Unilateral pedicle screw fixation through a tubular retractor via the Wiltse approach compared with conventional bilateral pedicle screw fixation for single-segment degenerative lumbar instability: a prospective randomized study

Clinical article

Jianwen Dong, M.D., Limin Rong, M.D., Feng Feng, M.S., Bin Liu, M.D., Yichun Xu, M.D., Qiyou Wang, M.D., Ruiqiang Chen, M.D., and Peigen Xie, M.D.

Department of Spine Surgery, Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China

Object. Treatment of patients with single-segment degenerative lumbar instability using unilateral pedicle screw fixation can achieve stability and fusion rates similar to those of bilateral pedicle screw fixation. The aim of this study was to analyze the clinical outcome of using unilateral pedicle screw fixation through a tubular retractor via the Wiltse approach to treat single-segment degenerative lumbar instability.

Methods. Thirty-nine consecutive patients with single-segment, low-grade, degenerative lumbar instability were randomly assigned to treatment with either unilateral (n = 20) or bilateral (n = 19) pedicle screw fixation. In the unilateral group, patients underwent unilateral posterior lumbar interbody fusion (PLIF) and ipsilateral pedicle screw fixation through a tubular retractor via the Wiltse approach. In the bilateral group, patients underwent modified bilateral PLIF with bilateral pedicle screw fixation via the posterior midline approach. During follow-up, patients were evaluated using a visual analog scale (VAS), the Japanese Orthopaedic Association (JOA) score, and the Oswestry Disability Index.

Results. The unilateral group had a shorter operative duration (p < 0.05) and less blood loss (p < 0.001). All patients completed more than 2 years of follow-up (mean 36 months). In general, the time trends in improvement on the VAS and JOA differed slightly between the groups through 2 years, but no significant difference in back pain VAS score or leg pain VAS score was found between these 2 groups at the 2-year follow-up. Complete bone fusion was shown on CT in all patients at the 2-year follow-up.

Conclusions. Unilateral pedicle screw fixation through a tubular retractor via the Wiltse approach appears to be as safe and effective as bilateral pedicle screw fixation for the treatment of single-segment degenerative lumbar instability.

KeY woRDS • degenerative lumbar instability • minimally invasive surgery • posterior lumbar interbody fusion • unilateral pedicle screw fixation

Unilateral pedicle screw fixation has been found to achieve stability and fusion rates similar to those of bilateral pedicle screw fixation in the treatment of patients with single-segment degenerative lumbar instability.1,3,7,12,18 as well as in the treatment of patients with double-segment degenerative lumbar instability.1,8 However, these studies used conventional lumbar fusion surgery that has drawbacks, such as the need for extensive soft tissue dissection with resulting iatrogenic tissue injury, which can lead to increased pain postoperatively, longer recovery duration, and impairment of spinal function.4 While making a traditional lumbar midline incision, the dorsal and medial rami of the lumbar spinal nerves may be easily damaged during the stripping of the paraspinous muscles, leading to denervation of the mul-

Abbreviations used in this paper: GEE = generalized estimating equation; JOA = Japanese Orthopaedic Association; ODI = Oswestry Disability Index; PLIF = posterior lumbar interbody fusion; TLIF = transforaminal lumbar interbody fusion; VAS = visual analog scale.
The multifidus muscle that plays an important role in maintaining the dynamic stability of the spine. In addition, the prolonged traction during the operation can also result in edema and ischemic necrosis of the muscle. These constitute the important factors that contribute to postoperative intractable low-back pain.\(^{6,7}\)

In 1968, Wiltse et al. pioneered lumbosacral fusion through a paramedian incision, which allowed surgical access via the space between the multifidus and longissimus muscles.\(^{21}\) Such an approach can help surgeons significantly reduce injury to the multifidus muscle, provide easy access to and exposure of articular processes, and facilitate decompression of nerve roots and placement of pedicle screws. However, its clinical application is far less common than that of the midline incision, because it usually takes 2 incisions to meet the demands for bilateral decompression and fixation, and the anatomy of the space is unfamiliar to the majority of spine surgeons. The Wiltse approach has again become a focus of attention with the development of unilateral fixation techniques and lumbar decompression and fusion with the help of tubular retractors in recent years. Performing unilateral fixation through a tubular retractor via the Wiltse approach could significantly decrease injury to paraspinal muscles that could result from conventional posterior lumbar surgery.\(^{4,19,21}\) Minimally invasive transfemoral lumbar interbody fusion (TLIF) with unilateral pedicle screw fixation appears to be a promising surgical procedure; in 1 study it was reported to produce good results in 17 (85%) of 20 patients during follow-up ranging from 6 to 12 months.\(^{2}\)

Although minimally invasive techniques for treating patients with lumbar instability have been increasingly advocated, prospective studies directly comparing minimally invasive techniques with conventional techniques are lacking. Therefore, the aim of this study was to directly compare the clinical outcomes of unilateral fixation through a tubular retractor via the Wiltse approach with those of bilateral fixation via the posterior midline approach for treatment of patients with single-segment degenerative lumbar instability who presented with unilateral radicular symptoms in a lower extremity.

**Methods**

**Patient Population**

A total of 39 consecutive patients with single-segment degenerative lumbar instability were enrolled in this prospective study from November 2008 to June 2010. The patients were randomly divided into 2 groups through lot drawing by full-time postgraduates who did not participate in the operations. The patients were divided into 2 groups in accordance with the sequence interval of the patients. There were 20 patients randomized to the unilateral fixation group and 19 to the bilateral group (Fig. 1). All patients experienced a course of disease ranging from 6 months to 10 years, with exacerbation of symptoms ranging from 2 months to 1 year. The lesions involved the L4–5 level in 27 patients and the L5–S1 level in 12 patients.

All patients met the following inclusion criteria: back pain concomitant with radicular symptoms involving 1 lower extremity, which persisted through nonsurgical treatment for more than 3 months with poor outcome or multiple recurrence; intermittent claudication; radiological changes featuring lumbar degeneration (mainly intervertebral disc degeneration); and low-grade degenerative spondylolisthesis (less than Grade 2) and/or segmental instability, defined as changes in the intervertebral angle of more than 10\(^{\circ}\) or intervertebral translation of more than 3 mm as shown by dynamic radiographs. Patients were excluded if they had radicular symptoms involving bilateral lower extremities; degenerative spondylolisthesis more than Grade 2; or isthmic spondylolisthesis, severe osteoporosis, or obesity. The study was approved by the institutional review board of our hospital. All patients signed informed consent forms for this trial.

**Surgical Strategies**

In the unilateral group, patients underwent unilateral posterior lumbar interbody fusion (PLIF) and ipsilateral pedicle screw fixation through a tubular retractor via the Wiltse approach. To clarify the operative procedures, we will use the diseased segment of L4–5 as an example.

The patient was placed prone under general anesthesia. A 2.8–3.0-cm-long incision was made under guidance of fluoroscopy approximately 3.5–4.5 cm off the midline by connecting the reference points of the L–4 and L–5 pedicle centers on the side of the radicular symptoms. Then the skin, subcutaneous tissue, and lumbosacral fascia were cut open for blunt dissection of the multifidus and longissimus space. The ipsilateral target lamina and the articular processes were revealed via the Wiltse approach. Next, a guidewire was docked on the junction of the L–4 lamina and inferior articular process, and dilators were sequentially placed to release and dilate the muscle space to stretch and protect the multifidus muscle and carefully strip the residual soft tissue attached to the bone surface. Selected retractor blades of appropriate depth, attached to the light source, and flexible arm attachment and open blades of a MAST Quadrant Retractor (Medtronic Sofamor Danek) or Pipeline (DePuy Spine) system were used as needed to establish the working access and achieve clear visualization of the ipsilateral L–4 and L–5 articular processes and interlaminar space. With conventional insertion of pedicle screws that were kept at proper trajectories, the working access could be adjusted and the flexible arm could be temporarily released, if necessary, to accommodate the placement of the pedicle screws during the surgery. Conventional unilateral PLIF was then performed.

During the process, decompression should cover the range of the ipsilateral lamina and more than the medial half of the upper and lower articular processes; if needed, complete removal of the inferior articular process may be performed to allow enough space for cage placement. Autograft spongy bone particles were implanted into the anterior and central part of the intervertebral space and into the central cavity of the cage, which was then inserted into the intervertebral space in an oblique course. The prepared rod was inserted; moderate decompression was performed at the intervertebral space and then it was verified that thor-
Unilateral fixation for lumbar instability

ough decompression was achieved after the completion of fixation. In the bilateral group, patients underwent modified bilateral PLIF with bilateral pedicle screw fixation via the posterior midline approach, in which spinous processes and interspinous ligaments were retained.

Postoperative Treatment, Follow-Up, and Clinical Effects Analysis

The postoperative procedures were implemented in the following order: removal of the drainage tube 1 day after surgery, intravenous methylprednisolone 160 mg/day for 3 to 5 days to reduce postoperative neurological reactive edema, ambulation with bracing 1 week after surgery, and bracing for 3 months with prohibition of excessive or overstretched waist movement for half a year. Patients were followed-up immediately after surgery, and at 3 months, 6 months, 1 year, and 2 years. Sagittal and coronal images were obtained to assess the condition of the intervertebral fusion using Toshiba 320-row dynamic volume CT (1–2-mm thin-layer scanning). Fusion was determined in accordance with the Shah method. In this method fusion is determined by the formation of continuous trabecular bone observed in and around the fusion cage, or lumbar dynamic images showing less than 5° of intervertebral movement at the fused segment.

Statistical Analysis

Continuous data with normal data distributions were expressed as mean ± SD, while those with nonnormal data distributions were presented as median (interquartile range). The independent t-test and Mann-Whitney U-test were used to test the differences in continuous variables between the 2 groups. Categorical variables were presented as number (%) and tested using the chi-square test. The generalized estimating equation (GEE) was performed to test the time trend of the visual analog scale (VAS), Japanese Orthopaedic Association (JOA) scale, and Oswestry Disability Index (ODI), and the differences in these measurements between the 2 groups. An interaction term was also included in the equation for examining the interaction between time and groups. Once a significant result related to the interaction term was revealed, the time effect was tested separately by diverse groups. All statistics were 2-sided. The analysis was performed using SPSS software (version 15.0, SPSS Inc.). A probability value < 0.05 was considered statistically significant.

Results

The characteristics of the 39 patients are summarized in Table 1. The 2 groups of patients were similar in age, sex distribution, disease segment, and duration of hospitalization. Two patients in the unilateral group and 3 patients in the bilateral group had Grade 1 degenerative spondylolisthesis (p > 0.05). The mean age of all patients was 55.3 ± 13.3 years and the mean hospital stay was 17.2 ± 5.0 days. The majority of patients were female (69.2%). Most patients experienced pain at L4–5 (69.2%). The unilateral group had a significantly shorter operative duration (p = 0.038) and less blood loss (p < 0.001) compared with the bilateral group. As of December 2012, all patients in the 2 groups were followed up between 28 and 43 months (mean 36 months).
Outcome Assessments

The back pain and leg pain VAS scores are shown in Fig. 2. The preoperative back pain VAS scores in both groups were similar (p = 0.315) and decreased over time (p < 0.001). The trends of the 2 groups were slightly different. In the unilateral group, the back pain VAS score decreased from 8.5 at the beginning to 2.38 at 1 week, 1.23 at 3 months, 0.55 at 1 year, and 0.25 at 2 years after the operation; the back pain VAS score significantly decreased through the whole study period. However, the decrease of the back pain VAS score in the bilateral group was only significant during the 1st year after surgery (from 8.29 before surgery to 0.61 at 1 year after surgery); after that, the VAS score slightly and nonsignificantly declined to 0.45 at the end of the study (Fig. 2 upper). The preoperative leg pain VAS scores in both groups were similar (p = 0.0633) and significantly declined over time (p < 0.001). The preoperative leg pain VAS score in both groups was 7.14 initially and then significantly declined to 0.53 at 3 months, 0.10 at 12 months, and 0.06 at 2 years (Fig. 2 lower).

The JOA scores for both groups increased over time (p < 0.001). The time trend slightly differed in the 2 groups. In the unilateral group, the JOA score soared 1 week after the operation (from 15.85 at the beginning to 25.20), while a second increase was observed after a 3-month plateau (from 25.90 at 3 months to 28.05 at 2 years). The increase in the JOA score in the bilateral group was observed during the 1st year after surgery, from 15.95 initially to 24.11 at 1 week, 25.89 at 3 months and then to 27.26 at 1 year, and was maintained thereafter (Fig. 3 upper). The ODI scores for the 2 groups were similar. Nevertheless, a contrary trend was demonstrated: the ODI score in both groups combined decreased rapidly from 31.96 before surgery to 6.23 at 3 months, 3.29 at 1 year, and 2.52 at 2 years after surgery (Fig. 3 lower).

Complications

There were no nerve root injuries. No translation or slippage of the cage, or loosened or ruptured pedicle screws, was recorded on the dynamic radiographs and CT scans during follow-up. The images taken at 1 year postoperatively showed that in the unilateral group there were 17 patients with complete bone fusion and 3 patients with partial bone fusion, while in the bilateral group, there were 17 patients with complete bone fusion and 2 with partial bone fusion. The complete bone fusion rates at 1 year postoperatively were 85% in the unilateral group and 89.5% in the bilateral group. However, no instability was recorded by dynamic radiography with regard to the operated segments during the entire follow-up period, and no translation or slippage of the cage, or loosened or ruptured pedicle screws, was recorded on the dynamic radiographs and CT scans during follow-up.

**TABLE 1: Clinical features and biochemical indices of the 39 patients in the study**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unilateral Fixation (n = 20)</th>
<th>Bilateral Fixation (n = 19)</th>
<th>p Value (test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>mean age ± SD (yrs)</td>
<td>54.0 ± 12.3</td>
<td>56.6 ± 14.7</td>
<td>0.555 (t-test)</td>
</tr>
<tr>
<td>no. of females (%)</td>
<td>14 (70.0)</td>
<td>13 (68.4)</td>
<td>0.999 (chi-square)</td>
</tr>
<tr>
<td>disease segment (%)</td>
<td></td>
<td></td>
<td>0.557 (chi-square)</td>
</tr>
<tr>
<td>L4–5</td>
<td>13 (65.0)</td>
<td>14 (73.7)</td>
<td></td>
</tr>
<tr>
<td>L5–S1</td>
<td>7 (35.0)</td>
<td>5 (26.3)</td>
<td></td>
</tr>
<tr>
<td>mean operative duration ± SD (min)</td>
<td>146.8 ± 14.0</td>
<td>156.3 ± 13.8</td>
<td>0.038 (t-test)*</td>
</tr>
<tr>
<td>median blood loss in ml (IQR)</td>
<td>215.0 (172.5–250.0)</td>
<td>400.0 (350.0–450.0)</td>
<td>&lt;0.001 (Mann-Whitney U-test)*</td>
</tr>
<tr>
<td>mean hospital stay ± SD (days)</td>
<td>15.9 ± 4.3</td>
<td>16.8 ± 5.5</td>
<td>0.089 (t-test)</td>
</tr>
</tbody>
</table>

* Significant difference between groups (p < 0.05). IQR = interquartile range.
Unilateral fixation for lumbar instability

In this study, we performed unilateral PLIF and unilateral pedicle screw fixation for the treatment of degenerative lumbar instability via the Wiltse approach using a tubular retractor in an attempt to minimize surgical trauma. During the process, blood loss was significantly decreased in the unilateral group compared with the bilateral group, and the results obtained from follow-up evaluations showed that clinical outcomes were similar for both groups. Also, the rate of complete bone fusion was similar to that of the bilateral group at 1-year follow-up, and both groups had a 100% fusion rate at 2-year follow-up, which is consistent with reports in the literature.2–4,7,18,19,21 Importantly, there was a significant difference in back pain VAS scores between the unilateral and bilateral groups at 1 week after surgery (p = 0.019), but there was no significant difference between the groups in leg pain VAS score at 1 week after surgery (p > 0.05). This finding indicated that the unilateral group had less surgical trauma resulting in a lower pain score in the lumbar area at the early postoperative stage; that is, patients felt less pain and therefore required less medication for pain following the operation. However, both groups had similar pressure relief, as indicated by no significant difference in leg pain VAS score. This difference between the groups reflects the early surgical efficacy of the unilateral approach that permits more rapid recovery with regard to low-back pain. There was also a significant improvement in back pain VAS scores in the unilateral group at 2 years after surgery, possibly indicating a manifestation of minimal invasion with the unilateral approach. Longer follow-up is needed to provide more evidence regarding this observation.

Deutsch and Musacchio2 conducted a prospective study of 20 patients who underwent minimally invasive TLIF with unilateral pedicle screw fixation and were followed up from 6 to 12 months. The patients were evaluated postoperatively with the ODI, and a 20-point reduction was defined as a good result. As noted above, a good result was achieved in 85% of the patients. Computed tomography showed that 13 patients had some degree of fusion at the 6-month follow-up. Although the patients were not followed up for longer than 1 year, the results suggested that the minimally invasive procedure was effective.

It is not uncommon clinically to have patients suffering from degenerative lumbar instability concomitant with unilateral radicular symptoms of a lower extremity undergo treatment using ipsilateral nerve root decompression and interbody fusion, which results in a favorable clinical outcome.11,15 It has also been found in biomechanical and clinical studies that unilateral fixation can help restore enough stability in single-segment degenerative instability and instability after decompression to meet the needs of patients for interbody fusion of the diseased segment. This can avoid contralateral surgical procedures and reduce intraspinal procedures, muscle stripping, operative time, intraoperative blood loss, and medical expenses, and quicker recovery can be expected for patients after unilateral surgery in comparison with conventional bilateral fixation. Similar postoperative interbody fusion rates and a similar incidence of complications as compared with bilateral fixation can be expected, and reduced stiffness at the level that has been internally fixed is theoretically able to help reduce the incidence of adjacent-segment degeneration.1–3,7,12,16,18,20 Although no uniform criteria have been established, it has been generally accepted that interbody fusion for the treatment of degenerative lumbar instability can be performed. However, there has been a debate about whether there is a need to perform bilateral fixation, an internal fixation of high stiffness, if simple lumbar instability is shown only by dynamic radiography or if there is just mild instability in patients with spondylolisthesis of less than Grade 2. This is why unilateral fixation is performed in unilateral...
PLIF or TLIF intended for patients with mild degenerative instability who present with unilateral radicular symptoms. Suk et al. and Fernández-Fairen et al. went even further, applying such a technique to fix Grade 2 degenerative spondylolisthesis, isthmic spondylolisthesis, and double-segment lumbar instability, but the incidence of failed internal fixation was found to have increased. Therefore, the indications should be strictly followed; the patients selected should be limited to only those suffering from unilateral radicular symptoms before surgery, and careful radiographic evaluation should be conducted to exclude the presence of contralateral nerve root canal stenosis. Due to the limitations and difficulties in operating the tubular retractor, its application is not advocated in severely obese patients or those with high-seated iliac crests. Because a patient with mild degenerative instability at a single segment, as occurs in spondylolisthesis less than Grade 2, can have the displaced segment restored to different extents simply by placing the patients prone (which may not be done), unilateral fixation can be expected to prepare the patient well for interbody fusion.

Studies have shown that single-segment unilateral PLIF and unilateral fixation can be performed perfectly via the Wiltse approach with a tubular retractor, which can help to accurately reveal the reference points for implantation of pedicle screws and help to insert the screws at proper angles. During the operation, repeated adjustments to the retractor are rarely needed; thus the operative duration can be shortened and muscle injury and blood loss can be reduced. In our study, operative time was significantly shorter and blood loss was significantly less for the unilateral group compared with the bilateral group. Deutsch and Musacchio reported mean blood loss of 100 ml using minimally invasive surgery, whereas we measured a median of 215 ml; the mean operative duration in their study (4.1 hours) was longer than in our study (146.8 minutes, or 2.4 hours). The light source attached to the retractor blades can provide clear visualization for the precise and focused decompression of the nerve root canal, and the surgery should be focused on procedures that involve the nerve roots, such as decompression. The utilization of a nerve root retractor along with the other instruments to protect the nerve root is the key to avoiding injury to the nerve roots. As a result, no nerve root injury occurred in the unilateral group of this study. Deutsch and Musacchio reported no permanent neurological injuries in their study. Either the Quadrant system or Pipeline system can meet the needs of a double-segment operation. Previous clinical practice and a recent biomechanical study have shown that unilateral fixation can be used in patients with double-segment degenerative instability for interbody fusion. However, we did not include patients with double-segment lumbar instability in our study.

Because unilateral fixation is an asymmetrical operation, a disadvantage is that contralateral radicular symptoms or secondary scoliosis may ensue after surgery; therefore an appropriate model cage should be selected. A best effort should be made to place the cage at the very center of the intervertebral space and avoid contralateral nerve root compression that may be caused by its backward placement, and autograft bone particles should be implanted mostly in the front of the intervertebral space to prevent bone particles from being squeezed backward to the contralateral side by the cage, which may compress the contralateral nerve roots. Moderate compression should be applied when performing unilateral fixation to avoid secondary scoliosis or contralateral stenosis of the nerve root canal that can be caused by excessive compression. Due to the limitation of surgical visualization under a tubular retractor, fluoroscopy or myelography, if necessary, should be used to verify the position of implants, the appropriateness of compression, and whether or not contralateral stenosis of the nerve root canal has occurred. In this study, none of the patients had contralateral radicular symptoms after surgery, but 3 had recorded occurrence of scoliosis during a follow-up evaluation. However, the scoliosis was not exacerbated during subsequent follow-up and no relevant clinical symptoms were presented by the patients. The occurrence of scoliosis may be associated with multiple factors such as asymmetry of unilateral fixation and the progression of spinal degeneration.

Our study was limited by sample size, with the unilateral group consisting of only 20 patients. Another limitation was that all patients were treated at a single center. Therefore, larger multicenter studies with long-term follow-up are needed to evaluate the unilateral fixation procedure using the Wiltse approach. Also, we did not compare unilateral PLIF–aided unilateral fixation with unilateral PLIF–aided bilateral fixation (unilateral fusion for pressure relief) so that the only variable would have been fixation. We could not perform this comparison because of a limitation in case numbers of unilateral PLIF–aided bilateral fixation.

Conclusions

Our results show that unilateral fixation via the Wiltse approach through a tubular retractor is a safe, effective, and minimally invasive surgical option for the treatment of single-segment, mild, degenerative lumbar instability in patients who present with unilateral radicular symptoms, so long as strict indications and standardized operative procedures are followed.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: Rong, Dong. Acquisition of data: all authors. Analysis and interpretation of data: Dong. Drafting the article: Dong. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: Rong. Statistical analysis: Feng. Administrative/technical/material support: Feng. Study supervision: Rong, Dong.

References

Unilateral fixation for lumbar instability


Manuscript submitted January 28, 2013. Accepted September 26, 2013. Please include this information when citing this paper: published online November 15, 2013; DOI: 10.3171/2013.9.SPINE1392. Address correspondence to: Limin Rong, M.D., Department of Spine Surgery, Third Affiliated Hospital of Sun Yat-sen University, No. 600 Tianhe Rd., Tianhe District, Guangzhou 510630, China. email: ronglimin@21cn.com.