A prospective, randomized clinical study was performed to determine whether unilateral pedicle screw fixation was comparable with bilateral fixation in 1- or 2-segment lumbar interbody fusion. One hundred eight patients with lumbar degenerative diseases were randomly assigned to the unilateral (n=56) or bilateral (n=52) pedicle screw fixation group. Interbody fusion was performed in 1 or 2 levels with 1 cage. Operative time, blood loss, duration of hospital stay, functional outcome, fusion rate, and complication rate were recorded and compared statistically. The patients were followed for 3 years postoperatively.

Successful radiographic fusion was documented in all patients. No flexion–extension hypermobility or pedicle screw loosening or breakage occurred during the follow-up period. No significant difference existed between the 2 groups when comparing the union rate, complication rate, and functional outcome scores (P>0.05). However, compared with the bilateral pedicle screw group, a significant decrease occurred in operative time, duration of hospital stay, and blood loss in the unilateral group (P<0.01). Unilateral pedicle screw fixation was as effective as bilateral fixation when performed in addition to 1- or 2-level lumbar interbody fusion. The authors recommend the use of unilateral fixation in lumbar interbody fusion with 1 cage for lumbar degenerative diseases without major instability.
Posterior lumbar interbody fusion, as a biomechanically optimal fusion, was introduced by Dr Ralph Cloward more than 50 years ago.\(^1\)\(^2\) Posterior lumbar interbody fusion has the advantages of restoring disk height, immobilizing the unstable degenerated intervertebral disk area, decompressing the dura sac and nerve roots, and restoring load bearing to anterior structures.\(^3\)\(^4\) The additional instrumentation provides initial stability until the anterior construct fuses. Posterior lumbar interbody fusion also has the advantages of no external immobilization, early ambulation, restoration of sagittal alignment and segment height, and improved fusion rates.\(^5\)\(^6\)\(^7\)\(^8\) Segmental rigidity increases after instrumentation. The mobility decreases and the fusion rate increases.\(^9\) The increased stiffness of the fused motion segments not only will reduce the bone mineral content in the vertebrae adjacent to fusion,\(^10\)\(^11\) but also has a positive effect on the degeneration of the adjacent segments.\(^11\)\(^12\)\(^13\) Furthermore, the morbidity, complication, and reoperation rates increase with instrumented lumbar arthrodesis.\(^14\) Therefore, the use of unilateral pedicle screw fixation had been postulated to decrease the stiffness of the instrumented segment.

In 1992, Kabins et al\(^15\) reported that clinical results with unilateral variable screw placement instrumentation were nearly identical to those of bilateral instrumentation in single-level (L4-L5) posterolateral fusion. Since then, prospective, randomized studies were performed on posterolateral fusion. In a prospective, randomized study, Suk et al\(^16\) reported that unilateral pedicle screw fixation was as effective as bilateral pedicle screw fixation in lumbar spinal posterolateral fusion independent of the number of fusion segments (1 or 2) or pedicle screw systems. Fernández-Fairen et al\(^17\) reported in a prospective, randomized study that unilateral instrumentation for the treatment of degenerative lumbar spondylolisthesis was as effective as bilateral instrumentation when performed in addition to 1- or 2-level posterolateral fusion. Although several reports exist on unilateral instrumentation in interbody fusion,\(^18\)\(^19\)\(^20\) no studies were performed in a prospective, randomized fashion. Hence, the current authors conducted a prospective, randomized study to evaluate the relative effectiveness of unilateral and bilateral pedicle screw fixation in lumbar interbody fusion.

**MATERIALS AND METHODS**

Between January 2006 and January 2008, one hundred eight patients were prospectively treated with decompression with 1- or 2-level interbody fusion. Of the 108 patients, 56 were randomly assigned to the unilateral pedicle screw fixation group and 52 were assigned to the bilateral pedicle screw fixation group. This study was approved by the Committee of Medical Ethics and the institutional review boards of the authors’ institutions.

Inclusion criteria were:
1. Recurrent lumbar disk herniation, symptomatic lumbar stenosis with segmental instability, or symptomatic degenerative disk disease.
2. Age between 30 and 70 years.
3. Persistent or recurrent low back pain or leg pain lasting at least 6 months and resulting in a significant reduction of quality of life, despite conservative therapy, including physical therapy and pain management.
5. One- or 2-level intended interbody fusion between L3 and S1.

Exclusion criteria were:
1. Active infection, metabolic disease, severe osteoporosis, symptomatic vascular disease, gross obesity, and smoking.
2. Previous spinal surgery other than lumbar discectomy in L3-L4, L4-L5, or L5-S1.
3. Any major psychological problem.
4. Combination of degenerative spondylosis and degenerative or ischemic spondylolisthesis.
5. Workers’ compensation claims.

**Recruitment and Randomization Process**

A priori power analysis was conducted prior to the study. The risk of a type 1 error was set at 5%, and the risk of a type 2 error was set at 20%. The minimum size of each group was estimated given the SD and difference of the Short Form 36 (SF-36) and Japanese Orthopedic Association (JOA) scores. Potential patients were identified and screened by the principal investigators (H.M., J.Z.). The treating surgeon (J.Z.) explained in detail the randomization process, potential surgical procedures, and required follow-up to all potential candidates. Once a patient agreed to participate, informed consent was obtained. The patient was given a registration number and was allocated randomly to one of the surgical treatment groups by computer.

The unilateral fixation group comprised 24 men and 32 women. Mean patient age was 56.2 years (range, 34-66 years). Preoperative diagnoses were recurrent lumbar disk herniation (n=6), lumbar stenosis with segmental instability (n=40), and symptomatic degenerative disk disease (n=10). One-level fusion was performed in 42 patients and 2-level fusion in 14 patients.

The bilateral fixation group comprised 24 men and 28 women. Mean patient age was 55.0 years (range, 34-68 years). Preoperative diagnoses were recurrent lumbar disk herniation (n=4), lumbar stenosis with segmental instability (n=36), and symptomatic degenerative disk disease (n=12). One-level fusion was performed in 36 patients and 2-level fusion in 16 patients. No statistically significant difference existed between the 2 groups regarding age, sex, preoperative diagnosis, or number of fusion segments (Table 1).

**SURGICAL TECHNIQUE**

The patient was placed in the prone position. General anesthesia was used.

**Unilateral Fixation Group**

The unilateral paravertebral muscles on the symptomatic side were split and...
retracted laterally to the outer edge of the facet joint, and the lamina and facet joint were exposed. Unilateral laminectomy and facetectomy were performed on the symptomatic side. Then, the entire nerve root and same-side intervertebral space were exposed. Adequate decompression could be accomplished simultaneously. Posterior segmental instrumentation was performed with the CD Horizon system (Medtronic Sofamor Danek, Memphis, Tennessee). Multiaxial screws were used unilaterally. Surgicel (Ethicon, Inc, Somerville, New Jersey) was used as a tamponade above and below the disk space, and the dura and nerve roots were displaced medially and laterally, respectively.

The diskectomy and endplate preparation were performed. The disk space was sequentially distracted until the original disk space height was obtained and normal foraminal opening was restored. One Telamon polyether ether ketone (PEEK) cage (Medtronic Sofamor Danek) was inserted obliquely, which filled with the morselized bone from the facetectomy and laminectomy.

### Bilateral Fixation Group

The bilateral paravertebral muscles were split and retracted laterally to the outer edge of the facet joint. The decompression procedure and the implantation of 1 Telamon PEEK cage were performed in the same manner as in the unilateral fixation group. However, bilateral posterior segmental instrumentation was performed with the CD Horizon system. Multiaxial screws were used bilaterally.

### Postoperative Follow-up

Operative time, blood loss, duration of hospital stay, functional outcome, fusion rate, and complication rate were recorded and assessed by an independent observer (Y.X.). The patients were asked to return for follow-up at 3, 6, and 12 months postoperatively and annually thereafter. Japanese Orthopedic Association scores and SF-36 scores were used to assess the function preoperatively and functional outcome at 12, 24, and 36 months postoperatively.

Fusion status was recorded for each surgically treated segment at each follow-up. Anteroposterior and lateral flexion and extension radiographs were used to evaluate fusion status. Levels were regarded as solidly fused if radiographic evidence existed of bone bridging the disk space without lucency and the motion between the fused segments was less than 4° on flexion and extension views. More than 4° of motion or the presence of translation was considered a failure of fusion. Thin-section, high-resolution helical computed tomography was used to more accurately evaluate the bony trabeculae in the disk space every year postoperatively. All images were independently reviewed by 2 experienced radiologists who were blinded to the clinical outcome and had not taken part in any other stage of the study.

### Statistical Analysis

Demographic data were compared by chi-square test, except for age, which was compared by t test. Operative time, blood loss, and duration of hospital stay were compared by Student’s t test. Functional outcomes between 2- and 3-year follow-up were compared by Student-Newman-Keuls test. Fusion rates and complication rates were compared by chi-square and Fisher’s exact tests. The limit of statistical significance was set at 5%.

### RESULTS

All the patients were treated as originally randomized and were followed for a minimum of 3 years (range, 36-48 months). No patient was lost to follow-up. Mean operative time was 129 minutes (range, 87-157 minutes) in the unilateral fixation group and 168 minutes (range, 141-195 minutes) in the bilateral fixation group, which was statistically significant ($P<.01$). Mean blood loss was 410 mL (range, 250-670 mL) in the unilateral fixation group and 558 mL (range, 440-690 mL) in the bilateral fixation group.

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### Table 1

<table>
<thead>
<tr>
<th>Demographic</th>
<th>Unilateral Fixation Group</th>
<th>Bilateral Fixation Group</th>
<th>$P^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>56</td>
<td>52</td>
<td>NS</td>
</tr>
<tr>
<td>Age range, y</td>
<td>34-66</td>
<td>34-68</td>
<td>NS</td>
</tr>
<tr>
<td>No. of women/men</td>
<td>32/24</td>
<td>28/24</td>
<td>NS</td>
</tr>
<tr>
<td>BMI range, kg/m²</td>
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<td>19-31</td>
<td>NS</td>
</tr>
<tr>
<td>Symptom duration range</td>
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<td>7.5 mo to 24 y</td>
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</tr>
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<td></td>
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<tr>
<td>Recurrent LDH</td>
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<td>4</td>
<td>NS</td>
</tr>
<tr>
<td>Lumbar stenosis</td>
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<td>36</td>
<td>NS</td>
</tr>
<tr>
<td>Symptomatic DDD</td>
<td>10</td>
<td>12</td>
<td>NS</td>
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<td>Operated level, No.</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>L3-L4/L4-L5/L5-S1</td>
<td>10/20/12</td>
<td>10/18/12</td>
<td>NS</td>
</tr>
<tr>
<td>L3-L5/L4-S1</td>
<td>6/8</td>
<td>5/7</td>
<td>NS</td>
</tr>
</tbody>
</table>

*Abbreviations: BMI, body mass index; DDD, degenerative disk disease; LDH, lumbar disk herniation; NS: not significant.

*Data were compared by chi-square test, except for age, which was compared by t test.
Mean preoperative JOA score was 14.5 ± 3.2 in the unilateral fixation group and 15.1 ± 2.9 in the bilateral fixation group. At 1 year postoperatively, mean JOA score improved to 25.7 ± 2.2 in the unilateral fixation group and 24.8 ± 2.8 in the bilateral fixation group. At final follow-up, mean JOA score was 26.1 ± 1.9 in the unilateral fixation group and 25.2 ± 3.2 in the bilateral fixation group. A significant difference existed when comparing preoperative and postoperative JOA scores in both groups (P < .01) (Table 2). No significant difference existed when comparing JOA scores between the 2 groups at every postoperative follow-up (P > .05).

Short Form 36 scores improved in both groups at each subscale: physical function, role physical, bodily pain, general health, vitality, social function, role emotional, and mental health (Table 3). A significant difference existed when comparing pre- and postoperative SF-36 scores (P < .01). The improved scores remained stable to final follow-up. No significant difference existed in SF-36 subscale scores between the 2 groups at every postoperative follow-up (P > .05).

Fusion status was judged on the radiographs and computed tomography scans 12 months postoperatively. No pseudoarthrosis occurred in either group. Fusion status was similar in 1- and 2-level fusions in each group. The mature trabeculae bridging the fused segments could be observed in the sagittal reconstructed computed tomography images. Fusion status remained stable to final follow-up (Figure). No flexion–extension hypermobility or pedicle screw loosening or breakage occurred during the follow-up period.

No device-related complications, such as hardware loosening or breakage, cage retropulsion, or neurological injury due to violation of the pedicle cortex by the screws, occurred in either group. Four nondevice-related complications occurred in the unilateral fixation group and 5 occurred in the bilateral fixation group (Table 4). The complication rate was 7.14% in the unilateral fixation group and
Unilateral and Bilateral Pedicle Screw Fixation | Xie et al

and B C 2; how 1 2 To achieve optimal 1.05). No flexion–extension Three prospec In 2 human cadaver Few reported that the less rigid unilat - whereas the fusion rate demonstrated that

The current increases the initial 
The fusion rate in the 

immobilization can lead to device-related osteoporosis of the vertebrae10,26 and makes the adjacent segment prone to degeneration by increasing load and motion.11,12 To achieve optimal biomechanical conditions in the fused segment and fewer adverse effects in the adjacent levels caused by instrumentation, the use of less rigid systems of fixation is advocated.27,28

In an in vitro study, Goel et al29 reported that the less rigid unilateral VSP system (DePuy Spine, Raynham, Massachusetts) was likely to reduce stress shielding of the fixed vertebral bodies and diminish the stress rising in the upper and lower adjacent levels compared with the bilateral VSP system. It has been shown that unilateral fixation can be used in posterolateral fusion.15-17 The current prospective study was performed to show that posterior lumbar interbody fusion with a single diagonal fusion cage and bilateral transpedicular instrumentation enabled sufficient decompression and solid interbody fusion with minimal invasion of the posterior spinal elements.30 Few clinical reports exist on interbody fusion combined with unilateral fixation.18-21,31-33 Only abstracts are available for 3 studies presented at meetings.31-33 Three prospective reports address microinvasive surgery with unilateral pedicle fixation18-20; however, they are all preliminary reports with follow-up less than 2 years and no control groups. In a retrospective study with 3-year follow-up, Zhao et al21 achieved good clinical and radiographic outcomes for lumbar stenosis with posterior lumbar interbody fusion in combination with unilateral pedicle screw fixation.

The fusion rate of posterolateral fusion with unilateral fusion ranges between 90% and 97%,15-17 whereas the fusion rate of interbody fusion ranges between 96% and 100%.18,21,31,32 The fusion rate in the current study agrees with the literature. The stability provided by the instrumentation is one of the factors that will affect the fusion result. An experimental study by Chen et al34 showed that unilateral fixation with a cage was sufficient to maintain the initial stability. They compared the biomechanical properties among various spinal fixations, including bilateral vs unilateral fixation with posterior lumbar interbody fusion and cages, in an in vitro biomechanical study with a porcine L3-L6 degenerative disk disease model and found that unilateral posterior instrumentation combined with 1 cage was stiffer than the intact spine except in compression and was appropriate to stabilize the deficient spine.34 In 2 human cadaver models, Kasai et al35 demonstrated that the unilateral pedicle screw system offered uneven fixation with dispersion of rigidity depending on the direction of bending and rotation. Less rigidity in the unilateral pedicle screw system than in the bilateral system may be beneficial to adjacent segmental degeneration.

In the current study, the complication rate in the unilateral fixation group was not higher than that in the bilateral fixation group. No hardware loosening or breakage occurred during the follow-up period. However, a significant decrease in operative time, duration of hospital stay, and blood loss occurred in the unilateral fixation group. The minimal instrumentation compromises less on the final stiff-

9.62% in the bilateral fixation group. The nondevice-related complications included superficial wound infection, laceration of the dural sac, and transient motor weakness. When comparing complications, no significant difference existed between the groups (P> .05). No flexion–extension hypermobility occurred in the segments adjacent to the fused segments.

**DISCUSSION**

Decompression, deformity correction, and fusion have been widely used to treat spinal degenerative diseases. The addition of pedicle screw instrumentation to the fusion procedure24,25 increases the initial stability and the probability of achieving a successful spinal fusion in the fusion segment. However, the rigidity of spinal instrumentation can lead to device-related osteoporosis of the vertebrae10,26 and

![Figure: Follow-up anteroposterior (A) and lateral (B) radiographs of a 40-year-old man with L4-L5 lumbar stenosis treated with decompression, interbody fusion, and unilateral pedicle screw fixation. No metal failure or pseudarthrosis occurred. Computed tomography scan reconstruction showing the continuous trabeculae bridging the disk space (C).](image)
ness of the spine. The unilateral approach only dissected 1 side of the paravertebral muscles and bone. Lesser soft tissue dissection allows for early recovery and rehabilitation of the patient. It leads to less postoperative pain and blood loss and reduced operative time.18

Several points should be kept in mind to achieve satisfactory clinical outcomes when posterior lumbar interbody fusion is performed with unilateral pedicle fixation and 1 cage. First, the cage should be appropriately positioned. In the current authors’ experience, when 1 cage is used, it should be inserted obliquely into the disk space and the anterior part of the cage should cross the midline of the vertebral body to support the contralateral part of anterior column. The intact bone and soft tissue, including the paravertebral muscles in the contralateral side, helps to provide stability postoperatively. Second, if bilateral radiculopathies exist, bilateral decompression could be performed through the laminectomy window on the unilateral fixation side.21 Third, the cephalic facet joint should be well preserved to reduce the chance of adjacent segmental degeneration. Meticulos surgical dissection without injuring the top-level facet joints, proper instrumentation of pedicle screws with an appropriate entry site and trajectory, and the use of top-loading screw heads are some ways that surgeons can minimize the risk of top-level facet joint violation.36

This study had some limitations. Less-rigid unilateral fixation is supposed to reduce the possibility of adjacent segmental degeneration, and no radiological signs of adjacent segmental degeneration existed in either group in this study. However, 3-year follow-up is not long enough to verify this finding. A longer follow-up is necessary to elaborate the process of degeneration. The sample size in this study was relatively small, although it exceeded the size for detecting a statistical difference in clinical and radiological outcomes. Further multicenter studies with more patients should be performed.

**CONCLUSION**

This prospective, randomized study demonstrated that unilateral pedicle screw fixation is equally as effective as bilateral pedicle screw fixation in 1- or 2-level interbody fusion with 1 cage for lumbar degenerative diseases without major instability. Unilateral fixation appears to be a valid substitute for bilateral fixation for interbody fusion due to its shorter hospital stay, less blood loss, and rapid postoperative recovery.

**REFERENCES**


