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# Comparison of the Unilateral and the Bilateral Pedicle Screw Fixation without Using an Interbody Cage: Randomized Clinical Trial

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**Abstract**

**BACKGROUND:** Lumbar spine instability is one of the main causes of low back pain and has become more prevalent in recent years. Bilateral pedicle screw fixation is used to perform posterior lumbar stabilization, which is complemented by the installation of an interbody cage.

**AIM:** The aim of the study was evaluating of the results of unilateral and bilateral pedicle screw fixation without using of an interbody cage.

**METHODS:** A prospective randomized study of 96 patients was carried out. Forty-seven patients were assigned to the group of the unilateral pedicle screw fixation versus 49 patients were moved to the group of the bilateral pedicle screw fixation of the lumbar spine. Of the 96 patients, 80 patients eventually were included in the study. However, seven patients in the first group and nine patients were lost to follow-up. Surgery timing, blood loss volume, clinical outcomes (scores on the Oswestry disability index [ODI], EQ-5D and visual analogue scale [VAS]) were evaluated in 6–12 months after surgical treatment. All the patients included in this study underwent functional and control computed tomography in 12 months after surgery.

**RESULTS:** Both groups showed a significant improvement in VAS, EQ-5D, and ODI in 1 year after surgical treatment. The two groups significantly differed in the surgery timing (unilateral – 90.2 min; and bilateral – 129.4 min) and blood loss volume (unilateral – 152.7 ml; and bilateral – 230.1 ml), $p < 0.05$.

**CONCLUSIONS:** Unilateral and bilateral pedicle screw fixation showed similar clinical results, while results in both types of fixation differed in slight manner. However, the duration of surgical treatment and intraoperative blood loss volume proved to be lower for the unilateral fixation group, which indicates that the use of the unilateral fixation can be the choice of performing posterior stabilization at a single-level instability of the spine without using an interbody cage.

## Introduction

Degenerative diseases of the spine are a widespread problem in world healthcare [1]. Lumbar instability is an important cause of low back pain and has become more prevalent recently [2]. Fusion of the spinal motion segment is a recognized surgical technique in the treatment of degenerative, traumatic diseases of the lumbosacral spine, as well as in the treatment of spinal deformities [3], [4].

The question of choosing between unilateral and bilateral pedicular fixation is of interest to many practicing specialists of our time.

Pedicular screw fixation is traditionally performed bilaterally; however, some authors have recently shown that unilateral pedicle screw fixation is as effective in performing fusion at the level of the lumbar spine as bilateral fixation, and that it allows for shorter operation time as well as shorter duration of hospital stay [5], [6], [7].

Some studies conducted with the use of interbody implants have shown good and similar clinical results and indicators of the formation of fusion between unilateral and bilateral pedicle screw fixation [8], [9]. However, none of the researchers studied the issue of using different types of fixation without the use of an implant that replaces the interbody space [10], [11], [12]. Opinions on the effectiveness and choice in favor of a particular technique vary and require further study.

We hypothesize that not only bilateral but also unilateral pedicle screw fixation can be used in the treatment of clinical instability of the lumbar spine with similar clinical results.

The aim of this prospective randomized trial was to compare the clinical outcomes, intraoperative, postoperative, and radiological results of unilateral and bilateral pedicle screw fixation without performing interbody fusion for 12 months after surgery for treatment of instability of the spine.

## Materials and Methods

The randomized controlled trial sequentially included 96 patients, who underwent surgical treatment in the period from January 2019 to October 2019. Of the 96 patients, 80 patients were included in the study. However, seven patients in the first group and nine patients were lost to follow-up. The patients were randomly divided into two groups, using the computer program Microsoft Excel (version 2019, Microsoft, Redmond, WA) [13]. Patients in Group 1 underwent unilateral pedicle screw fixation (n = 40) (Figures 1 and 2), and Group 2 – bilateral pedicle screw fixation (n = 40). Treatment results were analyzed for all the patients included into both groups. Clinical outcome and quality of life were primary to assess the study. All patients underwent magnetic resonance imaging (MRI), functional computed tomography (CT) before surgery. The indication for surgical treatment was single level instability of the lumbar spine, which was confirmed by functional CT and MRI. Posner's checklist was used to confirm instability of the lumbar spine [14]. In all patients, conservative treatment lasting at least 6 months before surgery did not lead to a positive result. Inclusion criteria to the trial were as follows:

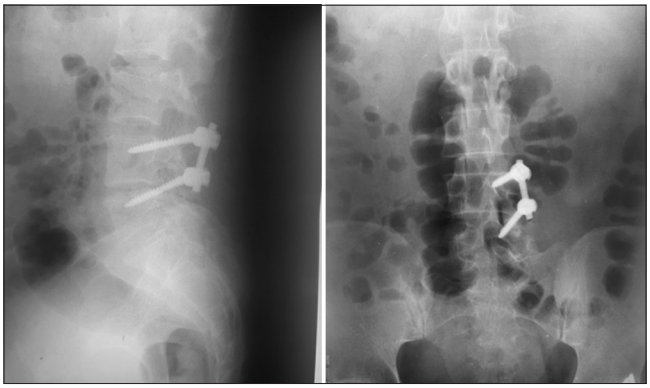

*Figure 1: X-ray of a patient from group i (unilateral pedicle screw fixation) on the 1st day after surgery*

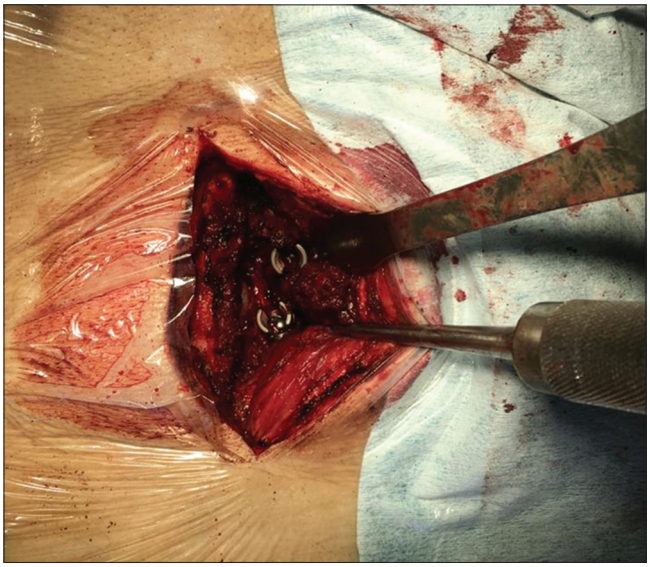

*Figure 2: Surgical approach for unilateral pedicle screw fixation*

- Written informed consent of the patient to participate in the study
- Patients with instability of the lumbar spine
- The opportunity for observation during the entire study period (12 months)
- Mental adequacy, ability, willingness to cooperate, and follow the doctor's recommendations.

Our exclusion criteria were as follows:

- Confirmed spondylolisthesis
- The refusal of a patient from surgery
- The presence of contraindications to surgery
- Severe forms of diabetes (glycosylated hemoglobin >9%)
- Blood diseases (thrombocytopenia, thrombocytopenia, and anemia).

Surgical treatment was performed under endotracheal anesthesia by the open method using the posterior approach on the side that was more symptomatic (based on the patient's complaints, clinical, and physical examination data). An incision was made in the projection of the spinous processes of the treated spinal motion segment. The arches and articular processes of the vertebrae were sharply exposed. The decompressive stage of surgical treatment was completed. After decompression of neural structures under C-arm control, unilateral pedicle screw fixation was performed for Group I with a bone graft at the facet joint, while bilateral pedicle screw fixation with a bone graft at the facet joints was performed for Group II with open surgical approach from the contralateral side. The bone graft was made from the resected bone during decompressive stage.

The wound was treated with antiseptic solutions and layers of sutures with aseptic treatment. All patients were operated by one surgeon.

Intraoperative evaluation of the results included: Time of surgery and volume of blood loss during surgery. All patients underwent a course of standard rehabilitation treatment. Clinical and functional results were assessed using visual analog scale (VAS) for back and leg pain, EQ-5D, and Oswestry Disability Index (ODI): Before surgery, and then 3, 6, and 12 months after surgery. Control CT in 12 months after surgery was assessed by roentgenologist. Glassman classification was used to rate posterior spinal fusion [15]: No fusion (Grade 1), partial unilateral fusion (Grade 2), partial bilateral fusion (Grade 3), solid unilateral fusion (Grade 4), and solid bilateral fusion (Grade 5). Completed posterior lumbar fusion was considered as Glassman Grade 4 and Glassman Grade 5.

Registration: NCT04415814 (ClinicalTrials.gov identifier).

### *Statistical data assessment*

Statistica 10.0 software for Windows (StatSoft Inc., USA) was used for statistical analysis of the results. Quantitative variables were described using standard methods of variation statistics, where the arithmetic mean (M) and standard deviation were applied (δ). Average values are presented as M ± δ. Qualitative variables were described as absolute and relative frequency ratios. Differences were considered significant at $p < 0.05$. Methods of statistical analysis were used to evaluate the results: Student's t-test.

Ethics committee approval was obtained to conduct the study. The study was carried out in accordance with ethical standards.

All patients who took part in the study gave their informed consent before their inclusion in the study.

## Results

Based on the results of the pre-operative examinations, all patients were diagnosed with single level instability in the spinal motion segment of the lumbosacral spine.

In all studied patients, 12 months after surgery, completed posterior spinal fusion was detected and recorded on a control CT, which was rated by Glassman.

The average follow-up period was 15.2 ± 3.7 months, and the average age of patients was 57.2 ± 17.1 years. Both groups were comparable in age, gender (male to female ratio 17:23 [1st group] and 19:21 [2nd group]) ($p > 0.05$), and the operated segments L4-L5: 34 patients (Group 1) and 35 patients (Group 2); and L5-S1: Six patients (Group 1) and five patients (Group 2), ($p > 0.05$).

According to intraoperative estimates, the time of surgical intervention for the 1st group (90.2 min) was significantly shorter than for the 2nd group (129.4 min; $p < 0.05$), and the average blood loss for the 1st group (152.7 ml.) was lower than for Group 2 (230.1 ml., $p < 0.05$; Table 1). Regarding clinical results, the ODI index significantly improved within 1 year after surgery in both groups (from 69.5% to 23.8% for Group 1, and from 70.1% to 23.2% for Group 2, $p < 0.05$).

**Table 1: Characteristics of the observed patients groups**

| Groups | Age, years | Time of observation, months | Timing of operation, minutes | Intraoperative blood loss, ml[1] |
|---|---|---|---|---|
| Group I (unilateral fixation) | (57.1 ± 17.2) | (15.5 ± 2.1) | (90.2 ± 28.7) | (152.7 ± 38.4) |
| Group II (bilateral fixation) | (56.8 ± 16.8)* | (14.9 ± 2.3)* | (129.4 ± 31.2)** | (230.1 ± 36.7)** |

(*): No significant differences between groups, $p > 0.05$, (**): Differences between groups are significant, $p < 0.05$, [1]ml: Milliliter.

The EQ-5D index in patients of Group 1 was 0.091 and 0.041 in Group 2; a year after surgery, the index value was 0.835 and 0.799, respectively ($p < 0.05$). In each group the indicators significantly improved 1 year after surgery compared to the clinical state before surgery. The VAS score for back pain significantly improved 6 months after surgery (from 84 mm to 22 mm for Group 1, and from 82 mm to 23 mm for Group 2, $p < 0.05$), and the VAS score for leg pain also improved significantly (from 76 mm to 18 mm for Group 1, and from 75 mm to 19 mm for Group 2, $p < 0.05$). There were no statistically significant differences between the groups ($p > 0.05$, Figure 3).

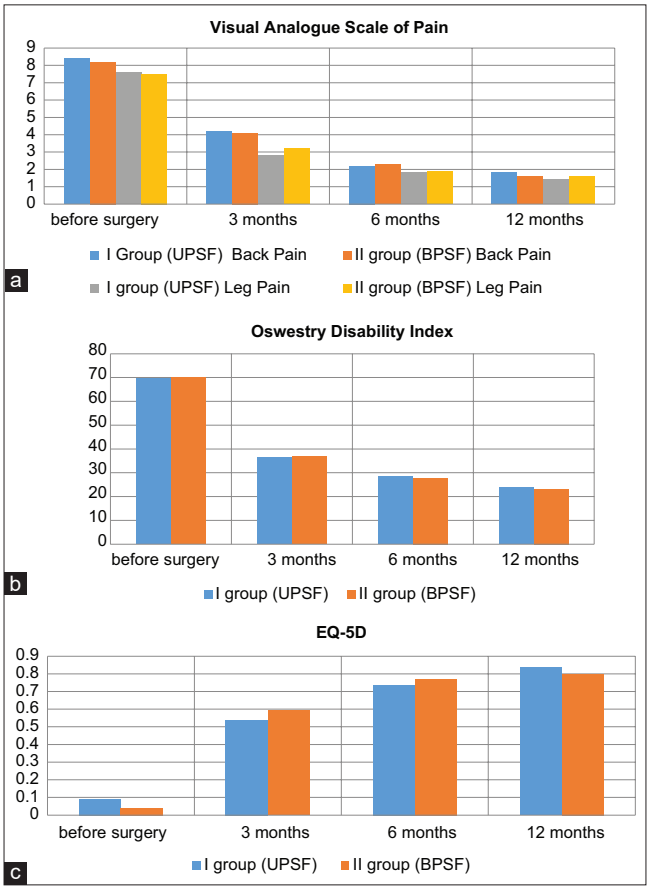


*Figure 3: Dynamics of clinical and functional indicators: (a) Visual analog scale; (b) EQ-5D; (c) Oswestry Disability Index; $p < 0.05$*

Of all 80 patients, one case of complications associated with the operation with the performance of intervention due to infectious postoperative complications was identified. The patient underwent repeated surgery in the amount of primary surgical treatment of the wound with excision of the post-operative scar, removal of suture material, and treatment of the wound with antiseptic solutions. During revision surgery, it was decided to keep the pedicle screw fixation system. During 1 year follow-up after revision surgery, there was no difference in the clinical assessment with other included patients.

## Discussion

We hypothesized that not only bilateral but also unilateral pedicle screw fixation can be used in the

treatment of clinical instability of the lumbar spine with similar clinical results.

Despite the existence of numerous studies evaluating the results of unilateral and bilateral pedicle screw fixation in the formation of lumbar fusion, data on assessing the possibility of using pedicle screw fixation without the introduction of an interbody implant are quite rare and controversial, and the conclusions of many of these studies contradict each other in terms of identifying which fixation method is more effective in the treatment of instability of the lumbar spine [16], [17], [18].

Fernández-Fairen *et al*. compared unilateral and bilateral pedicle screw fixation in 82 patients with high-grade spondylolisthesis. The authors claim similar clinical results in the two groups of patients, with reduced duration of surgical treatment, reduced blood loss, and lower cost of implants [19].

Recently, several systematic reviews have been performed based on meta-analyses [20], [21], which can provide information that can help an operating surgeon. However, the conclusions of most of the studies are inconsistent and oftentimes contradictory. For example, a meta-analysis by Lu *et al*. [22] did not reveal any obvious differences between the two methods of fixation of the lumbar spine in terms of functional parameters, length of hospital stay, rate of fusion, and the frequency of complications.

In addition, unilateral pedicle screw fixation has an advantage over bilateral fixation in terms of the duration of surgery and blood loss, but it increases the risk of interbody cage migration. Based on the above findings, the researchers concluded that unilateral fixation is recommended as the optimal fixation method in the formation of lumbar fusion.

Nevertheless, according to some studies, unilateral fixation causes adverse effects due to the asymmetry of the spine and reduced stability of the operated segment; however, it should be noted that there were no differences in the rate of fusion formation, the risk of revision intervention or post-operative complications in comparison with bilateral pedicle screw fixation [23]. Moreover, most of the available works describe the use of unilateral transpedicular fixation exclusively in the surgical treatment of one- or two-level degenerative diseases of the lumbar spine [5], [24].

Some studies have shown that unilateral pedicle screw fixation significantly reduces surgery time and blood loss compared to bilateral pedicle screw fixation during decompression and stabilization operations on the lumbar spine, and less trauma associated with surgical access performed on one side was noted [25], [26], [27].

Our study and the results obtained allowed us to show the absence of significant differences in the clinical and functional results of both types of surgical treatment, as well as to confirm the available data on the low volume of intraoperative blood loss and the shorter duration of the operation. It is useful to extend the follow-up period and continue further trials on the use of unilateral pedicle screw fixation in the treatment of lumbar spine instability.

## Conclusions

Unilateral and bilateral pedicle screw fixation showed similar clinical and functional results. However, the timing of surgical treatment, the number of implants used, as well as intraoperative blood loss are lower in the unilateral fixation group, which indicates that the use of unilateral fixation can be the choice of performing posterior stabilization in case of a single-level instability of the spine without using an interbody implant.

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