



## Research Article

# Clinical Outcome-Supported Advance of Cement Lumbar Interbody Fusion for Degenerative Lumbar Scoliosis

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## Abstract

**Objective:** Couple surgical methods have been used to treat symptomatic Degenerative Lumbar Scoliosis (DLS) with various outcomes and limitations. This retrospective case series study was to report the outcomes of the mini-open far-lateral approach of Cement Lumbar Interbody Fusion (CLIF) for DLS.

**Method:** Between June 2012 and Dec 2017, 70 patients with degenerative scoliosis bearing low back and leg pain were treated with mini-open far-lateral approach for foraminoplasty/laminotomy and CLIF with interspinous process devices. The mean age was  $68.2 \pm 7.1$  years and mean follow-up, 68 months.

**Result:** Mean operative time per segment was  $28.2 \pm 4.3$  min; blood loss per segment,  $47.5 \pm 27.7$  mL, and hospitalization,  $2.7 \pm 1.4$  D. Mean preoperative, 3-month follow-up, and final visit VAS and ODI were  $7.9 \pm 0.8$  and  $67 \pm 9.1$ ;  $2.5 \pm 0.9$  and  $27.2 \pm 10.2$ ; and  $2.3 \pm 1.0$  and  $24.3 \pm 8.7$ , respectively. The average coronal Cobb's scoliosis angles were  $32.6^\circ \pm 14.5^\circ$  preoperatively,  $6.3^\circ \pm 3.8^\circ$  at 3-month follow-up and  $10.4^\circ \pm 7.2^\circ$  at final visit ( $P < 0.001$ ). The lumbar lordosis angles were  $12.2^\circ \pm 10.3^\circ$  preoperatively,  $35.2^\circ \pm 11.5^\circ$  at 3-month follow-up and  $30.2^\circ \pm 9.6^\circ$  at final visit. Intervertebral bridging osteophytes were noted in 42 patients. Adjacent CLIF during follow-up was performed for 6 patients. Only one major complication with radiculopathy caused by leaked cement received reoperation within 30 days.

**Conclusion:** The CLIF for DLS merited significant improvement of VAS and ODI scores and correction of lumbar scoliosis and lordosis at the mean 68-month follow-up with low rate of complications.

**Keywords:** Cement lumbar interbody fusion (CLIF); Degenerative lumbar scoliosis; Lumbar kyphosis; Mini-open far-lateral approach

## Introduction

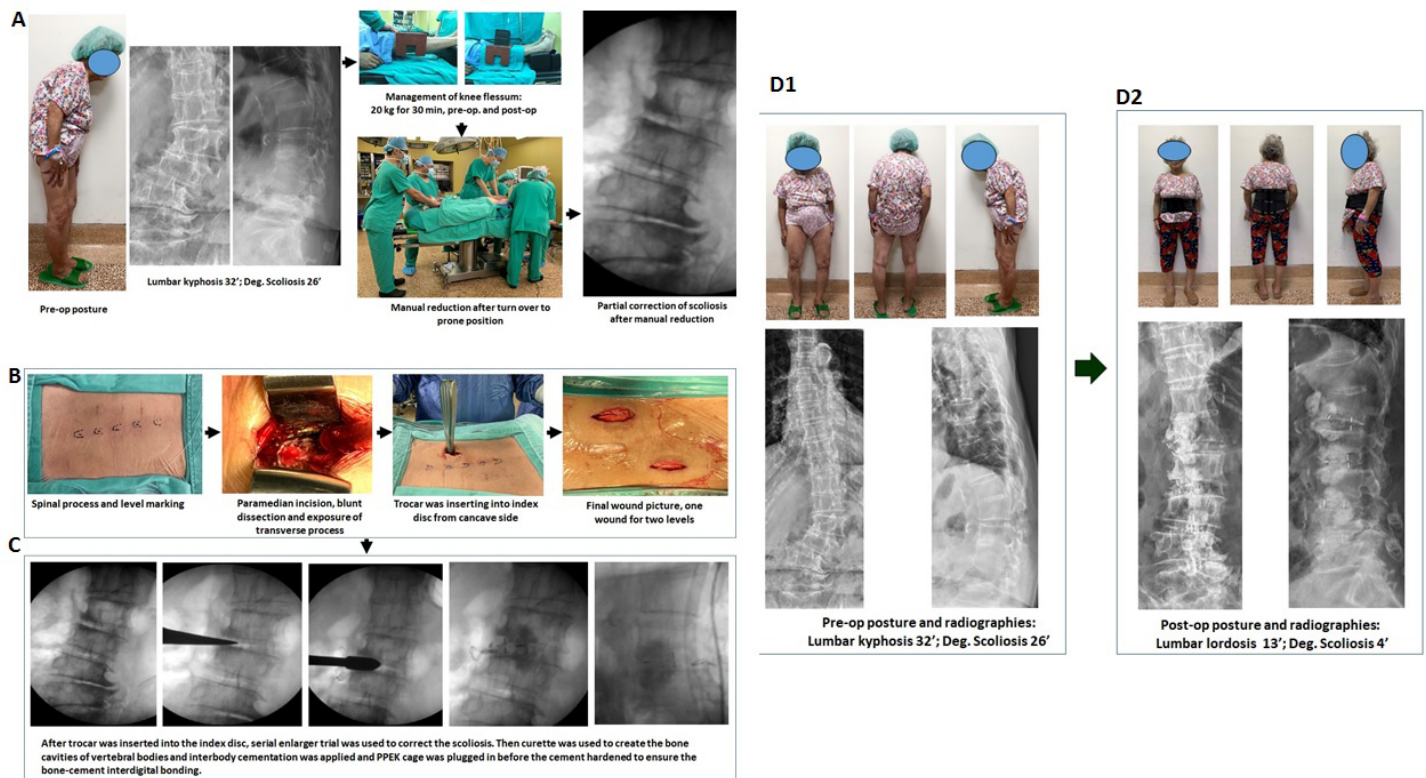
Degenerative Lumbar Scoliosis (DLS) for the elderly is a frequent cause of Low Back Pain (LBP) and may lead to disability [1,2]. As conservative treatments failed, the followed operation addressed on spinal decompression or fusion is recommended. However, posterior instrumentation with bone graft for the treatment of DLS is not only time consuming but with high risk of complications [3-5]. Complex spinal fusions for the elder with fragile comorbidities may increase risk to face major

complications [6]. Even with modern technology of Minimally Invasive Surgeries (MIS), the intraoperative and post-operative complications were 2.5 and 10.2% respectively for Transforaminal Lumbar Interbody Fusion (TLIF), and 2.2 and 7.8% respectively for percutaneous endoscopic TLIF [7]. For the octogenarian patients with fragile medical conditions, MIS-TLIF might cause up to 66.7% perioperative complications and 9.5% mortalities [8]. The high incidence of both short and long-term complications has raised an urgency to develop an alternative treatment in the past decade.

A minimally invasive surgical technique named Percutaneous Cement Discoplasty (PCD) [9-11] was intended to decrease spinal instability for the advanced lumbar degeneration and promise

clinical results with low complications. As reported, PCD was reported with satisfied target therapy for pain relief but was comparatively poor for spinal stenosis and scoliosis correction. Camino-Willhuber reported that, basically, there was no significant improvement for lumbar lordosis or scoliosis after PCD and 14.7% of the 156 PCD patients have received decompression surgery [11]. Based on our own experiences, adjacent vertebral fracture may occur and cause disc cement migration and pain recurrence for the elders due to severe osteoporosis. Especially, it would be worse and more likely to cause fracture when scoliosis was corrected to concentrate more stress on vertebral bodies at the concave side.

To prevent the potential complications of posterior instrumentation in traditional fusion surgery and increase the correction rate of scoliosis and lordosis in PCD, we have developed a mini-open far-lateral approach of Cement Lumbar Interbody Fusion (CLIF) (Figure 1) for the elders with DLS bearing both back and leg pain. This study aims to retrospectively investigate the radiological and clinical results of CLIF.



**Figure 1:** Procedure of the detailed operation of interbody cementation (CLIF); A: posture and radiographies of a demonstrated case who was subjected to manual reduction; B: operation to create body cavities ready for cementation; C: operation of cementation; and D: comparison of postures and radiographies before (D1) and after (D2) receiving CLIF surgery of a demonstrated case.

## Materials and Methods

### General Information

This retrospectively observational, single institute case series study was approved by the St Martin De Porres Hospital, Chia-Yi, Taiwan ethics review board (IRB 20C-006).

### Patient Population and Data Collection

Between June 2012 to December 2017, 82 patients with low back and leg pain and advanced degenerative scoliosis were treated with CLIF. The criteria for inclusion were as followed: patients with moderate-to-severe both low back and leg pain (visual analog scale [VAS] of 6 or more), who did not respond to conservative treatment after a minimum of 6 months, with DLS and moderate-to-severe lumbar stenosis. Patients with active infection or oncologic condition were excluded. Five patients died due to medical diseases and 7

patients lost follow-up. Finally, 70 patients with minimum 5-year follow-up were enrolled. The follow-up rate was 85.3%.

### **Preoperative Radiological Studies**

Before indication of surgery, all cases by conventional X-rays, CT scan, and magnetic resonance imaging were integrated for studies. The radiological studies were performed in standing position (anterior-posterior and lateral views). CT scan of the thoracolumbar and lumbar spine was performed routinely. Magnetic resonance imaging was used to analyze the levels and severity of the spinal stenosis.

### **Operating Technique**

The procedure was performed under general anesthesia to obtain maximum muscular relaxation. The detailed procedure is stepwise presented and interpreted in Figure 1. All patients initially underwent manual reduction (Figure 1A). Patients were changed from supine to prone position first and C-arm fluoroscopy was used to locate the scoliosis site and monitor the cementation. Manual reduction was done by five people. One anesthesiologist held the patient's head, two assistants held the patient's shoulders, two assistants held the patient's legs, and the surgeon compressed the convex side of spine by one hand holding the contralateral pelvis and pushing the scoliosis apex by another hand. Manual reduction began with gentle traction of the trunk by the leg assistants with greater force at the concave side and, simultaneously, the surgeon gradually increased the pushing force onto the spine of convex side. The flexible scoliosis was reduced easily by the manual procedure, leaving a substantial disc opening in the concave side. However, when an ankylosing scoliosis is encountered, which could not be reduced by manual reduction and spur discontinuity procedure is needed thereafter.

After manual reduction, the index levels were identified by C-arm image precisely (Figure 1B). The midline spinal process tips were marked and the incision was made about 3-4 cm away from the midline at the concave side. One incision about 3 cm long to allow CLIF for two continuous discs. The skin and faciae were incised and muscle was bluntly dissected until transverse process was identified. The radicular vessels were coagulated. Through Kambin triangle, one trocar was inserted into target disc just cephalic to the next transverse process under C-arm guide, where the trocar was keeping a safe distant from the exiting root. Then, the pathway was enlarged by serial trials until the scoliosis was corrected as complete as possible. Ankylosing spur was broken by the enlarger trial or osteotome. Then, one curette of 1-cm scoop was used to create the bony cavities at both vertebrae adjacent to the index disc. In usual, it is an easy step to finish due to osteoporosis. The disc material was removed. The bone from the lamina chips and vertebral bodies were harvested and inserted into the disc space as bone graft to assist fusion. The cement (Surgical

Simplex P, Howmedica Osteonics Corp. NJ, USA) was inserted into the disc space and the created bony cavities, which would be solidified as a three-dimensional interbody fixator (Figure 1C). The PEEK cage (12-14 mm, 8°-10° lordosis angle BAUI Biotech CO., LTD., Taiwan) was pushed into the disc space before cement hardened. In some cases, when the lordosis has been corrected well by manual reduction, cages were not used. Injection cement volume for each level was 12 mL (9 to 15 mL). The cement height beyond half of the vertebral bodies to reach the optimal fixation power was appropriate to prevent cement loosening. Because the cement-bone bonding is good to resist the compression stress caused by spine flexion, but poor to tensile force generated by spine extension, the interspinous process device (Rocker, Paonan Biotech CO., LTD., Taiwan) (Figure 1D) was applied around the scoliosis apex segments to prevent the spine over-extension and enforce the cement-bone construct. After CLIF was done, the foramen and roots were checked routinely by nerve probe. If stenosis was still identified after indirect decompression of scoliosis correction, unilateral foraminoplasty or partial facetectomy would be done. The hemovac drainage was not used and back brace, not needed.

In some cases, due to compensatory mechanism to spine deformities, knee flexion contracture was noted for the severe patients. The knee manipulation was designed as followed: the patient was in supine position with knee extension and solid support of 20 cm height at the heel region, which keeps the knee off the bed. The weight of 10-20 kg was continuously put on the knee region to press the knee into full or over extension posture for 30 min, which will release contracture of the posterior knee capsule and other soft tissues. The procedure can be repeated for 3-5 times every 3 days before and after operations.

### **Outcome Measures**

Clinical evaluation was performed preoperatively and postoperatively at 3, 6, 12, 24, 36 and 48 months, and the last follow-up. Overall VAS score (0-10) and Oswestry Disability Index (ODI; 0-100) were applied for evaluation [12,13]. Radiological evaluation included spinal sagittal and coronal alignment, vertebral compression fracture, cement loosening, and adjacent segment pathology. Complications at 30 days were recorded and classified as major and minor using the Glassman classification [14]. In this regard, major complications were defined as complications leading to permanent neural deficit or impairment, whereas minor complications were defined as who did not result in permanent damage and no reoperation afterward.

### **Statistical Analysis**

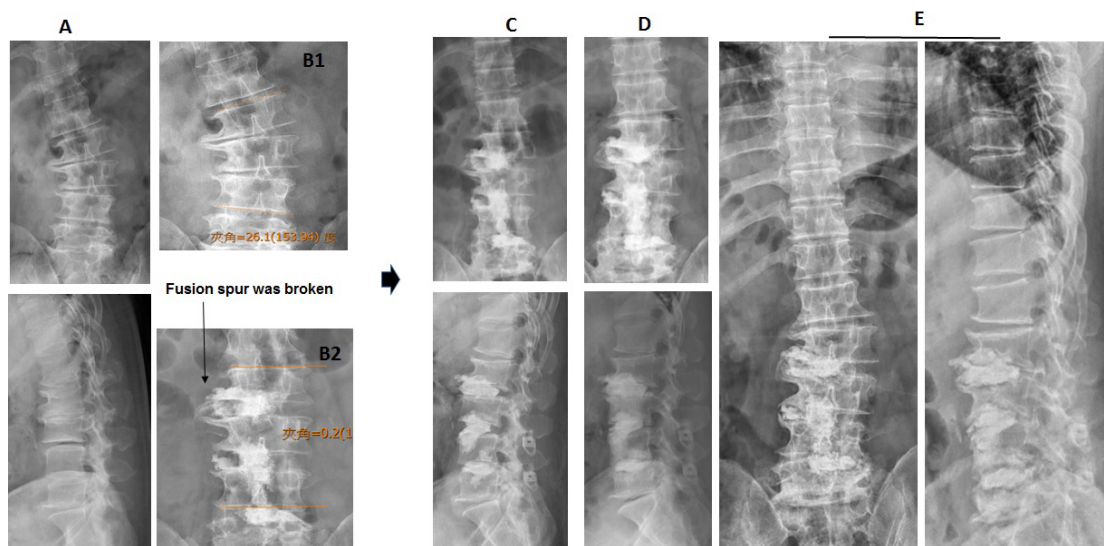
The quantitative variables were described as mean  $\pm$  standard deviation. Preoperative and postoperative VAS and ODI scores were compared through a paired t-test; the statistical significance ( $P < 0.05$ ) of these differences was calculated. The statistical

analysis was performed with the Excel (Microsoft, Classic 2021 versions, USA).

## Results

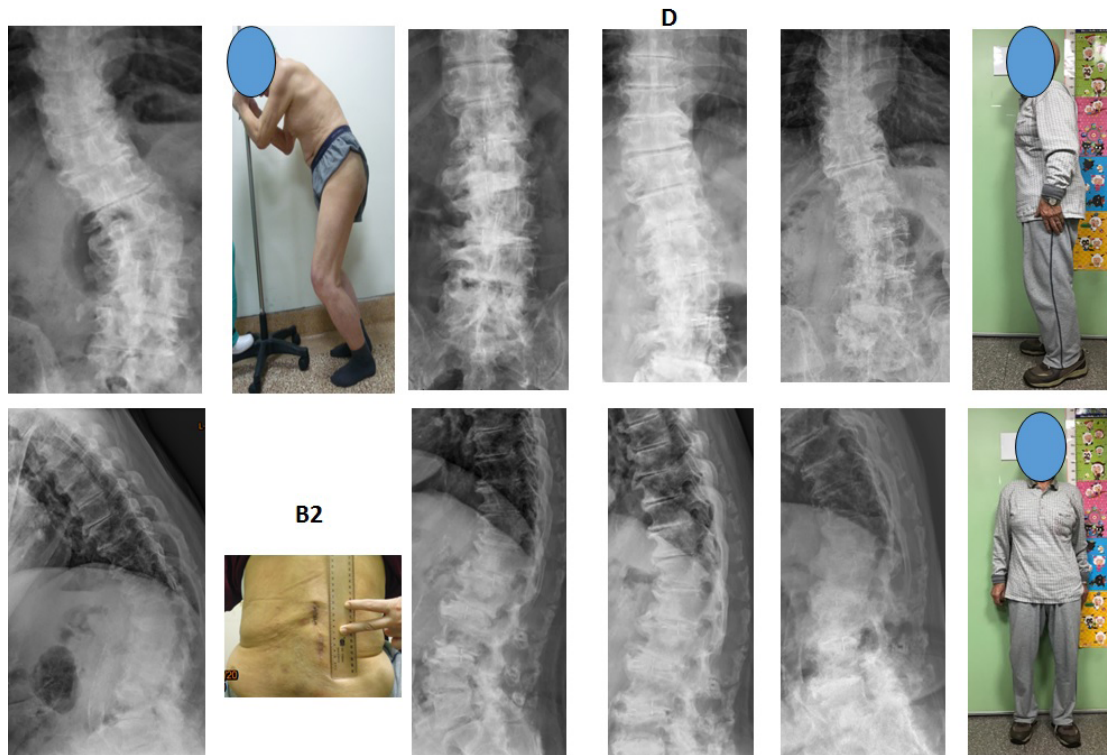
### Patient Background and Operation Practice

A total of 70 patients were finally included in our analysis with a mean age of  $68.2 \pm 7.1$  years (43-87), a mean BMI of  $23.9 \pm 3.2$ , and male to female ratio of 22:48. The mean follow-up was 68 months. The operative time per segment was  $28.2 \pm 4.3$  min with an estimated blood loss of  $47.5 \pm 27.7$  mL. The mean hospitalization was  $2.7 \pm 1.4$  D. All patients were able to leave bed to walk at the operation day and 38 patients were discharged within 24 hours after surgery. Two demonstrated cases are highlighted and interpreted in Figures 2 and 3.



**Figure 2:** Case demonstration of a 53-year male patient with 26° DLS; A: pre-operation; B1: measured angle before operation; B2: measured angle after operation; C: post-operation initial follow-up; D: 3-year follow-up and E: 78-month follow-up, still an active farmer.





**Figure 3:** Case demonstration of a 77-year-old male patient with DLS before and after receiving interbody cementation operation; A: pre-operation; B1: side photograph of the patient; B2: surgical wounds; C: post-operation 1-month follow-up; receiving L5/S1 CLIF due to L5 radiculopathy 8 months later; D: 3-year follow-up; E: 5-year follow-up and F: photographs at 5-year follow-up.

### Clinical Results

Preoperative mean VAS and ODI were  $7.9 \pm 0.8$  and  $67 \pm 9.1$ , respectively. At 3-month follow-up, mean VAS was  $2.5 \pm 0.9$  and ODI,  $27.2 \pm 10.2$ . At 12-month follow-up, mean VAS was  $1.8 \pm 0.7$  and ODI,  $21.2 \pm 9.4$ . At the final visit, mean VAS and ODI values were  $2.3 \pm 1.0$  and  $24.3 \pm 8.7$  ( $P < 0.0001$ ), respectively.

### Radiological Findings

As generalized, significant improvement of lumbar lordosis and Cobb's angle have been observed. The average coronal Cobb's scoliosis angles were  $32.6 \pm 14.5^\circ$  preoperatively,  $6.3 \pm 3.8^\circ$  at 3-month follow-up and  $10.4 \pm 7.2^\circ$  at final visit ( $P < 0.001$ ). The lumbar lordosis angles were  $12.2 \pm 10.3^\circ$  preoperatively,  $35.2 \pm 11.5^\circ$  at 3-month follow-up and  $30.2 \pm 9.6^\circ$  at final visit. The intervertebral bridging osteophytes, without any bone graft or bone morphogenetic protein, were noted in 42 patients (60%) at the final visit (Figure 2 and 3). Asymptomatic cement loosening with limited halo sign in somewhere of the cemented construct was noted in 9 patients without further management. No cement dislodgement was observed. Ten patients accidentally were found to have silent proximal adjacent or remote wedge fractures, which just left for observation. There was one vertebral body fracture at the concave site with fracture line cross upper and lower cement blocks. Percutaneous vertebroplasty with 6 mL cement injection was done to subside the symptoms.

### Additional CLIF and Complications

Additional CLIF was performed in 6 patients (8.6%) in immediately cranial or caudal to the previous CLIF due to symptomatic junctional scoliosis with radiculopathy. Thereafter, the VAS and ODI statuses were improved significantly after additional CLIF. As generalized, there were 9 patients suffered minor preoperative complications including transient radiculopathy (3 cases), superficial skin infection (3 case), urinary tract infection (2 case), and superficial thrombophlebitis (1 case). Only one major complication with radiculopathy caused by leaked cement received reoperation within 30 days.

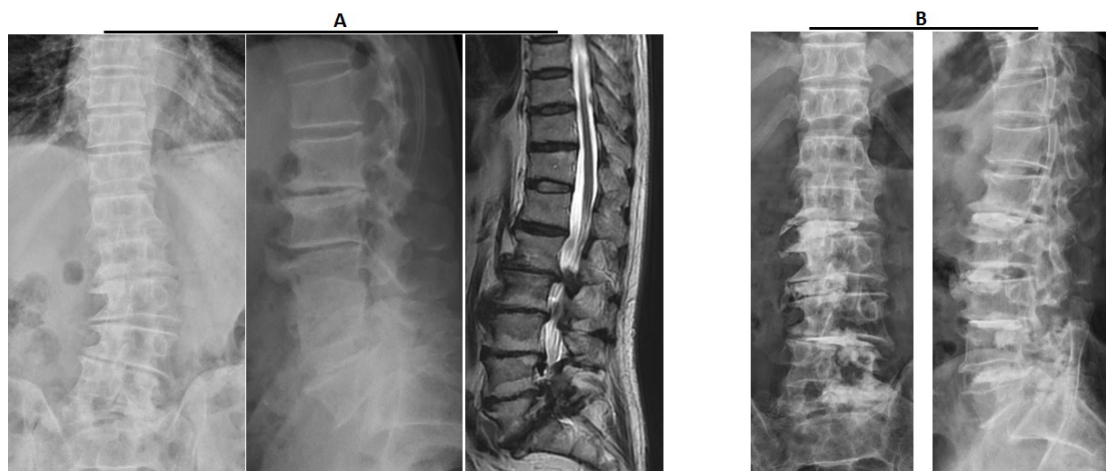
## Discussion

Posterior instrumentation with bone graft, the standard method to treat DLS, is not only time consuming but with high risk of complications [3-5]. PCD is reported to improve low back pain at 2 years of follow-up and 84% of the patients have reached the minimal improvement of VAS and ODI [11]. When treating DLS, PCD can avoid time-consuming and blood-losing procedures including wound opening and closure, bone graft, and posterior instrumentation. However, PCD is less effective to correct lumbar scoliosis and lordosis [11,15-17]. Therefore, in this study, the mini-open far-lateral approach CLIF was developed with an attempt to additionally correct lumbar scoliosis and lordosis along with the same advantages of PCD, featuring small wound, limited blood loss, no bone graft, and no instrumentation. In further, the interbody cementation was effective to prevent osteoporotic compression fracture at the concave side, where mechanical stress is highly increased after scoliosis correction.

Comparing with traditional decompression and arthrodesis for DLS [3, 4,18-21], the complication and reoperation rates of CLIF were relatively low. The complication rates of traditional surgery were closely related to age, blood loss, operative time, and the number of fusion levels [3, 4, 6, 21-26]. For the older patients after receiving posterior decompression and arthrodesis, the complication rate was reported as high as 79.6% in which 21.4% was major complication [20]. Reoperation of traditional fusion surgery within 6-year follow-up was about 26 - 44%, which

increased with more fusion levels [18,27,28]. Even with minimally invasive technology, severe misplacement rate of pedicle screw studied by Schwender was up to 4.1% [29], which may induce instability and neurological, vascular, and visceral injuries. Thus, CLIF could provide an alternative option, especially for the selected cases with higher risk of complications.

After correction of spinal deformity, the long-term post-operative stability is the major concerned. As addressed in our long-term series, there was no patient needing revision caused by symptomatic cement loosening. Based on our observations, there are two possible mechanisms. First, interbody cementation can maintain the stability long enough until the spontaneous bridging spur has developed. Second, if cement height was over one half of the vertebral body, the cement loosening was unlikely to become a sensible problem. The loosening micromotion might mimic and not exceed the natural disc micro-motion and not alter the mechanical motion axis. Therefore, there was no observed subject symptoms due to undetectable loosening micromotion. In comparison, the cost of bone cement (Surgical Simplex P, Howmedica Osteonics Corp. NJ, USA) per package is much cheaper than that of MIS-TLIF screw systems. After accumulation of 10-year experiences, the manual reduction can recover much better lumbar lordosis; therefore, interbody cementation without PEEK cages becomes popular (Figure 4). This merits to decrease operation time, avoid potential complications, and be affordable for the patients.



**Figure 4:** A: One 77-year male farmer with back and leg pain due to DLS with Cobb's angle (L2/L5) 23.1° and lumbar lordosis (L1/L5) 35.7°; B: He received IBD without PEEK cages and discharged 24 hours after operation. One-week postoperatively, the radiographies showed Cobb's angle (L2/L5) 1.0° and lumbar lordosis (L1/L5) 41.3°. C: One-month postoperatively, the radiographies showed Cobb's angle (L2/L5) 1.0° and lumbar lordosis (L1/L5) 41.8°.

However, some limitations should be considered when interpreting our data. First, the retrospective design might lead to selection bias and the small sample size might reduce the stringency of our result. Second, this was a single - institute study with small sample size. Third, the minimum follow - up time was 5 years, which may be not long enough. Further multi-center, prospective, long - term studies involving a large sample size are required to confirm our findings.

## Conclusion

In this study, it is of merit to demonstrate that the mini-open far-lateral CLIF for DLS was leading to significant VAS and ODI improvements and adequate maintaining correction of scoliosis and lordosis with a minimum 5-year follow-up. The operation time, blood loss, hospitalization, complication rate, and reoperation rate were much less than traditional surgery. CLIF could be regarded a potential alternative option for the DLS patients with fragile comorbidities.

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