Observational Study

A Comparative Analysis of Single versus Double Intravertebral Reduction Device Implantation for Single-Level Osteoporotic Vertebral Fractures: Radiological and Clinical Outcomes

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Background: Intravertebral reduction devices have been used for treating osteoporotic vertebral fractures (OVFs), with the advantage of fracture reduction before cement injection and the potential to prevent the secondary loss of vertebral height. While double devices via bipedicle insertion are commonly recommended, there is currently no report on the safety and efficacy of using a single device to treat OVFs.

Objective: This study aims to compare the radiological and clinical outcomes of single intravertebral reduction device implantation to those of double intravertebral reduction device implantation in the treatment of single-level OVFs.

Study Design: Observational cohort study.

Setting: The study was conducted at a tertiary medical center. Data were collected by reviewing the electronic medical records of a consecutive series of individuals from January 2015 to December 2020.

Methods: Patients with single-level OVFs between T8 and L4 who underwent single (n = 27) or double (n = 56) intravertebral device implantation were included in the study and analyzed. Outcome measures included radiographic assessments and the evaluation of clinical outcomes. Multiple linear regression analysis was used to examine the associations among the number of implants, body mass index (BMI), bone mineral density, and presence of radiographic vacuum clefts on vertebral height correction.

Results: Both the single- and double-device groups demonstrated significant improvements in fracture reduction and functional outcomes. The single-device group had a shorter operating time (36.0 ± 2.82 min vs. 62.92 ± 16.49 min, $P = 0.012$) and lower cement volume usage (3.60 ± 0.00 mL vs. 5.04 ± 1.56 mL, $P = 0.032$).

However, the double-device group showed greater improvement in anterior vertebral height (7.02 ± 3.34 mm, 95% CI: 6.13–7.91 vs. 5.24 ± 3.94 mm, 95% CI: 3.68–6.80, p = 0.034) and regional kyphotic angle correction (6.79 ± 6.50°, 95% CI: 4.83–8.75 vs. 2.79 ± 6.79°, 95% CI: 0.10–5.48, $P = 0.011$). Despite these radiological differences, long-term functional outcomes at the last follow-up were comparable between groups. There were no significant differences in complication rates between the 2 groups. Higher BMI and the presence of an intravertebral vacuum cleft appeared as potential risk factors for the re-collapse of vertebral body height.

Limitations: This study is retrospective and has inherent limitations related to sample size and variability. Some measurements showed a high degree of variability, which could have led to overlapping confidence intervals and a potential risk of Type II errors.

Conclusion: Single intravertebral reduction device implantation is an effective and safe treatment option for OVFs, yielding clinical outcomes comparable to those of double device implantation. Additionally, certain risk factors, such as higher BMI and the presence of an intravertebral vacuum

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cleft, should be evaluated carefully, since they may contribute to vertebral height re-collapse following expandable device augmentation. However, prospective randomized controlled trials are still warranted to further evaluate the efficacy of single versus double device implantation.

Key words: Osteoporotic fracture, spinal fractures, kyphoplasty, intravertebral device, uni-pedicle approach, vertebral height, kyphotic angle, coronal angle

Ethical Review Committee Statement: This study obtained institutional review board approval from National Cheng Kung University Hospital, Tainan, Taiwan (No. A-ER-112-289)

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Osteoporosis poses a significant health concern, since it is strongly associated with the loss of bone density, increasing the risk of fractures, particularly in the spine. Osteoporotic vertebral fractures (OVF) occur in 30% to 50% of people over the age of 50 and are more prevalent in women (1,2). The incidence of OVF is increasing worldwide due to the aging global population (3). These fractures impact patients' quality of life significantly and can lead to numerous complications (4). Although conservative management, including bed rest, pain medication, and back brace protection, is typically sufficient for most OVF cases, such treatment may fail, thus requiring certain patients to receive surgical intervention (5). Vertebral augmentation procedures, such as vertebroplasty and balloon kyphoplasty, have emerged as surgical treatment options aimed at restoring stability promptly in cases of vertebral fractures. These minimally invasive procedures not only alleviate pain but also improve the overall quality of life, potentially reducing mortality rates, especially for frail elderly patients (4).

Intravertebral reduction devices have been used for vertebral augmentation, with the advantage of fracture reduction before cement injection and the potential to prevent the secondary loss of vertebral height (8). The Spinejack® (SJ®), a titanium implantable vertebral augmentation device, has been used widely since 2012. The efficacy of the device in restoring and maintaining vertebral body height restoration has been proven by biomechanical studies (7,8). Clinical studies have also confirmed the ability of SJ® treatment to restore vertebral height and improve clinical outcomes (5,9,10).

In the surgical guidance for the administration of the SJ®, the use of double devices through bipedicle insertion is generally recommended. However, due to differences in national conditions and health care insurance systems, patients in our country may opt for a single SJ® for surgery based on economic considerations. Although this choice constitutes off-label use, our team has observed that patients who undergo surgery with a single SJ® appear to achieve favorable postoperative clinical, surgical, and radiographic outcomes. This observation has led us to collect past cases to conduct a head-to-head comparison between single and double SJ® implantation. Additionally, single pedicle insertion may offer potential benefits, including shorter operation times, simpler surgical procedures, and lower costs. Currently, there is a lack of literature exploring the use of a single SJ® for osteoporotic vertebral fractures (OVF). To address this gap, our study aims to determine whether there are significant differences in clinical and radiographic outcomes between single and double SJ® implantation. Because this study is retrospective, selection bias will be addressed by analyzing the demographic data of both the single-device and the double-device groups.

Methods

Patients and Study Design

After obtaining approval from the institutional review board of our hospital, we conducted a retrospective cohort study on patients with osteoporotic thoracolumbar fractures treated at a tertiary medical center. Data were collected by reviewing the electronic

medical records of a consecutive series of individuals from January 2015 to December 2020. The inclusion criteria were as follows: 1) the patient was at least 50 years old, 2) a single-level acute OVF was present between T8 and L4, as confirmed by plain radiography, 3) the fracture's existence had additional confirmation through imaging modalities such as magnetic resonance imaging, computed tomography (CT) , or bone scan, 4) conservative treatment had failed after more than 14 days, and 5) the patient had been treated with either a single or double SJ® device within 3 months of the fracture's occurrence. At our hospital, the standard clinical practice for intravertebral augmentation devices recommends the use of double devices for all patients in accordance with surgical manual guidelines, except in cases in which financial considerations influence the decision. Patients were excluded if they had a history of prior spine fractures or spinal implantation adjacent to the target vertebra, had experienced high-energy trauma, or had pathological fractures such as those caused by tumors or infections. The procedures were performed by 3 highly skilled spine surgeons, all certified by the national spine association, the Taiwan Spine Society. The experimental design is illustrated in Fig. 1, and the follow-up timeline is shown in Fig. 2. We hereby declare that this study has not received any commercial sponsorship or funding. Additionally, the authors have no conflicts of interest related to the content of this article.

Surgical Techniques

Patients were positioned prone on a Jackson table for the procedure, and general anesthesia was administered. After aseptic preparation, a cannula was inserted through the pedicle under fluoroscopic guidance, and a guide wire was threaded into the vertebral body. A reamer was then used to create space for the final device, and a template was employed to prepare the implant site and confirm the appropriate implant length. An unexpanded SJ® was guided into the vertebral body along the guide wire.

For single SJ® implantation, the side of approach was determined by the surgeon based on preference, with the goal of positioning the augmentation device in the midline of the vertebra. For double SJ® implantation, the procedure was performed on both sides to ensure symmetrical placement. Once the optimal positions of the implants were confirmed, the SJs® were expanded to restore the height of the vertebral body, and bone cement was injected to stabilize the fracture. The sequential fluoroscopy images of the single SJ® procedure are shown in Fig. 3.

Following surgery, patients were advised to lie flat for 2 hours and to wear a back brace for one month.

The Collection of Patients' Clinical and Radiological Data

Patient information, including demographics, comorbidities, level of fracture, hospital stay, and complications, was recorded. We classified these OVFs according to the OF system (12). Therapeutic outcomes were measured by pain and functional scales. Pain intensity was assessed with a visual analog scale (VAS) ranging from 0 to 10 points. Functional outcomes were measured using the Oswestry Disability Index (ODI). Patients completed both the VAS and ODI questionnaires at each time point.

Imaging Parameters Assessment

The following measurements were obtained through manual measurement on standing radiographs: anterior vertebral body height (AVH), middle vertebral body height (MVH), and posterior vertebral body height (PVH) (Fig. 4). Additionally, the local kyphotic angle, regional kyphotic angle, coronal angle, and Cobb's angle were measured (Figs. 5 and 6). Quantitative image analysis was carried out by 2 spine fellows using the PACS system (version 2.3, Centricity Enterprise Web V3.0, GE Medical Systems SCS, France/GE Healthcare, USA). The intraobserver and interobserver reliabilities were 0.78-0.93 and 0.71-0.94, respectively. Radiographically speaking, CT images were utilized to assess the presence of preoperative vertebral body vacuum clefts. Cement leakage was evaluated by analyzing CT and classified into 3 types: B (via the basivertebral vein), S (via the segmental vein), and C (through a cortical defect), following the reference classification system (13). Radiographic assessments were performed at 3 specific time points, as previously mentioned.

Sample Size and Statistical Analysis

The statistical analysis for sample size determination was conducted using G*Power version 3.1.3 (available at www.gpower.hhu.de; Heinrich Heine University of Düsseldorf). An a priori power analysis was conducted based on an effect size of 1.17, derived from the study by Liu et al (14), an α error probability of 0.05, and a desired statistical power (1-β) of 0.95. The analysis calculated a minimum required sample size of 40. Since our study included 83 patients, the sample

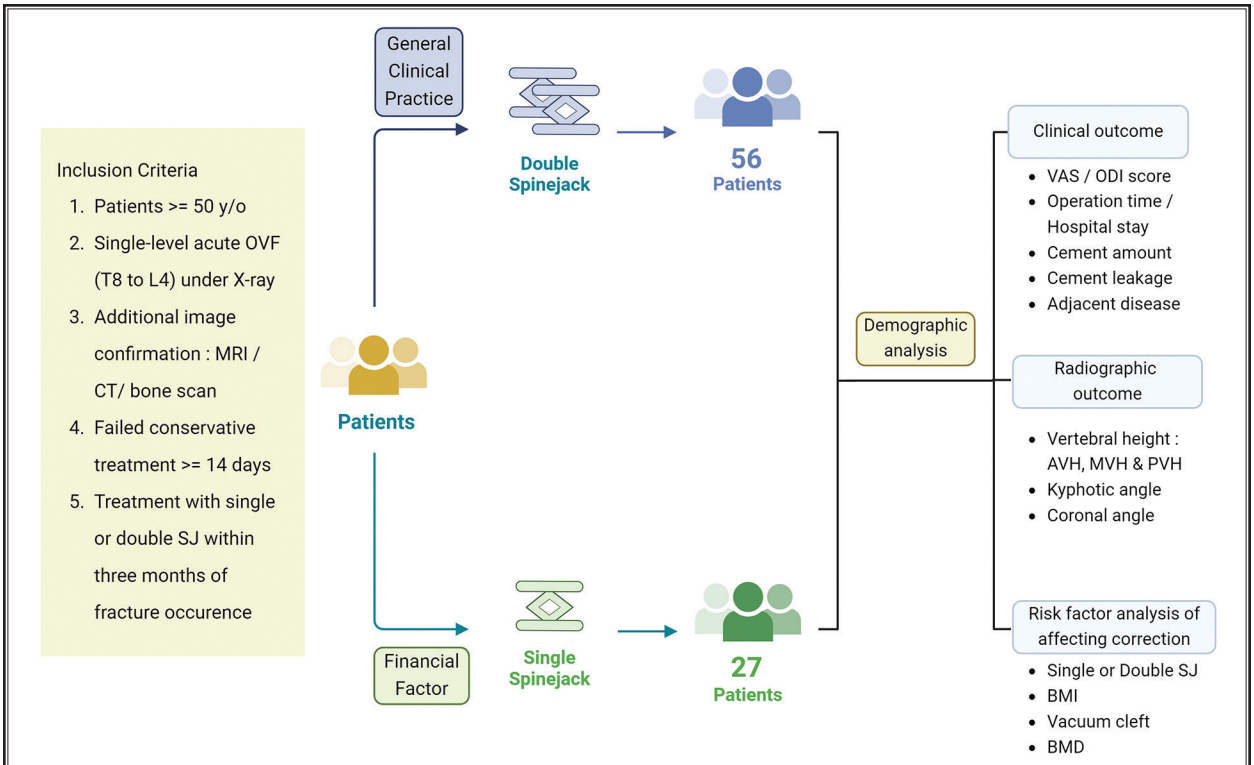

Fig. 1. *Experimental design. The study primarily includes patients with acute osteoporotic compression fractures who did not respond to conservative treatment and subsequently received either a single or double intravertebral augmentation device. By brand name, the device was known as a Spinejack® (SJ®). The choice of a single SJ® was influenced by each patient's financial considerations. To address potential selection bias, a demographic analysis was conducted to evaluate intergroup variance. Finally, preoperative, postoperative, and follow-up clinical and radiographic outcomes were analyzed thoroughly.*

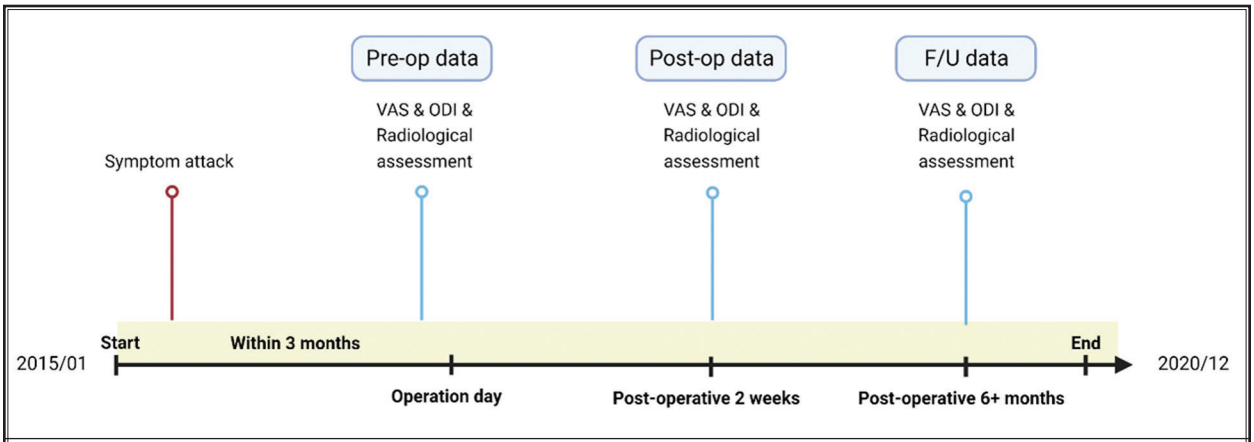

Fig. 2. *The illustration of the timeline of the retrospective study. Patients with single-level vertebral fractures and no exclusion criteria were included from January 2015 to December 2020. The clinical and radiological outcomes of the patients were assessed at 3 specific time points: the day before the operation, 2 weeks after the surgery, and a minimum of 6 months post-surgery.*

size was more than sufficient to achieve the required power.

Data processing and analysis were performed using SPSS 25.0 (IBM Corp.). Independent Student's

t-tests were used to compare radiographic findings, clinical outcomes, and complications between groups. We performed a multiple linear regression analysis to examine the factors influencing the amount of post-operative correction in the local kyphotic angle, regional kyphotic angle, coronal angle, and Cobb's angle. We explored the relationships among the number of SJ® implants, the body mass index (BMI), the bone mineral density (BMD), radiographic vertebral body vacuum clefts, and longitudinal changes in radiographic parameters.

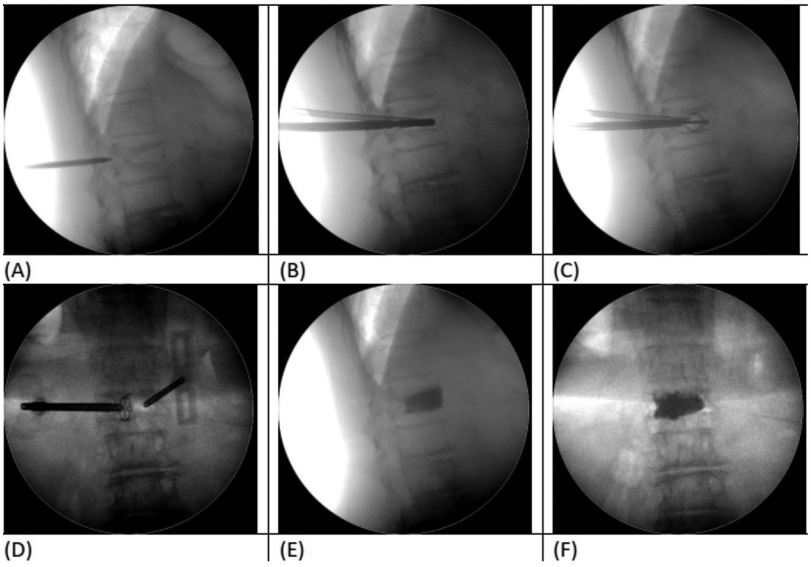

Fig. 3. *The surgical procedure of single SJ® implantation: (A) Two cannulas were inserted through the pedicles under fluoroscopy, one for SJ® implantation and one for cement injection. (B) The reamer was inserted, which followed the guide wire to the vertebral body to create the space for the final device. (C) The SJ® was expanded to reduce the fracture and restore the vertebral body height. (D) Anterior-posterior (AP) view after fracture reduction. (E) (F) The AP and lateral view after bone cement injection.*

Results

A total of 83 patients with single-level OVFs who underwent vertebral augmentation with the SJ® device between January 2015 and December 2020 were included and analyzed in this study. Out of the 83 patients, 27 received a single SJ® device implantation, while 56 received double SJ device implantation. The mean follow-up time is 23.04 ± 6.47 months. Table 1 provides an overview of the patients' demographics and clinical characteristics. No significant differences were observed between the 2 groups in terms of gender, age, BMI, BMD T-score, preoperative VAS pain score, preoperative Oswestry Disability Index (ODI) score, fracture morphology, and the presence of vertebral body vacuum clefts.

Table 2 summarizes the outcome parameter values in the single SJ and double SJ groups. The surgical variables indicated that the single SJ group had a shorter operation time (36.0 ± 2.82 minutes vs. 62.92 ± 16.49 minutes, $P = 0.012$) and a lower cement volume (3.60 ± 0.00 mL vs. 5.04 ± 1.56 mL, $P = 0.032$) compared to the double SJ group. There was no significant difference between the single and double SJ groups in terms of hospital stay, rate of adjacent fractures, and cement leakage rate. No major complications such as infection, neurological deficit, or cement embolism were observed during the follow-up period in either group. Both the single and double SJ groups demonstrated significant improvement in the VAS pain score and ODI

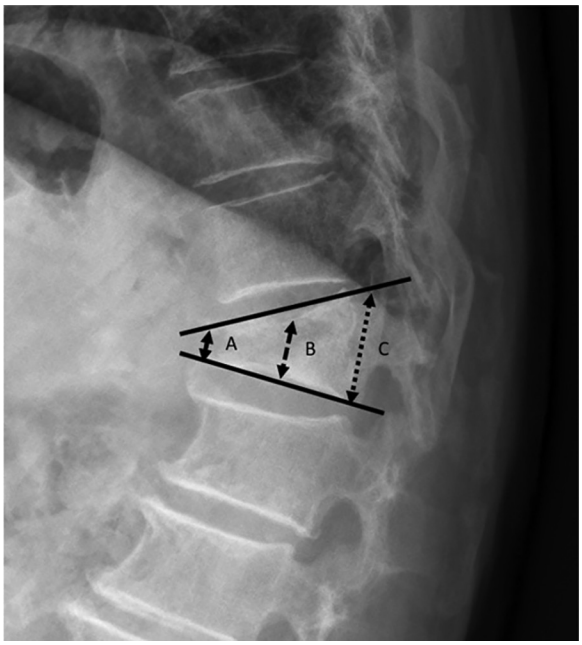

Fig. 4. *(A) Anterior vertebral height (AVH), (B) middle vertebral height (MVH), (C) posterior vertebral height (PVH).*

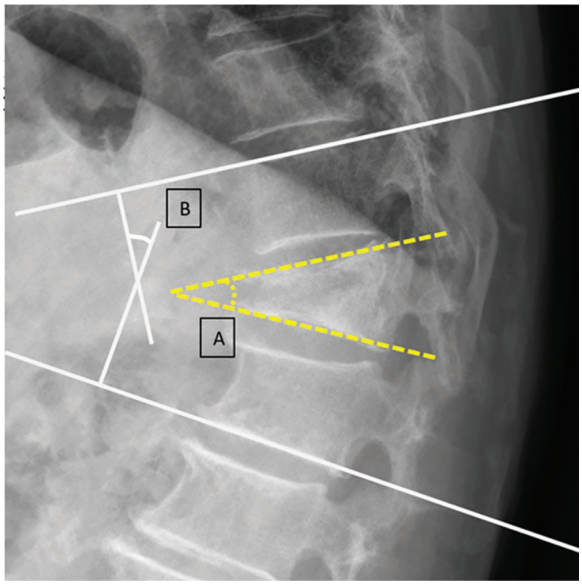

Fig. 5. *(A) Local kyphotic angle, angle between 2 yellow lines. (B) Regional kyphotic angle, angle between 2 white lines.*

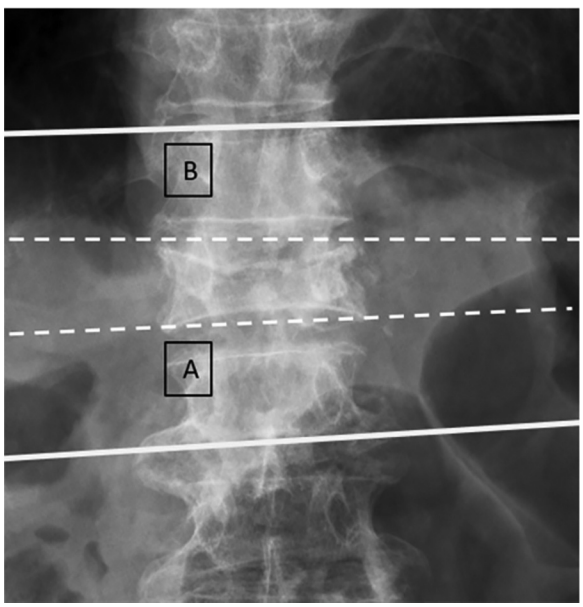

Fig. 6. *(A) Local coronal angle, angle between 2 dotted lines. (B) Cobb's angle, angle between 2 white lines.*

functional score after surgery, with sustained long-term benefits during the follow-up period. There was no significant difference in the pain score between the single and double groups at the postoperative stage

Table 1. *Demographic data between single device group and double devices group.*

Variables	Single device (n = 27)	Double devices (n = 56)	*P* value
Male/Female (N)	6/21	13/43	0.502
Age (years, mean ± SD)	72.7 ± 8.26	73.1 ± 8.32	0.815
Body mass index (kg/m^2, mean ± SD)	25.4 ± 3.06	25.3 ± 4.06	0.979
Height (m, mean ± SD)	1.53 ± 0.81	1.54 ± 0.82	0.890
Weight (kg, mean ± SD)	60.20 ± 9.54	60.60 ± 9.52	0.470
Surgical levels			
T10 (N, ratio)	0 (0%)	1 (2%)	
T11 (N, ratio)	3 (12%)	5 (9%)	
T12 (N, ratio)	4 (15%)	21 (38%)	
L1 (N, ratio)	9 (33%)	16 (29%)	
L2 (N, ratio)	5 (18%)	6 (10%)	
L3 (N, ratio)	4 (15%)	1 (2%)	
L4 (N, ratio)	2 (7%)	6 (10%)	
Osteoporotic Fractures classification			0.210
OF1 (N, ratio)	0 (0%)	0 (0%)	
OF2 (N, ratio)	2 (8%)	0 (0%)	
OF3 (N, ratio)	20 (74%)	45 (80%)	
OF4 (N, ratio)	5 (18%)	11 (20%)	
OF5 (N, ratio)	0 (0%)	0 (0%)	
T score (g/cm^2, mean ±SD)	-2.5±1.21	-2.5±1.35	0.582
Vacuum cleft of vertebral body (N, ratio)	8 (30%)	15 (27%)	0.786

N, number; kg, kilogram; m, meter, g, gram; cm, centimeter; BMD, bone mass density; VAS, visual analog scale; ODI, Oswestry Disability Index; Pre-OP, preoperative; Post-OP, post-operative; F/U, follow-up; *: *P* value < .05.

and final follow-up. The postoperative ODI score was significantly lower in the double device group (17.51 ± 5.66, 95% CI: 15.99–19.03) compared to the single device group (25.92 ± 4.89, 95% CI: 23.99–27.85) (*P* = 0.001). However, at the last follow-up, ODI scores between groups were not significantly different (13.29 ± 7.82, 95% CI: 10.20–16.38 vs. 14.10 ± 7.38, 95% CI: 12.00–16.20, *P* = 0.120).

Radiographic measurement

The radiographic parameters of Single SJ and Double SJ group were summarized and compared in Table 3. The increase in anterior vertebral height (Δ AVH) was significantly higher in the double device group (7.02 ± 3.34 mm, 95% CI: 6.13–7.91) compared to the single device group (5.24 ± 3.94 mm, 95% CI: 3.68–6.80) (*P* =

Table 2. *Clinical outcomes between single device group and double devices group.*

	Single device (n = 27)	Double devices (n = 56)	*P* Value
VAS for pain			
Preoperative	7.3 ± 0.76	7.36 ± 0.76	0.984
Postoperative	2.92 ± 1.20	3.16 ± 1.04	0.243
Last follow-up	2.48 ± 1.47	2.44 ± 1.36	0.631
ODI score			
Preoperative	63.33 ± 2.27	63.92 ± 2.40	0.284
Postoperative	25.92 ± 4.89	17.51 ± 5.66	0.001*
Last follow-up	13.29 ± 7.82	14.10 ± 7.38	0.120
Hospital stay (mean ± SD)	3.50 ± 0.70	3.14 ± 0.70	0.240
Cement amount (ml, mean ± SD)	3.60 ± 0.00	5.04 ± 1.56	0.032*
Operation time (min, mean ± SD)	36.0 ± 2.82	62.92 ± 16.49	0.012*
Cement leakage (N, ratio)	11 (41%)	15 (27%)	0.199
Adjacent fracture (N, ratio)	2 (7%)	9 (16%)	0.081

VAS, visual analog scale; ODI, Oswestry Disability Index; *: *P* value < 0.05.

0.034). Similarly, the improvement in regional kyphotic angle was greater in the double device group (6.79 ± 6.50°, 95% CI: 4.83–8.75°) compared to the single device group (2.79 ± 6.79°, 95% CI: 0.10–5.48°) (*P* = 0.011). However, there was no significant difference in other parameters between these two groups.

Both the single and double SJ groups demonstrated significant improvements in AVH, MVH, local kyphotic angle, regional kyphotic angle, and coronal angle from preoperative to postoperative and last follow-up assessments. Figure 7 demonstrates the radiographic changes in a case that was treated with a single SJ.

Factors affect the reduction of vertebral fracture

Multiple linear regression was used to analyze the association between the number of SJ, BMI, BMD, radiographic vacuum phenomenon, and longitudinal changes in radiographic parameters.

The results indicate that the number of SJ implants and the presence of a vertebral body vacuum cleft were positively associated with the correction of the regional kyphotic angle within the initial two weeks after the operation (Number of SJ: Standardized Coefficient Beta = 0.285, *P* = 0.011; Vacuum cleft: Standardized Coefficient Beta = 0.254, *P* = 0.025). These results suggest that patients with pre-existing vertebral clefts and those who received double SJ implants demonstrated better postoperative correction ability.

However, a higher BMI and the presence of a

Table 3. *Radiological data between single device group and double devices group.*

Variables	Single device (n = 27)	Double devices (n = 56)	*P* value
Vertebral height (mm, mean ± SD)			
Pre-OP AVH	15.42 ± 4.45	15.06 ± 4.83	0.746
Post-OP AVH	20.66 ± 4.78	20.40 ± 4.22	0.801
Δ AVH	5.24 ± 3.94	7.02 ± 3.34	0.034*
F/U AVH	20.15 ± 4.23	18.15 ± 4.01	0.057
Pre-OP MVH	14.21 ± 3.78	13.42 ± 4.12	0.404
Post-OP MVH	21.96 ± 3.43	22.10 ± 2.82	0.843
Δ MVH	7.75 ± 3.98	8.38 ± 3.05	0.427
F/U MVH	21.51 ± 3.24	21.39 ± 3.09	0.877
Pre-OP PVH	27.78 ± 3.18	27.77 ± 8.13	0.453
Post-OP PVH	27.59 ± 3.19	27.36 ± 2.61	0.728
Δ PVH	0.19 ± 2.00	0.48 ± 2.47	0.217
F/U PVH	27.74 ± 3.26	26.74 ± 3.52	0.242
Kyphotic angle (degree, mean ± SD)			
Pre-op local kyphotic angle	18.34 ± 5.60	20.20 ± 6.70	0.218
Post-op local kyphotic angle	10.75 ± 6.22	10.27 ± 5.15	0.708
Δ Local kyphotic angle	7.5 ± 5.24	9.92 ± 5.45	0.067
F/U local kyphotic angle	11.75 ± 5.96	12.72 ± 5.34	0.481
Pre-op regional kyphotic angle	14.62 ± 12.10	20.93 ± 11.94	0.027*
Post-op regional kyphotic angle	11.82 ± 12.42	14.13 ± 11.64	0.41
Δ Regional kyphotic angle	2.79 ± 6.79	6.79 ± 6.50	0.011*
F/U regional kyphotic angle	12.07 ± 13.32	16.90 ± 12.73	0.068
Coronal angle (degree, mean ± SD)			
Pre-op coronal angle	2.77 ± 5.64	2.49 ± 2.47	0.323
Post-op coronal angle	1.01 ± 0.81	1.51 ± 1.13	0.064
ΔCoronal angle	1.75 ± 5.78	1.27 ± 3.02	0.521
F/U coronal angle	1.18 ± 0.94	1.85 ± 1.78	0.025*
Pre-op Cobb angle	3.87 ± 3.66	3.96 ± 3.47	0.911
Post-op Cobb angle	2.81 ± 2.41	3.10 ± 2.45	0.953
Δ Cobb angle	1.06 ± 2.64	0.86 ± 2.65	0.747
F/U Cobb angle	4.02 ± 3.48	4.32 ± 4.15	0.578

N, number; mm, millimeter; Δ, Delta changes; Pre-OP, pre-operative; Post-OP, post-operative; F/U, follow-up; AVH, anterior vertebral height; MVH, middle vertebral height; PVH, posterior vertebral height; %, percentage; *: *P* value < 0.05.

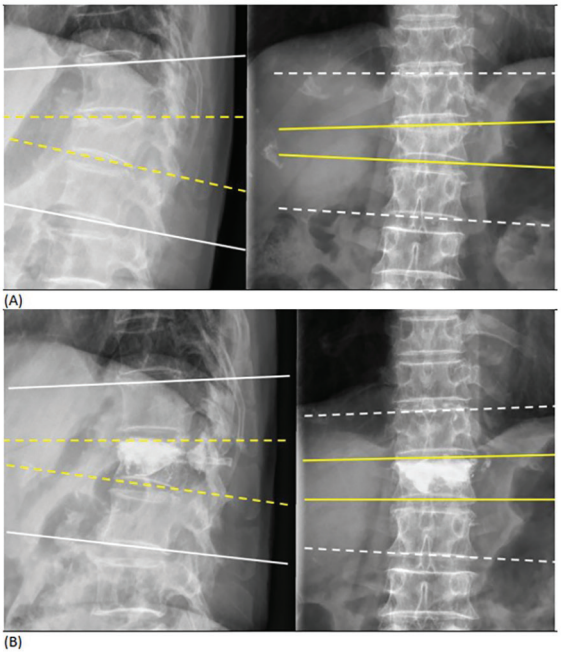

Fig. 7. *We present the case of an 85-year-old woman with an L1 compression fracture who underwent a single SJ® implantation. (A) Preoperative standing radiography revealed a local kyphotic angle (angle between 2 dotted lines) of 21.74°, a regional kyphotic angle (angle between 2 white lines) of 21.82°, a coronal angle (angle between 2 dotted lines) of 4.57°, and a Cobb angle (angle between 2 white lines) of 7.97°. (B) Standing radiography taken one year after the operation showed a local kyphotic angle of 8.83°, a regional kyphotic angle of 17.28°, a coronal angle of 1.34°, and a Cobb angle of 3.57°. All parameters displayed notable improvement when compared to the preoperative measurements.*

vertebral vacuum cleft were negatively correlated with the change in the local kyphotic angle between preoperative and the last follow-up (BMI: Standardized Coefficient Beta = -0.267, $P = 0.035$; Vertebral vacuum cleft: Standardized Coefficient Beta = -0.302, $P = 0.028$). These results suggest that individuals with higher body weight and those with pre-existing vertebral clefts had poorer vertebral kyphotic angles at the last follow-up.

Discussion

Vertebral reduction devices have become increasingly popular in the treatment of osteoporotic vertebral fractures (OVFs) due to their ability to significantly improve symptoms and restore vertebral alignment. These devices have been shown to achieve sustainable correction of vertebral deformities and improve patients' quality of life (15,16). SJ® is a percutaneous vertebral reduction system that implants permanent expandable devices to restore the spine structure mechanically (5,8,9,17). Clinical studies consistently show that these devices can provide short-term, mid-term, and long-term improvements in pain relief, functional outcomes, and restoration of vertebral body height and sagittal alignment (5,17). While the standard protocol for SJ® vertebral augmentation typically involves the use of double implants for vertebral augmentation, the efficacy and safety of using a single implant have remained uncertain. Our study contributes evidence that a single-implant approach may offer comparable clinical outcomes to the double-implant method. We observed significant improvements in pain scores (VAS) and functional outcomes (ODI) immediately after surgery, which were sustained over the follow-up period. Although patients in the double-implant group exhibited better short-term ODI scores, there was no significant difference between the 2 groups at the final follow-up. Furthermore, the single-implant approach also offers certain procedural advantages, including shorter operative times and reduced cement volume. These factors may potentially lead to decreased vertebral body stiffness and a lower risk of adjacent fractures (18). However, the double-implant approach provides better correction of postoperative anterior body height and regional kyphotic angles. Importantly, major complications, such as symptomatic cement leakage and the incidence of adjacent vertebral fractures, were comparable between the single- and double-implant groups. Based on our findings, single SJ® implantation can be considered as a viable alternative option for the treatment of OVFs.

Previous studies comparing unilateral and bilateral approaches to balloon kyphoplasty (BKP) for the treatment of single-level OVCFs have shown that both approaches can significantly reduce pain, restore vertebral body height, and correct vertebral kyphotic angles for at least one year. The unilateral approach has the advantage of consuming less bone cement while providing similar efficacy to that of the bilateral approach (19). Another study comparing unilateral and bilateral BKP for treating osteoporotic thoracolumbar burst fractures found similar improvements in VAS pain scores, ODI scores, vertebral height, and sagittal Cobb's angles. Additionally, complication rates did not differ significantly between the approaches (11). The study underscored the advantages of unilateral KP, including shorter operative time, reduced trauma, lower cost, and less radiation exposure. Our investigation yielded

Table 4. *Factors affecting correction (The day before operation - post operative 2 weeks)*

(A) Local kyphosis		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	-0.204 (-4.965~0.215)	0.072
BMI	-0.100 (-0.513~0.219)	0.472
Vacuum cleft	-0.153 (-4.688~0.909)	0.183
BMD	-0.136 (-1.605~0.464)	0.275

BMI, body mass index; BMD, bone marrow density; * significant difference

(B) Regional kyphosis		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	0.285 (7.206~0.966)	0.011*
BMI	-0.041 (-0.516~0.366)	0.735
Vacuum cleft	0.254 (7.244~0.501)	0.025*
BMD	-0.043 (-1.470~1.022)	0.722

BMI, body mass index; BMD, bone marrow density; *: *P* value < 0.05.

(C) Coronal angle		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	0.116 (-1.472~3.476)	0.551
BMI	0.006 (-0.359~0.374)	0.688
Vacuum cleft	0.080 (-2.033~3.629)	0.330
BMD	-0.010 (-1.016~0.947)	0.944

BMI, body mass index; BMD, bone marrow density; * significant difference

(D) Cobb's angle		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	0.102 (-0.859~1.974)	0.433
BMI	0.272 (-0.008~0.415)	0.059
Vacuum cleft	-0.104 (-2.273~1.000)	0.438
BMD	-0.315 (-1.206~-0.072)	0.074

BMI, body mass index; BMD, bone marrow density; * significant difference

Table 5. *Factors affecting correction (The day before operation - Last follow up)*

(A) Local kyphosis		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	-0.118 (-5.160~1.956)	0.370
BMI	-0.267 (-1.031~-0.733)	0.035*
Vacuum cleft	-0.302 (-8.737~-0.518)	0.028*
BMD	0.023 (-1.310~1.539)	0.873

BMI, body mass index; BMD, bone marrow density, * significant difference

(B) Regional kyphosis change		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	-0.037	0.745
BMI	0.059	0.640
Vacuum cleft	-0.203	0.082
BMD	0.002	0.989

BMI, body mass index; BMD, bone marrow density, * significant difference

(C) Coronal angle		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	0.110 (-1.498~3.459)	0.431
BMI	0.077 (-0.276~0.465)	0.612
Vacuum cleft	-0.100 (-1.325~0.660)	0.505
BMD	0.040 ((-2.460~3.265))	0.779

BMI, body mass index; BMD, bone marrow density, * significant difference

(D) Cobb's angle		
	Standardized coefficients Beta (95%CI)	***P* value**
Number of devices	0.117 (-0.845~2.195)	0.377
BMI	0.235 (-0.041~0.414)	0.106
Vacuum cleft	-0.196 (-1.032~0.186)	0.169
BMD	-0.181 (-2.935~0.577)	0.184

BMI, body mass index; BMD, bone marrow density, * significant difference

results that were consistent with the findings of previous studies. Both single-SJ® and double-SJ® procedures demonstrated sustainable clinical improvements and vertebral height correction. Importantly, there was no significant difference in the complication rate between the 2 groups. The results of a biomechanical study have suggested that SJ® may be a more effective option than balloon kyphoplasty for the treatment of compression fractures, since the former provides better restoration of sagittal height and stronger reduction and maintenance power (8). This finding might partly explain why a single SJ® is an adequate technique for treating OVFs, as supported by our study. While our results demonstrate statistically significant differences between the single-and double-device groups in terms of radiographic and short-term functional outcomes,

the clinical significance of these differences—particularly the magnitude of improvement—should be interpreted with caution. We acknowledge the potential for Type II error due to the overlap of standard deviations, particularly in variables such as ΔAVH and regional kyphotic angles. Our 95% confidence interval (CI) analysis confirms that although certain radiological outcomes exhibit statistical significance, the CIs indicate substantial overlap between the groups, suggesting considerable variability in these measurements. This variability may have affected the statistical power of our study. However, it is important to note that despite these variations, both groups achieved comparable long-term functional outcomes (ODI scores), suggesting that the clinical impact of these differences may be minimal. Furthermore, the 95% CIs for ODI scores were relatively narrow, particularly when compared to the radiographic measurements. To further validate the statistical robustness of our ODI outcomes, a post hoc power analysis was conducted, yielding a power of 0.99. This result confirms that, despite concerns regarding variability in radiographic parameters, the functional outcomes measured by ODI were statistically robust and unlikely to be influenced significantly by excessive variability. Thus, while we acknowledge the potential for Type II error in the radiographic analyses, we believe that our primary clinical outcome, ODI, remains statistically reliable and clinically meaningful. To strengthen the validity of these findings, future studies with larger sample sizes and prospective designs are warranted.

In this study, we attempted to identify predictive factors that could impact the change in kyphotic and coronal angles after surgery. Our findings revealed that the presence of a vacuum cleft is a significant risk factor influencing the vertebral kyphotic angle at the last follow-up. Patients with vertebral vacuum clefts showed worse correction of local kyphotic angles than did patients without vacuum clefts at the last follow-up. This difference suggests that the presence of a vertebral body vacuum cleft may contribute to the re-collapse of vertebral compression fractures after vertebral augmentation. Previous studies have also reported that preoperative osteonecrosis or pseudoarthrosis may be crucial predisposing factors for vertebral body re-collapse following vertebroplasty (20). Furthermore, studies comparing therapeutic outcomes for osteoporotic compression fractures with or without intravertebral clefts have found that restored vertebral height and kyphotic angles may worsen during the 2 years after surgery in patients with intravertebral clefts. These patients also had worse VAS and ODI scores than did patients without intravertebral clefts (21). Multiple studies have shown that an intervertebral cleft is a risk factor for re-collapse of the augmented vertebra (22-25). Though vertebral augmentation devices offer the advantage of reducing and maintaining vertebral height and kyphotic angles (5), our study found that vertebral height re-collapse occurred during the long-term follow-up, particularly in patients with intravertebral clefts. Further studies comparing SJ® with vertebroplasty or balloon kyphoplasty in patients with intravertebral clefts may provide more insights into whether the vertebral augmentation devices can effectively reduce the risk of re-collapse. Previous studies have not identified BMI as a risk factor for re-collapse after vertebroplasty (23). However, our study indicates that patients' BMI does influence the final vertebral kyphotic angles after surgery. Specifically, we found that patients with higher BMI tended to have a worse vertebral local kyphotic angle at the last follow-up. This observation suggests that BMI may influence the long-term radiographic outcome of vertebral augmentation procedures.

Limitations

This study has several limitations that should be acknowledged. Firstly, this study is retrospective and has inherent limitations related to sample size and variability. Some measurements showed a high degree of variability, leading to overlapping CIs and a potential risk of Type II errors. Although our sample size was sufficient for detecting major differences, a larger cohort would further reduce variability and improve statistical power. Future prospective randomized controlled trials with larger sample sizes are warranted to strengthen these findings. Secondly, the accuracy of the data relied on manual measurements, which may be subject to measurement bias and variability. This factor could have influenced the radiographic values and subsequent outcomes. Thirdly, the study did not evaluate the impact of different types of bone cement on vertebral height reduction, which previous studies have reported to vary based on cement viscosity (26). However, the retrospective design of the study prevented control over the brand of cement used. Finally, the follow-up period varied among patients, which could have introduced additional bias. Therefore, a prospective study with longer-term follow-up is necessary to assess the sustained clinical outcomes of single-SJ® treatment for OVFs.

Conclusion

The implantation of a single intravertebral reduction device is an effective and safe treatment option for OVFs, yielding clinical outcomes comparable to those of double device implantation. However, certain risk factors, such as a higher BMI and the presence of an intravertebral vacuum cleft, should be considered carefully, since they may contribute to vertebral height re-collapse after expandable device augmentation. Additionally, the high variability observed in certain parameters suggests that larger sample sizes are necessary to confirm these findings. Future prospective randomized controlled trials are warranted to further evaluate the efficacy of single versus double device implantation.

Author Contributions

Yuan-Fu Liu contributed to the conception and design of the study, acquisition of data, and drafting of the manuscript. Hao-Jun Chuang contributed to statistical analysis and interpretation of data. Yu-Chia Hsu contributed to the acquisition of data. Fu-Yao Fan contributed to the acquisition of data. Chao-Jui Chang contributed to statistical analysis. Cheng-Li Lin contributed to the conception of the study, supervised the research, and obtained funding for the study.

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