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A comparative study of lumbar spine stabilization with 2-stage surgery and cement augmentation in osteoporosis patients: a randomized clinical trial

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The biggest challenge for osteoporotic patients after spinal stabilization is screw loosening. Therefore, the present study was conducted with the comparative aim of stabilizing the lumbar spine with 2-stage surgery and cement augmentation in osteoporotic patients. 66 patients selected through convenience sampling and randomly assigned to two groups: CAPS and 2-stage surgery. In the CAPS group, lumbar spine fixation was performed in a single stage, accompanied by cement augmentation. In the 2-stage surgery group, spinal stabilization was conducted in 2 stages. In the first stage, pedicle screws were implanted, followed by the pedicle screw anchoring process 6 months later. fusion rate, screw loosening, pain levels (VAS), and patients' disability (ODI) were measured in each group. The fusion rate in the 2-stage Surgery group significantly increased. Screw loosening in the CAPS group showed a significantly higher difference. The rate of pain and disability in patients early postoperatively, in comparison to preoperative measures, significantly decreased in both groups. In the final follow-up, the CAPS group experienced a significant increase in pain and disability. The 2-stage Surgery stabilization, when compared to the CAPS technique, demonstrates superiority in enhancing the biomechanical stability of screws and achieving successful fusion.

Keywords Fusion, Stabilization, Osteoporosis, Bone cemente, Spine

Posterior Spinal Fusion (PSF) is considered one of the most commonly used surgical approaches for degenerative lumbar diseases. The pedicle screw-based fixation system has increasingly gained popularity worldwide[1]. Pedicle screws restrict vertebral movement across all planes, enhancing fusion speed between vertebrae[2]. Despite reported effectiveness, fixation surgery is associated with certain complications, often leading to repeated surgery. The most crucial aspect of spinal stabilization is the of pedicle screws loosening (PSL)[3]. This issue becomes particularly pronounced with advancing age and an increased risk of more serious pathological conditions. Osteoporosis stands out as one of the most common causes of screw instability and pseudarthrosis post-surgery[4]. Osteoporosis is defined by a bone mineral density (BMD) reduction in the trabecular section for lumbar regions, averaging less than 0.8 g/cm^2 or a T-Score $\leq$ -2.5[5]. The loss of trabecular structure disrupts the mechanical adherence of pedicle screws to the bone, hindering the osteointegration process. In other words, due to increased osteolysis, a clear zone around pedicle screws emerges, indicating Pedicle Screw Loosening (PSL)[6]. Therefore, many surgeons believe that performing surgery in patients with osteoporosis, despite progressive deformity of the spinal (scoliosis) and severe clinical manifestations (radiculopathy and limping), is not rewarding[7,8].

With advances in surgical techniques, medical equipment, and growing patient expectations, various approaches have been developed to reduce the incidence of PSL and enhance stabilization. Cement-Augmented Pedicle Screw (CAPS) is a common technique in this regard, strengthening the mechanical force between the screw and the bone[5]. Bone cement, scientifically known as polymethyl methacrylate (PMMA), creates a robust anchor point for stabilization by filling the trabecular spaces[9]. Although the benefits of the CAPS method are evident, scientific reports associated with spinal canal extrusion, nerve injury, vascular occlusion, and pulmonary

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cement embolism have limited its use[10]. Despite the frequent use of PMMA for spinal stabilization, surgeons are still seeking more effective methods with fewer complications. ÖZER et al. have adopted a novel approach. They investigated a 2-stage dynamic lumbar stabilization approach in patients with osteoporosis[11]. 2-stage dynamic lumbar stabilization is an innovative surgical method that minimizes complications associated with cement leakage[12]. This technique is inspired by implant technology in dentistry, where an implant is initially placed on a tooth and undergoes a 6-month osteointegration process. Then, the tooth is attached to the implant[13,14]. The responsibility for osseous integration primarily lies with living tissue through mechanisms akin to fracture healing. Creating a cavity in the bone before screw placement can damage the bone tissue, leading to specific stages of wound healing[15]. In the screw-rod system, pedicle screws are initially implanted into lumbar vertebrae. During this process, the bone surrounding the screws undergoes adaptive changes, and the screws are firmly secured within the bone matrix over six months[16]. In the second stage of the surgery, the pedicle screw anchoring process is performed[11]. Subsequently, the radiological effects and screw loosening, represented by radiolucent halos around the screws, are assessed. Generally, long-term follow-up and management strategies for PSL in osteoporotic patients require more attention than conventional fusion methods. The ability to predict the risk of screw loosening through the examination of specific biomechanical aspects can contribute to advancing surgical outcomes. Extensive discussions have taken place regarding methods to enhance the strength of pedicle screws, evaluating their effectiveness and risks. However, selecting the best technique as the gold standard in this field necessitates assessing new approaches and determining their effectiveness. Therefore, in this study, the biomechanical properties of the commonly used pedicle screw augmentation technique (CAPS) with 2-stage surgery are evaluated as an innovative surgical method.

Materials and methods

Study design

This study is a randomized clinical trial (IRCT20230222057496N3 in 2024-02-26) conducted at the Iran Teaching Hospital in Qom province. Patients were enrolled prospectively from December 2021 to September 2022. The researcher enrolled the participants and established the allocation sequence. Eventually, They were divided into two intervention groups, CAPS (surgical approach involving pedicle screw augmentation with bone cement) and 2-stage (surgical approach performed in 2 stages), based on a randomized block design with 4-patient blocks. The manuscript follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Setting and participants

All patients were followed up for 12 months. The surgeries were performed under general anesthesia by a single surgeon. Dual-energy X-ray absorptiometry (DEXA) scans were used to determine bone mineral density. In the first six months post-surgery, all patients were prescribed Teriparatide and Bisphosphonates (Alendronic acid 70) to enhance bone mineral density.

Sample size calculation

According to the study by Imani et al., the average pain score seven days post-discetomy surgery was reported as 6.97 ± 1.24 and 8.23 ± 1.04 for the two surgical methods, respectively[17]. Considering an 80% power of the study and a type l error level of 0.05, the sample size in each group was estimated at 25 individuals using the formula. The final sample size in each group was set at 33 participants for the study, accounting for a 30% dropout rate.

$$n = \frac{(z_\alpha + Z_\beta)^2 (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)^2}$$

Inclusion and exclusion criteria

Inclusion criteria

Patients aged $\geq$ 50 years with a T-score ≤ -2.5 (L1–S1), multilevel lumbosacral disease, and BMI between 20 and 30 were enrolled in the study.

Exclusion criteria

Previous lumbar surgeries, degenerative disorders in other vertebrae, and opioid use were considered exclusion criteria. Additionally, lack of willingness for follow-up, inaccessibility to patients, and absence of X-ray and CT scans in the final follow-up were considered exclusion criteria.

Surgical technique

Intervention 1: cement augmentation pedicle screw

Initially, a midline posterior incision was made, and decompression (bilateral partial facetectomy) was performed for all patients. Before screw placement, a two-sided entrance hole was created in the pedicles of the vertebrae using an awl, followed by a 3 mm diameter pilot hole with a Lenke-type probe. The selected screw geometry was a solid core with a titanium alloy. C-arm radiography was employed To determine the precise screw trajectory. High-viscosity 2 ml cement with bone fillers was injected into the pilot hole, and immediately screws (length between 40 and 50 mm and outer diameter of 6–6.5 mm) were placed using the technique described by Weinstein et al.[18]. Preparation and injection of PMMA were performed according to the guidelines provided by the company (DePuy Spine, Raynham, MA). Subsequently, rods and nuts were assembled, and the construct was firmly secured. Perivertebral cement assessment was conducted via CT scan within 72 h post-surgery, following the classification by Yeom et al.[19].

2-Stage surgery: intervention 2

Step 1 According to the previous surgical method, after creating a posterior incision for all patients, decompression (bilateral partial facetectomy) was performed. In this procedure, only the medial one-quarter of the facets was removed, leaving the spinous processes intact. The facet capsules were preserved, with only a minimal portion of the medial facets opened. Additionally, the interspinous ligament was left undisturbed, and the hemilaminectomy was performed with a narrow approach to maintain spinal stability. In essence, the procedure involved carefully undermining the facets to maintain structural stability. In the first stage of surgery, pedicle screws (length between 40 and 50 mm and outer diameter of 6–6.5 mm) were placed bilaterally under fluoroscopic guidance without cement injection in the two-sided pilot hole. Without inserting the rod and establishing a connection between the screws, the incision area was closed in a layered fashion.

Step 2 six months after the first surgery, when sufficient osseointegration occurred between the screws and the lumbar vertebrae, and this process was confirmed by a CT scan, the surgical site was reopened, and the pedicle screw anchoring procedure was performed. In other words, the screws were connected with a 5.5 mm diameter rod, tightened by adjusting nuts, and the fixation process was completed.

Radiographic assessment

The loosening of screws and the extent of fusion at the last follow-up (12 months) were independently assessed by a specialized neuroradiologist and an experienced radiologist based on computerized tomography scans (CT scans) and dynamic radiographs. The fusion rate was determined using the modified Brantigan–Steffee–Fraser (mBSF) scale, categorizing fusion into three grades: Grade 1 (radiographic pseudarthrosis), Grade 2 (Indeterminate fusion), and Grade 3 (solid radiographic fusion)[20].

The criterion for screw loosening in CT scans was identified as an area without signal, encompassing the entire screw body in the image. Due to metal artifacts, no signal region was visible at the tip of the screw, and we did not consider it as screw loosening. The criteria for screw loosening in X-ray radiography were a radiolucent area with a thickness of 1 mm or the presence of a "double halo" sign around the screw[6]. In Fig. 1, A: the CT scan axial image of an adult is visible. An area of signal loss around the entire body of the screw indicates screw loosening. B: relates to fluoroscopic control during cement injection to halt the injection in case of leakage into the spinal canal (Fig. 1).

Clinical assessment

Pain rate were assessed using the Visual Analog Scale (VAS), a linear pain scale rated from 0 to 10 (Score 0: No pain, Score 10: Unbearable pain). Functional outcomes were assessed using the Oswestry Disability Index (ODI). The minimum and maximum scores achievable on this questionnaire are 0–100. Accordingly, five disability categories were established: patients with mild disability (0–20%), moderate disability (21–40%), severe disability (41–60%), incapacitated (61–80%), and bed-bound (81–100%)[21]. Both questionnaires (VAS, ODI) were evaluated before surgery, early post-surgery (one month after surgery for the CAPS group and one month after the second surgery for the 2-stage surgery group), and at the latest follow-up (12 months after surgery).

Statistical analysis

Data analysis was conducted using SPSS software version 16. The normality of the data was assessed using the Shapiro–Wilk test. The impact of time on pain and disability variables in the two intervention groups was statistically evaluated using repeated measures analysis. Fusion levels and screw loosening were examined through the independent samples Kruskal–Wallis test.

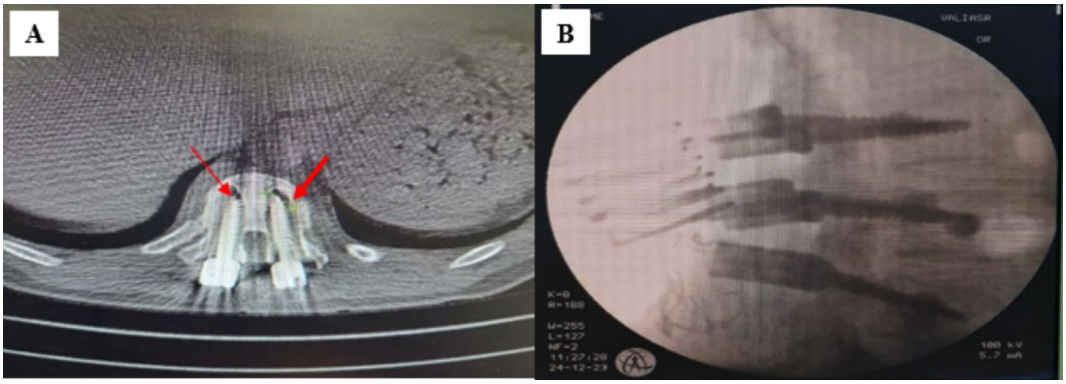


Fig. 1. (**A**) CT scan axial plane. A no signal zone surrounding whole body of screw indicates the loosening of the screw. (**B**) The Fluoroscopic control during cement application.

Results

Baseline characteristics

66 patients meeting the inclusion criteria were enrolled in the study. Due to limited access to patient records and insufficient X-ray and CT scan data, eight patients in the CAPS group and seven patients in the 2-Stage group were excluded from the final follow-up analysis, resulting in 25 patients in the CAPS group and 26 patients in the 2-stage group (Fig. 2). Before the intervention, both groups exhibited no significant differences in demographic and clinical characteristics, demonstrating homogeneity. The average scores of pain index and functional disability in both groups before surgery do not show any significant difference (Table 1).

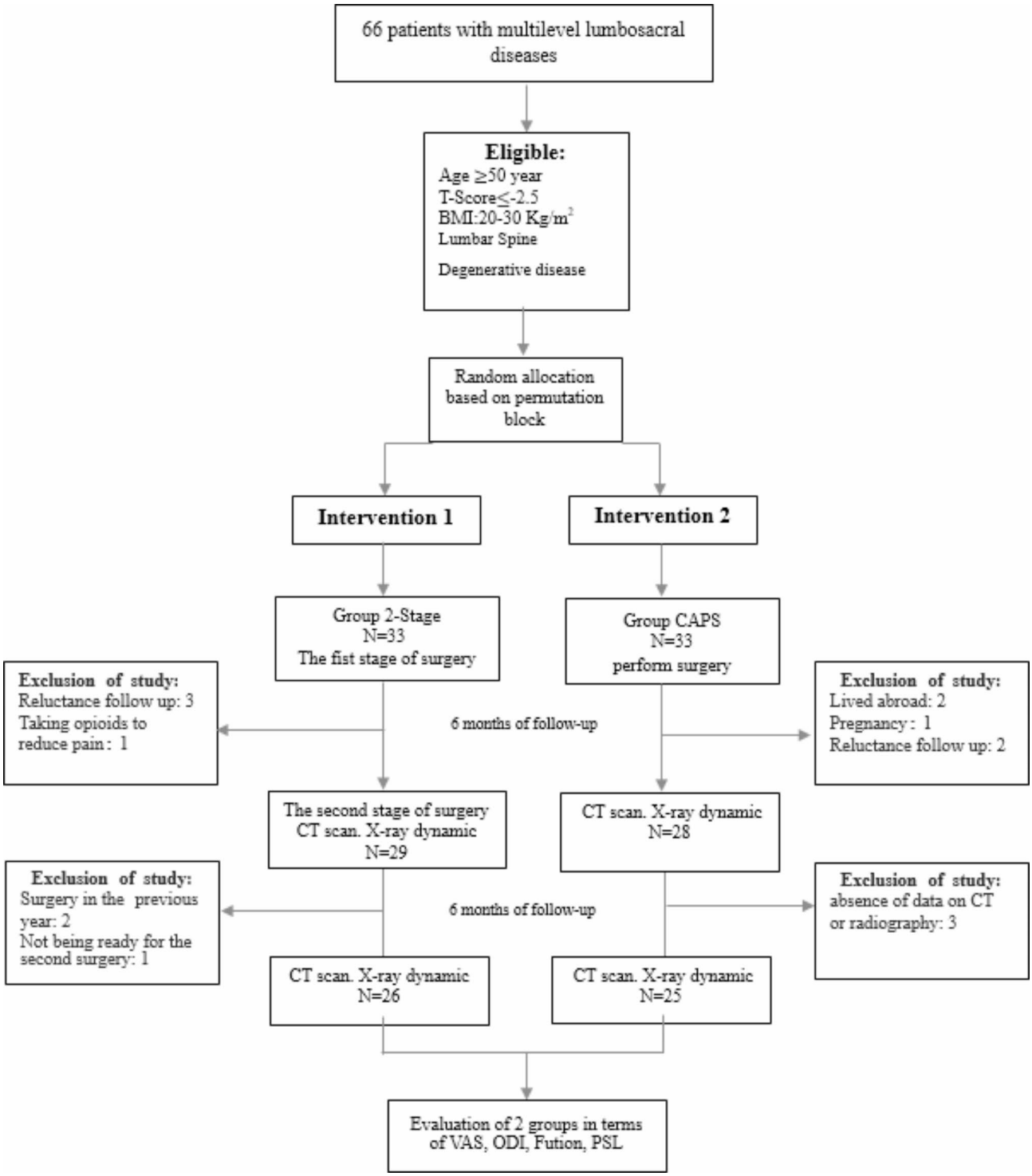


Fig. 2. CONSORT.

	CAPS	2-Stage	
	N = 25	*N* = 26	‡*p*-value
Age † (years), mean(SD)	61.32(4.413)	61.96(3.156)	0.555
Gender*, No (%)			
Male	10(40.0%)	12(46.2%)	0.67
Female	15(60.0%)	14(53.8%)	0.853
Height† (cm), mean (SD)	163.80(5.058)	164.65(5.230)	0.556
Weight† (kg), mean (SD)	72.12(8.467)	74.15(7.379)	0.343
BMI† (kg/m^2), mean (SD)	26.93(3.350)	28.47(2.519)	0.069
Employment status*, N. (%)			
Unemployed	10(40%)	10(38.5%)	1
Employed	15(60%)	16(61.5%)	0.857
Smoking status*, No. (%)			
Yes	18(72.0%)	17(65.4%)	0.866
No	7(28.0%)	9(34.6%)	0.617
Marital status*, No. (%)			
Single	4(16.0%)	3(11.5%)	0.705
Married	21(84.0%)	23(88.5%)	0.763
Level of education*, No. (%)			
Diploma	18(72.0%)	18(69.2%)	1
Bs	4(16.0%)	6(23.1%)	0.527
Ms	1(4.0%)	1(3.8%)	1
PhD	2(8.0%)	1(3.8%)	0.564
BMD (T-score)†, mean (SD)	3.08(0.353)	3.04(0.272)	0.626
Fusion level*, No. (%)			
L1–S1	3(12.0%)	3(11.5%)	1
L2–L5	2(8.0%)	4(15.4%)	0.414
L3–S1	6(24.0%)	3(11.5%)	0.317
L1–L5	6(24.0%)	7(26.9%)	0.782
L2–S1	3(12.0%)	4(15.4%)	705
L1–L4	5(20.0%)	5(19.2%)	1
Spinal instability	5(20.0%)	6(23.1%)	0.763
Spondylolysis	5(20.0%)	5(19.2%)	1
Degenerative disc	7(28.0%)	8(30.8%)	0.796
Spondylolisthesis	8(32.0%)	7(26.9%)	0.796
VAS†-preoperative, mean (SD)	8.28(0.980)	8.04(0.871)	0.356
ODI†-preoperative, mean (SD)	70.64(6.311)	68.96(8.838)	0.44

Table 1. Demographic and clinical characteristics of the 2 groups. *Goodness of fit, †t-test, ‡Statistical significant as $p < 0.05$. *BS* Bachelor degree, *Ms* Master of science, *PhD* Doctor of philosophy, *BMI* Body mass index, *BMD* Bone minimal density, *CAPS* Cement augmentation pedicle screw, *VAS* Visual analog scale, *ODI* Oswestry Disability Index.

Clinical results

Descriptive statistics of pain levels over time for CAPS and 2-Stage surgical procedures are reported separately. Pain was assessed for both groups before surgery, early after surgery (1 month after surgery in the CAPS group and 1 month after the second stage of surgery in the 2-stage surgery group) and 12 months after surgery. Data analysis showed a decreasing trend in pain level throughout the follow-up period for the 2-stage group. In other words, the pain level of patients in the initial results of surgery (1 month after the second stage of surgery) was lower than the pain of patients before surgery. Also, patients in the two-stage surgery group experienced the least amount of pain in the final follow-up (12 months after surgery) compared to early after surgery (1 month after the second stage of surgery) and before surgery. However, the pain level in the CAPS group was significantly lower 1 month after surgery compared to the 2-stage group. Furthermore, in the CAPS group, the pain level 1 month after surgery was significantly lower than their pain level one year after surgery (Table 2, Fig. 3).

The results of the intergroup effects test indicate a significant group effect on the dependent variable of pain levels, meaning that the average pain levels differ between the two surgical methods, CAPS and 2-Stage. Specifically, the average pain level in the CAPS group is significantly higher than in the 2-stage group (Table 3).

ODI was assessed for both groups before surgery, early after surgery (1 month after surgery in the CAPS group and 1 month after second-stage surgery in the 2-stage surgery group) and 12 months after surgery. Data analysis indicates that the level of disability (ODI) in both CAPS and 2-Stage groups one month post-surgery

Descriptive statistics				
	Group	Mean	Std. deviation	*N*
VAS preoperative	CAPS	8.28	0.980	25
	2-stage	8.04	0.871	26
	Total	8.16	0.925	51
VAS early operative	CAPS	1.48	0.823	25
	2-stage	4.27	1.079	26
	Total	2.90	1.700	51
VAS 1-y postoperative	CAPS	6.76	0.926	25
	2-stage	1.08	0.977	26
	Total	3.86	3.020	51

Pairwise comparisons							
						95% confidence interval for difference[a]	
Group	(I) Time	(J) Time	Mean difference (I–J)	Std. error	Sig[a].	Lower bound	Upper bound
CAPS	1	2	6.800*	0.224	0.000	6.225	7.375
		3	1.520*	0.301	0.000	0.746	2.294
	2	1	− 6.800*	0.224	0.000	− 7.375	− 6.225
		3	− 5.280*	0.274	0.000	− 5.985	− 4.575
	3	1	− 1.520*	0.301	0.000	− 2.294	− 0 0.746
		2	5.280*	0.274	0.000	4.575	5.985
2-stage	1	2	3.769*	0.295	0.000	3.012	4.527
		3	6.962*	0.238	0.000	6.350	7.573
	2	1	− 3.769*	0.295	0.000	− 4.527	− 3.012
		3	3.192*	0.248	0.000	2.555	3.829
	3	1	− 6.962*	0.238	0.000	− 7.573	− 6.350

Table 2. Data analysis of VAS scores and pairwise comparisons. *VAS* visual analog scale, *CAPS* cement augmented pedicle screw. Based on estimated marginal means. *The mean difference is significant at the 0.05 level. [a]Adjustment for multiple comparisons: Bonferroni.

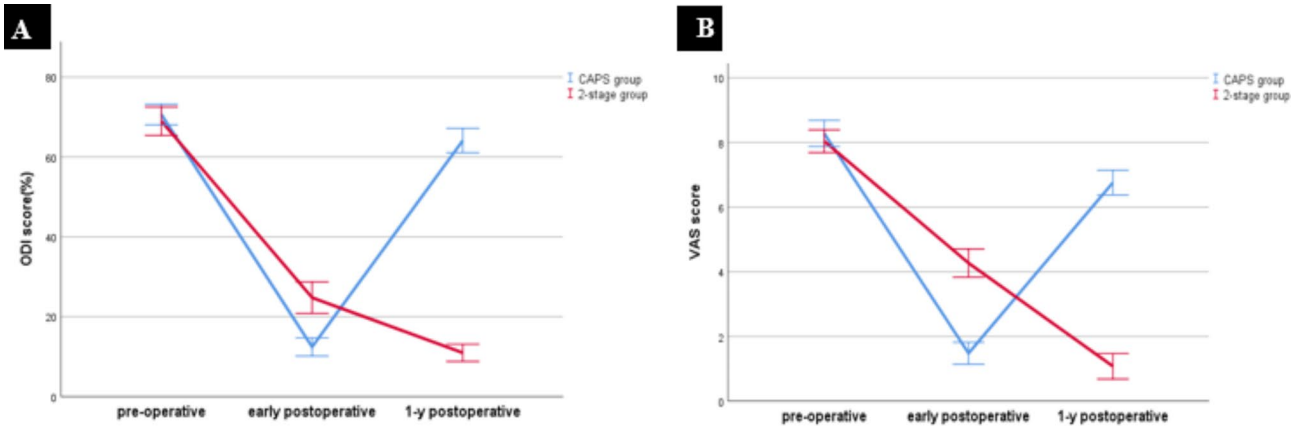


Fig. 3. Changes in clinical results between the two groups during follow-up period, (**A**) Mean Oswestry Disability Index (ODI) score; (**B**) Mean Visual Analog Scale (VAS) score.

Tests of between-subjects effects					
Source	Sum of squares	Df	Mean square	F	Sig.
Group	41.764	1	41.764	46.372	0.000

Table 3. The results of the between-subjects effects test for the VAS score.

Descriptive statistics				
	Group	Mean	Std. deviation	*N*
ODI preoperative	CAPS	70.64%	6.311%	25
	2-stage	68.96%	8.838%	26
	Total	69.78%	7.674%	51
ODI early operative	CAPS	12.44%	5.546%	25
	2-stage	24.77%	9.767%	26
	Total	18.73%	10.060%	51
ODI 1- y postoperative	CAPA	64.12%	7.401%	25
	2-stage	10.96%	5.340%	26
	Total	37.02%	27.584%	51

Pairwise comparisons							
						95% confidence interval for difference[a]	
Group	(I) Time	(J) Time	Mean difference (I–J)	Std. error	Sig[a].	Lower bound	Upper bound
CAPS	1	2	58.200*	1.674	0.000	53.891	62.509
		3	6.520*	2.134	0.016	1.028	12.012
	2	1	− 58.200*	1.674	0.000	− 62.509	− 53.891
		3	− 51.680*	2.101	0.000	− 57.088	− 46.272
	3	1	− 6.520*	2.134	0.016	− 12.012	− 1.028
		2	51.680*	2.134	0.000	46.272	57.088
2-stage	1	2	− 44.192*	2.390	0.000	38.060	50.324
		3	58.000*	2.075	0.000	52.676	63.324
	2	1	− 44.192*	2.075	0.000	− 50.324	− 38.060
		3	13.808*	2.552	0.000	7.260	20.355
	3	1	− 58.000*	2.075	0.000	− 63.324	− 52.676
		2	− 13.808*	2.552	0.000	− 20.355	− 7.260

Table 4. Data analysis of ODI scores and pairwise comparisons. *ODI* Oswestry Disability Index, *CAPS* cement augmented pedicle screw. Based on estimated marginal means. *The mean difference is significant at the 0.05 level. [a]Adjustment for multiple comparisons: Bonferroni.

Tests of between-subjects effects					
Source	Sum of squares	Df	Mean square	F	Sig.
Group	7676.389	1	7676.389	177.105	0.000

Table 5. The results of the effects test between subjects.

is significantly lower than their disability levels before surgery. In other words, both groups showed noticeable improvement after surgery. However, the disability level in the CAPS group, unlike the 2-stage group, increased one year after surgery compared to one-month post-surgery (Table 4; Fig. 3).

Table 5 displays the results of the intergroup effects test. The group effect on the dependent variable of disability level is significant, signifying that the average disability level differs between the two surgical methods, CAPS and 2-Stage. Specifically, the average disability level in the CAPS group is significantly higher than that in the 2-stage group (Table 5).

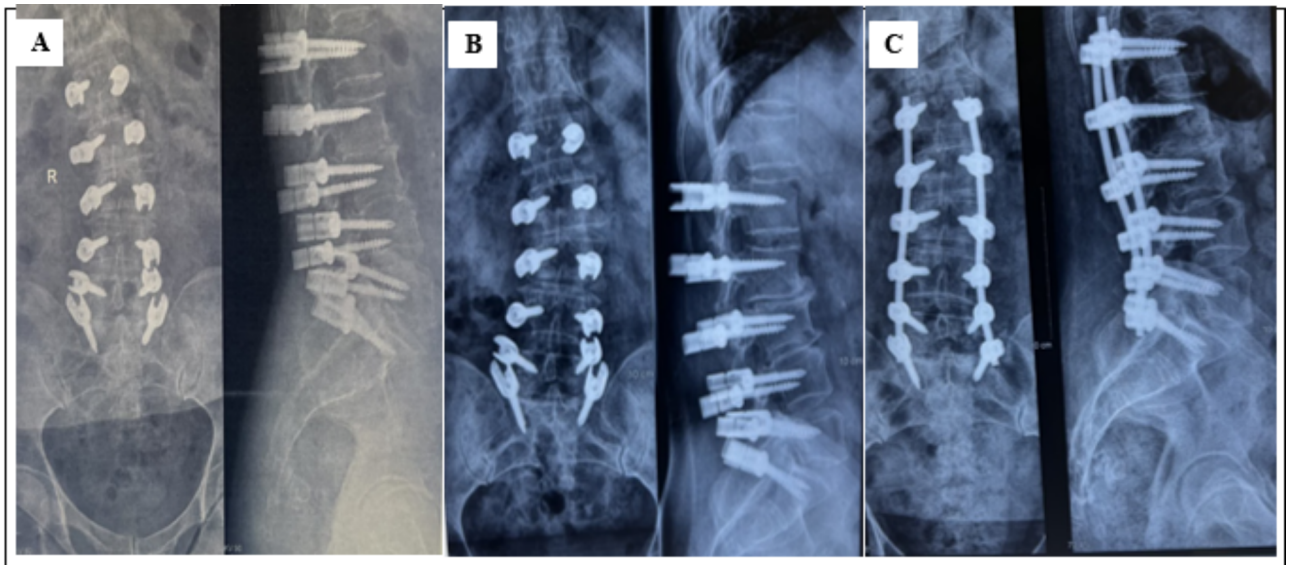
Radiographic results

The study results indicate a significantly higher rate of screw loosening in the CAPS group compared to the 2-stage surgery group during the final follow-up. Moreover, the complete fusion rate was significantly higher in the 2-stage surgery group. Although the rate of indeterminate fusion was higher in the CAPS group, this difference did not reach statistical significance. Pseudoarthrosis in the CAPS group was reported with a significantly higher difference (Table 6). The weighted kappa value between the observers was 0.776 (CI: 95%; $p < 0.001$.The intra-observer weighted kappa value was 0.893 (CI: 95%, $p < 0.001$), which indicates a good agreement.

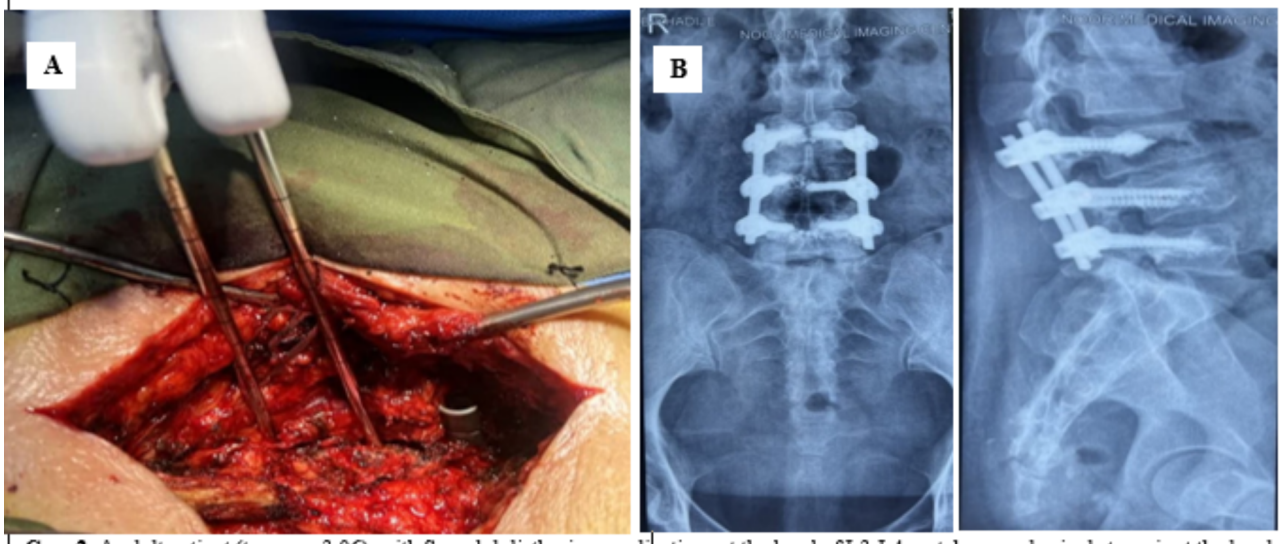
In Fig. 4, you can see the images of two-stage surgery (first, sixth months and 1 year after surgery) and cement reinforcement (during surgery and 6 months after surgery). Case 1: A adult patient (T score = − 2.86) with the complication of spondylolisthesis at the level of L5–S1 vertebrae and Disc degeneration at the level of L2–L3 underwent a 2-stage surgery. Picture A corresponds to 1 month after surgery, picture B corresponds to 6 months after surgery and picture C corresponds to 12 months after surgery. Case 2: A adult patient (T score = − 3.06) with Spondylolisthesis complications at the level of L3–L4 vertebrae and spinal stenosis at the level of L3–L4

		Comparison futon and PSL between two groups		
		CAPS ($n=25$)	2-stage ($n=26$)	Sig†.
Futon*	Solid	36% (9/25)	61.5% (23/26)	0.013
	Indeterminate	28% (7/25)	23.1% (2/26)	0.096
	Pseudarthrosis	36% (9/25)	15.4% (1/26)	0.011
PSL*	Yes	48%(12/25)	3.8%(1/26)	0.002
	No	52%(13/25)	96.1%(25/26)	0.037

Table 6. Comparison of radiological outcomes between two groups. *Goodness of fit, †Statistical significant as $p < 0.05$. *CAPS* cement augmented pedicle screw, *PSL* Pedicle screw loosing.



Case 1: A adult patient (t score=-2.86) with the complication of spondylolisthesis at the level of L5-S1 vertebrae and Disc degeneration at the level of L2-L3 underwent a 2-stage surgery. Picture **A** corresponds to one month after surgery, picture **B** corresponds to 6 months after surgery and picture **C** corresponds to 12 months after surgery.



Case 2: A adult patient (t score=-3.06) with Spondylolisthesis complications at the level of L3-L4 vertebrae and spinal stenosis at the level of L3-L4 underwent surgery at the level of L2-S1 vertebrae. picture **A,** bone fillers containing PMMA are inserted into the vertebra through the pedicle and are ready to be injected. Picture **B** is related to a Six months after surgery.

Fig. 4. Report of two cases of patients in both surgical groups.

underwent surgery at the level of L2–S1 vertebrae. picture A, bone fillers containing PMMA are inserted into the vertebra through the pedicle and are ready to be injected. Picture B is related to a Six months after surgery (Fig. 4).

Complications

The study revealed no cement leakage or embolism in any patients in the CAPS group. Among the 51 patients included in the study, only one patient experienced a fractured screw, and this occurred in a patient who underwent CAPS surgery. There were no occurrences of dural tears during surgery, postoperative infection, disc recurrence, or segmental kyphosis in any of the patients.

Discussion

This study aimed to compare the lumbar spine stability using the 2-stage and CAPS surgical techniques in osteoporotic patients. Data analysis revealed a significantly higher rate of pedicle screw loosening (PSL) in the CAPS group compared to the 2-stage group. In the final follow-up, only one patient in the 2-stage surgery group experienced PSL. The stability of screws in bone is contingent on the rate of the osteointegration process[22]. During this process, direct deposition of bone calcification layers on the screws occurs, and the thickness of these deposits is a function of the screw's base characteristics. In other words, the topography of the implant surface and its features (i.e., macrogeometry, surface properties, etc.) Play a crucial role in modulating cellular and molecular behavior and the speed of the osteointegration process[23]. The selected screws in the present study were made of titanium with a screw-root design. Titanium screws, especially those coated with calcium phosphate, exhibit better chemical bonding with bone, promoting enhanced integration[24]. Additionally, the screw-root design, with microgrooves and protrusions on the screw's surface, provides a platform for biological responses at the bone-implant interface, doubling the initial mechanical stability of the screw in the bone[25]. In their study, Hoellwarth et al. (2023) inserted titanium screws into mice, stating that by the end of the 16th week, the screws had integrated so well with the bone that bone fracture occurred upon screw removal in one specimen[26].

In the final assessment (12 months post-surgery), the loosening of screws in the CAPS group was significantly higher. Subsidiary analysis revealed visible radiolucent areas around the cement in X-ray and CT scans of CAPS patients, indicating a lack of adhesion between the cement mass and bone. In this regard, the results of a meta-analysis showed that the long-term reinforcement of pedicle screws with PMMA In the long term, it leads to the loss of adhesion between cement and bone, necessitating corrective surgery for patients[27]. Hsieh et al. stated that inadequate adhesion between PMMA and cancellous bone tissue results from the high curing and rapid cement solidification during injection[5].In the current study, this complication may arise from the high viscosity of cement during injection, disrupting the cement-bone interface. Baroud et al. and colleagues assert that the injection time of bone cement is the most crucial factor influencing its intrabone diffusion and adhesive strength[28].

In radiological evaluation, none of the CAPS patients showed cement leakage (CL) or pulmonary cement embolism (PCE). Mueller et al. also reported similar results[29]. However, Bokov et al. (2019) observed cement leakage from the anterior and posterior aspects into the spinal canal, involving nerve roots[10]. Multiple factors contribute to the occurrence of cement leakage and PCE. The degree of bone porosity, volume of injected cement, cement viscosity, and the injection site all play significant roles. The closer the cement injection site is to the vertebral pedicle, the higher the risk of leakage, as there is more cancellous bone around the pedicle[9].This study injected cement with high viscosity and a small volume into the center of the vertebrae to minimize the risk of cement leakage. Additionally, cement injection was performed under continuous fluoroscopic guidance to promptly halt injection upon the detection or suspicion of cement leakage.

Data analysis indicates that in the final follow-up, the rate of complete fusion between vertebrae (solid radiographic fusion) in the CAPS group is lower compared to the two-stage surgical group. The results of the study by Karaca et al. (2019) demonstrated a significant increase in pseudoarthrosis between vertebrae in the CAPS group after two years of follow-up[30]. Studies on 2-stage surgeries showed none of the patients had pseudoarthrosis in the final follow-up, and the successful fusion rate was high[11]. The reduced fusion in CAPS surgery is attributed to micromotions that occur less frequently in the two-stage surgery. In patients undergoing CAPS surgery, the entire construct (cement-reinforced screws, rod, and nuts) is placed in one stage, and bilateral facetectomy is performed for the patient. Therefore, despite stabilization between the vertebrae, removing facets leads to instability in the spinal[10]. However, in the 2-stage method, screws are implanted in the first stage, and facetectomy is performed for the patient. After six months of surgery, osteogenesis occurs, fibrotic tissues replace the facets, and the spinal cord reaches desirable stability, securing the construct.

In the present study, the level of Solid radiographic fusion in the CAPS group was reported to be lower compared to other studies. The results of Karius et al.'s study in 2017 indicate that most patients treated with the CAPS method demonstrate Solid radiographic fusion in the final follow-up[31]. Chandra et al. 2017 also achieved similar results in 80 patients undergoing CAPS surgery[4]. The difference in results in the current study is attributed to the high sensitivity of CT scans and dynamic X-rays in diagnosing fusion between the vertebrae of patients. Most previous studies assessed fusion between vertebrae using plain radiographs without a specific criterion. Metal artifacts, intestinal gas, and the viewing angle are among the factors that can distort the sensitivity of X-rays for evaluating loosening and may even lead to false interpretation of successful fusion as pseudoarthrosis[32]. Moreover, in other studies, the interpretation of radiological images was carried out by surgeons. Surgeons, unlike radiologists, have not received specific training in this field, and each individual provides different interpretations based on their experience. Therefore, in the present study, the interpretation of radiological images was performed by an experienced neuroradiologist and radiologist using CT scans and dynamic X-rays, leading to more accurate results.

The results of the study in the field of pain (VAS) and disability (ODI) in patients showed that the CAPS group had significant improvement in the initial assessment after surgery compared to the 2-stage surgery group. The chemical and thermal properties resulting from the heat polymerization process of the cement can cause damage to nerve endings inside the vertebrae, disrupting the neural signals of pain receptors[12,33]. Therefore, patients show significant improvement shortly after cement injection. But in the final evaluation, the 2-stage surgery group had a significant improvement with a significant difference that is due to the separation of the cement mass from the bone tissue in the CAPA group in the long term. Studies in this area have demonstrated that with 2-stage surgery, the pain and disability levels of patients have significantly improved after a 2-year follow-up[11]. Mo et al. (2011) showed that there was no significant difference between the two groups of patients with and without cement reinforcement in spine surgery in terms of postoperative pain and disability in the final follow-up[34]. Similarly, Wang et al. reported similar results, indicating the long-term detrimental effects of cement, leading many patients to require reoperation[35]. The 2-stage surgical stabilization has potential advantages and prevents subsequent corrective surgeries. It is a valuable technique for individuals with a broad spectrum of cardiovascular and respiratory diseases who lack organ reserves for lengthy surgeries and anesthesia. Additionally, elderly patients with spinal deformities requiring stabilization of a significant portion of their vertebrae necessitate increased attention to the 2-stage surgical approach.

Limitations

Given the current study's limitations, there are remaining research opportunities for several aspects of this investigation. We could not differentiate patients based on primary or secondary bone porosity (related to underlying diseases, drug-induced conditions, and hormonal disorders). The absence of similar studies on the two-stage surgical technique and insufficient information on its outcomes in different centers are notable constraints in this study.

Conclusion

Our study results indicate that the 2-stage surgical approach, compared to CAPS, has a higher preference and reduces potential complications resulting from cement injection. We observed screw loosening and unsuccessful fusion in only one patient in the two-stage surgery group, with most patients showing significant improvement in pain and functionality after surgery. Therefore, the 2-stage technique is suitable for all patients with poor bone quality and underlying diseases. Furthermore, concerns related to surgical complications in pedicle screw augmentation with cement in osteoporotic patients using the two-stage surgical method are quickly addressed. The results call for further investigations to solidify the knowledge gained in this study. We share this experience and recommend evaluating individuals with accompanying underlying diseases and severe spinal deformities, as our study group did not exhibit serious or symptomatic complications.

Data availability

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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References

1. Singh, V., Mahajan, R., Das, K., Chhabra, H. S. & Rustagi, T. Surgical trend analysis for use of cement augmented pedicle screws in osteoporosis of spine: a systematic review (2000–2017). *Glob. Spine J.* **9** (7), 783–795. https://doi.org/10.1177/2192568218801570 (2019).
2. Rometsch, E. et al. Screw-related complications after instrumentation of the osteoporotic spine: a systematic literature review with meta-analysis. *Glob. Spine J.* **10** (1), 69–88. https://doi.org/10.1177/2192568218818164 (2020).
3. Bostelmann, R. et al. Effect of augmentation techniques on the failure of pedicle screws under cranio-caudal cyclic loading. *Eur. Spine J.* **26**, 181–188. https://doi.org/10.1007/s00586-015-3904-3 (2017).
4. Chandra, V. R. et al. Segmental polymethylmethacrylate-augmented fenestrated pedicle screw fixation for lumbar spondylolisthesis in patients with osteoporosis—A case series and review of literature. *Neurol. India.* **65** (1), 89. https://doi.org/10.4103/0028-3886.198229 (2017).
5. Hsieh, M-K. et al. Improved fixation stability for repairing pedicle screw loosening using a modified cement filling technique in porcine vertebrae. *Sci. Rep.* **12** (1), 2739. https://doi.org/10.1038%2Fs41598-022-06724-4 (2022).
6. Wu, X. et al. Pedicle screw loosening: the value of radiological imagings and the identification of risk factors assessed by extraction torque during screw removal surgery. *J. Orthop. Surg. Res.* **14** (1), 1–9. https://doi.org/10.1186/s13018-018-1046-0 (2019).
7. Clerk-Lamalice, O., Irani, Z., Growney, M., Beall, D. P. & Hirsch, J. A. Parapedicular vertebral augmentation with polymethylmetacrylate for pedicle screw loosening. *Case Rep.* https://doi.org/10.1007/s00256-006-0192-3 (2018). 2018:bcr-2017-013548.
8. Hajilo, P., Imani, B., Zandi, S., Mehrafshan, A. & Khazaei, S. The comparison study of laminectomy with unilateral and bilateral pedicle screws fixation and laminectomy alone without fusion interbody in young patients with lumbar spinal stenosis: a randomized clinical trial. *Heliyon* **10** (15). https://doi.org/10.1016/j.heliyon.2024.e35435 (2024).
9. Choma, T. J., Pfeiffer, F. M., Swope, R. W. & Hirner, J. P. Pedicle screw design and cement augmentation in osteoporotic vertebrae: effects of fenestrations and cement viscosity on fixation and extraction. *Spine* **37** (26), E1628–E32. https://doi.org/10.1097/brs.0b013e3182740e56 (2012).
10. Bokov, A., Bulkin, A., Aleynik, A., Kutlaeva, M. & Mlyavykh, S. Pedicle screws loosening in patients with degenerative diseases of the lumbar spine: potential risk factors and relative contribution. *Glob. Spine J.* **9** (1), 55–61. https://doi.org/10.1177/2192568218772302 (2019).
11. Özer, A. F. et al. Lumbar dynamic stabilization with 2-stage surgery: early results. *Int. J. Spine Surg.* **16** (4), 638–645. https://doi.org/10.14444%2F8306 (2022).
12. Shokouhi, M. R., Torabi, M., Salimi, R. & Hajiloo, P. The relationship between professional moral courage and individual characteristics among emergency medical services providers. *Int. J. Emerg. Serv.* (2024).

13. Pellegrini, G., Francetti, L., Barbaro, B. & Del Fabbro, M. Novel surfaces and osseointegration in implant dentistry. *J. Investig. Clin. Dent.* **9** (4), e12349. https://doi.org/10.1111/jicd.12349 (2018).
14. Agarwal, R. & García, A. J. Biomaterial strategies for engineering implants for enhanced osseointegration and bone repair. *Adv. Drug Deliv. Rev.* **94**, 53–62. https://doi.org/10.1016/j.addr.2015.03.013 (2015).
15. von Wilmowsky, C., Moest, T., Nkenke, E., Stelzle, F. & Schlegel, K. A. Implants in bone: part I. A current overview about tissue response, surface modifications and future perspectives. *Oral Maxillofac. Surg.* **18**, 243–257. https://doi.org/10.1007/s10006-013-0398-1 (2014).
16. Smeets, R. et al. Impact of dental implant surface modifications on osseointegration. *Biomed. Res. Int.* **2016** https://doi.org/10.1155/2016/6285620 (2016).
17. Imani, B., Hajilo, P., Zandi, S. & Mehrafshan, A. Comparing the intraoperative and postoperative complications of the scalpel and electrocautery techniques for severing the inner layers of the lumbar disc during discectomy surgery. *Front. Surg.* **10**, 1264519. https://doi.org/10.3389/fsurg.2023.1264519 (2023).
18. Weinstein, J. N., Rydevik, B. L. & Rauschning, W. Anatomic and technical considerations of pedicle screw fixation. *Clin. Orthop. Relat. Res.*. **284**, 34–46 (1992).
19. Shi, M., Cai, Y., Xu, C., Guo, Y. & Yin, M. An independent inter-and intra-observer agreement assessment of Yeom classification for bone cement leakage following vertebroplasty/kyphoplasty. *Br. J. Neurosurg.* **37** (4), 589–594 (2023).
20. Min, J-H. et al. The clinical characteristics and risk factors for the adjacent segment degeneration in instrumented lumbar fusion. *Clin. Spine Surg.* **21** (5), 305–309. https://doi.org/10.1097/bsd.0b013e318142b960 (2008).
21. Fairbank, J. C. Oswestry disability index. *J. Neurosurgery: Spine*. **20** (2), 239–. https://doi.org/10.3171/2013.7.spine13288 (2014). 42.
22. Sprio, S., Fricia, M., Maddalena, G. F., Nataloni, A. & Tampieri, A. Osteointegration in cranial bone reconstruction: a goal to achieve. *J. Appl. Biomater. Funct. Mater.* **14** (4), 470–476. https://doi.org/10.5301/jabfm.5000293 (2016).
23. Mishra, S. K., Chowdhary, R., Chrcanovic, B. R. & Brånemark, P. I. Osseoperception in dental implants: a systematic review. *J. Prosthodont.* **25** (3), 185–195. https://doi.org/10.1111/jopr.12310 (2016).
24. Fischer, K. & Stenberg, T. Prospective 10-year cohort study based on a randomized controlled trial (RCT) on implant-supported full-arch maxillary prostheses. Part 1: sandblasted and acid-etched implants and mucosal tissue. *Clin. Implant Dent. Relat. Res.* **14** (6), 808–815. https://doi.org/10.1111/j.1708-8208.2011.00389.x (2012).
25. Swami, V., Vijayaraghavan, V. & Swami, V. Current trends to measure implant stability. *J. Indian Prosthodontic Soc.* **16** (2), 124–130. https://doi.org/10.4103/0972-4052.176539 (2016).
26. Hoellwarth, J. S., Tetsworth, K., Akhtar, M. A. & Al Muderis, M. Transcutaneous Osseointegration for amputees: what is it, how did it evolve, and what May develop? *Curr. Phys. Med. Rehabilitation Rep.* **11** (1), 6–15. https://doi.org/10.1007/s40141-023-00376-9 (2023).
27. Zhang, J., Wang, G. & Zhang, N. A meta-analysis of complications associated with the use of cement-augmented pedicle screws in osteoporosis of spine. *Orthop. Traumatology: Surg. Res.* **107** (7), 102791. https://doi.org/10.1016/j.otsr.2020.102791 (2021).
28. Baroud, G., Crookshank, M. & Bohner, M. High-viscosity cement significantly enhances uniformity of cement filling in vertebroplasty: an experimental model and study on cement leakage. *Spine* **31** (22), 2562–2568. https://doi.org/10.1097/01.brs.0000240695.58651.62 (2006).
29. Mueller, J. U. et al. Cement leakage in pedicle screw augmentation: a prospective analysis of 98 patients and 474 augmented pedicle screws. *J. Neurosurgery: Spine*. **25** (1), 103–109. https://doi.org/10.3171/2015.10.spine15511 (2016).
30. Karaca, S., Enercan, M., Ulusoy, O. L. & Hamaoglu, A. Radiologic and clinical outcome of the cement augmented pedicle screws after a minimum 2-year follow-up. *Acta Orthop. Belg.* **85** (2), 247–252. https://doi.org/10.1016/j.wneu.2023.03.006 (2019).
31. Karius, T. et al. Radiofrequency-activated PMMA-augmentation through cannulated pedicle screws: a cadaver study to determine the biomechanical benefits in the osteoporotic spine. *Technol. Health Care*. **25** (2), 327–342. https://doi.org/10.3233/thc-161273 (2017).
32. Ohtori, S. et al. Comparison of teriparatide and bisphosphonate treatment to reduce pedicle screw loosening after lumbar spinal fusion surgery in postmenopausal women with osteoporosis from a bone quality perspective. *Spine* **38** (8), E487–E92. https://doi.org/10.1097/brs.0b013e31828826dd (2013).
33. Tsai, K-J., Murakami, H., Horton, W. C., Fei, Q. & Hutton, W. C. Pedicle screw fixation strength: a biomechanical comparison between 4.5-mm and 5.5-mm diameter screws in osteoporotic upper thoracic vertebrae. *J. Surg. Orthop. Adv.* **18** (1), 23–27 (2009).
34. Paré, P. E. et al. Biomechanical evaluation of a novel fenestrated pedicle screw augmented with bone cement in osteoporotic spines. *Spine* **36** (18), E1210–E4. https://doi.org/10.1097/brs.0b013e318205e3af (2011).
35. Wang, W. et al. Comparison of the fenestrated pedicle screw and conventional pedicle screw in minimally percutaneous fixation for the treatment of spondylolisthesis with osteoporotic spine. *Clin. Neurol. Neurosurg.* **183**, 105377. https://doi.org/10.1016/j.clineuro.2019.105377 (2019). Epub 2019 May 23.

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Author contributions

BI: validation, funding acquisition, resources. PH: project administration, visualization, software, formal analysis. SZ: data curation, investiration, Writing-original draft. AM: conceptualization, supervision, Writing-review & esiting, methodology.

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Declarations

Ethics approval and consent to participate

This human study received approval from the Ethics Committee of Hamedan University of Medical Sciences (IR.UMSHA.REC.1402.667). The principles of the Helsinki Declaration were adhered to in this study. Informed and written consent for participation in the study and publication of radiological images was obtained from all patients.

Competing interests

The authors declare no competing interests.

Additional information

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