Retrospective Study

Clinical Outcomes for 52 Patients Treated with V-STRUT® Transpedicular Device for Osteoporotic and Pathologic Vertebral Compression Fractures in the United States

Reade A. De Leacy, MBBS[1,2], Kevin Buttet, MD[2], Daryl T. Goldman, MD[1], Aliya Siddiqui, MD[3], Henri Kolb, MD[2], Douglas P. Beall, MD[4], Dana Dunleavy, MD[5], Neal Khurana, MD[6], Amish Doshi, MD[1], David Mitchell, MD[7], Harry Brown, MD[8], David Rosenfeld, MD[9], Isador Lieberman, MD[10], Martin Oselkin, MD[11], Jesse Hatgis, MD[12], and Majid Khan, MD[13]

From: [1]Icahn School of Medicine at Mount Sinai, New York, NY; [2]Department of Neurosurgery, Mount Sinai Medical System, New York, NY; [3]Medical College of Wisconsin, Milwaukee, WI; [4]Spine Fracture Institute, Oklahoma City, OK; [5]Atlas Intervention Radiology, Buffalo, NY; [6]Vascular and Vein Institute of Siouxland, Dakota Dunes, SD; [7]Mary Black Hospital, Spartanburg, SC; [8]Amita Resurrection, Chicago, Il; [9]Alliance Spine and Pain Center, Atlanta, GA; [10]Texas Back Institute, Dallas, TX; [11]St. Luke's Hospital, Bethlehem, PA; [12]Anesthesia Pain Care Consultants, Tamarac, FL ; [13]Johns Hopkins Hospital, Baltimore, MD

Address Correspondence:
Reade A. De Leacy, MBBS
KCC 1-North, 1450 Madison Avenue, New York, NY, 10029
E-mail:
reade.deleacy@mountsinai.org

Disclaimer: There was no external funding in the preparation of this article.

Conflict of interest: RDL is a consultant for Stryker IVS and Hyprevention and part of the scientific advisory board for Hyprevention. RDL has a research grant supported by Hyprevention and is Principal Investigator for the RECONSTRUCT pilot study which was supported by Hyprevention. MK is a consultant for Hyprevention and part of the scientific advisory board.

Article received: 09-30-2024
Revised article received: 01-27-2025
Accepted for publication: 03-03-2025

Free full article:
www.painphysicianjournal.com

Background: In patients presenting with a vertebral compression fracture, there is minimal published data on safety and efficacy outcomes for the novel V-STRUT© (Hyprevention, Inc.) vertebral augmentation system for treating pathologic, traumatic, or osteoporotic vertebral compression fractures.

Objective: To assess the safety and effectiveness of a polyether ether ketone polymer transpedicular vertebral system (V-STRUT) combined with polymethylmethacrylate for treating vertebral compression fractures.

Study Design: A retrospective study.

Settings: Eleven clinical sites in the United States: interventional radiology, interventional pain, and spine surgery departments.

Methods: Fifty-two consecutive patients (23 men and 29 women; median age 71.5 years [SD = 10.8]) underwent treatment for vertebral compression fracture with V-STRUT and polymethylmethacrylate. Each patient's clinical and radiologic results were collected at 3 different time points (Baseline [preintervention], one-month, and 6-month follow-ups) using magnetic resonance imaging, x-ray, or computed tomography at the physician's discretion. Patients missing either the one-month follow-up (n = 11) or 6-months follow-up (n = 19) were excluded from Visual Analog Scale (VAS) score analysis for that time point, but were included for overall procedural data and safety analysis. Follow-up data were collected for 41 patients at one-month follow-up and 33 patients at 6-months follow-up. Fracture etiologies were osteoporosis in 43 (83%) patients and malignancy in 9 (17%). Data recorded were: procedure duration; fractured vertebral levels; treated vertebral levels; Genant Classification, and/or Magerl Classification fracture gradings; anesthesia; quantity of bone cement; implant sizes; and adverse events, including serious events. Pain was assessed using the Visual Analog Scale.

Results: The procedure was completed successfully in all patients. The mean procedure duration was 48 minutes (SD = 23.7). Asymptomatic bone cement leakage occurred in 7/52 patients (13.5%), remote level fractures occured in 2/52 (3.8%), and new adjacent level fractures occurred in 4/52 (7.7%) patients; 4/52 (7.0%) patients died prior to completing all study milestones. Across both osteoporotic and pathologic fracture groups, the mean baseline VAS score was 81 mm (SD = 18.5); one-month postoperative scores were 36 mm (SD = 32.2, P = 0.0.005) and 6-months postoperative scores were 18 mm (SD = 25.1, P = 0.005).

Limitations: Our study has limitations inherent in all retrospective studies. The study results are the authors' data collection and is subject to different forms of bias including selection and recall bias.

Conclusions: This study reflects clinical experience to date for the V-STRUT device in the

United States. This initial data demonstrates the safety and early efficacy for treating osteoporotic and malignant thoracolumbar compression fractures associated with severe refractory pain.

Key words: Kyphoplasty, transpedicular fixation, spine, cancer, osteoporosis, implants, vertebral fracture, pedicle fracture

Pain Physician 2025: 28:

Vertebral compression fractures (VCFs) are common, with an estimated incidence of 1,000,000 osteoporotic, 160,000 neoplastic, and 50,000 traumatic fractures reported yearly in the United States (1-7). These fractures pose a significant burden on the health care system and are responsible for more than 150,000 hospitalizations each year (8,9). VCFs result in a reduced quality of life, both acute and chronic pain, decreased physical and functional performance, negative psychosocial consequences, and a 3-fold increase in mortality (8,10,11). Nonsurgical management has been associated with doubling the risk of future fractures (22%) compared to vertebral augmentation procedures (11%) (12).

Early treatment with vertebral stabilizing Interventions such as vertebroplasty, vertebral augmentation with balloon kyphoplasty, and instrumented vertebral augmentation form the standard of care for patients with acute/subacute and ultimately chronic compression fractures associated with refractory pain (13-16). Kyphoplasty using expandable implants and polymethylmethacrylate (PMMA) such as SpineJack® (Stryker), and KIVA® (IZI Medical) provide vertebral height restoration in mobile fractures at the time of the treatment which is maintained with bone cement (9,17,18). These devices are intended to restore sagittal spinal alignment and minimize residual segmental kyphosis and deformity that can result from a VCF.

Biomechanically, adjacent, and remote level fracturing has been shown to be less common with normal alignment restoration (9). The phenomenon is, however, multifactorial and also known to be associated with low bone mineral density, the presence of pre-existing adjacent and remote fractures, spinal deformity, intradiscal bone cement leakage, diminished restoration of vertebral height, and the degree of kyphotic angle change from the initial VCF (19,20). Other factors such as body habitus, comorbid diseases, and prolonged immobility also play a significant role. Although these implants reflect significant clinical advances, the potential of progressive vertebral body collapse via pediculosomatic compression remains possible as the axial loading force is not intended to be redistributed to the middle and posterior column, especially in junctional vertebrae. Evaluating the long-term superiority of these implantable devices compared to vertebral augmentation alone continues (9,21).

The V-STRUT© vertebral implant (Hyprevention) is a minimally invasive, image-guided, percutaneous polyetheretherketone (PEEK) polymer transpedicular implant indicated for use in combination with PMMA for treating osteoporotic or pathologic VCFs in the thoracolumbar spine from levels T1 to L5 as well as pedicle fractures. Unlike currently available implantable devices, such as SpineJack and KIVA which restore vertebral height, the V-STRUT transpedicular implant anchors the anterior, middle, and posterior columns, which in conjunction with PMMA supports the superior vertebral endplate and re-establishes thoracolumbar spine stiffness, thereby reducing stress applied to the adjacent vertebral levels under compressive load (22,23) (Fig. 1). Biomechanically, this not only aims to decrease both the risk of progressive collapse and pediculosomatic force at the index fractured level, but also the risk of adjacent level or levels fractures through the above mechanisms (9).

The V-STRUT implant is composed of a PEEK polymer, (PEEK-OPTIMA™, Invibio Biomaterials Solutions™) which is more similar biomechanically to bone than titanium. Comparatively, transpedicular titanium implants are more rigid than bone and increase the overall stiffness of the treated vertebra and spinal segment (Fig. 1). Theoretically, this could comparatively increase the risk of adjacent fracture and disc degeneration (24,25). PEEK implants permit increased overall vertebral flex, and the combination of the V-STRUT geometry and material could potentially restore relatively normal vertebral and spinal segment biomechanics (25).

Our study reports initial safety and efficacy outcomes of 52 patients treated with the V-STRUT augmentation system to date for both pathologic and osteoporotic VCFs in the United States.

Methods

Study Design and Patient Selection

This multicenter retrospective cohort study reports

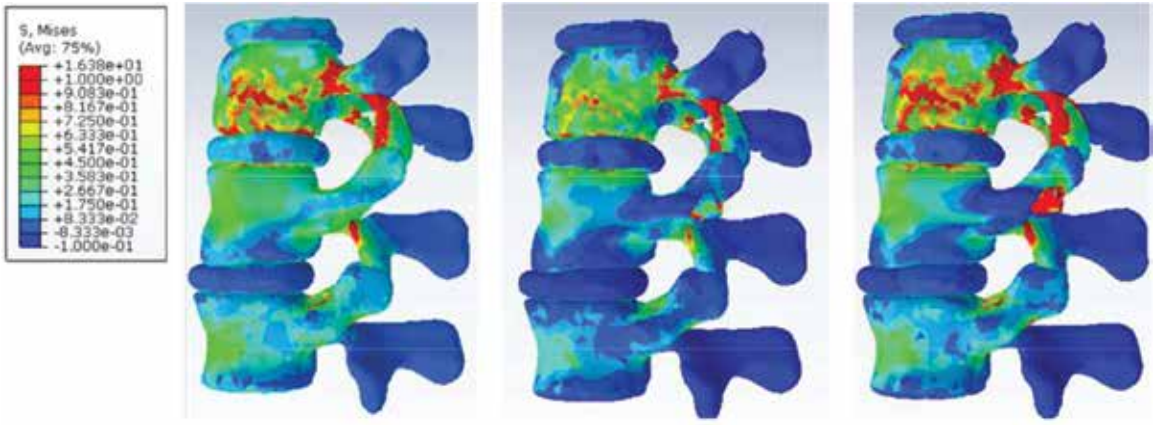

Fig. 1. *Finite element analysis of redistribution of stress under axial load: Finite element analysis (FEA) of vertebrae demonstrating target and adjacent level stress distribution between: (a) with no implant, (b) PEEK implant at middle level, and (c) titanium implant at middle level. The FEA model does not factor in PMMA. Utilizing the von Mises stress measurements when an applied force compresses the functional spinal unit, we can vizualize how the stress is redistributed with areas of greater stress displayed in red and of least in dark blue.*

V-STRUT procedures performed by physicians within the United States from October 2020 through May 2024. We received Institutional Review Board approval from the senior author's institution. Routine procedural informed consent was obtained from all patients who underwent V-STRUT implantation.

The decision to use the V-Strut device was at the sole discretion of the individual treating physician based on clinical and radiological findings. Adult patients with refractory painful VCFs related to osteoporosis or tumor involvement located between levels T9 to L5 who had failed conservative treatment and had an appropriate pedicle diameter to receive 5.5 mm or 6.5 mm implants, were included.

Since the present study was concluded, on-label indications for this device have expanded to include T1-T8 vertebral levels and isolated or combined pedicle fractures, in addition to a new implant diameter of 4.5 mm. At the time of this writing, 41/52 patients had available one-month follow-up data for pain response. Patients without one-month outcome data (n = 11) and patients without 6-months outcome data (n = 13) were excluded from the time point analysis.

Procedural metrics, fracture gradings, and adverse events such as the rate of adjacent and remote level fractures in the follow-up period were tracked and reported for the overall cohort and separated into osteoporotic and pathologic fracture populations. The primary outcome measure was the proportion of patients with a Visual Analog Scale (VAS) score < 40 mm at either postoperative one- or 6-months without adjacent level or target level refracture in the follow-up period verified by x-ray, magnetic resonance imaging, or computed tomography at the treating physician's discretion.

Procedure Description

All procedures were performed under fluoroscopy using single or biplane imaging. General anesthesia, monitored anesthesia care, or local anesthesia with sedation were used according to the operator's preference. All procedures were performed with the patient prone. An 11G or 13G bone needle was used to access each pedicle using standard access techniques. After positioning the bone needles, a 1.6mm Kirschner guidewire was introduced and positioned up to a maximum of 5 mm from the anterior wall cortex; the outer cannula was then removed.

A soft tissue dilator was inserted over the K-wire up to the target pedicle followed by inserting a protection tube. Sequential drilling of the proposed device channel was performed using 4.5 mm, 5.5 mm and 6.5 mm diameter hand drills. Sizing of the implant was determined by pedicle size on pre-operative cross-sectional imaging and by identifying the correct length device, 40 mm to 60 mm, from the measurement indicators on the side of each hand drill when the drill had advanced to the appropriate depth within the vertebral body.

The implants were then advanced over the K-wire through each pedicle, the K-wires were removed, and

the implants were cemented in place with PMMA. One of 4 cements were used according to operator preference: VertaPlex® HV (Stryker), 39/52 patients (75%); F20® (Teknimed) 8/52 patients (15.4%); Kyphon™ (Medtronic) 3/52 patients (5.7%); and Vertecem™ (DePuy Synthes) 2/52 patients (3.8%).

Bone access needles, guidewires, cement injectors, and all procedural tools were re-sterilized and stored for future use; vertebral implants were not re-used (Fig. 2). Anteroposterior and lateral radiographs were taken immediately following the procedure to assess final implant positioning and cement distribution.

Outcomes and Statistical Analysis

Basic patient demographics, fracture etiology, grading, and descriptives were documented (Table 1). Outcomes were reported relating to the overall population and separated into patients with osteoporotic and/or pathologic fractures. Procedural metrics were tracked and reported as were PMMA leakage rates, intraprocedural complications, as well as perioperative and postoperative serious adverse events. Adverse events were reported according to the Society of Interventional Radiology quality improvement guidelines for percutaneous vertebroplasty (26). Pain severity was assessed using the VAS at preprocedure, and at the one-

Fig. 2. *Procedural tools and devices with label.*

month and 6-months follow-up appointments. Verbal subjective outcomes from the patients were also included. Continuous variables were reported as mean (SD) or median (interquartile range [IQR]) where appropriate. Categorical variables were reported as percentages.

Statistical calculations were made using R 4.4.0 (R Foundation).

Results

Patient and Procedural Characteristics

A total of 52 patients (29 women and 23 men; mean age 71.5 years [SD = 10.8]) from 11 centers were included for final procedural and safety analysis. Forty-one patients were included in the one-month and 33 patients in the 6-months follow-up analysis. Fourteen interventionalists contributed cases.

Fracture etiology was osteoporosis in 43 patients and malignancy in 9 patients. Two patient examples are provided in Fig. 3. Baseline patient characteristics and procedural results are summarized in Table 1. Treated level distribution and Magerl fracture morphology are presented in Figs. 4 and 5. Magerl, Genant and AO fracture gradings were taken for 39/52 (64%) patients using preoperative radiographic imaging. Patients were graded as follows: Genant Grade 1 26/37 (70.3%), Genant Grade 2 10/37 (26.0%), and Genant Grade 3 1/37 (2.7%). AO fracture classifications: OF1 19/39 (48.7%), OF2 13/39 (33.0%), OF3 6/39 (15.4%). Magerl fracture classifications were A1 33/39 (84.6%), A2 5/39 (12.8%), and A3 1/39 (2.5%).

The procedure was safely completed in each patient. The mean procedure duration time, including the full time in the operating room, was 48 minutes (SD = 23.7). The mean volume of PMMA injected was 5.5 mL per level (SD = 2.3).

Table 1. *Demographic and descriptive fracture variables.*

	Total Population	Osteoporotic	Malignant
Gender, m/f no. (%)	23/29 (44/56)	17/26 (40/60)	6/3 (66/33)
Age (years; SD)	71.5 +/- 10.8	72.9 +/- 10.9	65.2 +/- 8.3
Fracture Etiology			
Osteoporotic	43	43	0
Malignant	9	0	9
Fracture Age (days; SD)	37.5 +/-29.8	37.3 +/- 32.6	38.4 +/- 11.5
Fracture Type			
Genant (n = 37)			
1	26	20	6
2	10	10	0
3	1	1	0
OF (n = 39)			
OF1	20	16	4
OF2	13	10	3
OF3	6	6	0
Magerl (n =39)			
A1	33	29	4
A2	5	1	4
A3	1	1	0
Fracture Level			
Rigid (T3-T10)	2	2	0
Junctional (T11-L1)	19	16	3
Mobile (L2-L4)	28	23	5
Junctional (L5-S1)	3	2	1
Anesthesia			
Local + Sedation	4	4	0
MAC	12	11	1
General	36	28	8
Cement Volume (mL; SD)	5.5 +/- 2.3	5.5 +/- 2.3	5.5 +/- 2.2
Procedure (mins; SD)	48 +/- 23.7	47.2 +/- 25.1	52/5 +/- 13.9

Outcomes

The primary outcome of VAS score of < 40 mm at 6-months follow-up was seen in 22/33 patients (66%). Four patients had a VAS score of < 40 mm at their one-month follow-up, but did not present to their 6-months follow-up. Overall, patients who reported a VAS score of < 40 mm at either follow-up point were 26/37 (70%) (Table 2; Fig. 6). Of the remaining study population, 4 patients died prior to the study's completion due to an unrelated comorbidity; 7 patients had not reached their 6-months follow-up at the time of this writing.

Of the 4 remaining patients with persistent pain and a VAS score > 40 mm at 6-months follow-up, one was an 86-year-old woman with an osteoporotic VCF who experienced an adjacent level fracture at 6 weeks postintervention and one was a 74-year old man who developed myeloma with an adjacent level fracture at 9 weeks postintervention, which was retreated. On his follow-up presentation he reported no pain. Another patient was a 67-year-old man who experienced a remote level VCF due to an unrelated fall at 6 weeks postintervention. The last patient was a 69-year-old

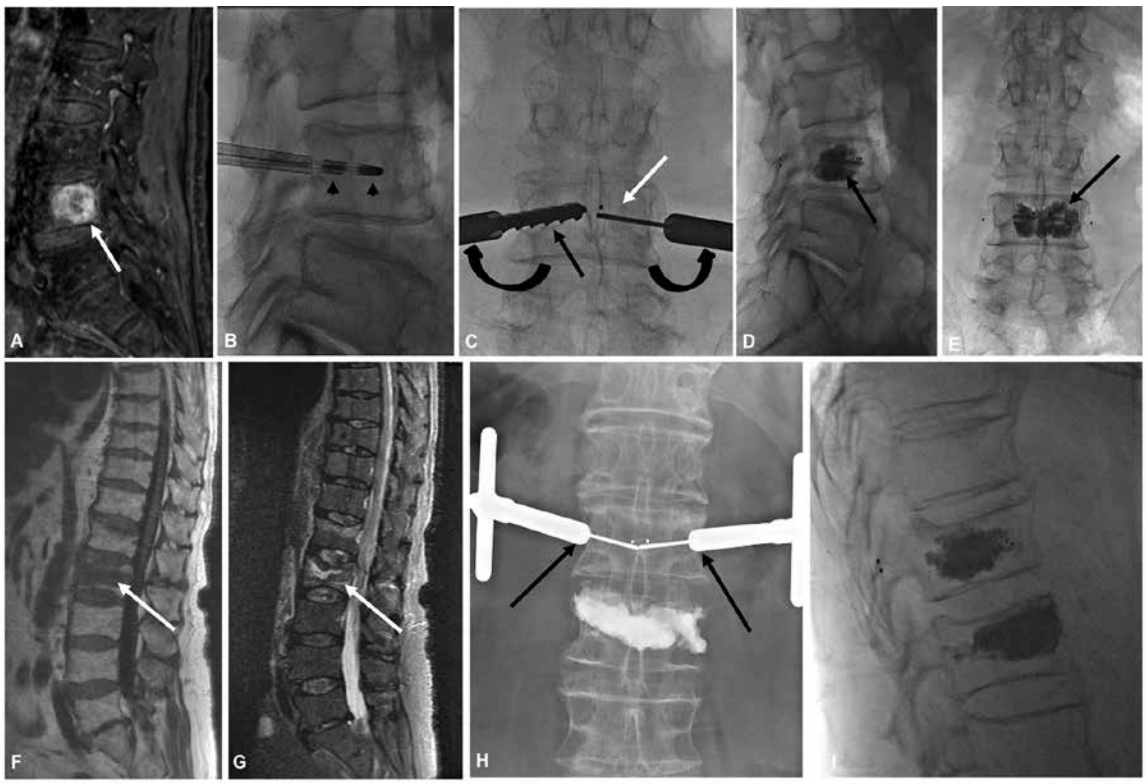

Fig. 3. *Patient 1 (a-e) is a 74-year-old man with a past medical history of hypertension, prostate cancer, and stage 4 HCC. Prior RFA and vertebral augmentation of C1, presents for L4 lesion (white arrow in a) (a) demonstrating rapid growth. (b) Lateral image of radiofrequency probes (black arrowheads) for ablation. (c) Shows left pedicle sizing drill (black arrow) access and implant placed on right over k-wire (white arrow). Soft tissue protection tubes are also seen (curved black arrows) (d, e) Final AP and lateral images of devices with PMMA (black arrows). Patient 2 (f-i) is a 72-year-old man who presented with severe axial lower back pain after all, and failure of medical management requiring hospital admission. The patient's VAS score was 90/100 and he was bed bound since admission. Imaging shows VCFs of L1 (Magerl A1.2) and L2 (Magrel A3.1/2 cleft) seen on sagittal T1 (f) and sagittal STIR (g) images (white arrows). Fluoroscopically guided bipedicular approach for fixation with the V-STRUT implantable device (black arrows) (h). Post intervention lateral (i) fluoroscopic images demonstrate satisfactory device positioning and cement placement. The patient tolerated the procedure well and the one month follow-up VAS score was 0/100.*

man who had an adjacent level fracture following a fall at 5-monthspostoperative.

Overall, the mean VAS score decreased from 81 mm at baseline (SD = 18.5) to 36 mm at the one-month follow-up (SD = 32.2, $P = < 0.005$) and to 18 mm at the 6-month follow-up (SD = 25.1, $P = < 0.005$). Patients' subjective improvement in postprocedural pain was also documented at one- and 6-months follow-ups respectively, excluding loss to follow-up and deceased patients for both categories: 12/40 (30.0%) and 9 /27 (33.3%) of patients reported total pain relief (VAS score of 0), 16/40 (40.0%) and 13/27 (48.1%) patients reported major pain relief (VAS score < 40), 6/40 (15.0%) and 3/27 (11.1%) of patients reported minor pain relief (VAS score decreased but still > 40), 6/40 (15.0%) and 2/27 (7.4%) reported no pain relief (VAS score ≥ to preoperative VAS score).

Adverse events occurred in 11/52 (21.2%) patients with one serious adverse event reported intra-operatively or within the follow-up period. The most common adverse events were asymptomatic cement leakage in 7/52 (13.5%) patients. No subsequent fractures at the treated level were observed. In terms of adjacent and remote level fractures identified in follow-up, new adjacent level VCFs were seen in 4/52 (7.7%) patients; each of those patients had only one adjacent fracture, with 3/43 (7.0%) occurring specifically in the osteoporotic patient subgroup. New remote level VCFs were

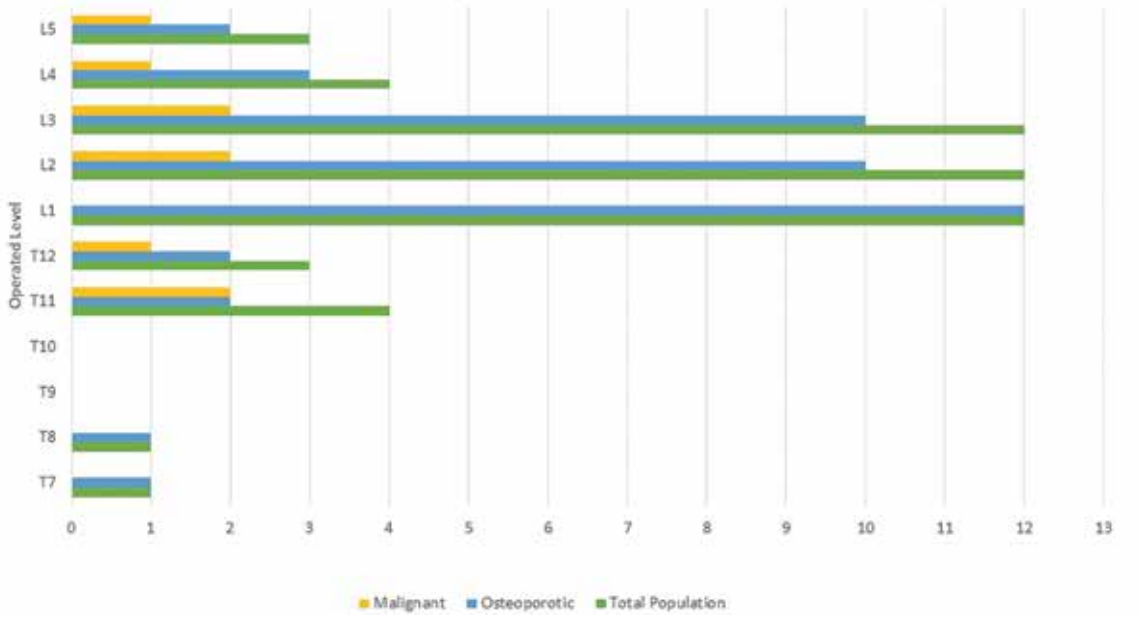

Fig. 4. *Treated vertebral level distribution.*

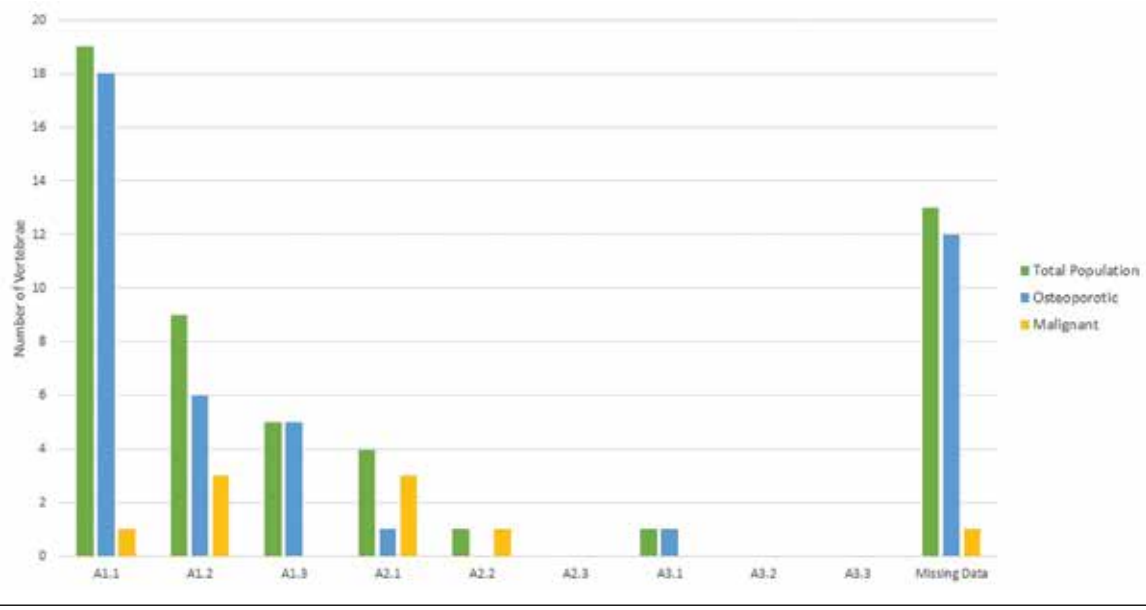

Fig. 5. *Treated level distribution by Magerl classification.*

reported in 2/52 patients (3.8%). One serious adverse event occured in a patient who developed osteomyelitis at the treated level during the follow-up period, in the setting of prior kidney transplant and immune suppression. This patient was treated with antibiotics which resolved the infection.

Discussion

This study reports outcomes for the first consecutive 52 patients in the United States where the V-STRUT vertebral implant was used for managing osteoporotic and pathologic VCFs. One serious adverse event was

Table 2. *Treated population Visual Analog Score (VAS) at baseline, one month and 6 month follow up with mean, median and range. Outcomes presented as total population, osteoprootic fracture population, and pathologic fracture population. P value to denote significant change with respect to baseline values.*

Pain Intensity VAS	n (% of total pop.)	Mean +/- SD	Median (IQR)	Range (min to max)	*P* Value (c/baseline)
Total Population					
Baseline	52(100)	82 +/- 16.2	80 (10)	21 to 100	
1 month	41 (78.8)	36 +/- 32.2	30 (60)	0 to 100	< 0.005
6 months	33 (63.5)	18 +/- 25.1	10 (20)	0 to 90	< 0.005
Osteoporotic					
Baseline	43 (100)	81 +/- 17.6	80 (10)	21 to 100	
1 month	33 (76.7)	40 +/- 34.6	40 (70)	0 to 100	< 0.005
6 months	28 (65.1)	20 +/- 27.2	10 (20)	0 to 90	< 0.005
Pathologic					
Baseline	9 (100)	85 +/- 8.7	85 (10)	80 to 100	
1 month	8 (89.0)	21 +/- 11.5	20 (12.5)	0 to 35	< 0.005
6 months	5 (55.6)	13 +/- 5.0	10 (2.5)	10 to 20	< 0.005

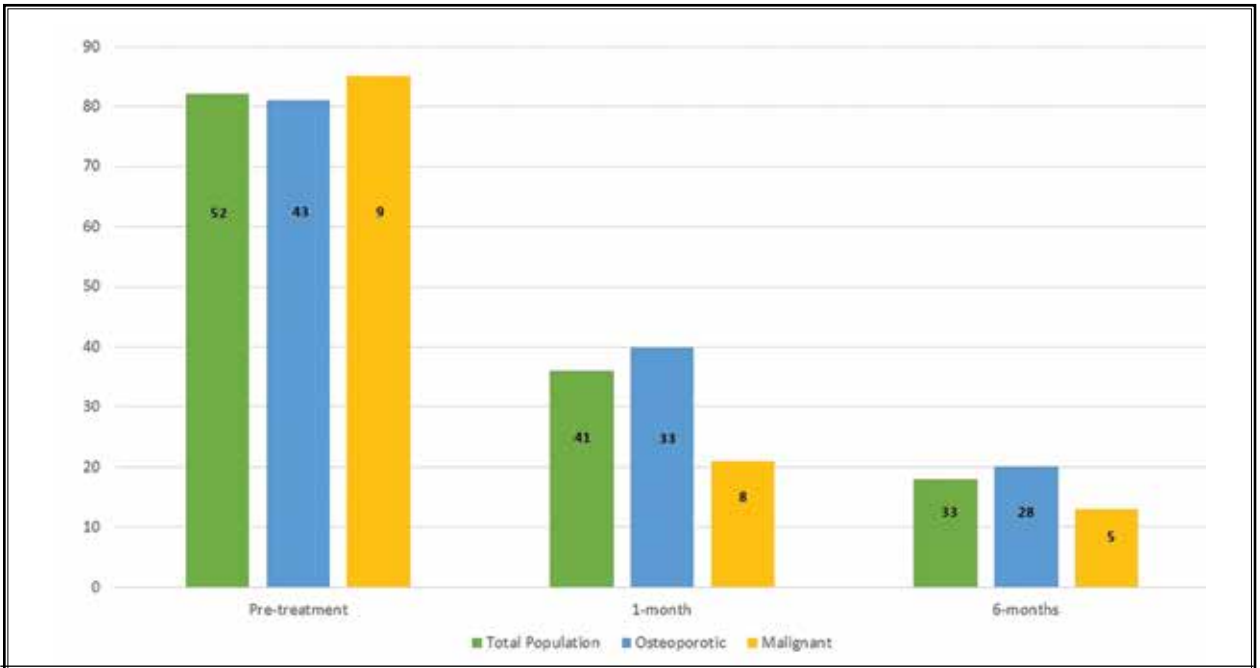

Fig. 6. *Visual analog scale response from baseline out to 6 months post treatment with number of patients at following time points. Number within the bars represents number of patients in cohort at that time point for which data is available.*

reported in which a patient with a prior, remote renal transplant developed osteomyelitis at the treated level in the first postoperative month. This was managed and resolved with antibiotics. Postoperative pain relief followed the pattern seen in the available vertebral augmentation literature (8,15,27,28). Subsequent fractures at the treated level, adjacent and remote level VCFs in the follow-up period were 0.0%, 7.7% and 3.8% respectively.

The V-STRUT vertebral augmentation system is designed to redistribute axial load under compression and reinforce the posterior elements of the vertebra across the anterior and middle column trabecular bone (25,29). This provides a physical anchor from the

vertebral body to the posterior column, theoretically decreasing the likelihood of progressive incident level collapse and pediculosomatic injury, ultimately improving the vertebral body's load-bearing capacity and optimizing support (19,30).

Biomechanically, it is proposed that the posterior column anchoring helps reinforce the superior vertebral endplate, enabling resistance to axial compression and reducing progressive endplate collapse and the resultant segmental kyphotic deformity, thus mitigating one major risk factor for adjacent fractures (30). Aebi, et al (19) tested how the addition of the V-STRUT device to a VCF can improve its ability to absorb more energy and withstand greater maximum forces (F_{max}) compared to vertebroplasty when comparing the fracture generation stage to the posttreatment stage. The compressive loading endpoint was determined to be when the vertebral body had a 25% reduction of its original height, similar to a Genant grade 1 wedge fracture. This was achieved through a 2-phase process: 1) a loading phase that incremented force by 5 mm/min to the Fmax followed by, 2) a continued displacement with a lesser load until the endpoint was reached. The Fmax that could be applied to the vertebra prior to treatment was 1,642N (SD = 262) in the V-STRUT group and 2,047N (SD = 530) in the vertebroplasty group, which had increased to 2,906N (SD = 1521) (77%) and 2,842N (SD = 712) (39%) respectively. The change in capacity of absorbed energy, which is the total quantity of force over time that the vertebra could withstand until a 25% vertebral reduction was achieved, was also noted to increase from 8,535N (SD = 3463) to 19,277N (SD = 5,638) (126%) with V-STRUT and from 9,729N (SD = 4,110) to 19,317N (SD = 6,105) (99%) with vertebroplasty(19). Overall, this study demonstrated at least equivalent biomechanical performance of the V-STRUT device compared to vertebroplasty (19).

The total patient population in our study exhibited a decrease in mean VAS score at baseline from 82 mm (SD = 12.9) to 36 mm (SD = 32.2) at postoperative one month and 18 mm (SD = 25.1) at postoperative 6 months. This VAS response was similar when the cohort was separated into patients whose fractures were due to osteoporosis or malignancy. While published data for this device remain limited, overall findings indicate similar outcomes when compared to existing implantable devices and routine vertebral augmentation in terms of pain reduction (9,15,17,18,28). Specifically in reference to the investigational device, Barral, et al (21) reporting the 2-month follow-up with 9 patients implanted with the V-STRUT device, found similar results: the median VAS score decreased from 55 mm (IQR 50 – 70) before the procedure to 25 mm (IQR 5 – 30, $P = 0.0003$). At the 6-month follow-up, the median VAS score decreased to 30 mm (IQR 15 – 40, $P = 0.14$) (21). Comparable device trials, such as SAKOS, demonstrated a 58.5 mm decrease in VAS scores at postoperative one month and a 62.6 mm decrease in VAS score at postoperative 12 months (9). The KIVA system saw a decrease in VAS scores by 70.8 mm at postoperative 12 months in the KAST study (17).

In our study of 52 patients, as in the initial V-STRUT pilot study of 9 patients, no subsequent fracture or fragmentation was identified at the treated level following VCF treatment with V-STRUT (21). The SAKOS study (9) conducted on patients with osteoporosis reported subsequent fracture rates of 3.6% (4/64) with SpineJack and 9.0% (6/67) with balloon kyphoplasty (BKP) at 6 months.

The risk of adjacent level fracture after treating a VCF is a subject of ongoing debate and concern. The majority of adjacent fractures manifest within the initial 3 months post osteoporotic VCFs treated with kyphoplasty (30,31). In the Barral, et al (21) study, no postprocedure adjacent fracture was reported during follow-up (median 193 days, IQR, 147–279) for 9 patients treated with V-STRUT (21). Adjacent fracture rates of 9.4% (6/64) were seen with SpineJack, with a total number of adjacent fractures of 9 and 25% (17/68) with balloon kyphoplasty with a total number of adjacent fractures of 23 at 6-months follow-up. Adjacent fractures rates of 12.9% (8/62) with SpineJack with a total number of adjacent fractures of 12, 20.9% with KIVA, and 22.3-27.3% with BKP were reported at postoperative 12 months (9,17).

In our study, new adjacent VCFs were reported in 3/43 patients with osteoporosis (7.0%), with a total number of adjacent fractures of 3; a single new remote VCF was seen in one patient (2.3%). While the current series is not directly comparable to the SAKOS (9) or KAST (17) trials in terms of methodological rigor and imaging core lab evaluation, close observation of these outcomes in subsequent studies examining V-STRUT will be of interest. The subsequent, adjacent and remote fracture rates in our study seem to compare favorably to other studies, however in the SAKOS study, most of the fractures treated were Genant grade 2 or 3 (88% [64/73]) with SpineJack and 88% (68/77) with balloon kyphoplasty, whereas the factures treated with V-STRUT were Genant grade 1 70.3% (26/37), grade 2 27% (10/37) and grade 3 2.7% (1/37). By its design, V-STRUT is not intended to provide height restoration;

fracture Genant grades 1 and 2 are mostly indicated and vertebral height was not measured in our study. In the SAKOS study, midline vertebral body height restoration between baseline and 12-months postoperative was measured at 1.31 mm (SD = 2.58) for SpineJack and 0.10 mm (SD = 2.34) for balloon kyphoplasty. Anterior vertebral body height restoration was not reported for wedge fractures in the SAKOS study.

Intra-operative PMMA leakage during vertebral augmentation is often asymptomatic. Rarely, complications such as bone cement venous embolism occurs, leading to significant patient morbidity (32). Extensive leakage into the disc space can also predispose adjacent endplate injury or fracture occuring (31,33).

Fracture morphology also appears to play a role in adjacent and remote fractures developing with relatively higher rates of additional fractures occurring following the percutaneous treatment of more complex VCFs, such as burst type fractures (Magerl A3) (32). This may be due to ongoing mobility at the fractured level, especially in loading or with pronounced bone cement leakage into the adjacent disc space. Using cavity creating tools or implants, in addition to high viscosity bone cement, may decrease the rate of bone cement leakage. In the present series, inflatable bone tamps, steerable bone curettes, and other anterior column implants, such as vertebral body stents, were not used in combination with the study device. This likely explains the relatively low average bone cement volume injected at each level.

In our study, the rate of asymptomatic bone cement leakage was 7/52 (13.5%); this was the most common adverse event reported. This was notably lower than the rates observed in the European study of V-STRUT (21) (55.6%); interestingly, this is fewer than those reported for similar procedures: 50.7% using SpineJack, 45.1% to 64.5% using balloon kyphoplasty, and 64.6% using KIVA(9,17,21). Since our series did not use a blinded core lab for imaging review, the rate of bone cement leakage is likely underestimated. A recently published study evaluating optimal bone cement volume partnered with V-STRUT based on finite element analysis suggested that 4 mL of PMMA was the ideal volume within the modelled lumbar spine for establishing normal target vertebral stiffness and decreasing load on the adjacent vertebral segments (29).

Recently, V-STRUT was cleared by the US Food and Drug Administration to address pedicle involvement detected by magnetic resonance imaging that is frequently seen in VCF due to osteoporosis or cancer (34). The efficacy of V-STRUT to reinforce a fractured pedicle, or one that is involved by malignancy, requires further study.

Limitations

Our study has several limitations inherent in all retrospective studies and is subject to several forms of bias, including selection bias and recall bias. Pain score follow-up to postoperative 6 months was available in 33 patients at the time of writing. Additionally, given the inclusion of multiple centers in this study, a heterogenous patient population was included, with varying fracture etiology as well as limited data on a patient's fracture grade. Limited patient demographic information is available to determine homogeneity across the cohort in terms of relevant medical comorbidities. Imaging outcomes were self-reported, and as such bone cement leakage rates may have been under-reported. Vertebral heights at pre- and postoperative were not measured. Additional longer-term studies with more patients, more complete follow-up data, and potentially randomized comparison to other treatment options, including other available implants and standard augmentation techniques, are necessary to demonstrate V-STRUT's comparative effectiveness and safety more accurately. A multicenter, prospective, single-arm study evaluating pain, disability, quality of life, and core lab-adjudicated imaging outcomes is currently underway in the United States (the RECONSTRUCT study; ClinicalTrials.gov ID# NCT05337696).

Conclusion

This study reflects the clinical experience to date for the V-STRUT device in the United States. This initial data demonstrate safety and early efficacy of the device for the treatment of osteoporotic and malignant thoracolumbar compression fractures associated with severe refractory pain. Based on initial biomechanical and clinical data, this novel device has the potential to further improve outcomes for patients with osteoporotic and pathologic VCFs. Further investigation is needed to determine if the absence of ongoing target level collapse and low rates of adjacent and remote VCF in this study are replicated in other studies with a greater number of patients and longer, more complete follow-up evaluations with further granular outcome measures. A prospective adjudicated multicenter pilot study, (the RECONSTRUCT study; ClinicalTrials.gov ID# NCT05337696), is currently underway to confirm the safety and efficacy of the V-STRUT device prospectively, with more complete long-term data and core lab-adjudicated imaging outcomes.

References

1. Mansoorinasab M, Abdolhoseinpour H. A review and update of vertebral fractures due to metastatic tumors of various sites to the spine: Percutaneous vertebroplasty. Interv Med Appl Sci 2018; 10:1-6.
2. Borgen TT, Bjørnerem A, Solberg LB, et al. High prevalence of vertebral fractures and low trabecular bone score in patients with fragility fractures: A cross-sectional sub-study of NoFRACT. Bone 2019; 122:14-21.
3. Barragán-Campos HM, Vallée JN, Lo D, et al. Percutaneous vertebroplasty for spinal metastases: complications. Radiology 2006; 238:354-362.
4. Crans GG, Silverman SL, Genant HK, et al. Association of severe vertebral fractures with reduced quality of life: reduction in the incidence of severe vertebral fractures by teriparatide. Arthritis Rheum 2004; 50:4028-4034.
5. Melton LJ, Kyle RA, Achenbach SJ, et al. Fracture risk with multiple myeloma: a population-based study. J Bone Miner Res 2005; 20:487-493.
6. Cole JS, Patchell RA. Metastatic epidural spinal cord compression. Lancet Neurol 2008; 7:459-466.
7. Quraishi NA, Gokaslan ZL, Boriani S. The surgical management of metastatic epidural compression of the spinal cord. J Bone Joint Surg Br 2010; 92:1054-1060.
8. Siegel RL, Miller KD, Jemal A. Cancer statistics, 2015. CA Cancer J Clin 2015; 65:5-29.
9. Noriega D, Marcia S, Theumann N, et al. A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study). Spine J 2019: 19:1782-1795.
10. Lyles KW, Gold DT, Shipp KM, et al. Association of osteoporotic vertebral compression fractures with impaired functional status. Am J Med 1993; 94:595-601.
11. Wardlaw D, Cummings SR, Meirhaeghe JV, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet 2009; 373:1016-1024.
12. Papanastassiou ID, Phillips FM, Meirhaehe JV, et al. Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies. Eur Spine J 2012; 21:1826-1843.
13. Madassery S. Vertebral Compression Fractures: Evaluation and Management. Semin Intervent Radiol 2020; 37:214-219.
14. Chandra RV, Maingard J, Asadi H, et al. Vertebroplasty and Kyphoplasty for Osteoporotic Vertebral Fractures: What Are the Latest Data? AJNR Am J Neuroradiol 2018; 39:798-806.
15. Beall DP, Chambers MR, Thomas S, et al. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. Neurosurgery 2019; 84:169-178.
16. Beall DP, De Leacy RA. Management of Chronic Vertebral Compression Fractures with Vertebroplasty: Focus on Clinical Symptoms. Radiology 2023; 308: e231243.
17. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva System As a Vertebral Augmentation Treatment-A Safety and Effectiveness Trial: A Randomized, Noninferiority Trial Comparing the Kiva System With Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. Spine 2015; 40: 865-875.
18. De Leacy RA, Chandra RV, Barr JD, et al. The evidentiary basis of vertebral augmentation: a 2019 update. J Neurointerv Surg 2020: 12:442-447.
19. Aebi M, Maas C, Di Pauli von Treuheim T, et al. Comparative biomechanical study of a new transpedicular vertebral device and vertebroplasty for the treatment or prevention of vertebral compression fractures. Clin Biomech 2018; 56:40-45.
20. Kurtz SM, Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials 2007; 28:4845-4869.
21. Barral M, Razakamanantsoa L, Tselikas L, et al. Polyetheretherketone Polymer Transpedicular Vertebral System to Treat Vertebral Compression Fracture: A Multicentre Pilot Study of Feasibility and Safety. Can Assoc Radiol J 2024; 75:644-648.
22. Cianfoni A, Distefano D, Isalberti M, et al. Stent-screw-assisted internal fixation: the SAIF technique to augment severe osteoporotic and neoplastic vertebral body fractures. J Neurointerv Surg 2019; 11:603-609.
23. Hambli R, De Leacy RA, Vienney C. Effect of a new transpedicular vertebral device for the treatment or prevention of vertebral compression fractures: A finite element study. Clin Biomech 2023; 102:105893.
24. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. J Vasc Interv Radiol 2014; 25:165-170.
25. Carli D, Venmans A, Lodder P, et al. Vertebroplasty versus Active Control Intervention for Chronic Osteoporotic Vertebral Compression Fractures: The VERTOS V Randomized Controlled Trial. Radiology 2023; 308:e222535.
26. Clark W, Bird P, Gonski P, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet 2016; 388:1408-1416.
27. Vienney C, Hambli R, De Leacy RA, et al. Effect of cement volume on biomechanical response of a spine segment treated with a PEEK polymer implant: a finite element comparative study with vertebroplasty. Front Bioeng Biotechnol 2024; 12:1399851.
28. Kim MH, Lee AS, Min SH, et al. Risk factors of new compression fractures in adjacent vertebrae after percutaneous vertebroplasty. Asian Spine J 2011; 5:180-187.
29. Ko BS, Cho KJ, Park JW. Early Adjacent Vertebral Fractures after Balloon Kyphoplasty for Osteoporotic Vertebral Compression Fractures. Asian Spine J 2019; 13:210-215.
30. Wang LJ, Yang HL, Shi YX, et al. Pulmonary cement embolism associated with percutaneous vertebroplasty or kyphoplasty: a systematic review. Orthop Surg 2012; 4:182-189.
31. Wang LJ, Yang HL, Shi YX, et al. A continuum mechanical porous media model for vertebroplasty: Numerical simulations and experimental validation. Biomech Model Mechanobiol 2023; 22:1253-1266.
32. Ishiyama M, Fuwa S, Numaguchi Y, et al. Pedicle involvement on MR imaging is common in osteoporotic compression fractures. AJNR Am J Neuroradiol 2010; 31:668-673.