Using percutaneous parapedicle screw vertebroplasty to treat transpedicle screw loosening

Kai-Chun Wang[a], Deng-Ho Yang[b,c,d], Ku-I Chang[e,f], Wei-Tzu Hsu[a], Chih-Yen Chang[g,h], Chien-Ying Wang[i,j], Yi-Ping Yang[i,k,l], Chian-Shiu Chien[k,l], Meng-Yin Yang[m,n,o,p,*], Chiung-Chyi Shen[m,q,r,*]

[a]Department of Orthopaedic and Spinal Surgery, Taichung Veterans General Hospital, Puli Branch, Taichung, Taiwan, ROC; [b]Division of Rheumatology/Immunology/Allergy, Department of Internal Medicine, Taichung Armed-Forces General Hospital, Taichung, Taiwan, ROC; [c]Department of Medical Laboratory Science and Biotechnology, Central Taiwan University of Science and Technology, Taichung, Taiwan, ROC; [d]Division of Rheumatology/Immunology/Allergy, Department of Internal Medicine, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan, ROC; [e]Department of Orthopaedic and Spinal Surgery, Da-Li Jan-Ai Hospital, Taichung, Taiwan, ROC; [f]Department of Healthcare Administration, Central Taiwan University of Science and Technology, Taichung, Taiwan, ROC; [g]Department of Medical Education and Research, Jen-Ai Hospital, Taichung, Taiwan, ROC; [h]Department of Elderly Care, Central Taiwan University of Science and Technology, Taichung, Taiwan, ROC; [i]Institute of Pharmacology, School of Medicine, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC; [j]Division of Trauma, Department of Emergency Medicine, Taipei Veterans General Hospital, Taipei, Taiwan, ROC; [k]Department of Medical Research, Taipei Veterans General Hospital, Taipei, Taiwan, ROC; [l]Institute of Pharmacology, National Yang Ming Chiao Tung University, Taipei, Taiwan, ROC; [m]Department of Neurosurgery, Neurological Institute, Taichung Veterans General Hospital, Taichung, Taiwan, ROC; [n]Department of Neurosurgery, Da-Li Jan-Ai Hospital, Taichung, Taiwan, ROC; [o]Department of Surgery/Neurosurgery, Tri-Service General Hospital, National Defense Medical Center, Taipei, Taiwan, ROC; [p]College of Nursing, Central Taiwan University of Science and Technology, Taichung, Taiwan, ROC; [q]Department of Physical Therapy, Hung Kuang University, Taichung, Taiwan, ROC; [r]Basic Medical Education Center, Central Taiwan University of Science and Technology, Taichung, Taiwan, ROC

Abstract

Background: Pedicle screw loosening (PSL) is a postsurgical complication of spinal fusion surgery that can result in morbidity. The aim of this study was to evaluate the efficacy and safety of percutaneous parapedicle screw vertebroplasty (PPSV) for pain reduction and motility improvement in patients with PSL.

Methods: The postsurgical solid inter-body fusion with inter-body bone mass formation of 32 patients who underwent lumbar-sacrum spinal fusion surgery was confirmed with plain films and CT scans. Each patient had one or two screws with symptomatic PSL and was treated with PPSV. All the patients were then followed up for 12 to 24 months. The visual analog scale (VAS) and Roland-Morris Disability Questionnaire (RMDQ) were used to evaluate each patient before the operation, after the operation, and during the follow-up period.

Results: A total of 32 patients with a total of 47 screws with PSL were treated with PPSV and experienced different results in terms of pain reduction (with the mean VAS score dropping from 7.97 ± 0.74 to 2.34 ± 1.59, $p < 0.001$) and motility improvement (with the mean RMDQ score dropping from 16.75 ± 1.84 to 7.21 ± 4.08, $p < 0.001$). The motility improvement was significantly correlated with pain reduction ($r = 0.42$, $p = 0.018$), with the mean follow-up period being 19.3 ± 6.2 months (range: 8-36 months). However, five patients who experienced moderate improvements had eventually received a revision operation after undergoing PPSV.

Conclusion: The PPSV procedure is effective and safe for the reduction of pain and improvement of life quality in patients with PSL. It can thus be considered as a possible option for the revision of spinal fusion surgery.

Keywords: Parapedicle screw vertebroplasty; Pedicle screw loosening; Roland Morris Disability Questionnaire; Visual analog scale

1. INTRODUCTION

Pedicle screw placement is a well-known and increasingly performed technique used to achieve fixation and fusion in thoracolumbar surgery. Since its introduction by Harrington and Tullos in 1969 and its further development by Roy-Camille et al. and Louis et al. in the late 1980s,[1] it has become the mainstay of spinal instrumentation. Currently, pedicle screw placement in spinal fusion surgery is known to be a safe procedure with overall high accuracy and a very low rate of clinically relevant complications. It provides immediate stability and a reduction of the curve in the spinal segment. This technique is widely used for degenerative, neoplastic, infectious, and malformative pathologies associated with axial instability.[2]

However, even with various technical advances over the last few decades, pedicle screw insertion is still associated with a risk of complications, such that revision surgery is sometimes necessary.[3,4] Amongst these complications, pedicle screw loosening (PSL) is common and reportedly occurs at a rate ranging from 0.8% to 27% that may even exceed 50% in patients with

Address correspondence. Dr. Meng-Yin Yang and Dr. Chiung-Chyi Shen, Department of Neurosurgery, Neurological Institute, Taichung Veterans General Hospital, 1650, Taiwan Boulevard Section 4, Taichung 407, Taiwan, ROC. E-mail address: yangmy04@gmail.com (M.-Y. Yang); shengeorge@yahoo.com (C.-C. Shen).

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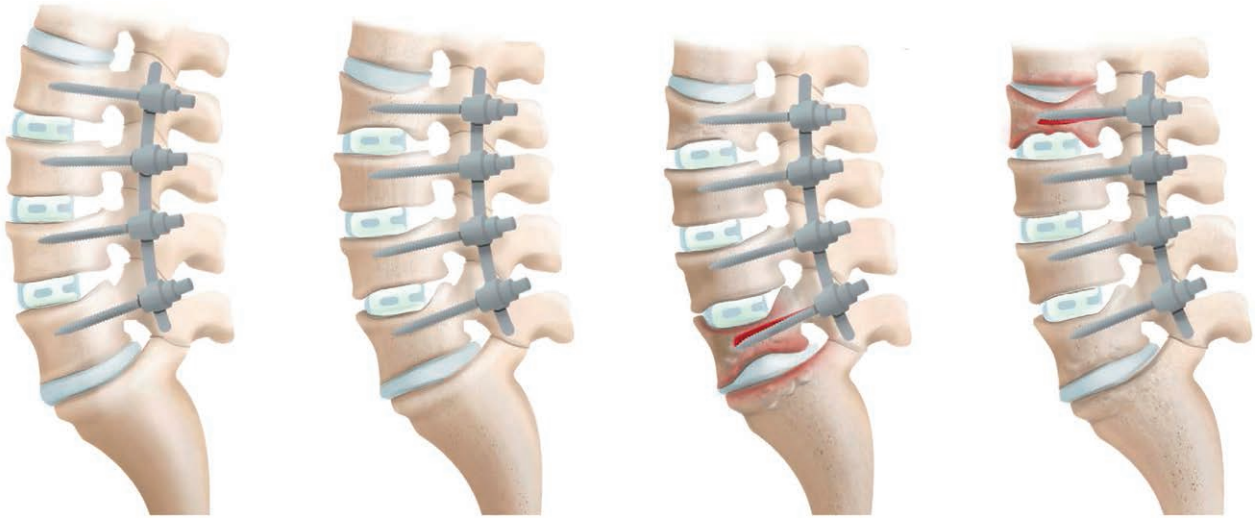

Fig. 1 Pedicle screws can loosen over time even after successful arthrodesis in patients with recurrent back pain.

osteoporosis.[5,6] PSL can be symptomatic and result in new or worsening back pain, leading to failed back surgery syndrome (FBSS).

In this study, we observed an interesting phenomenon. Although plain films (anteroposterior [AP], lateral flexion and extension) and CT scans revealed solid inter-body fusion with inter-body bone mass formation in the investigated patients, we could still observe instances of PSL in the patients (Fig. 1). This indicates that PSL not only happens in surgeries resulting in non-fused spinal segment but also in those yielding fused spinal segments. In this study, the screws exhibiting PSL were found mostly in both extremities of the given fused segments. When PSL occurs and results in back pain, treatment is required. Traditionally, the screws are removed in patients who have successfully undergone a surgery resulting in spinal fusion. If spinal fusion is not yet completed, however, another open surgery is considered to be the gold standard for hardware revision to achieve the highest level of stability for the pedicle screw or screws.

A vertebroplasty is a procedure for stabilizing compression fractures in the spine, one in which bone cement is injected into cracked or broken vertebrae. As the cement hardens, it will help to stabilize the fractures and support the spine. For people with severe, disabling pain caused by a compression fracture, vertebroplasty can relieve the pain, increase mobility, and reduce the use of pain medication.[7]

In the present study, a total of 32 patients with confirmed postsurgical solid inter-body fusion with inter-body bone mass formation were included. All the patients had experienced PSL-related back pain and a decrease in their quality of life. Conservative treatment was performed, but was ineffective. Percutaneous parapedicle screw injection of bone cement was then performed under local anesthesia to support the screws. We attempted this easy procedure to solve the various cases of PSL among the patients rather than using traditional revision surgery. We also then analyzed the effectiveness and indications of this procedure.

2. METHODS

2.1. Patients

The study included 32 patients who underwent lumbar-sacrum spinal fusion surgery (Table 1) who then had postsurgical PSL for a total of 47 screws detected on images. The patients all had symptoms resistant to conservative treatment, so the patients underwent a total of 47 instances of percutaneous parapedicle screw vertebroplasty (PPSV; each patient underwent one or two uses of PPSV, depending upon how many screws exhibited PSL) which were then analyzed. Bone mineral density measurements had been routinely performed within 6 months before this procedure and were considered as a valuable reference. The average bone mineral density of the lumbar spine among the patients was −1.57 ± 0.48 g/cm^2. Among the patients, the treated levels included L1 (n = 2), L2 (n = 6), L3 (n = 21), L4 (n = 5), L5 (n = 7), and S1 (n = 8). The amount of time between the PPSV and the last spinal fusion surgery for the patients ranged from 2 to 6 years (4.03 ± 1.43 years). All the patients underwent a functional X-ray imaging and CT scan examination to confirm the solid inter-body fusion and the number of loosened screws (Fig. 2A, B). The criterion for screw loosening was at least a 1-mm radiolucent zone around the screw and a double halo sign (ie, a radiolucent zone surrounded by an outer radiopaque rim of dense bone) (Fig. 2C, D).[5,8] Potential subjects were excluded

TABLE 1

The 32 patients who underwent lumbar-sacrum spinal fusion surgery who then had postsurgical PSL for a total of 47 screws detected on images

	Male	Female	Total	*p*
Number	6	26	32	
Age	76.33 ±2.16	74.92 ±4.00	75.19 ±3.74	0.467
BMD	−1.57 ±0.48	−2.16 ±0.58	−2.05 ±0.60	0.008**
Previous OP (year)	3.50 ±1.64	4.15 ±1.38	4.03 ±1.43	0.324
Fusion level	3.67 ±0.82	3.54 ±0.76	3.56 ±0.76	0.660
Treated screw level				
L1	0 0.0%	2 7.7%	2 6.3%	1.000
L2	0 0.0%	5 19.2%	5 15.6%	0.555
L3	4 66.7%	11 42.3%	15 46.9%	0.383
L4	0 0.0%	5 19.2%	5 15.6%	0.555
L5	2 33.3%	3 11.5%	5 15.6%	0.228
S1	1 16.7%	6 23.1%	7 21.9%	1.000
Follow up (month)	18.17 ±4.92	17.23 ±4.49	17.41 ±4.51	0.679

Fisher's exact test. Mann-Whitney U test.
*$p < 0.05$, **$p < 0.01$.
PSL = pedicle screw loosening.

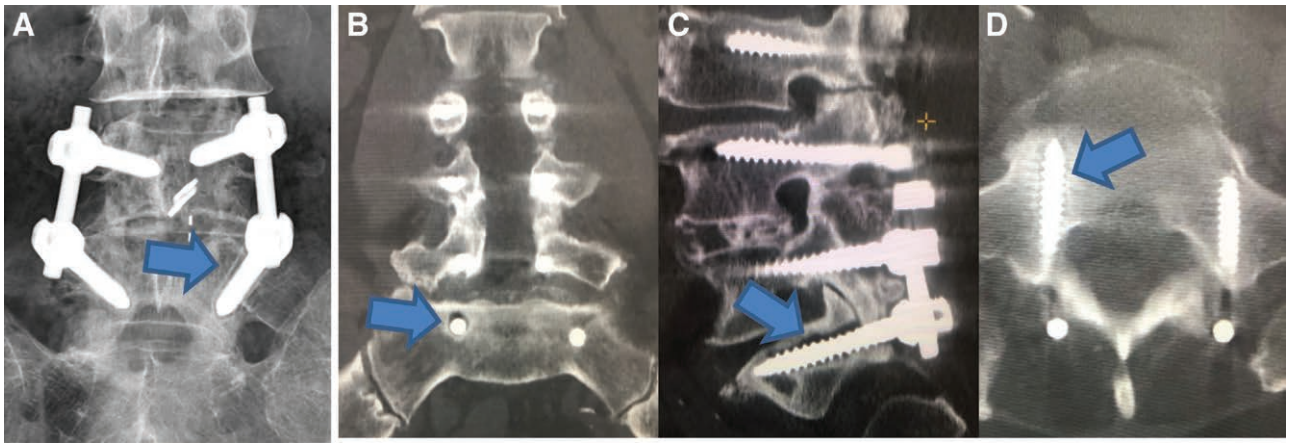

Fig. 2 A, Anteroposterior X-ray showed radiolucent zone and double halo around the screw (blue arrow) at left L5. B–D, CT scan showed typical radiolucent zone and double halo around the screw at right S1 which indicate screw loosening.

from participation if they had a neurological deficit or other comorbidity, such as an adjacent disease with a newly developed nerve compression and neurological deficit, recent exposure to high energy trauma, a screw with penetration out of the vertebral body, screw migration with kyphosis deformity, consecutive PSL or PSL at more than two levels, implant failure with a broken component, malignant compression fractures, or a suspected deep infection.

2.2. Procedures

This study was reviewed and approved by the local institutional review board committee, as long as all the applied methods were conventional, and no additional risks were found. The purpose and procedures involved in the study were fully explained to the patients, and informed consents were obtained from all the patients before data collection.

Each use of PPSV was performed with the patient in a prone position. We used axial preoperative CT images to calculate the distance from the midline to the skin entry point of the spinal needle (Fig. 3A). The needle trajectory was planned as lateral to the pedicle screw to avoid obstruction by the screw and vertical rod (Fig. 3B). Using C-arm fluoroscopy visualization, percutaneous entry was established at the level of the corresponding screw on the AP image (Fig. 4A). The final target point for introducing the spinal needle was the junction of the pedicle and the vertebral body on the lateral image (Fig. 4B). The spinal needle inserted through the skin lateral to the midline at a measured degree angle (on the CT image, Fig. 3A) would contact the body and then be replaced by a working cannula (Fig. 4C–F). The aim was to penetrate the halo cavity around the screw, so that the injected cement would later surround the screw (Fig. 5A–C). We then adjusted the direction of the working cannula slightly to go deeper. After reaching the posterior margin of the vertebral body, a sample of the bone marrow was obtained for histological analysis. Then polymethylmethacrylate (PMMA) cement was injected into the vertebral body, filling the anterior two-thirds of the body (Fig. 6A, B), while C-arm fluoroscopy was used to monitor the cement distribution for the purpose of avoiding leakage. A fluoroscopic examination was performed after crystallization.

2.3. Assessment indices

The primary endpoints were pain, which was evaluated using a visual analog scale (VAS: 0–10 scale), and disability, which was assessed using the Roland-Morris Disability Questionnaire (RMDQ). The VAS was used before the operation, immediately after the operation, 24 hours after the operation, and at 1 month, 3 months, 6 months, and 1 year after the operation. Meanwhile, the RMDQ was used before the operation, 24 hours after the operation, and at 6 months and 1 year after the operation. Plain film and CT scan evaluations were also arranged during the follow-up period.

2.4. Statistical analysis

All the data were expressed as mean ± SD. Measurement data, including the VAS and RMDQ scores, were compared using SPSS (IBM SPSS statistics 20.0). All the measurement data,

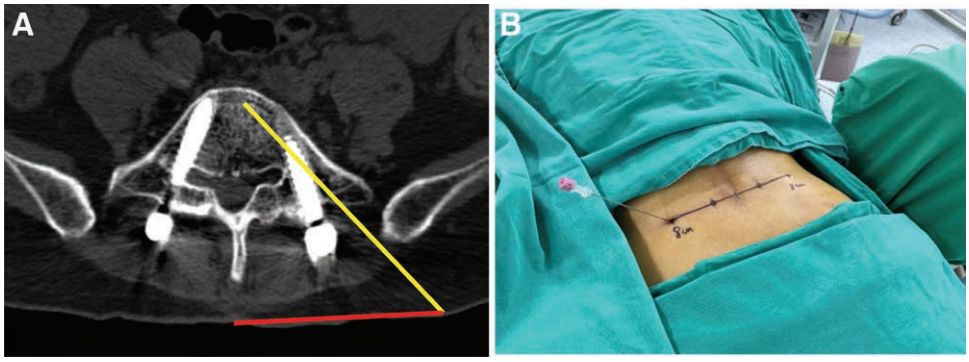

Fig. 3 A, Preoperative axial CT scan showed the entry point was 8.2 cm lateral to the midline (red line) with tilting 47° trajectory (yellow line) to the target point. B, entry point of spinal needle.

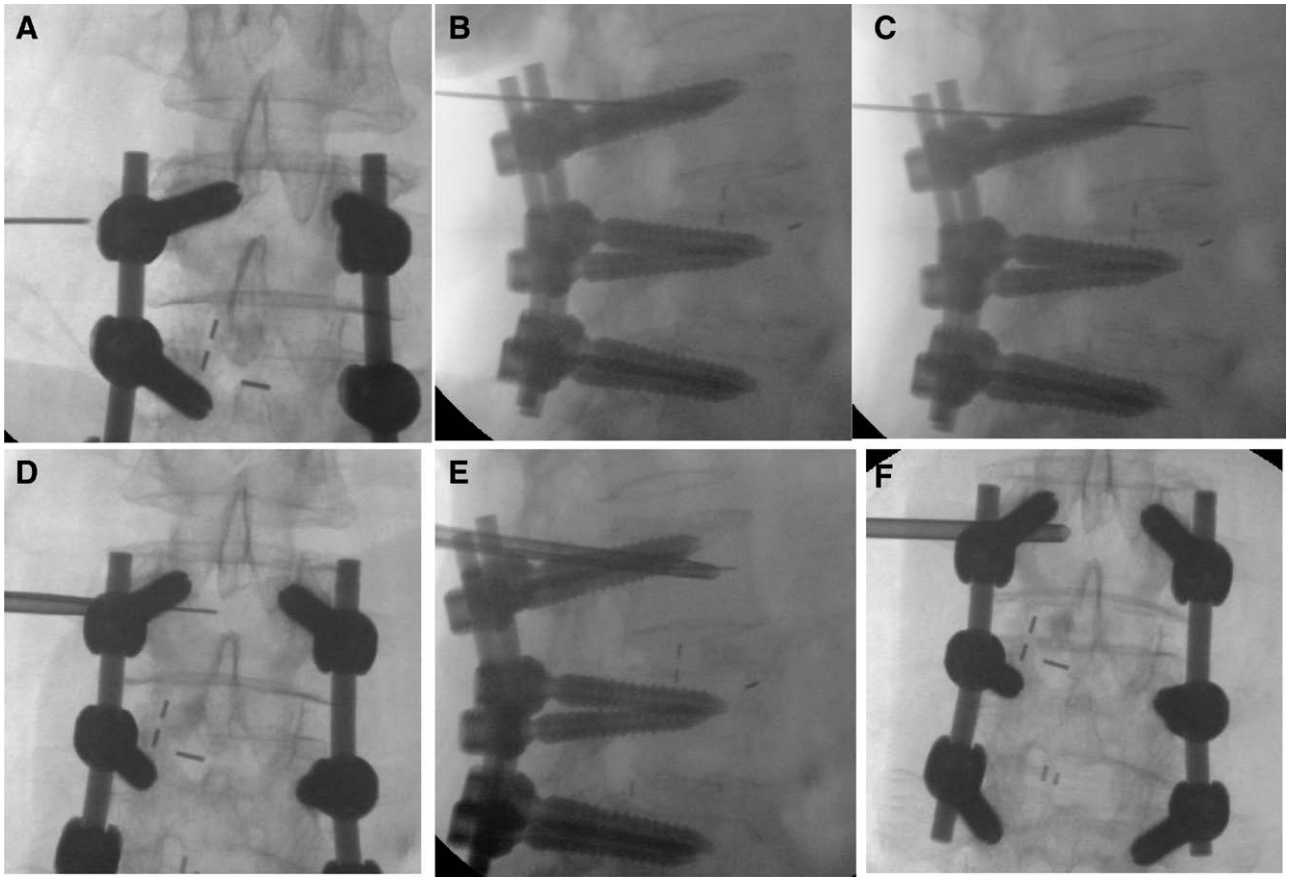

Fig. 4 Intraoperative C-arm fluoroscopy images. A, AP X-ray showed spinal needle approaching the target (junction of pedicle and body). B, Lateral X-ray showed the spinal needle on the target. C, AP view showed spinal needle was deeper. D, Lateral view showed spinal needle was deeper. E and F, The spinal needle was exchanged for a working cannula. AP = anteroposterior.

including the VAS and RMDQ scores, were tested by repeated measures Fisher's exact test and Mann-Whitney U test. Pearson correlation coefficients were calculated to assess the relationship between the decreased VAS scores and the improved RMDQ scores. Statistical analyses were conducted using SPSS version 20.0 (SPSS, Chicago, IL). $*p < 0.05$, $**p < 0.01$.

3. RESULTS

All 32 patients tolerated their surgeries well. The patients underwent follow-up periods ranging from 12 to 24 months (mean: 19.3 months). On average, the VAS pain scores decreased significantly from a preoperative value of 7.97 ± 0.74 to an immediate postoperative value of 2.34 ± 1.59 ($p < 0.001$) and then a 24-hour postoperative value of 2.59 ± 1.37 ($p < 0.001$). The scores decreased further to an average of 2.03 ± 1.23 at the final follow-up, which was also significantly different from the mean 24-hour postoperative value ($p = 0.006$) The RMDQ scores improved significantly from a preoperative average of 16.75 ± 1.84 to a postoperative average of 7.21 ± 4.08 ($p < 0.001$) and a 6-month postoperative value of 6.84 ± 4.07. The average RMQD score increased further to 6.375 ± 4.34 at

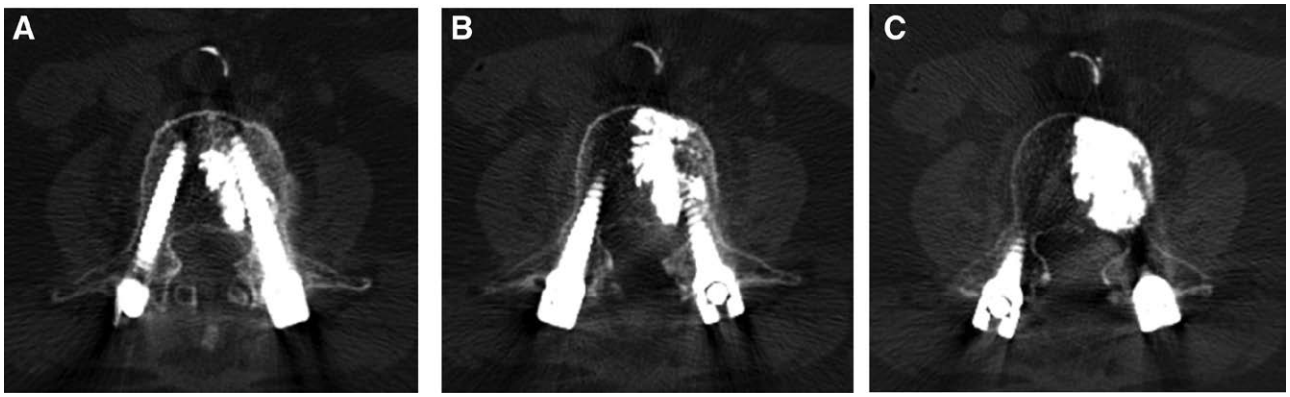

Fig. 5 Postoperative axial CT scan showed the bone cement filling the body and around the screw.

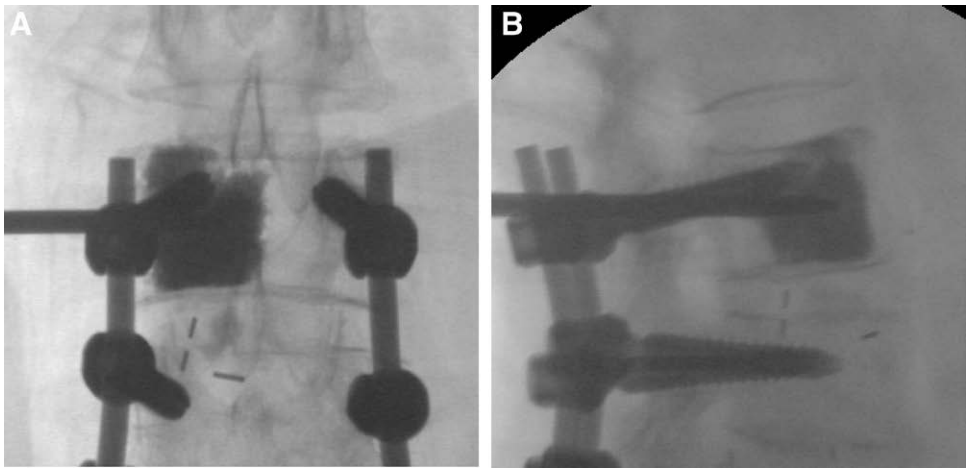

Fig. 6 Intraoperative C-arm fluoroscopy images. A and B, AP and lateral X-ray showed the bone cement filling the anterior two-thirds parts of the body. AP = anteroposterior.

the final follow-up. Additionally, that value was significantly different from the 24-hour postoperative value ($p < 0.001$). The improvement of the VAS score displayed a significant correlation with the improvement in the RMDQ score (r = 0.42, $p = 0.018$). There were six patients (one male patient and five female patients) who experienced moderate pain reductions (VAS improvement <4), and five patients who eventually underwent another surgery to remove the loosened screws. None of the patients declared a loss of autonomy or a decrease in their activity. No patient experienced a cement embolism or the development of neurologic deterioration, although two subjects had cement leaks.

4. DISCUSSION

Pedicle screws are regularly used in spinal fusion surgery, particularly during lumbar fusion. The screws are placed both above and below the fused vertebrae and attached to a rod to add support for the spine as it heals, while also preventing any movement that may adversely affect the healing process. This screw and rod system has proven its durability and strength in many mechanical studies.[3,9]

However, the solid fixation of a screw-bone-interface is impacted by load transmission and the bone mineral density of the patient.[10] In the available published literature, studies have shown that the pedicle screws used for spinal fusion surgery loosen over time, particularly in osteoporotic patients.[6,11] PSL is a typical and common complication following spinal fusion surgery that can result in morbidity in patients. It presents the characteristic findings of radiolucent zones around the screw. These loosened screws are associated with decreased pullout strength and extraction torque.[6] A loosened pedicle screw can be regarded as a type of instrument failure and is associated with pseudoarthrosis. Previously, patients without any marked discomfort were usually prescribed analgesic medications and the use of a brace and were regularly scheduled for reexaminations until spinal healing was confirmed, after which the internal fixation was removed.

However, PSL may result in the creation of new or worsening back pain, leading to FBSS, which usually needs to be revised surgically. Traditionally, a patient's screws are removed during a successful fusion spinal surgery.[11] If spinal fusion has not yet been completed, however, an additional open surgery will be considered as the best option for instrument revision to regain stable fixation between the screw-bone interface.[4] To prevent loosening of the pedicle screws, many new implants, including coated screws, cemented screws, expandable pedicle screws, and cannulated screws with or without the use of bone cement (PMMA) are being rapidly developed, and these implants have shown promise in terms of improving pull-out strength. However, patients provided with these modern implants may have to undergo a longer surgery and more difficult procedure, in addition to potentially incurring costlier medical fees.

Vertebroplasty is a well-known and ideal option for the treatment of acute vertebral compression fractures. It is a relatively easy procedure requiring a minimally invasive injection of bone cement to stabilize the given fracture, prevent abnormal motion, restore vertebral height, and, in some cases, to correct the patient's kyphosis. It is effective in terms of pain reduction, and satisfactory clinical outcomes can be obtained after the elimination of the microfractures and vertebral stabilization.[6]

In this study, we selected patients who had undergone a successful lumbar or lumbar-sacrum spinal fusion surgery but subsequently had loosened screws. Screws with PSL were found mostly at upper or lower end of the spinal fusion segments, which means that there was still weight loading over the screws at the ends of fused spinal segments. Bearing weight would eventually cause screw loosening, especially in osteoporotic patients. There was also another finding that supports this theory. The most common symptom among these patients was low back pain and soreness when they were changing position, sitting, walking, or bending. The pain typically subsided, however, when the patients laid down. The symptoms are very similar to those of an acute compression fracture. Relatedly, the injured vertebral body may not have tolerated the weight loading.

PPSV was performed to relieve the patients' back pain and improve their quality of life. In this study, some of the patients experienced significant pain relief after PMMA augmentation of the injured vertebral body. Most of them had well-embedded screws surrounded with PMMA, which effectively enhanced the bone-screw interface. However, there were also some patients who had the bone-screw halo space only partially filled with PMMA but still experienced significant pain relief. In any case, these results indicated that PMMA augmentation could stabilize microfractures and osteoporotic vertebral bodies. It basically provided support to the loosened screws for weight bearing.

PSL is commonly seen in patients with long segmental fusions, osteoporosis, and trauma, as well as in patients who bear heavy weights during their work. Additionally, trauma can cause the acute onset of severe back pain, and most of the patients in our

study experienced a late onset of back pain after spinal fusion surgery (at 4.6 ± 1.6 years after the surgery). This may have been due to the rest and brace support during the first several months after spinal fusion surgery.

Identifying symptomatic loosened screws is critical. The decision to subject a patient to a second surgery with PPSV, or to an open surgery, must be carefully evaluated. The causes of pain in cases of PSL are multifactorial, with such pain mainly considered to occur from micro-movements of the bone-screw interface.[6] A loosened pedicle screw may move due to spinal movements, which could trigger painful para-spinal muscle spasms. Conservative analgesic treatment would initially be prescribed, along with a brace support for a minimum of 3 months. CT scan examinations would be performed routinely to confirm any low-grade screw loosening. Serial dynamic plain films (lateral flexion and extension) would also be arranged during follow-up. If the back pain persisted or even worsened, bothering the patient, PPSV would be arranged for augmentation of the vertebral body. The main goal of PPSV is to regain a stable fixation between the screw-bone interface. Our results in this study showed that PPSV treatment was associated with a significant improvement in pain, along with improved quality of life, in patients with painful PSL over a 2-year follow-up period.

To the best of our knowledge, vertebroplasty has not previously been evaluated as a method for treating low-grade screw loosening-related pain. Only a few case reports involving use of the procedure can be found.[12–14] In patients with spinal fusion, a vertical rod and pedicle screw limits access to the vertebral body when a conventional transpedicular approach is used. We present a lateral perpendicular approach which offers a more favorable route to the center of the vertebral body in this circumstance.[15,16] Because the entry point of the spinal needle is more lateral to the screw and rod, the working cannula we used for PPSV was longer than usual. Once the vertebral body is reached, the working cannula can be adjusted to the depth and angle for the approach to the posterior margin of the vertebral body. This procedure promotes circumferential cement instillation around the screw, leading to better consolidation of the screw and bone. Despite this conventional procedure being considered both easy and safe, to prevent any nerve root injury during the operation, local anesthesia is recommended. All of the patients in this study tolerated the PPSV procedure well.

The strategies used for revision surgery in patients with PSL vary, and should be customized according to both the condition of the patient's health and the implant. In any case, PPSV cannot totally replace open surgery for revision under all the potential circumstances. In certain cases without contraindications, however, we may try PPSV before open revision surgery, as it is considered an easy, safe, and minimally invasive procedure.

In conclusion, a PPSV is a simple and effective surgical technique for select patients with symptomatic PSL. PPSV can be used as an alternative method before an open revision surgery for the removal of screws. However, additional clinical analyses during long-term follow-up, along with additional biomechanical studies, are still needed.

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