Unilateral versus Bilateral Pedicle Screw Fixation for Degenerative Lumbar Diseases: A Meta-Analysis of 10 Randomized Controlled Trials

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Background: The common and effective treatment for degenerative lumbar diseases is lumbar spinal fusion. Controversy still exists on the choice for instrumentation with spinal fusion procedures. Therefore, we conducted this meta-analysis exclusively of RCTs to compare the clinical outcomes of patients receiving bilateral versus unilateral pedicle screw fixation (PSF).

Material/Methods: After systematic review of published and unpublished literature, a meta-analysis was conducted to compare the 2 treatment strategies. The methodological quality of the literature was assessed using the PEDro critical appraisal tool.

Results: Data synthesis showed less blood loss (P<0.001) and shorter operative time (P<0.001) in patients receiving unilateral PSF compared to bilateral PSF. However, there was no significant difference in fusion rates and functional outcomes between the 2 groups.

Conclusions: The meta-analysis indicated no significant difference in fusion rates and functional outcomes between the 2 treatment procedures, but unilateral PS fixation reduced blood loss and operative time.

MeSH Keywords: Meta-Analysis • Spine • Surgery Department, Hospital

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Background

Lumbar spinal fusion is a common and effective surgical procedure for the treatment of degenerative lumbar diseases (DLD), such as spondylolisthesis, lumbar spinal canal stenosis associated with deformities, or discogenic pain identified by provocative discography [1–3]. The goal of lumbar fusion surgery is to regain a solid arthrodesis of spinal segments while restoring disk height, immobilizing the unstable segment, and restoring load bearing to anterior structures [4–7]. Generally, pedicle screw fixation (PSF) can effectively improve bone fusion rate and correct lumbar alignment [8].

Although spinal fusion with pedicle screws is widely performed, there is controversy about the need for instrumentation with spinal fusion procedures. Traditionally, bilateral PSF is considered as a widely accepted method for the treatment of a variety of spinal diseases [9]. This standard procedure provides both biomechanical and clinical advantages [10,11]. However, due to the excessive rigidity of bilateral PSF, this instrumentation is suspected to cause the reduction of bone mineral content and degeneration of adjacent segments [12]. Aiming to decrease the rigidity of internal fixation, the unilateral construct seems to be more attractive because it avoids soft tissue disruption of the contralateral side, may take less time, and can be associated with lower implant costs [13–16]. The effectiveness of unilateral fixation as compared to bilateral fixation in lumbar fusion has been frequently investigated in previous studies [15,17–19]. Biomechanical studies have shown that unilateral fixation provided less rotational stability and stiffness than bilateral pedicle screw fixation [10]. However, previous studies involving clinical outcomes have showed good and similar functional results and fusion rates between the 2 methods after spinal fusion [17,20,21].

An increasing number of studies have compared the clinical effects of the 2 procedures for the management of DLD. However, it is still uncertain whether unilateral screw fixation is more effective than bilateral screw fixation. Hence, the purpose of this meta-analysis was to critically assess the clinical effects of the 2 techniques for the treatment of DLD in randomized controlled trials (RCTs).

Material and Methods

Eligibility criteria

Studies were included in this review only if they were prospective randomized trials comparing the clinical effects of bilateral and unilateral screw fixation for the management of DLD. Quasi-randomized studies (nonrandom treatment allocation) were excluded. Inclusion criteria were: (1) the study compared the clinical and/or radiological outcomes of lumbar fusion with unilateral versus bilateral PSF, (2) a minimum of 12-month follow-up, and (3) 1 or more outcomes of interest postoperatively. Exclusion criteria were: (1) non-English language articles, (2) technique papers, (3) patients with spinal deformities, trauma, or spinal tumors, (4) involved previous lumbar surgery, (5) only described unilateral or bilateral screw fixation, (6) involved patients with another disease, such as severe osteoporosis, active infection, metabolic disease, or symptomatic vascular disease, and (7) letters, case reports, reviews, or repeated studies. If more than 1 study by the same author was included, the absence of overlap of data was carefully assessed by comparing patient demographics or by contacting the author if these data were not provided. If an article provided data on multiple variations of a technique, the data were combined. All studies considered eligible were retrieved, and the final decision on inclusion was based on the full article.

Search technique

We performed a thorough search of Medline, EMBASE, Cochrane Library, and PubMed for English-language articles published from January 1969 to July 2014. The search was conducted with the use of the following search terms: (1) “degenerative lumbar diseases (DLD),” (2) “lumbar spinal fusion,” (3) “pedicle screw,” (4) “unilateral,” and (5) “bilateral.”

The bibliographies of retrieved articles, books, and expert opinion review articles were manually searched and reviewed. The potentially relevant articles were identified and reviewed for inclusion/exclusion criteria. Eligibility requirements were the same for abstracts and full articles. Only studies that met the inclusion criteria were considered for the final analysis. We independently reviewed the titles to identify articles that potentially met the eligibility criteria. These abstracts or articles were then collected and reviewed to determine whether they were appropriate for inclusion.

Data extraction and evaluation of methodological quality

Data was extracted by 2 independent reviewers. The extracted information included: (i) the first author, country, published year, and study type; (ii) the number and characteristics of subjects; (iii) surgical information, including surgical segment and levels, instrumentation, and graft type; and (iv) the clinical outcomes. The 2 reviewers reached agreement on selected articles and extracted information and if they disagreed, a third reviewer was invited to resolve the differences. Any discrepancies were resolved by discussion. The methodological quality of each study was assessed using the Physiotherapy Evidence Database (PEDro) scale [22]. To minimize selection bias, 2 investigators rated each study independently and subsequently assigned a score based on the PEDro scale.
Outcome measurement

The fusion rate, screw complications, and postoperative functional outcomes were used as the primary outcomes in patients managed with lumbar fusion. The secondary outcomes under investigation included operative time, blood loss, and duration of hospital stay. Fusion was assessed by the X-ray films and computed tomography at the end of the follow-up period. The included screw complications were screw loosening, screw malposition, and screw breakage. Functional outcomes were included Japanese Orthopedic Association (JOA) score, visual analog scale (VAS), and Oswestry disability index (ODI).

Statistical analysis

All statistical analyses were performed using Review Manager 5.2. Analysis of the treatment effect was performed when no
Table 2. PEDro critical appraisal score.

| Study                        | A | B | C | D | E | F | G | H | I | J | K | Total score |
|------------------------------|---|---|---|---|---|---|---|---|---|---|---|-------------|
| Fernández-Fairen et al. 2007 | Y | Y | Y | Y | N | N | N | Y | N | Y | Y | 7           |
| Xue et al. 2012 [15]         | N | Y | Y | N | N | N | N | Y | N | Y | 6           |
| Aoki et al. 2012 [16]        | N | Y | Y | N | N | N | N | Y | N | Y | Y | 6           |
| Duncan et al. 2012 [20]      | Y | Y | Y | N | N | N | N | Y | N | Y | 5           |
| Xie et al. 2012 [12]         | Y | Y | Y | N | N | Y | N | Y | 8           |
| Choi et al. 2013 [21]        | Y | Y | N | Y | N | N | N | Y | N | 6           |
| Zhang et al. 2013 [22]       | Y | Y | Y | N | N | N | N | Y | N | 7           |
| Lin et al. 2013 [8]          | N | Y | Y | N | N | N | N | Y | N | 6           |
| Dong et al. 2014 [23]        | Y | Y | Y | N | N | N | N | Y | N | 7           |
| Shen et al. 2014 [24]        | Y | Y | Y | N | N | N | N | Y | Y | 7           |

A – eligibility criteria; B – random allocation; C – concealed allocation; D – baseline comparability; E – blind subject; F – blind clinician; G – blind assessor; H – adequate follow-up; I – intention-to treat analysis; J – between-group analysis; K – point estimates and variability; Y – yes; N – no.

Figure 2. Asymmetry for the contour funnel plot of screw complications.

Through initial electronic database searches, a total of 1242 relevant titles were identified. The flow diagram of the study search process is presented in Figure 1. Finally, 10 RCTs [9,13,15,17,18,24–28] were identified as meeting the eligibility criteria. Table 1 shows the characteristics of the included studies. The mean PEDro score of the 10 trials was 6.5 (SD=0.81), and detailed results are summarized in Table 2. Blinded subjects, blinded clinicians, and intention-to-treat analysis were not used in any of the RCTs. Only 1 study [13] used the blind assessor method. One RCT [24] did not report the point estimates or variability. There was no statistically significant asymmetry for the contour funnel plot of screw complications (Figure 2).
META-ANALYSIS

Table 3. The results of pooled analysis.

| Outcome               | Study                  | Odds ratio effect/mean difference (95%CI) | $P$ value | Heterogeneity | $I^2$ | $P$ value |
|-----------------------|------------------------|------------------------------------------|-----------|---------------|------|-----------|
| Fusion rate           | [8,14–16,21–24]        | 0.62 [0.33, 1.20]                         | 0.16      | 0             | 0.96 |           |
| Screw complications   | [8,12,14–16,20–24]     | 0.88 [0.52, 1.48]                         | 0.62      | 0             | 0.74 |           |
| JOA score             | [12,16,23]             | 0.52 [0.23, 0.81]                         | 0.0004    | 54%           | 0.12 |           |
| VAS score             | [8,15,16,22,24]        | 0.02 [–0.36, 0.40]                        | 0.93      | 63%           | 0.03 |           |
| ODI                   | [8,15,22–24]           | –0.08 [–0.54, 0.39]                       | 0.75      | 0             | 0.44 |           |
| Hospital stay         | [12,14,15,22–24]       | –2.56 [–6.92, 1.80]                       | 0.25      | 99%           | <0.001 |       |
| Operative time        | [12,14–16,21–24]       | –45.93 [–40.95, –41.90]                   | <0.001    | 97%           | <0.001 |       |
| Blood loss            | [12,14,16,21–24]       | –139.46 [–205.27, –73.64]                 | <0.001    | 98%           | <0.001 |       |

Results of pooled analysis

Of the 10 included RCTs, 731 patients in total were enrolled. Three hundred fifty-six patients were treated using unilateral PSF techniques, and 375 patients were treated using bilateral PSF techniques. There were no differences between the groups of patients within each of 10 studies in terms of sample size, sex, mean age, and mean duration of follow-up. Detailed results of the pooled analysis are presented in Table 3.

Primary outcomes

Eight [9,15,17,18,25–28] of the 10 RCTs assessed the postoperative fusion rate of patients (Figure 3A). There was no significant heterogeneity among these trials ($I^2=0\%$, $P=0.96$), and the fixed-effects model was used to pool the results. Meta-analysis showed that the fusion rate of patients with unilateral PSF was not significantly different than that of patients with bilateral PSF (OR=0.62, 95% CI: 0.33 to 1.20, $P=0.16$).

As 1 of the study’s functional outcome, analysis showed a statistically significant difference between the 2 treatment strategies in respect to JOA score [13,18,27] (MD=0.52, 95% CI: 0.23 to 0.81, $P=0.0004$) (Figure 3C). Due to significant heterogeneity ($I^2=54\%$, $P=0.12$), the random-effects model was used to pool the results.

With respect to screw complications rates, VAS score, and ODI, we found no significant difference between the 2 techniques ($P=0.62$, $P=0.93$, and $P=0.75$, respectively) (Figure 3).

Length of hospitalization, operation time, and blood loss

Six studies [13,15,17,26–28] included data on hospital stay (Figure 4). The pooled mean difference in hospital stay between the 2 groups was –2.56. The test of heterogeneity found significant differences across the included studies ($P<0.001$, $I^2=99\%$). The data on hospital stay between the 2 groups had no statistical significance at final follow-up (95% CI: –6.92 to 1.80, $P=0.25$; Figure 4A). With respect to operative time for the 2 procedures (Figure 4B), a statistically significant difference was found between the 2 treatment groups ($P<0.001$, Table 3), with significant heterogeneity. After combining the data from 8 of the 10 included RCTs [9,13,15,17,18,25–28], significantly less blood loss was observed in the unilateral screw fixation group compared to patients who received lumbar fusion surgery with bilateral screw fixation (MD=–139.46, 95% CI: –205.27 to 73.64, $P<0.001$) (Figure 4C), with a high degree of heterogeneity across the studies ($P<0.001$, $I^2=98\%$).

Discussion

In this meta-analysis, we summarized findings in the clinical literature on the outcomes of bilateral and unilateral screw fixation for the management of DLD. In this study, unilateral PSF reduced blood loss and operative time. This study also demonstrated a higher JOA score in patients whose lumbar fusion surgery used unilateral PSF.

Lumbar spinal fusion is recognized as an effective treatment for DLD [29–31]. Since Cloward et al. [32] first introduced the method 50 years ago, lumbar fusion has been widely used to treat spinal disorders. Stable fusion helps to improve the results of surgical treatment. It is generally accepted that essential PSF, to maintain the initial stability of the segment, is the basis of successful interbody fusion. However, there is controversy regarding the choice between unilateral or bilateral PSF in lumbar fusion.
### Meta-analysis

#### Unilateral versus bilateral pedicle screw fixation for degenerative lumbar diseases...

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**Heterogeneity:** Chi² = 3.77, df = 4 (P = 0.44); I² = 0%

| Study or subgroup | Unilateral | Bilateral | Weight |
|-------------------|------------|-----------|--------|
| Zhang 2013        | 15.4       | 34.0      | 0.10   |
| Lin 2013          | 30.8       | 37.5      | 0.10   |
| Dong 2014         | 23.0       | 32.0      | 0.10   |
| Fernández-Fairen 2007 | 34.0       | 35.0      | 0.10   |
| Lin 2013          | 15.4       | 34.0      | 0.10   |
| Shen 2014         | 23.0       | 32.0      | 0.10   |
| Xue 2012          | 15.4       | 34.0      | 0.10   |
| Zhang 2013        | 30.8       | 37.5      | 0.10   |

**Total (95% CI):** 254 (267) 100.0% 0.63 [0.33, 1.20]

Total events: 230

**Test for overall effect:** Z = 0.32 (P = 0.75)

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**Heterogeneity:** Tau² = 0.10; Chi² = 10.92, df = 4 (P = 0.03); I² = 63%

| Study or subgroup | Unilateral | Bilateral | Weight |
|-------------------|------------|-----------|--------|
| Zhang 2013        | 2.1        | 3.4       | 0.10   |
| Xue 2012          | 3.1        | 3.2       | 0.10   |
| Lin 2013          | 15.4       | 34.0      | 0.10   |
| Aoki 2012         | 23.0       | 32.0      | 0.10   |
| Dong 2014         | 23.0       | 32.0      | 0.10   |
| Xie 2012          | 23.0       | 32.0      | 0.10   |
| Shen 2014         | 23.0       | 32.0      | 0.10   |
| Lin 2013          | 30.8       | 37.5      | 0.10   |
| Aoki 2012         | 23.0       | 32.0      | 0.10   |
| Lin 2013          | 15.4       | 34.0      | 0.10   |
| Shen 2014         | 23.0       | 32.0      | 0.10   |
| Xue 2012          | 23.0       | 32.0      | 0.10   |
| Zhang 2013        | 23.0       | 32.0      | 0.10   |

**Total (95% CI):** 356 (375) 100.0% 0.88 [0.52, 1.48]

Total events: 29

**Test for overall effect:** Z = 0.50 (P = 0.62)

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**Heterogeneity:** I² = 0%

| Study or subgroup | Mean difference |
|-------------------|-----------------|
| Aoki 2012         | 0.20 [–0.22, 0.62] |
| Dong 2014         | 0.79 [0.36, 1.22]  |
| Xie 2012          | 0.90 [–1.84, 3.64] |

**Total (95% CI):** 101 (96) 100.0% 0.52 [0.23, 0.81]

**Test for overall effect:** Z = 3.53 (P = 0.0004)

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**Heterogeneity:** Tau² = 0.10; Chi² = 10.92, df = 4 (P = 0.03); I² = 63%

| Study or subgroup | Mean difference |
|-------------------|-----------------|
| Aoki 2012         | 2.40 [0.87, 3.93] |
| Lin 2013          | –0.20 [–0.54, 0.14] |
| Shen 2014         | –0.20 [–0.86, 0.46] |
| Xue 2012          | 0.00 [–0.27, 0.27]  |
| Zhang 2013        | –0.10 [–0.74, 0.54] |

**Total (95% CI):** 168 (179) 100.0% 0.52 [0.36, 0.60]

**Test for overall effect:** Z = 0.08 (P = 0.93)
### Figure 3

(A) Forest plot to assess postoperative fusion rates between the 2 treatment strategies; (B) forest plot to assess screw complications events between the 2 treatment strategies; (C) forest plot to assess JOA scores between the 2 treatment strategies; (D) forest plot to assess VAS scores between the 2 treatment strategies; (E) forest plot to assess ODI between the 2 treatment strategies.

| Study or subgroup | Unilateral Mean | SD | Total | Mean | SD | Total | Weight | Mean difference IV, random, 95% CI | Mean difference IV, fixed, 95% CI |
|------------------|----------------|----|-------|------|----|-------|--------|-----------------------------------|----------------------------------|
| Aski 2012        | 171.5          | 43.72 | 25 | 232.3 | 45.79 | 25 | 2.6% | –60.80 [–85.62, –35.98] |                                  |
| Choi 2013        | 84.23          | 41.86 | 26 | 13.759 | 32.92 | 27 | 4.0% | –53.36 [–73.63, –33.09] |                                  |
| Dong 2014        | 146.8          | 14 | 20 | 156.3 | 13.8 | 19 | 21.3% | –9.50 [–18.23, –0.77] |                                  |
| Fernández-Fairen 2007 | 168 | 37 | 40 | 203 | 35 | 42 | 6.7% | –35.00 [–50.61, –19.39] |                                  |
| Shen 2014        | 101.4          | 27.2 | 31 | 143.1 | 22.5 | 34 | 10.9% | –41.70 [–53.90, –29.50] |                                  |
| Xie 2012         | 125.5          | 20.31 | 56 | 168 | 15.59 | 52 | 35.1% | –42.50 [–49.30, –35.70] |                                  |
| Xue 2012         | 136.3          | 20.1 | 37 | 245.1 | 26.5 | 43 | 15.5% | –108.80 [–119.03, –98.57] |                                  |
| Zhang 2013       | 204.25         | 43.91 | 33 | 243 | 41.78 | 35 | 3.9% | –38.75 [–59.15, –18.65] |                                  |

Total (95% CI) 268 277 100.0% –45.93 [–49.95, –41.90]

Test for overall effect: Z=22.34 (P<0.00001)

### Figure 4

(A) Forest plot to assess hospital stay events between the 2 treatment strategies; (B) forest plot to assess operative time events between the 2 treatment strategies; (C) forest plot to assess blood loss events between the 2 treatment strategies.

| Study or subgroup | Unilateral Mean | SD | Total | Mean | SD | Total | Weight | Mean difference IV, random, 95% CI | Mean difference IV, fixed, 95% CI |
|------------------|----------------|----|-------|------|----|-------|--------|-----------------------------------|----------------------------------|
| Dong 2014        | 15.9           | 4.3 | 20 | 16.8 | 5.5 | 19 | 16.5% | –0.90 [–4.01, 2.21] |                                  |
| Fernández-Fairen 2007 | 3.97 | 1.01 | 40 | 3.85 | 0.54 | 42 | 18.0% | 0.12 [–0.23, 0.47] |                                  |
| Shen 2014        | 4.4            | 1.5 | 31 | 6.6 | 2.1 | 34 | 17.9% | –2.20 [–3.08, –1.32] |                                  |
| Xie 2012         | 9.75           | 4.27 | 56 | 12.25 | 10.1 | 52 | 16.6% | –2.50 [–5.46, 0.46] |                                  |
| Xue 2012         | 12.1           | 1.4 | 37 | 21.1 | 1.2 | 43 | 17.9% | –9.00 [–9.58, –8.42] |                                  |
| Zhang 2013       | 13.25          | 16.52 | 33 | 13.35 | 8.37 | 35 | 13.1% | –0.10 [–6.38, 6.18] |                                  |

Total (95% CI) 217 225 100.0% –2.56 [–6.92, 1.80]

Test for overall effect: Z=1.15 (P=0.25)
Previous biomechanical studies are negative about the ability of unilateral fixation to maintain adequate support of the spine for fusion. In a study by Goel et al. [33], unilateral PSF reduced the rigidity and diminished the stress arising in the upper and lower adjacent levels. A study by Kasai et al. [34] reported that the fixation achieved by unilateral PSF in all directions was not as good as that achieved by bilateral fixation. However, some authors were satisfied with the use of unilateral PSF. Chen et al. [35] found that unilateral fixation with cage implantation was a good alternative to maintain the stability of the lumbar spine. In 1992, Kabins et al. [36] showed a similar fusion rate in the unilateral screw fixations group compared with the bilateral fixations group.

Clinical results in patients with treatment of unilateral PSF versus bilateral PSF were shown in a number of studies. In 2010, Aoki et al. [37] showed negative results in an unilateral fixation group in their study. They stated that spine surgeons should consider the potential for postoperative cage migration and limitations of unilateral fixation. However, Toyone et al. [38] demonstrated a lower incidence of adjacent segment degeneration in lumbar fusion with unilateral PSF than that in lumbar fusion with bilateral PSF during a 5-year follow-up. Many RCTs comparing unilateral and bilateral fixations have been reported, but there remains no clear evidence-based standardized treatment protocol.

Our meta-analysis suggests that no significant difference was detected between the 2 groups in terms of primary outcomes except for JOA score. There was no statistically significant difference in fusion rate between the 2 fixation approaches in our meta-analysis, showing that the effectiveness of unilateral PSF procedure might be similar to the bilateral PSF procedure. However, we found a trend toward a higher fusion rate in patients with lumbar fusion of bilateral PSF. This result showed that although unilateral instrumentation might provide sufficient stability, the greater stiffness of the bilateral screw led a higher fusion rate at the final follow-up. Han et al. [39] in their meta-analysis showed similar results and advised that unilateral instrumentation was more suitable for a single-level fusion.

There was no difference between the 2 groups for total complications with no heterogeneity. However, some studies have reported that unilateral fixation was too unstable to prevent fusion cage migration [24], perhaps due to the inherent symmetry of the unilateral screw fixation. In addition, this study demonstrated a higher JOA score in patients undergoing unilateral PSF lumbar fusion, but a significant heterogeneity across the studies was found. Furthermore, both groups demonstrated more excellent outcomes at the final follow-up compared to the preoperative assessment; therefore demonstrating that both unilateral and bilateral PSF can maintain the initial stability of the lumbar spine after intervertebral decompression.

This study demonstrated a relatively lower operative time and blood loss in the unilateral PSF group with high heterogeneity across the studies, but there was no significant difference between the 2 groups in hospital stay time. It may be that both the medical system and skill of the surgeons have effects on all of these 3 indexes. Reduced soft tissue dissection favors early recovery and rehabilitation [40–42]. Although no difference was shown in hospital stay in this study, some studies have reported that the hospital stay for unilateral fixation patients was shorter than that for bilateral fixation patients [26,43,44]. Therefore, unilateral fixation has a relative advantage in these 3 indexes.

The results of this meta-analysis should be interpreted and generalized with caution due to several limitations in the studies. First, although we included 10 RCTs in this meta-analysis, the sample sizes of these studies might not be large enough to show significant differences between the 2 groups. Second, there was no criterion standard outcome with which to compare the postoperative clinical effect across these studies. Third, blinding of outcome assessors was used in only 1 of the RCTs included, and none of them reported adequate intention-to-treat analysis. Thus, detection bias might have been introduced. Finally, the length of follow-up varied between the included studies.

**Conclusions**

Based on this systematic review and meta-analysis, unilateral fixation has no obvious statistical difference in primary outcomes compared with bilateral fixation. However, the unilateral PSF procedure possessed decreased blood loss and shorter operative time. Due to the limitations of the available studies, the findings of this review should be interpreted with caution. Future well-designed RCTs with a larger number of patients and longer follow-up durations are needed.

**Competing interests**

The authors declare that they have no competing interests.

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