

SINGLE-SESSION MULTILEVEL VERTEBROPLASTY AND KYPHOPLASTY: EVALUATION OF SAFETY AND EFFICACY IN THE TREATMENT OF SPINAL COMPRESSION FRACTURES

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ABSTRACT

Objective: Single-session multi-level vertebroplasty (VP) and kyphoplasty (KP) are minimally invasive techniques for spinal compression fracture treatment. This study aimed to retrospectively evaluate the safety and clinical efficacy of three or more KP/VP procedures performed in a single session.

Materials and Methods: Between 2017 and 2024, clinical data from 13 patients who underwent single-session multilevel (>3 levels) KP/VP for spinal compression fractures were retrospectively analyzed. Pain severity was assessed pre-operatively and post-operatively using the Visual Analogue Scale (VAS), while functional recovery was evaluated using the Oswestry Disability Index (ODI). The procedure-related complication rates, including cement leakage, were also analyzed and categorized according to clinical significance.

Results: A significant reduction in pain levels was observed based on VAS scores ($p < 0.05$). The mean pre-operative VAS score was 8.38 ± 1.26 , which decreased to 5.15 ± 1.72 in the early post-operative period and further to 2.15 ± 1.14 in the late post-operative period. Similarly, the mean pre-operative ODI score was 70.72 ± 11.65 , which decreased to $33.56 \pm 10.4^*$ in the late post-operative period ($p < 0.05$). The complication rate related to the procedure remained minimal, with a cement leakage rate of 18%.

Conclusion: Single-session multi-level KP and VP are reliable and effective treatment methods for spinal compression fractures, and they can significantly reduce pain and achieve functional improvement with a low complication rate. This approach has been implemented in a limited number of centers worldwide and has a high clinical success rate.

Keywords: Multilevel vertebroplasty, multilevel kyphoplasty, spinal compression fractures, minimally invasive techniques

INTRODUCTION

Back pain is a common problem that affects millions of people worldwide and significantly reduces quality of life. The source of the pain may be collapsed or fractured vertebrae in the spine. Various factors can lead to vertebral collapse or fractures. Aging-related bone mass loss, muscle loss, and the development of kyphotic deformities in the spine can render vertebrae more vulnerable to trauma, increasing the risk of fractures⁽¹⁾.

Multilevel vertebral compression fractures are a serious issue caused by the collapse of multiple spinal bones. This condition can result in chronic pain, loss of mobility, and a significant decrease in quality of life⁽²⁾. Patients may struggle to perform daily activities and even become dependent on others⁽³⁾.

Painkillers, muscle relaxants, physical therapy, and orthopedic braces are conservative treatment methods that can be beneficial in many cases. Particularly in patients with mild to moderate compression fractures, these methods are effective

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in alleviating symptoms and promoting recovery without the need for surgical intervention⁽⁴⁾.

Vertebroplasty (VP) and kyphoplasty (KP) are procedures used to treat vertebral compression fractures. VP is a minimally invasive procedure aimed at alleviating fracture-related pain, reducing opioid dependency, and enabling patients to resume daily activities⁽⁵⁾.

VP can be performed under local or general anesthesia. It provides rapid pain relief and biomechanical stability, slowing the progression of kyphosis by preventing vertebral collapse. It involves injecting a special cement mixture into the fractured bone (VP) or inserting a balloon into the fractured bone to create a cavity, followed by filling it with cement (KP)⁽⁶⁾. Procedures such as VP or KP carry a risk of cement leakage, which can lead to serious complications. The spread of cement outside the vertebral fractures may cause nerve damage, paralysis, or even death.

Therefore, performing VP or KP on more than four levels in a single session has been a controversial topic among surgeons. Due to potential complications such as cement leakage, many authors recommend limiting VP or KP to no more than three levels in a single session⁽⁷⁾.

Because of the increased risk of leakage and potential complications in such procedures, surgeons often prefer to treat fewer levels. Barr et al.⁽⁸⁾ reported that single-level percutaneous kyphoplasty (PKP) is more effective than multilevel PKP. According to some studies, injections should be limited to six levels in a single session due to the higher risk of leakage and complications⁽⁹⁾.

Other studies suggest that percutaneous vertebroplasty (PVP) performed on a single fracture level and multiple fracture levels is equally effective and safe⁽¹⁰⁾. However, this may vary depending on the individual characteristics of the patient, fracture pattern, and other health factors.

In this study, we retrospectively analyzed the efficacy and safety of KP or VP procedures performed on more than three levels in selected patients. This analysis aims to help surgeons better understand the challenges and risks associated with these procedures and guide future treatment planning.

MATERIALS AND METHODS

Between January 2017 and February 2024, this study included a total of 13 patients who underwent multilevel VP or KP procedures. All patients presented with common symptoms

of back and lumbar pain. Of the patients, 5 were male (38.5%) and 8 were female (61.5%). The mean age of the patients was 66 years (± 14.97), with a range of 22 to 88 years (Table 1). All patients experienced pain that affected their daily lives, highlighting the necessity and effectiveness of the procedure. Upon examining the performed procedures, VP or KP was performed on 8 patients at 4 levels, 2 patients at 6 levels, 1 patient at 7 levels, and 2 patients at 8 levels, totaling 67 vertebrae treated (38 thoracic and 29 lumbar levels) (Table 2). Patients included in the study had stable compression fractures that did not cause radiological neural compression. Patients with fractures involving more than 3 levels and causing pain were included in the study. VP or KP cases that did not meet these criteria were excluded.

Additionally, 4 patients underwent VP, 6 patients KP, and 3 patients a combination of VP and KP (Table 3). These different approaches were determined based on the individual needs of the patients and the characteristics of the fractures. A comprehensive evaluation method was employed to determine the effectiveness and safety of the procedure. Pre-and post-

Table 1. Patient demographics and procedures

Category	Value
Total patients	13
Male patients	5 (38.5%)
Female patients	8 (61.5%)
Mean age (years)	66 (± 14.97)
Age range	22-88

This table summarizes the demographic distribution of the study's 13 patients, including their gender (61.5% female) and age range (22 to 88 years). The table highlights the diversity of patient demographics and underscores the range of cases included in the analysis

Table 2. Levels treated and vertebra distribution

Levels treated	Number of patients	Total vertebrae treated
4 levels	8	32
6 levels	2	12
7 levels	1	7
8 levels	2	16

The distribution of vertebral levels treated shows that the majority of patients (61.5%) underwent procedures at 4 levels, with a total of 67 vertebrae treated across thoracic and lumbar regions. This table emphasizes the multilevel treatment strategy adopted in this study

Table 3. Distribution of surgery types

Surgical type	Frequency	Percent (%)	Valid percent (%)	Cumulative percent (%)
Vertebroplasty	4	30.8	30.8	30.8
Kyphoplasty	6	46.2	46.2	76.9
Vertebroplasty+kyphoplasty	3	23.1	23.1	100.0
Total	13	100.0	100.0	100.0

This table categorizes patients based on the surgical approach used: kyphoplasty (46.2%), vertebroplasty (30.8%), and a combination of both techniques (23.1%). Kyphoplasty emerged as the most frequently performed procedure in this cohort

procedure X-rays were used to assess the healing status of the fractures and identify any potential complications. Ethical approval for the study was obtained from the Ordu University Non-interventional Research Ethics Committee (approval number: 2024/154, date: 24.10.2024).

Statistical Analysis

Pain levels were assessed using the Visual Analogue Scale (VAS) pre-operatively, in the early post-operative period, and in the late post-operative period. Functional status was measured using the Oswestry Disability Index (ODI), with scores recorded pre-operatively, in the early post-operative period, and in the late post-operative period.

The statistical analysis was conducted as follows:

- Paired t-test; was applied to compare differences in pre-operative and post-operative VAS and ODI scores.
- Shapiro-Wilk normality test; was used to assess the normality of data distributions for VAS and ODI scores.

A p-value of <0.05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics, version 26.0.

Monitoring Complications

Complications during surgery were continuously monitored under fluoroscopy, with special attention paid to cement leakage into the foramen or spinal canal. If any concern arose, the procedure was halted, and reevaluation was performed. Post-operatively, patients were neurologically assessed immediately upon waking in the operating room and compared with their pre-operative condition.

Follow-up Period

Patients were evaluated in early and late post-operative periods, specifically at the 3rd month. During these follow-ups, VAS and ODI scores were reassessed along with the identification of potential complications.

RESULTS

In this retrospective study, 13 patients who underwent KP/VP procedures were analyzed in detail. Regarding gender distribution, female patients constituted 61.5% (n=8), while male patients accounted for 38.5% (n=5). No significant differences were observed in treatment outcomes between genders. The mean age of the patients was recorded as 63.38 (± 14.97) years, with an age range between 22 and 77 years.

During the early post-operative period, patients were regularly monitored, and their recovery processes were evaluated at the third month using short-tau inversion recovery (STIR)-sequenced whole spinal magnetic resonance imaging (MRI) (Figures 1, 2). During follow-up, two patients passed away in the late period; however, it was concluded that these deaths were not directly related to the treatment. No severe complications, such as cement embolism, fat embolism, or pulmonary embolism (PE), were observed during or after the procedure. Only one patient reported temporary shortness of breath, which showed no abnormalities on radiological examination and resolved spontaneously.

Cement Leakage Analysis

In total, 67 vertebrae were injected, and cement leakage was detected in 12 levels (18%). Of these leakages, 4 (5.97%) extended into the disc space, 5 (8.95%) into the paravertebral area, and 3 (4.47%) into the epidural space (Table 4). All these leakages were considered clinically insignificant, and no complications, such as radicular compression or canal stenosis, were observed in any patient.

Pain and Functional Outcomes

A significant reduction in pain levels was recorded:

VAS Scores: The mean pre-operative VAS score was 8.38 (± 1.26), which decreased to 5.15 (± 1.72) early post-operatively and further to 2.15 (± 1.14) late post-operatively. This reduction

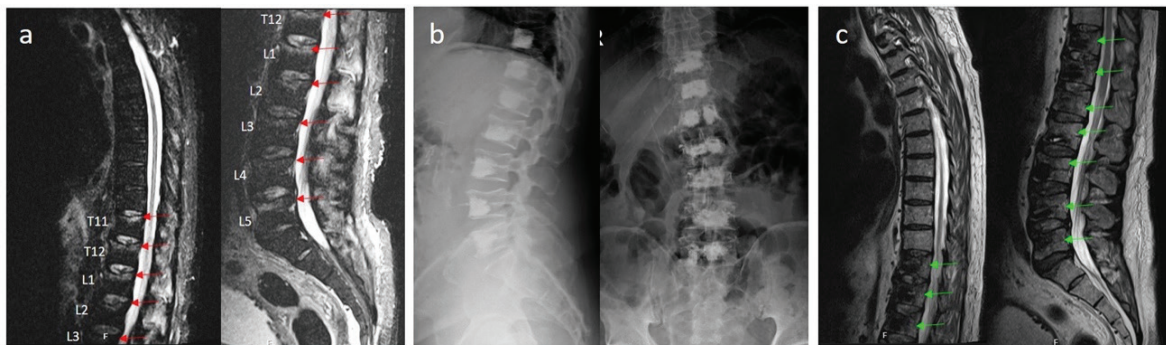


Figure 1. A 27 years old male patient with a history of prolonged steroid use and no evidence of trauma presented with persistent back pain lasting for one week. A whole-spine MRI revealed multilevel vertebral body compression fractures with acute compression and edema observed on STIR sequences. These were treated with single-session multilevel KP. (a) Pre-operative STIR-sequenced MRI images show acute compression fractures at seven levels (T11-L5) marked with red arrows. (b) Post-operative X-ray images display cement fillings without any cement leakage into the spinal canal. (c) Post-operative STIR-sequenced MRI images demonstrate cement fillings covering all edematous areas, indicated by green arrows

MRI: Magnetic resonance imaging, STIR: Short-tau inversion recovery, KP: Kyphoplasty

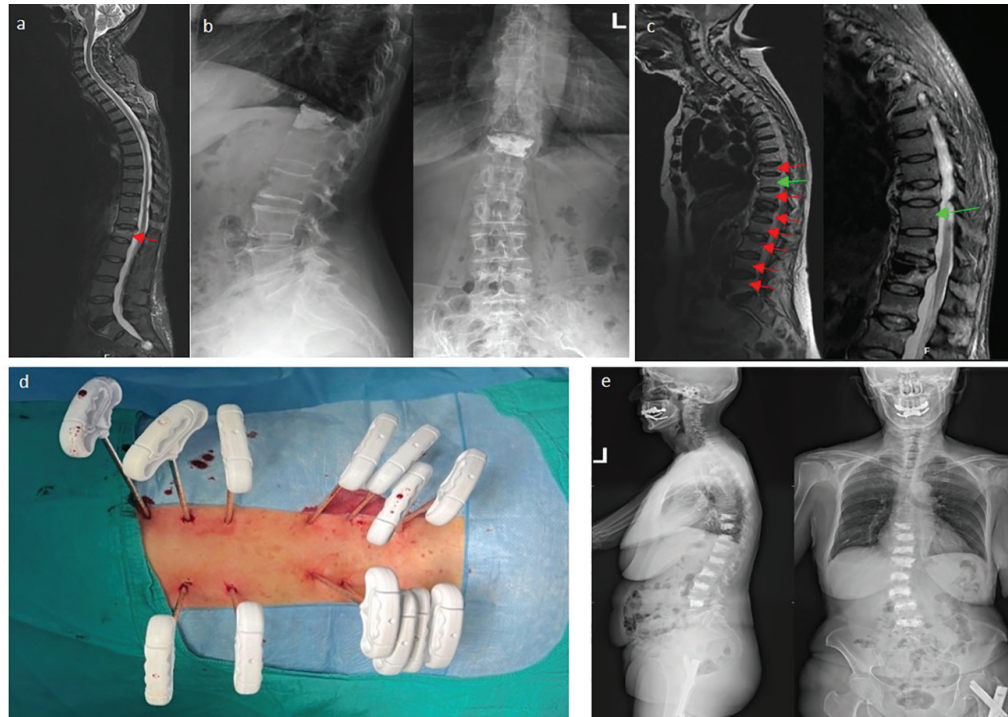


Figure 2. A 70-year-old female patient with a history of an L1 traumatic compression fracture treated with vertebroplasty and osteoporotic bone T-score levels presented with spontaneous acute back pain. (a) Initial pre-operative STIR-sequenced MRI images indicating an acute compression fracture at the L1 level. (b) Post-operative X-ray images after the first surgery, showing that the T12 vertebra was treated with vertebroplasty while the other vertebrae remained intact. (c) Whole-spine STIR-sequenced MRI images obtained after the onset of new back pain. Red arrows indicate newly developed multilevel compression fractures, while the green arrow highlights the intact T11 vertebral body. (d) Intraoperative multilevel single-session procedures. (e) Post-operative X-ray images, demonstrating that all fractured levels were filled with cement. Although the T11 vertebra had not collapsed, it was included in the treatment with vertebroplasty to prevent a high likelihood of fractures between the T10 and T12 vertebrae following KP

STIR: Short-tau inversion recovery, MRI: Magnetic resonance imaging

Table 4. Cement leakage distribution

Leakage location	Number of levels	Percentage (%)
Disc space	4	5.97%
Paravertebral area	5	8.95%
Epidural space	3	4.47%

Cement leakage was observed in 18% of the treated levels, categorized into disc space (5.97%), paravertebral area (8.95%), and epidural space (4.47%). Despite leakage in these areas, no clinically significant complications, such as radicular compression, were reported

was statistically significant ($p < 0.001$) as confirmed by paired t-test analysis. A 6.51-point reduction was observed in the late post-operative period (Table 5).

Functional improvement was also evident:

ODI Scores: The mean pre-operative ODI score was ± 11.65 (70.72%), which decreased to ± 11.37 (52.33%) early post-operatively and further to ± 10.43 (33.56%) late post-operatively. This difference was statistically significant ($p < 0.001$) and reflects a notable improvement in patients' daily functional capacities (Table 5).

Statistical Confirmation

Statistical analysis revealed that all comparisons yielded statistically significant results with a p-value of < 0.05 . The

Shapiro-Wilk normality test confirmed that pre-operative and post-operative VAS scores followed a normal distribution, while post-operative ODI scores did not. Paired t-tests demonstrated statistically significant differences in both VAS and ODI scores across pre-operative and post-operative periods, validating the effectiveness of the procedures.

DISCUSSION

This study demonstrates that VP and KP procedures performed on three or more levels in a single session provide high safety and efficacy in the treatment of spinal compression fractures. Minimally invasive procedures such as VP and KP are well-known methods for the rapid relief of pain caused by



Table 5. Summary statistics and paired t-test results

Measure	Mean	Median	SD	Range	Minimum	Maximum	t-value	p-value
Preop VAS	8.38	8.47	1.26	3.77	7.00	10.77	-	-
Postop VAS	5.15	5.50	1.72	4.75	4.00	8.75	7.08	<0.001
Late postop VAS	2.15	1.75	1.14	3.46	-0.46	3.00	-	-
Preop Oswestry	70.72	67.50	11.65	20.83	54.17	75.00	-	-
Early postop Oswestry	52.33	53.00	11.37	20.00	40.00	60.00	9.52	<0.001
Late postop Oswestry	33.56	32.00	10.43	30.18	17.81	47.99	18.03	<0.001

This table presents the pain (VAS) and functional (ODI) outcomes of the procedures, showing significant improvements post-operatively. Pre-operative VAS scores averaged 8.38, decreasing to 2.15 in the late post-operative period. Similarly, ODI scores improved from 70.72% pre-operatively to 33.56% in the late post-operative period, reflecting enhanced patient mobility and pain relief. Paired t-tests confirmed significant improvements in both scores, validating the clinical efficacy of the procedures with p-values <0.001

SD: Standard deviation, VAS: Visual Analogue Scale, ODI: Oswestry Disability Index

Table 6. Complications table

Complication type	Number of cases	Percentage (%)	Comments
Cement leakage	12	18%	Clinically insignificant in all cases
Disc space	4	5.97%	No radicular compression or canal stenosis
Paravertebral area	5	8.95%	No clinical symptoms
Epidural space	3	4.47%	No neurological deficits observed
Pulmonary embolism	0	0%	Not observed
Fat embolism	0	0%	Not observed
Temporary shortness of breath	1	<1%	Resolved spontaneously without intervention

Cement leakage was the most common complication, occurring in 12 levels (18%), predominantly in the paravertebral area (8.95%). However, these leakages were clinically insignificant, with no cases of pulmonary embolism or severe systemic complications reported

compression fractures. However, multi-level applications are less frequently used, and data in this area remain limited. Our study bridges this gap by focusing specifically on the clinical efficacy of multi-level applications and confirms the significant pain relief and functional improvement achieved, as evidenced by VAS and ODI scores.

Although VP is an effective minimally invasive method for treating vertebral fractures, like all medical procedures, it carries some complications. Most complications are transient and vary in severity. Mild complications typically present as temporary pain increase and hypotension. Moderate complications include infections and cement leakage. Lastly, severe complications can include cement extravasation into the vasculature, PE, cardiac perforation, and cerebral vessel occlusion, all of which pose life-threatening risks⁽¹¹⁾.

This risk is one of the most common complications. According to Wang et al.⁽¹²⁾ (2012) meta-analysis, the cement leakage rates in VP range from 2.1% to 26%. Other studies report an overall leakage rate of 41.7% for cement injected into vertebral fractures⁽¹³⁾. In our study, the cement leakage rate was recorded as 12 levels (18%), predominantly in the paravertebral area (8.95%), but no serious systemic complications such as PE were observed (Table 6). This underscores the importance of careful measures during the procedure and the appropriate viscosity of the cement injected.

Similarly, the study by Chen et al.⁽¹⁴⁾ (2021) found that the use of high-viscosity cement resulted in lower leakage rates. This systematic review and network meta-analysis aimed to compare cement leakage rates after VP with high- and low-viscosity cements, as well as after KP. However, some differences were observed across studies.

Likewise, Wang et al.⁽¹⁵⁾ (2022) study focused on comparing the clinical outcomes and complications of high- versus low-viscosity bone cement in patients with osteoporotic vertebral compression fractures treated with PVP or PKP. Similar findings were reported in this study⁽¹⁴⁾.

Rare complications following VP, such as infections, epidural hematoma⁽¹⁶⁾, fat embolism⁽¹⁷⁾, cardiac damage⁽¹⁸⁾, arterial or renal embolism⁽¹⁹⁾, and intradural cement leakage⁽²⁰⁾, have been documented in the literature. Fortunately, none of these complications were observed in our study. Awareness of these risks and taking preventive measures are critical for minimizing complications and optimizing treatment outcomes. Preventive measures include employing an experienced team, ensuring the correct cement viscosity, using imaging techniques, low-pressure injection, and careful patient monitoring.

Cement injection is one of the most critical stages of VP. Proper preparation and administration of the cement mixture directly impact the success of the procedure and the risk of complications⁽²¹⁾. High-viscosity cements may resist flow

more easily, require higher injection pressures, and potentially increase leakage risk. Conversely, low-viscosity cements may flow more easily but are associated with increased leakage risk if not properly controlled. Rapid injection can lead to undesired cement extravasation and increase the risk of PE⁽²¹⁾, while delayed injection can cause the cement to harden within the working channels, resulting in procedural failure. Therefore, cement injection must be performed at the correct timing and speed. In VP, excessive cement injection into the vertebral body increases the risk of leakage and complications. Studies suggest using as much cement as possible without causing leakage⁽²²⁾. However, excessive cement volumes may lead to leakage and other complications. Some studies report that the amount of cement injected is not associated with leakage but significantly increases the incidence of adjacent fractures⁽²³⁾. In this study, the volume of cement injected into the vertebral body was maintained between 4 and 9 cc. Cement injection was performed gradually and carefully under fluoroscopic guidance, ensuring no signs of complications. If rare complications were detected during the procedure, the operation was terminated. Based on our experience, as long as these principles are followed, multi-level procedures can be performed as safely as single-level procedures.

Efficacy and Advantages of the Procedure

In this study, VP was performed on patients presenting with complaints of back and lumbar pain. Pre- and post-operative assessments showed a significant reduction in pain in all groups. The pre-operative VAS scores averaged ± 26.1 (8.38), which decreased to ± 14.1 (2.15) post-operatively ($p < 0.001$, paired t-test). This marked reduction demonstrates the effectiveness of multi-level procedures in reducing pain. Our results not only showed a reduction in pain but also significantly improved patients' limitations in daily activities, as evidenced by the ODI. Pre-operative ODI scores averaged ± 11.65 (70.72%), which decreased to ± 43.10 (33.56%) post-operatively ($p < 0.001$, paired t-test). These findings align with results reported in the literature⁽²⁴⁾, clearly demonstrating that patients were able to perform daily activities more easily and comfortably after the procedure.

Single-session multi-level VP and KP offer distinct advantages such as shorter recovery times, reduced hospital stays, and enhanced patient satisfaction. The significant reductions in VAS and ODI scores in our study align with the findings of Zidan et al.⁽²⁵⁾ (2018), who reported accelerated clinical recovery with multi-level minimally invasive techniques.

Although the literature on multi-level VP and KP is limited, existing data demonstrate the high clinical efficacy of these procedures, especially in elderly patients and cases with multiple compression fractures⁽²⁵⁾.

One advantage of the procedure is its ability to stabilize the spine, particularly in preventing kyphosis associated with multiple fractures⁽²⁶⁾. This technique may play a significant role in treating vertebral fractures and correcting spinal

deformities. Proper stabilization of the spine helps patients maintain postural balance and mobility. Additionally, achieving stabilization can reduce pain associated with vertebral fractures and enhance the patient's quality of life⁽⁸⁾.

The results of our study demonstrate that multi-level VP/ KP is an effective and safe method for significantly reducing pain and improving mobility and quality of life in patients with compression fractures. Furthermore, it suggests that this method may be effective in managing chronic pain in such patients. This technique can also provide long-term biomechanical stability. A study by Cosar et al.⁽²⁷⁾ found that KP causes fewer complications compared to VP. This is attributed to the volume of cement injected into the cavity created by the balloon during KP, making it the preferred method.

Detailed pre-operative planning and careful execution during the operation can help avoid potential complications, such as cement leakage and PE, or minimize their effects. Additionally, the experience of the surgical team and the use of appropriate techniques contribute to the successful completion of the operation and optimize the patient's recovery process.

Study Limitations

One of the primary limitations of our study is the relatively small sample size. Larger prospective studies could provide a clearer understanding of the long-term efficacy and safety of multi-level VP and KP. Moreover, the retrospective design may introduce some inaccuracies, which could limit the generalizability of the results. Future randomized controlled trials can help better understand the outcomes of this treatment strategy in different patient groups.

CONCLUSION

Single-session multi-level VP and KP applications offer a reliable and effective option in the treatment of spinal compression fractures. Our study demonstrates that these procedures may play a significant role in improving patients' quality of life and reducing pain. Future prospective studies involving larger patient groups could strengthen these findings and further establish the place of these methods in clinical practice.

Ethics

Ethics Committee Approval: Ethical approval for the study was obtained from the Ordu University Non-Interventional Research Ethics Committee (approval number: 2024/154, date: 24.10.2024).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.H., A.T.B., H.Ö., F.E., U.Ö., M.Y.A., T.Ö., A.F.Ö., Concept: A.F.Ö., Design: M.H., A.T.B., T.Ö., A.F.Ö., Data Collection or Processing: M.H., H.Ö., F.E., B.K., Analysis or

Interpretation: H.Ö., U.Ö., B.K., Literature Search: M.H., M.Y.A., Writing: M.H., B.K.

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