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ABSTRACT

BACKGROUND AND PURPOSE: Vertebral compression fracture represents a major health burden for the aging populations globally. However, limited studies exist on the relative efficacy and safety of surgical interventions for vertebral compression fracture. Here, we aim to compare clinical and patient-reported outcomes following vertebral augmentation using balloon kyphoplasty, vertebroplasty, and SpineJack vertebral implant.

MATERIALS AND METHODS: An institutional review board–approved, retrospective, multi-institutional review of patients undergoing vertebral augmentation with kyphoplasty, vertebroplasty, and/or a SpineJack vertebral implant was performed between 2018 and 2021. Primary outcomes included pre- and postprocedural pain ratings and vertebral body height restoration. The secondary outcome was a change in the local kyphotic angle. The Kruskal-Wallis test was used to compare outcomes across 3 treatment options. Complications were reviewed during and 30–90 days after the procedure.

RESULTS: Vertebral augmentation of 344 vertebral compression fracture levels was performed during the study period. Sixty-seven patients had 79 kyphoplasty procedures (55% women; mean age, 64.2 [SD, 12.3] years). Seventy-four patients underwent a mean of 84 vertebroplasty procedures (51% women; mean age, 63.5 [SD, 12.8] years), and 61 patients had a mean of 67 SpineJack vertebral implant procedures (57.4% women; mean age, 68.3 [SD, 10.6] years). Following kyphoplasty, vertebroplasty, and SpineJack vertebral implant, pain scores improved significantly ($P < .001$). Resting pain improvement was similar across the 3 procedures, whereas improvement of "worst pain" was significantly better following a SpineJack vertebral implant compared with kyphoplasty and vertebroplasty ($P < .001$). Patients with a SpineJack vertebral implant had greater improvement in vertebral body height restoration and local kyphotic angle compared with those undergoing kyphoplasty and vertebroplasty. Adjacent level fractures (6.7% incidence) occurred similarly in the 3 procedure types. There were no other peri- or postoperative complications.

CONCLUSIONS: The SpineJack vertebral implant showed equivalent pain improvement compared with vertebroplasty and kyphoplasty, but it had superior vertebral body height restoration and local kyphotic angle improvement. This study supports the SpineJack vertebral implant as a safe and effective alternative (adjunct) for vertebral augmentation, especially in patients with moderate-to-severe vertebral compression fractures for greater improvement in vertebral body height restoration.

ABBREVIATIONS: KP = balloon kyphoplasty; LKA = local kyphotic angle; PMMA = polymethylmethacrylate; SJ = SpineJack vertebral implant; VCF = vertebral compression fracture; VH = vertebral body height; VP = vertebroplasty

Vertebral compression fractures (VCFs) are common throughout the world, especially affecting older populations.[1] In the United States alone, there have been up to 1.5 million VCFs annually.[2,3] VCFs are caused by trauma, infection, cancer, and, most commonly, osteoporosis—especially in postmenopausal women.[3,4] VCFs frequently cause severe pain and disability, limiting activities of daily living and resulting in decreased quality of life.[5,6] Limiting

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From the Department of Biomedical Engineering (T.L.), Johns Hopkins School of Medicine, Baltimore, Maryland; Department of Emergency Medicine (S.P.), Massachusetts General Hospital, Boston, Massachusetts; Russell H. Morgan Department of Radiology and Radiological Science (R.E., F.K.H.), The Johns Hopkins Hospital, Baltimore, Maryland; Johns Hopkins School of Medicine (A.G., D.B., S.M.), Baltimore, Maryland; Neurointerventional Surgery Division (F.K.H.), The Queen's Medical Center, Honolulu, Hawaii; Non-Vascular Interventional Neuroradiology (M.K.), Department of Radiology, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania; and Division of Neuroradiology and Division of Interventional Radiology (M.K.), Russell H. Morgan Department of Radiology and Radiological Science, The Johns Hopkins Hospital, Baltimore, Maryland.

F.K. Hui and M. Khan are senior authors.

Please address correspondence to Taibo Li, MS, Medical Scientist Training Program, Department of Biomedical Engineering, Johns Hopkins School of Medicine, 1830 E Monument St, Suite 2-130 Baltimore, MD, 21205; e-mail: taiboli@jhu.edu; @taibo_li

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activities of daily living and concurrent medical conditions can complicate patients' health and nutrition and increase morbidity and mortality rates compared with the general population.[3] Most important, patients who have had a VCF are at higher risk for recurrent fracture, further limiting the quality of life of the patient and leading to repeat hospital visits and increased costs.

There are multiple nonsurgical and surgical treatment options for VCFs. Nonsurgical treatments include bed rest, analgesics, hyperextension braces (used for benign fractures), and radiation therapy for pathologic fractures (including stereotactic body radiation therapy and proton beam therapy for oligometastatic and diffuse pathologic osseous involvement). However, these treatments may not be effective and can result in multiple complications; for example, immobilization from bed rest can lead to weakness, pressure ulcers, and venous thromboembolism. Minimally invasive surgical treatments include balloon kyphoplasty (KP), percutaneous vertebroplasty (VP), internal bracing, and, more recently, vertebral implants such as the SpineJack vertebral implant (SJ) system (Stryker). Surgical options have become increasingly popular because their effects have been found to be rapid and sustained.[7-11] Vertebral augmentation strategies have been shown to greatly reduce stresses for various preaugmentation vertebral heights in 3D reconstruction models of compression fractures.[10] There have been controversial studies considering serious complications following surgical treatments, such as new vertebral fractures, but more recent meta-analyses did not replicate these conclusions.[9,12] Furthermore, patients with osteoporotic compression fractures were found to have decreased mortality following vertebral augmentation compared with nonsurgical treatment.[8] Nevertheless, older patients who present with VCF along with multiple comorbidities often face risks and contraindications to vertebral augmentation, leading to poorer outcomes, such as increased morbidity and mortality and postoperative complications.[13-15]

Vertebral implant procedures such as SJ introduce permanent titanium implants to help restore vertebral height, and received FDA approval in 2018.[16] While with VP, polymethylmethacrylate (PMMA) is directly injected into the VCF space and KP uses an inflated balloon to prepare a cavity before injection of PMMA, SJ uses a bilateral transpedicular approach with placement of implants within the vertebral body,[9,17,18] allowing progressive and well-controlled reduction of vertebral fractures.[17] The amount of PMMA injected is lower than in VP or KP, theoretically decreasing the risk of PMMA leakage and adjacent vertebral body fractures.[17] While the SJ has only been approved for osteoporotic and traumatic fractures, its efficacy in vertebral height restoration may aid in reducing other vertebral fractures, such as fractures secondary to tumors.[17,19]

In this study, we hypothesized that a vertebral implant is a safe and effective approach for patients with VCF under broad indications. Consequently, we aimed to evaluate patient outcomes of KP, VP, and SJ by comparing clinical outcomes (pre- and postprocedural pain scores), radiologic measurements (anterior and middle vertebral body height [VH] and local kyphotic angle [LKA]), and complications following vertebral augmentation among the 3 types of procedures.

MATERIALS AND METHODS

This was an institutional review board–approved, retrospective, multi-institutional cohort study, located at 2 tertiary care hospital centers (The Johns Hopkins Hospital and Thomas Jefferson University Hospital), of 202 patients who received vertebral augmentation for a total of 344 vertebral levels from November 1, 2018, to September 1, 2021. Medical records including demographics, pain scores, and imaging measurements were obtained and reviewed. Treatment efficacy was defined by primary and secondary objectives. Primary outcome variables included pre- and postprocedural pain ratings and VH restoration. The secondary outcome variable was a change in the LKA. Complications of the cohort during and after procedures (follow-up time varied) were reviewed to assess safety.

Inclusion Criteria

We included patients experiencing intractable mechanical back pain from osteoporotic or pathologic vertebral fractures, which were augmented using KP, VP, and/or SJ during the study period. Pathologic compression fractures were included in this study on an off-label basis.

Exclusion Criteria

We excluded patients who experienced primarily radicular back pain without a mechanical component and patients experiencing pathologic fractures with epidural tumor extension or spinal canal and/or cord compression.

Clinical Assessment

Clinical outcomes collected included patient-reported pain scores (both "at rest" and "at worst") before and after the vertebral augmentation procedure (KP, VP, and/or SJ) and complication rates. Preprocedural evaluation occurred generally 1 month before the procedure. Postprocedural clinic evaluations occurred 3 weeks to 3 months after the procedure. The pain scale used was a 10-point numeric scale, in which 0 indicates no pain and 10 indicates the "worst pain" ever experienced. Pain scores were assessed both in the presurgical assessment and during a follow-up clinic visit, in which patients were asked about their level of pain at baseline (at rest) and about their worst ever level of pain during the assessment periods regardless of triggering events (at worst).

Radiographic Assessment

Technical outcomes involved radiographic assessments of LKA and VHs in the craniocaudal dimension at the mid and anterior vertebral body levels before and immediately after the procedure for all patients (Fig 1), which were reviewed by attending radiologists (F.K.H., M.K.). An increase in VH and a decrease in the LKA represented improvement in vertebral height restoration.

Safety Assessment

Follow-up evaluations ranged from 30 to 90 days after the procedure. Procedural and clinic notes were reviewed to evaluate complications. Complications assessed included perisurgical technical complications, device removal, cement leakage, and postprocedural compression fractures. Follow-up imaging with radiographs or CT performed during follow-up clinic visits between 3 and 6 months was used to assess any evidence of adjacent level fractures or other adverse events.

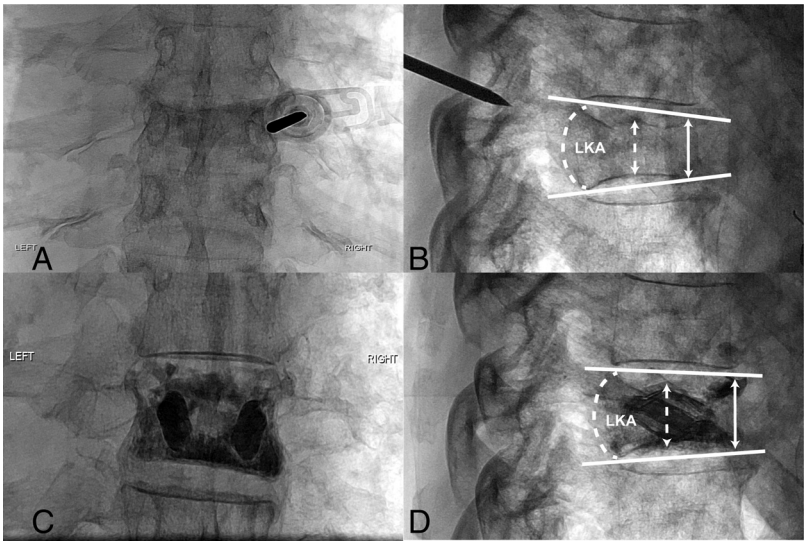

FIG 1. Sample radiographic measurements. A 72-year-old man with a history of osteoporosis presented with severe midthoracic back pain. Anterior-posterior (*A*) and lateral (*B*) projections of fluoroscopic images of the thoracic spine with the needle at the level of T8 demonstrate a preprocedural T8 vertebral compression fracture, as shown by an increased LKA formed by *solid white lines* along the superior and inferior endplates and decreased midvertebral (*dashed arrow*) and anterior-vertebral (*solid arrow*) body heights. Following vertebral augmentation with SJ, anterior-posterior (*C*) and lateral (*D*) projections show postprocedural changes with improvement in LKA and VH at T8.

Table 1: Patient demographics

	Kyphoplasty	Vertebroplasty	SJ
No. of patients	67	74	61
No. of total procedures	79	84	67
Age (mean) (yr)	64.2 (SD, 12.3)	63.5 (SD, 12.8)	68.3 (SD, 10.6)
No. of female (%)	37 (55.2)	38 (51.4)	35 (57.3)
No. of African American (%)	12 (17.9)	15 (20.3)	14 (22.9)
No. of European (%)	46 (68.6)	49 (66.2)	37 (60.7)
No. of other race (%)	9 (13.4)	10 (13.5)	10 (16.4)
BMI (mean)	28.2 (SD, 7.3)	26.8 (SD, 5.8)	28.7 (SD, 7.1)
No. of pathologic fractures[a]	46	59	19
No. of structural fractures[a]	19	15	42
No. of treatment sessions			
1 Procedure	58	64	57
2 Procedures	7	10	2
3 Procedures	1	0	2
4 Procedures	1	0	0
Median follow-up period (days)	39.5	70	94

[a] Not all patients had recorded fracture type.

Statistical Analysis

Baseline characteristics of total procedures were summarized as count, mean (SD), and frequency. Some patients underwent multiple procedures on the same day (ie, KP at 1 vertebral level and SJ at another). In those cases, each type of procedure performed was counted in the total count of procedures. To account for patients who received >1 type of VCF treatment, we applied a bootstrapping algorithm to assess changes in pain scores and radiographic augmentation outcomes pre- and postsurgery, so that for each outcome variable, a total of 1000 subsamples were drawn from the patient cohort in which data from each patient appeared only once. A 2-sample *t* test was then conducted to assess statistical significance between bootstrapped sample means, and the Kruskal-Wallis H test was used to compare among different procedures (KP, VP, and SJ). Pain score and adjacent level fracture outcomes were assessed during individual clinical visits and may occur in patients having undergone >1 type of procedure. In these cases, an additional subgroup analysis was performed using data from those patients with only 1 type of augmentation procedure. A mixed-effect linear logistic model was constructed to assess the influence of demographic (age, sex, race) and clinical (body mass index, total levels operated, type of procedure) variables on adjacent level fractures using patient as the random effect. Statistical significance was assessed at $\alpha = .05$. All statistical computation was performed using the R statistical and computing software (Version 3.4.0; http://www.r-project.org/).

RESULTS

Demographics and Case Characteristics

Sixty-seven patients underwent 79 KP procedures (55.2% women; mean age, 64.2 [SD, 12.3] years), 74 patients had 84 VP procedures (51.4% women; mean age, 63.5 [SD, 12.8] years), and 61 patients had 67 SJ procedures (57.4% women; mean age, 68.3 [SD, 10.6] years). Additional demographic data are reported in Table 1. Because the number of treatment sessions varied on the basis of the patient's clinical presentation and progression, total treatment sessions are also reported in Table 1. KP and VP were more often performed for pathologic fractures, whereas SJ was performed more for structural fractures (Table 1). SJ procedures had the longest median follow-up of 94 days, followed by VP (70 days) and KP (40 days). There were no major complications immediately postprocedure in all cases. Of note, 1 augmentation procedure was aborted due to patient oxygen desaturations while supine, before starting the procedure.

Patient-Reported Outcomes

In all 3 procedures, pain scores reported both at rest and at worst improved significantly after the procedure compared with prior to it (all, $P < .001$, Fig 2 and Table 2). Patients' worst pain scores improved following KP (8.3 to 4.1; 95% confidence interval of the change [95% CI Δ]: 3.4–5.1; $P < .001$), VP (7.8 to 4.1; 95% CI Δ: 2.9–4.4; $P < .001$), and SJ (8.6 to 3.7; 95% CI Δ: 4.3–5.5; $P < .001$).

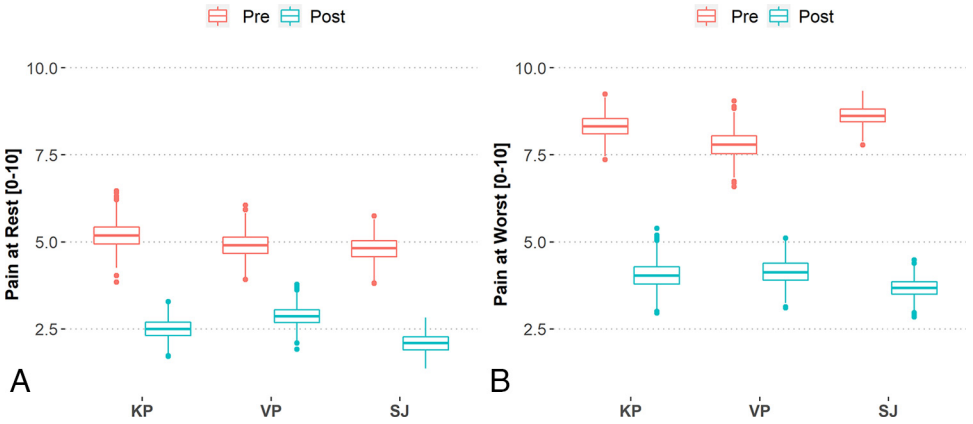

FIG 2. Pain score comparison. *A*, Distribution of patient-reported pain scores on a scale between 0 and 10 at rest for 3 procedure types pre- (red) and postprocedure (blue). *B*, The same pain score distribution reported at worst. Shown are median and interquartile ranges.

Table 2: Patient-reported outcomes

Pain Score at Rest (0–10)	KP	VP	SJ	*P* Value[a]
Pre (mean)	5.2	4.9	4.8	>.05
Post (mean)	2.5	2.9	2.1	
Δ 95% CI	(1.9–3.5)	(1.3–2.7)	(2.1–3.3)	
P value[b]	<.001	<.001	<.001	
Pain score at worst (0–10)				
Pre (mean)	8.3	7.8	8.6	<.001
Post (mean)	4.1	4.1	3.7	
Δ 95% CI	(3.4–5.1)	(2.9–4.4)	(4.3–5.5)	
P value[b]	<.001	<.001	<.001	

[a] The *P* value was calculated with Kruskal-Wallis χ^2 tests across procedures.
[b] The *P* value was calculated with bootstrapping.

Following SJ, patients reported a larger reduction in pain at worst compared with VP and KP, though improvement in pain scores at rest was comparable in all procedure types. Similar results were obtained if comparisons were restricted to patients who underwent only 1 type of procedure (44 patients with KP [8.2 to 3.8 at worst; 5.3 to 2.5 at rest], 45 patients with VP [6.9 to 3.6 at worst; 4.9 to 2.9 at rest], and 37 patients with SJ [8.8 to 3.4 at worst; 4.6 to 1.6 at rest]. Notably, in a subanalysis on the underlying pathology of these procedures, patients' pain scores improved more following SJ for pathologic fractures compared with structural fractures (Online Supplemental Data).

Radiographic Outcomes

Anterior and middle vertebral body measurements from before and after vertebral augmentation procedures showed improved height restoration following KP, VP, and SJ (Table 2). Both absolute change in VH (craniocaudal length) and percentage change of VH were significantly increased in all procedure groups when comparing pre- with postprocedural measurements ($P < .001$, Fig 3, and Table 3). Most important, SJ had significantly greater VH restoration, both in the anterior and middle columns of the vertebral body, compared with both KP and VP (each, $P < .001$, Table 2). The kyphotic angle was also measured before and after procedures, which showed patients having undergone SJ with a significantly improved LKA compared with both KP and VP (each $P < .001$, Table 2).

Complications

There were no perioperative adverse events, symptomatic cement leakage, or device-removal complication in any of the cases in this study. However, of the 344 VCF levels treated, there were 23 adjacent vertebral fractures, representing a 6.7% adjacent level fracture rate. Lumbar levels were over-represented in all procedures in which combination treatment was performed in multilevel fractures on the basis of vertebral height loss (Online Supplemental Data). Overall, adjacent level fractures were rare among patients undergoing only 1 type of procedure (1/44 KP, 3/46 VP, and 1/37 SJ visits, Table 4). There were a total of 23 adjacent level fractures in 13 patients. The logistic regression model revealed that there was no difference in the fraction of these fractures across the 3 procedure types ($P > .05$). Demographic variables such as sex, race, and body mass index were not significantly associated with the outcome of adjacent level fracture, while the total number of levels operated were, so that each increased level of augmentation resulted in a 2.4-fold increase in the odds of having an adjacent level fracture (95% CI, 1.8–3.2).

DISCUSSION

Among the many distinct types of surgical interventions for VCFs, vertebral implant systems such as the SJ were the most recently approved by the FDA.[16] Therefore, limited data exist to benchmark clinical outcomes between vertebral implant and other vertebral augmentation procedures, representing a major gap in the current knowledge on treatment-planning for patients with VCF. In this multi-institutional retrospective study, patient-reported and radiographic outcomes were compared in patients receiving balloon KP, VP, and SJ vertebral implant for VCFs. We hypothesized that vertebral implant systems such as SJ will lead to comparable, if not better, clinical improvement for patients with increased vertebral height restoration, therefore justifying its application in a wide range of indications, including osteoporotic and pathologic fractures.

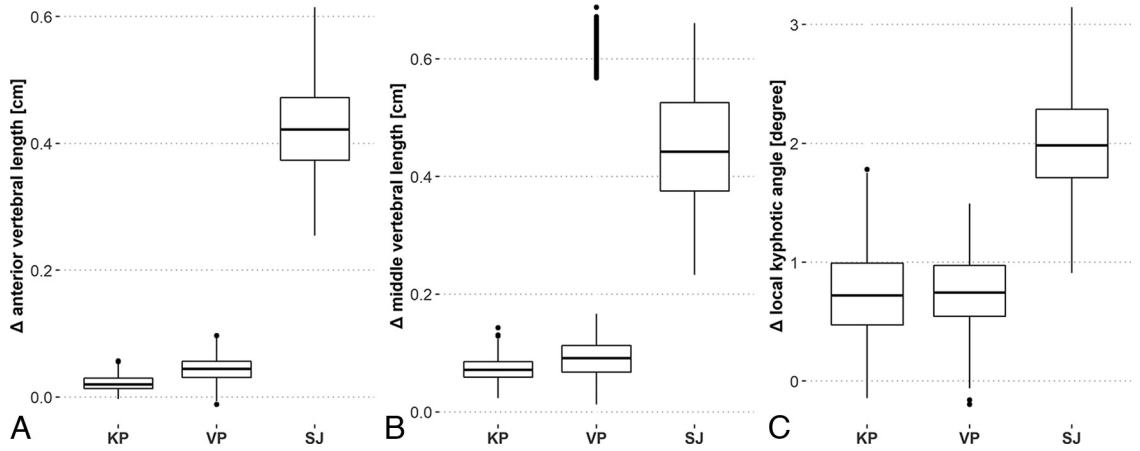

FIG 3. Vertebral augmentation radiologic changes. *A*, Distribution of changes in radiographic vertebral augmentation measurements for anterior vertebral length for the 3 procedures *B*, The same distribution of changes for middle vertebral length. *C*, The same distribution of changes for local kyphotic angle. Shown are median and interquartile ranges.

Table 3: Augmentation measurement outcomes

	KP	VP	SJ	*P* Value[a]
Anterior vertebral length (mm)				
Pre (mean)	18.4	20.6	13.0	<.001
Post (mean)	18.6	21.0	17.3	
Δ 95% CI	(0.03–0.4)	(0.09–0.79)	(3.1–5.6)	
% Increase (mean)	1.1	2.2	32.4	
% CI	(0.14–2.59)	(0.4–3.9)	(23.5–43.6)	
Middle vertebral length (mm)				
Pre (mean)	15.9	17.9	12.7	<.001
Post (mean)	16.6	19.5	17.2	
Δ 95% CI	(0.4–1.1)	(0.4–6.5)	(3.0–6.0)	
% Increase (mean)	4.5	5.0	35.6	
% CI	(2.3–7.1)	(2.1–36.8)	(24.0–46.4)	
LKA				
Pre (mean)	7.6°	6.8°	8.9°	<.001
Post (mean)	6.9°	6.1°	6.9°	
Δ Angle				
Δ 95% CI	(0.09°–1.38°)	(0.15°–1.33°)	(1.24°–2.80°)	

[a] The *P* value calculated with Kruskal-Wallis χ^2 tests across procedures.

In a pilot study with 30 patients with osteoporotic VCFs, patients having undergone SJ had better vertebral height and local kyphotic angle restoration compared with those undergoing KP.[20] In another early study following 77 patients who had undergone SJ for 5 years, patients experienced improvement in pain relief, self-sufficiency quality of life, and vertebral height.[21] While there has been promising data on the use of SJ for VCFs, existing studies remain limited in the scope of comparison and/or monocenter design because a comprehensive study involving VP, KP, and SJ is lacking. Our data show that pain score improvement for resting pain after SJ procedures was comparable with that after KP and VP. Moreover, patients having undergone SJ reported larger pain score improvement for pain at worst over the other 2 procedures. Vertebral height and kyphotic angle improvement were all significantly greater in patients having undergone SJ than in those having undergone KP and VP.

Our conclusions are similar to findings from previous studies which showed improved pain scores, VH, and LKA after vertebral implant compared to kyphoplasty,[17,20,22-24] although vertebroplasty was not included in those comparisons. Additionally, most previous studies comparing vertebral augmentation outcomes have compared KP with VP. One meta-analysis showed that KP tended to have significantly better pain reduction than nonsurgical management and better height restoration than VP, while VP had better pain reduction (though not statistically significant) than nonsurgical treatment.[25] This result was in contrast to no significant difference in pain and disability outcomes between KP and VP in a separate meta-analysis by Gu et al.[26] Another review study noted multiple randomized controlled trials,[9] including the Kyphoplasty And Vertebroplasty In the Augmentation and Restoration of Vertebral Body Compression Fractures (KAVIAR) trial,[27] showing longer procedural times with KP, but no difference in clinical outcomes or rates of complication.[9] Furthermore, a retrospective study found that KP and VP were both safe and effective procedures for patients, but it noted complications of PMMA leakage and epidural hematomas.[28] Among the few studies on clinical outcomes and safety involving SJ, one small study compared KP with SJ and VP patient groups, which found improved kyphotic angle and middle VH restoration in the KP with the SJ group, and no difference in pain scores or complication rates.[29] Nevertheless, that study combined KP with SJ in the comparison. In the present study, we directly compared SJ outcomes with KP and VP outcomes, a comparison that is more clinically relevant because KP and VP are the currently accepted and popular procedures for VCFs, while SJ is only approved for osteoporotic and traumatic fractures and more recently approved for use in clinical practice in the United States.

Although SJ is a much newer vertebral augmentation method, as shown in our study and in a handful of others, it presents better improvement in terms of pain scores and shows significant improvement of VH and LKA compared with KP and VP.

Table 4: Adjacent level fracture statistics

	KP	VP	SJ
By visit[a]			
Total No. of procedures	44	46	37
No. of visits with adj. fracture	1	3	1
Total No. of individuals with adj. fracture	1	3	1
No. of levels with adj. fractures	6	8	9
By level[b]			
Total No. of levels	113	132	102
Total No. of individuals with adj. fracture	5	8	4

Note:—adj. indicates adjacent.
[a] Only visits with 1 type of procedure (KP, VP, or SJ) were included.
[b] All visits were considered.

Furthermore, because it is currently only FDA-approved to treat osteoporotic and traumatic VCFs, our direct outcome comparison including pathologic or secondary VCFs informs the interventional community of benefit in off-label use of SJ and may support future approval of use in other pathologies. We found that pain scores showed greater improvement for pathologic fractures following vertebral implants in our subanalysis. In practice, we performed microwave ablation on approximately 25% of pathologic fractures regardless of the choice of surgical procedures, which, in itself, could palliate the pain during coagulation necrosis of the tumor and destruction of the nerve ending. Future research is warranted to optimize the combination of ablation and surgical interventions for VCF management. Notably, our data suggest that major complications such as adjacent level fractures were not more common in vertebral implants compared with well-established procedures, advocating the use in a wider range of future clinical applications.

In our multi-institutional cohort, patients selected for SJ had less anterior and middle vertebral heights and larger local kyphotic angles than patients selected for KP and VP before each procedure. This outcome was because patients with moderate-to-severe height loss were preferentially selected to receive vertebral implants because of the suspected clinical advantage of height restoration in these patients. This secondary benefit of SJ was confirmed by this study, further supporting the potential utility of a vertebral implant as a safe and effective treatment for moderate-to-severe VCFs. However, the observed benefits of SJ in comparison with those from other procedures should be interpreted with caution, given the retrospective nature of this study.

Additional limitations of this study include retrospective review and a moderately sized patient population, particularly in the vertebral implant group. This limitation is partially due to the novelty of this procedure and the lack of FDA approval for cancer-related VCF indications. Although this may limit the generalizability of our results, we noted that our multi-institutional, multiprovider study design was aimed at minimizing confounding effects on clinical outcomes. Additionally, we found a potential trend toward improved reduction in worst pain with SJ in patients with VCF, but we may be limited in the power to detect benefits of one procedure type over another. Future larger randomized controlled trials would be needed to directly compare these procedures. Another limitation is that some patients received >1 type of vertebral augmentation, which may introduce correlations in our data set and violate the independence assumptions of statistical testing. We addressed this challenge by designing a rigorous bootstrapping procedure to avoid inflation of type 1 errors. We further confirmed our findings by performing a separate analysis using data from visits with only 1 type of vertebral augmentation, which did not alter our findings.

Overall, we present the first systematic study analyzing patient-reported and radiographic outcomes following 3 types of VCF procedures, demonstrating vertebral implants as safe and effective alternatives to VP or KP in a wide variety of clinical scenarios. With vertebral implants becoming more common and consistent across the United States, this study may contribute to better understanding of their implications in patients in comparison with alternative therapies.

CONCLUSIONS

Vertebral implant systems demonstrated similar pain improvement in patients with structural and pathologic VCFs compared with KP and VP, but they showed superior VH restoration and LKA improvement. Our findings support the vertebral implant as a safe and effective treatment option for vertebral augmentation. Future studies are warranted to establish comparative advantages of each procedure for optimal treatment-planning of specific groups of patients with VCFs.

Disclosure forms provided by the authors are available with the full text and PDF of this article at www.ajnr.org.

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