viscosity cement at a low pressure.[30] Although balloon kyphoplasty can minimize the likelihood of cement leakage, recovery of the vertebral height may be transient with partial or total body recollapse after balloon deflation and removal and before injection of bone cement.[3]

Recently, minimally invasive techniques of mechanical kyphoplasty, utilizing intravertebral metallic implants, have been proposed to inhibit the loss of height restoration before injection of bone cement. These techniques are widely used today for treatment of osteoporotic VCFs because it can restore the vertebral body indefinitely and stabilize the fracture via injection of high viscosity bone cement with minimal risk of cement leakage.[28] In the present study, we used the Spine Jack® system which consists of bilateral expandable titanium implant, supplemented with high viscosity PMMA bone cement. The implant is inserted into the fractured vertebral body through a bilateral transpedicular approach and is accompanied by a mechanical working system that allows a gradual controlled reduction of the fracture through distraction. After vertebral body height restoration, PMMA bone cement is injected to stabilize the reduction.[18]

In the present study, pain scores (VAS) improved from 7.3 before surgery to 2.9 at final follow-up (60.2% decrease in mean VAS score). Improvement in disability was obtained accordingly. The ODI scores decreased from 61.4 preoperatively to 28.7 at the final visit (53.2% decrease in mean ODI score). Ostelo et al. reported that a minimum 30% reduction of pain from the baseline can be considered significant clinical improvement.[20]

Radiological assessment showed notable and maintained correction of the kyphotic deformity following the procedure as well. Immediate reduction of the average local kyphotic angle of 8.1° was observed 2 days after surgery (21.4±3.7° preoperatively versus 13.3±1.4° postoperatively). The reduction rate is comparable to the rate reported by Noriega et al.[18] (5.4°±6.3°) in a multicenter clinical series consisting of 22 patients with osteoporotic VCFs who were treated with the Spine Jack device (14.5° preoperatively versus 9.2° postoperatively; P< 0.001), and it was similar to the rate reported by Baeesa et al.[1] (8.21°) in a study comprising 19 patients with osteoporotic VCFs of the thoracolumbar spine who were subjected to percutaneous reduction using Spine Jack® device (13.7° preoperatively versus 5.5° postoperatively; P<0,001). Minimal secondary loss of height was observed at 3 months and at final assessment. However, the final reduction rate remained statistically significant compared to preoperative values.

Krüger et al.[11] evaluated vertebral body restoration following percutaneous augmentation of 24

osteoporotic VCFs using two different procedures: balloon kyphoplasty (n=12) and Spine Jack® augmentation (n=12). The Beck indices were 0.0±0.06 and 0.1± 0.06 following balloon kyphoplasty and Spine Jack augmentation, respectively, with the values for the Spine Jack® group being significantly greater ($p < 0.05$). The study demonstrated that height restoration was significantly better when using Spine Jack® than balloon kyphoplasty because the Spine Jack® implant can direct the force needed to reduce the fracture only in the craniocaudal direction, which resembles a theoretical advantage over balloon kyphoplasty where the direction of force varies according to the individual vertebral anatomy.

In the present study, small amounts of PMMA bone cement (mean, 4.7 mL) were applied to the existing cavity made by the Spine Jack® implant. Cement leakage was diagnosed in 2 patients (11.7%) by CT scan. This rate of cement leakage is low compared to leakage rates shown in previous publications on vertebroplasty[4] and is comparable to the mean rate reported for kyphoplasty.[31] CT scan is a more sensitive method than plain radiographs in identifying cement leakage. Dohm et al.[7] reported a high cement leakage rate identified on CT scans of 82% and 73% for vertebroplasty and balloon kyphoplasty, respectively.[4] Giannitsios et al. found a correlation between viscosity of bone cement and rate of leakage in their study on vertebroplasty and clearly defined cement viscosity as a key parameter influencing leakage risk and the final outcome.

Review of literature revealed that the risk of developing adjacent level fracture is around 0–8% and 19–25% following vertebroplasty and balloon kyphoplasty, respectively.[22,24] None of our patients developed adjacent fractures during follow-up period which could be explained by the lower average age of our patients (60.37 years) relative to the ages in most studies about osteoporotic VCFs. Limitations of the present study were the small sample size, the short follow-up period, and the absence of control group which could affect adequacy of the statistical power. Future studies using larger cohorts, longer follow-up periods, and more objective tools for biomechanical evaluation of vertebral reduction are recommended to define the possible advantages of this technique.

CONCLUSION

Our results have demonstrated that minimally invasive stabilization of osteoporotic VCFs utilizing the Spine Jack® system can achieve safe and effective vertebral body restoration. The procedure allowed rapid and significant pain relief and maintained improvement in disability. Furthermore, the achieved biomechanical restoration could inhibit the domino effect and limit the development of adjacent fractures.

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الملخص العربي

استخدام رافعة الفقرة عبر الجلد لعلاج كسور الهشاشة المنضغطة بالفقرات الصدرية القطنية: تقييم النتائج السريرية والإشعاعية

البيانات الخلفية: استعدال تحدب الفقرات الناتج عن كسور الهشاشة المنضغطة باستخدام البالون يقلل من درجة تحدب الفقرة إلى حد كبير، ومع ذلك لا يمكن الحفاظ على هذه الدرجة بعد إزالة البالون أثناء الجراحة قبيل حقن الأسمنت العظمى، لذلك فقد تم تصميم تقنيات جديدة لتجنب فقدان الاستعدال قبل حقن الأسمنت العظمى إلى جسم الفقرات المكسورة.

تصميم الدراسة: دراسة الحالة السريرية بأثر مستقبلي.

الغرض: تقييم مدى فعالية وأمان استخدام رافعة الفقرة لعلاج كسور الهشاشة المنضغطة بالفقرات الصدرية القطنية.

المرضى والطرق: خلال الفترة من أبريل 2016 إلى مارس 2018 ، تم دراسة الحالة السريرية لسبعة عشر مريضا كانوا يعانون من كسور هشاشة منضغطة بالفقرات الصدرية القطنية ومصحوبة بآلام بالظهر لم تتحسن بعد شهر على الأقل من العلاج التحفظي. تم استبعاد المرضى الذين يعانون من كسور مرضية أو عجز عصبي أو غير لائقين طبيا. شملت الدراسة 6 ذكور و11 أنثى بمتوسط عمر 60.37 سنة. عولجت الكسور جراحياً باستخدام رافعة الفقرة والتي تم إدخالها لجسم الفقرة المكسورة عبر الجلد عن طريق عنييق الفقرة. تم تقييم شدة ألم الظهر ودرجة الشفاء الوظيفي للمرضى قبل وبعد الجراحة باستخدام المقياس البصري التماثلي ومؤشر أوسوسترى للإعاقة على التوالي، في حين تم تقييم التشوه القطاعي للفقرات المكسورة باستخدام الأشعة السينية والأشعة المقطعية وشمل قياس زاوية التحدب المحلية وقياس مؤشر بيك للفقرات المكسورة.

النتائج: تم متابعة المرضى لمدة 6 أشهر على الأقل بعد الجراحة. في المتابعة النهائية، كان هناك تحسن كبير في متوسط درجة الألم من درجة 7.3 إلى درجة 2.9 على المقياس البصري التماثلي، وتحسن لمتوسط الحالة الوظيفية من 61.4 إلى 28.7 على مؤشر أوسوسترى للإعاقة. أظهر التصوير الإشعاعي بعد الجراحة تحسن في متوسط مؤشر بيك من 0.68 إلى 0.77، وكذلك تحسن في متوسط زاوية التحدب المحلية من 21.4 درجة قبل الجراحة إلى 14.3 درجة أثناء المتابعة النهائية. لوحظ وجود تسرب للأسمنت العظمى في عدد 2 من المرضى (11.7 ٪) ولكن بدون مضاعفات سريرية. لم يصاب أي من المرضى بتدهور عصبي أو كسر مجاور أو مضاعفات متعلقة برافعة الفقرة أثناء فترة المتابعة.

الاستنتاج: استخدام رافعة الفقرة عبر الجلد طريقة فعالة وآمنة لعلاج كسور الهشاشة المنضغطة بالفقرات الصدرية القطنية حتى مع وجود كسر بالجدار الخلفي لجسم الفقرة. أظهرت النتائج السريرية فاعلية هذه الطريقة في تخفيف آلام الظهر وتحسن في الحالة الوظيفية لهؤلاء المرضى بعد الجراحة، مع الحصول على درجة استعدال جيدة لتحدب الفقرات المكسورة.