



Unilateral versus Bilateral Pedicle Screw Instrumented Transforaminal Interbody Fusion in a Single Level Lumbar Spondylolisthesis

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Abstract

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AIM: This is a prospective non-randomized study aiming to assess the efficiency, safety, and outcome of unilateral pedicle screw fixation with transforaminal lumbar interbody fusion (TLIF) versus bilateral pedicle screw fixation with TLIF in cases of single level spondylolisthesis by comparing clinical, functional outcome and the complication rates.

METHODS: We prospectively collected demographics and clinical data of the patients with surgically treated single level lumbar spondylolisthesis Grade 1 (n = 60) with follow-up and comparison between clinical/functional outcomes and complication rates between January 2020 and January 2021 operated by surgeons from Neurosurgery Department at Cairo University hospitals. We allocated the patients with the unilateral pedicle screw fixation with TLIF as Group A and the patients with the bilateral pedicle screw fixation with TLIF as Group B.

RESULTS: Clinical outcome showed statistical significance between Group A and Group B (p < 0.001); functional outcome (using Oswestry disability index) between Groups A and B also showed statistical significance (p < 0.001) in favor of Group B. Complications in Group A was higher especially cage migration in 26.7% of cases with p = 0.026 while it was only present in 3.3% of the Group B cases.

CONCLUSION: We concluded that the bilateral approach showed a statistically significant better clinically/functional outcomes with the lower rates of complication in comparison with the unilateral approach.

Introduction

Transforaminal lumbar interbody fusion (TLIF) has been increasing in popularity since its introduction by Harms and Rolinger in 1982. The TLIF procedure involves approach to the disc space through the vertebral foramen combined with posterior instrumentation. This procedure promotes circumferential fusion based on the principle of load sharing and provides anterior column support and a posterior tension band. TLIF is designed for fusion, restoring lumbar lordosis, and widening the neural foramina. TLIF was conceptualized as a modified unilateral approach to posterior lumbar interbody fusion (PLIF). It has been repeatedly shown to be an effective method of spinal fusion associated with a lower risk for complications. Compared with the PLIF, the TLIF requires less thecal sac manipulation and decreases the chance of CSF leaks and nerve root damage [1].

The traditional TLIF, through a posterior median approach, achieves rigid fixation with the bilateral placement of pedicle screws. However, based on clinical and biomechanical studies, excessively rigid

fixation may lead to some adverse reactions, such as device-related osteoporosis, reduction of bone mineral content in adjacent vertebrae and adjacent segment degeneration [2]. Therefore, some surgeons have suggested unilateral instrumented TLIF. The unilateral instrumented TLIF is based on traditional TLIF, but is less invasive. There have already been several short-term reports and biomechanical studies concerning unilateral instrumented TLIF [3].

These reports have showed that, compared with traditional TLIF, unilateral instrumented TLIF achieves similar clinical outcomes and with little increase in the incidence of complications. Further, unilateral instrumented TLIF has been shown to reduce the placement of pedicle screws resulting in decreased stiffness of the instrumented segment and less stress shelter between adjacent segments. Thus, this procedure could potentially delay post-operative adjacent segment degeneration, prevent bone mass decline and avoid device-related osteoporosis. Unilateral instrumented TLIF also retains muscle and facet joint on the contralateral side, significantly reducing operating time and blood loss. The reduction

in both instrumentation and soft-tissue destruction could potentially yield other benefits, such as earlier mobilization, a shorter hospital stays, and a faster return to work [4].

Methods

Patients

Patient Selection

Patients with single level lumbar Grade 1 spondylolisthesis with failed conservative management in the form of bed rest, medical treatment, and physiotherapy for a period of at least 4–6 weeks were divided into two groups according to the operative technique: Half of the patients done with unilateral pedicular screw fixation and the other half with bilateral pedicular screw fixation by the Department of Neurosurgery, Cairo University Hospitals from January 2020 to January 2021 and all patients gave informed consent before being enrolled into the study; the aim of the study is to compare primarily the clinical/functional outcomes of both groups and secondary outcomes as post-operative complications.

Patient population

Sixty patients were conducted in this study; 30 in Group A (unilateral pedicular screw fixation) and 30 in Group B (bilateral pedicular screw fixation) after being filtered by the inclusion (Single level lumbar spondylolisthesis Grade 1 [degenerative and lytic types]) and exclusion criteria (More than a single level, other lumbar pathologies as infection, tumors, and finally recurrent cases).

Pre-operative clinical and radiological evaluation

All patients were subjected to complete history taking and neurological examination including motor and sensory examination and were subjected to functional assessment using Oswestry disability index (ODI); then pre-operative routine laboratory investigations including complete blood picture, coagulation profile, liver and kidney functions were done and radiological investigations including MRI lumbosacral spine and X-ray LSS dynamic view to assess stability.

Surgical technique

Under general anesthesia and with intraoperative IV antibiotics the patient was placed

in a prone position on a radiolucent operation table a team of a surgical main operator with at least 6 years of Neurosurgical experience with an assistant surgeon with 3–5 years of experience.

The involved segments were identified by a C-arm machine and then marked on the skin of the patient.

Group A, Unilateral Instrumented transforaminal lumbar interbody fusion

A midline skin incision and dissecting through both sides. Subperiosteal muscle separation and split of the Sacro spinalis to expose the facet joint, transverse processes, and vertebral lamina on one side (the more symptomatic side) while the other side we expose the lamina only; placement of posterolateral pedicle screws, ipsilateral facetectomy is done on the desired side and full laminectomy is performed with adequate decompression of both ligamentum flavum, ventral side of the lamina, and medial part of both facet joints were removed until the Dural sac and both nerve roots were totally decompressed; complete discectomy was conducted and the intervertebral space was sequentially distracted and prepared followed by a PEEK cage (filled with autologous bone) placement into the center of the disc space (Figures 1 and 2).



Figure 1: Intraoperative photo of unilateral pedicle screw fixation (left side) and transforaminal lumbar interbody fusion cage

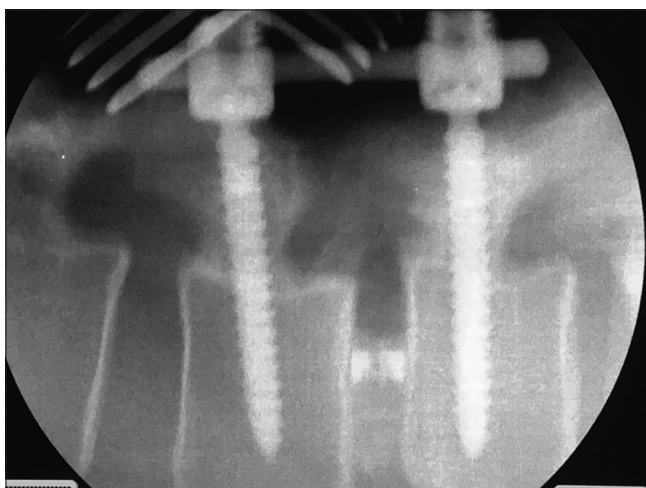


Figure 2: Intra-operative C-arm fluoroscopy image of L4-5 fixation and transforaminal lumbar interbody fusion

Group B, Bilateral Instrumented transforaminal lumbar interbody fusion

A standard technique was carried out through a midline incision and bilateral posterolateral pedicle screws were placed. Adequate decompression of both ligamentum flavum, ventral side of the lamina, and medial part of both facet joints were removed until the Dural sac and both nerve roots were totally decompressed; Complete discectomy was conducted and the intervertebral space was sequentially distracted and prepared followed by a PEEK cage (filled with autologous bone) placement into the center of the disc space.

For both groups, a drain was placed routinely and the incision was closed in a standard layered manner finally.

Intraoperative and post-operative follow up

Immediate post-operative assessment of visual analog scale (VAS) for low back pain and lower limb pain

were assessed and patients were asked to return for follow-up at 3, 6 months for pain and functional outcome using ODI; radiographic assessment postoperatively by LSS X-ray and CT (Figures 3 and 4) included screw/rod failure (malposition, breakage, and loosening), cage migration defined as posterior movement of the cage >3 mm compared with the immediate postoperative state.

Statistical analysis

Data were coded and entered using the Statistical Package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean and standard deviation for quantitative variables and frequencies (number of cases) and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using unpaired *t*-test. For comparing categorical data, Chi-square (χ^2) test was performed. Exact test was used instead when the expected frequency is <5. $p < 0.05$ was considered as statistically significant [5].

Ethical Committee Approval Number: Cairo University, Faculty of Medicine: MD-50-2020.

Results

Patient's demographics

The age ranged from 26 to 58 years old with Group (A) mean age 45.07 ± 6.83 while Group (B) mean age 45.57 ± 7.65 ; regarding gender; the study had 27 male patients (45%) and 33 female patients (55%).

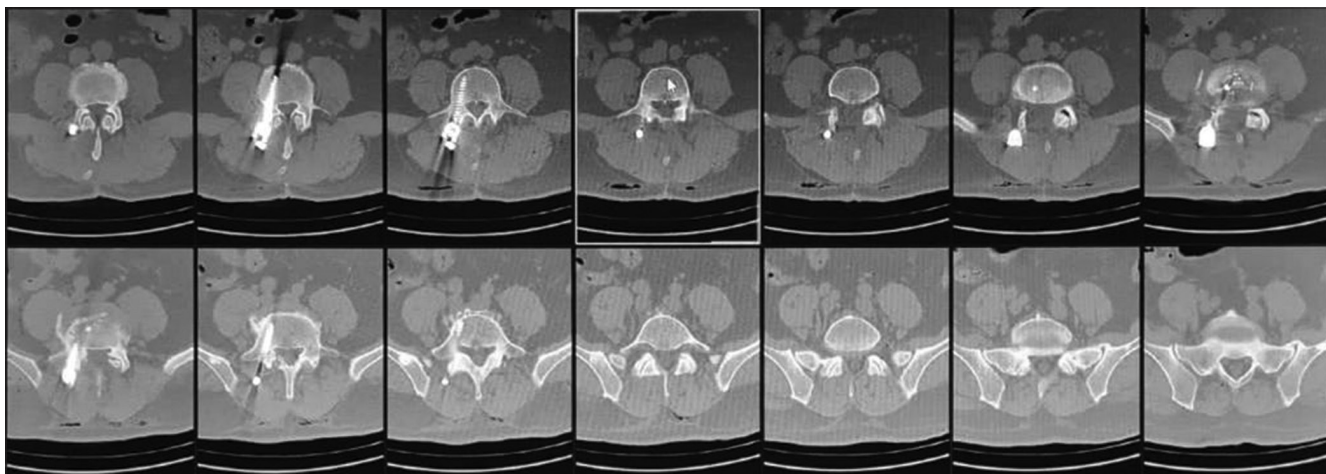


Figure 3: Computed tomography post-operative axial cuts of lumbar spine with unilateral fixation of L4-5 and transforaminal lumbar interbody fusion Insertion

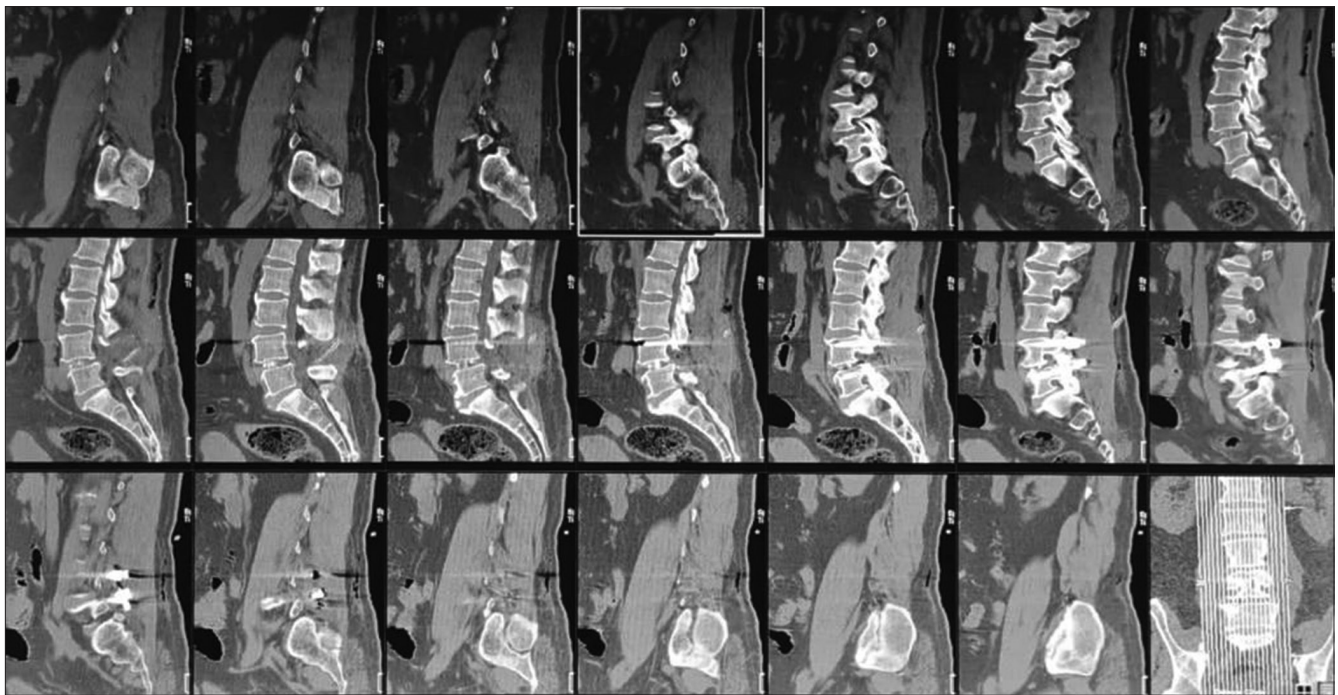


Figure 4: Computed tomography post-operative sagittal cuts of Lumbar spine with Unilateral fixation of L4-5 and transforaminal lumbar interbody fusion Insertion

Levels

Group A shows L4/5 was the most common level involved with 18 patients (60%), L5/S1 was involved in 9 patients (30%), Group B results showing L4/5 was the most common level involved in 19 patients (63.3%), and L5/S1 comes second with 8 patients involved (26.7%) (Figure 5).

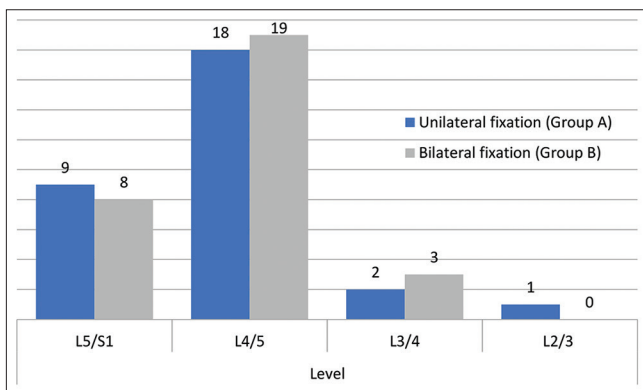


Figure 5: Levels of spondylolisthesis in Group A and Group B

Clinical outcome

Low back pain visual analogue scale outcome

Group A had a mean pre-operative VAS for LBP was 8.2, Mean post-operative VAS was 3.83, follow-up after 3 months yield a mean 5.77 and follow-up after 6 months yield a mean of 6.27.

Group B had a mean pre-operative VAS for LBP was 7.27, mean post-operative VAS was 4.23, follow up after 3 months yield a mean 2.57 (p < 0.001) and follow-up after 6 months yield a mean 2.8 (p < 0.001) (Table 1).

Table 1: Comparison between Visual Analogue Scale of low back pain in Group A and Group B in preoperative, post-operative, 3 months and 6 months duration

Low back pain VAS	Mean ± SD		p
	Group A	Group B	
LBP VAS pre	8.20 ± 0.61	7.27 ± 1.17	
LBP VAS post	3.83 ± 0.99	4.23 ± 0.82	0.092
LBP VAS 3 months	5.77 ± 1.33	2.57 ± 0.97	< 0.001
LBP VAS 6 months	6.27 ± 1.08	2.80 ± 0.71	< 0.001

SD: Standard deviation, LBP: Low back pain, VAS: Visual Analogue Scale.

Lower limb pain visual analogue scale outcome

Group A had a mean pre-operative VAS for LLP was 6.93, mean post-operative VAS was 4.13, follow-up after 3 months yield a mean 3.50 and follow up after 6 months yield a mean of 4.07.

Group B had a mean pre-operative VAS for LLP was 7.30, mean post-operative VAS was 2.83 (p < 0.001), follow-up after 3 months yield a mean 2.40 (p < 0.001) and follow-up after 6 months yield a mean 2.57 (p < 0.001).

Functional outcome (Figure 6)

ODI was assessed pre-operatively and on follow-up after 6 months and was compared between the 2 groups. In Group A; pre-operative mean score was 48.6 and follow-up after 6 months yields a mean 30.10; In Group B; pre-operative mean score was 48.33 and follow-up after 6 months yield a mean of 18.53 which is statistically significant compared to Group A (p < 0.001).

Complication rates

Intraoperative complications (Dural tear, Nerve injury) and post-operative complications (wound

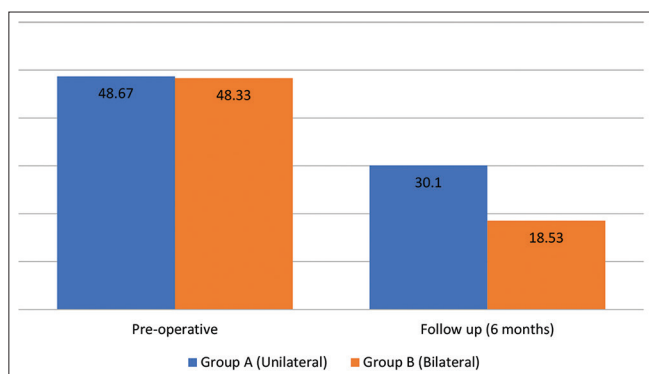


Figure 6: Comparison between pre-operative Oswestry Disability Index score and follow up after 6 months between 2 groups

infection, system failure “Broken screws or rod,” and cage migration) were compared between the two groups in a period of 6 months and a statistical significance was found between the two groups as follows; Complicated cases in Group A (Unilateral) was 13 patients (43.3%) while Group B had only five patients (16.7%) with a $p = 0.024$.

Cage migration is the most common complication found in Group A (Unilateral) with eight cases (26.7%) in comparison of a single patient (3.3%) in Group B (Bilateral) with statistical significance between the two groups. ($p = 0.026$); dural tear occurred in one patient (3.33%) in Group A (Unilateral) and CSF leak occurred post-operative which was managed by medical treatment and lumbar drain; Group B (Bilateral); 1 patient had dural tear and was managed by primary sutures intra-operatively with no CSF leak post-operative; Wound infection occurred in two patients (6.7%) in each of Groups A and B and was managed with intravenous antibiotics without the need for debridement; System failure (Broken screws or rod) Group A had 2 cases (6.7%) with system failure; the 2 had pulled out screws which occurred after 4 months, 7 months respectively; Group B had 1 case (3.3%) with system failure with a broken rod after 6 months with no statistical significance between the 2 groups; There was no cases of nerve root injury in both groups (Figure 7 and Table 2).

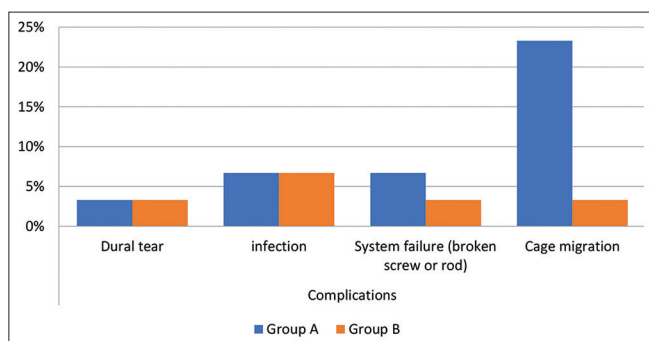


Figure 7: Detailed comparison in complications of each group

Table 2: Detailed comparison in complications of each group

Complications	Count (%)		p
	Unilateral fixation (Group A)	Bilateral fixation (Group B)	
Dural tear	1 (3.3)	1 (3.3)	1
Infection	2 (6.7)	2 (6.7)	1
System failure (broken screw or rod)	2 (6.7)	1 (3.3)	1
Cage migration	8 (26.7)	1 (3.3)	0.026
No complications	17 (56.7)	25 (83.3)	0.024

Discussion

Availability of clinical studies comparing unilateral vs bilateral pedicle screw instrumentation have produced conflicting results regarding clinical outcome and hardware complications [6].

TLIF preserves more of the posterior vertebral column, but requires total facetectomy which necessitates pedicle screw fixation for maintaining stability of vertebral segment, recently many trials reported good results with unilateral pedicle screw placement such as less blood loss, shorter operative time, similar clinical outcomes and others [7]. Furthermore, many studies suggested higher rate of complications in unilateral group and worse ODI and VAS in follow-up in unilateral group [7], [8], [9].

Our study focused on a single pathology in all our patients which was single lumbar level Grade 1 spondylolisthesis which limited the number of patients gathered while in other studies a number of lumbar pathologies and multiple levels were involved, for example, Duncan and Bailey [8] and Liang *et al.* [10] studied different type of lumbar pathologies which can lead to differences in outcome either clinically or in complication rates.

Clinical outcome

Regarding the low back pain and lower limb pain which were assessed by VAS post-operatively, at 3 months and 6 months follow-up in our study; Showing a better long-term outcome of back pain improvement in the bilateral group in comparison to the unilateral ones in a statistically significant manner while in Xue H., *et al.* study showed no significant difference between the 2 groups; Shen, X., *et al.* study also showed no significant difference between pre-operative and follow up VAS of low back pain [11], [12]. Other studies including Dahdaleh *et al.* showing a better outcome in the bilateral group than unilateral ones with no statistical significance in this study is suggested due to small sample size and also the diversity of lumbar pathologies operated upon [13].

Functional outcome

The ODI comparison between Group A and Group B showed a statistical significance between

the two groups showing better results in the bilateral group; it's attributed to the lower complication rates; Group A had a mean of 48.67 pre-operative and 30.1 at 6 months follow-up; while Group B had a mean of 48.33 pre-operative and 18.53 at 6 months follow-up with $p < 0.001$. Other studies revealed similar results such as Dahdaleh *et al.* with mean pre-operative ODI of 39.2 and post-operative ODI of 17.9 in the bilateral group versus a pre-operative ODI of 37.4 and a post-operative ODI of 22.7; Shen *et al.* study showed similar outcomes between unilateral and bilateral groups with a mean pre-operative ODI of 56.6, 3 months mean of 27.4, 12 months mean of 24 in Group A while the other group showed similar results as follows; pre-operative ODI mean is 51.58, 3 months mean of 26 and 12 months mean of 22.4; this can be attributed to different pathologies and lower complication rate in this study than ours [11], [13].

Complication rates

Our study showed a statistical significance between Group A and Group B with the lower complication rate in bilateral pedicle screw (Group B) with 16.7% versus 43.3% in Group A with $p = 0.024$; the main and statistically significant difference is the rate of cage migration in both groups for which Group A had 8 cases of cage migration (26.7%) versus 1 case of cage migration in Group B (3.3%) with $p = 0.026$; In Duncan *et al.* study; the cage migration in unilateral group was 23% versus 11% in the bilateral group with a $p = 0.03$ (Statistically significant difference) [8]. In Ren *et al.* collective study, cage migration rates were also higher in a statistically significant manner between unilateral group (15.5%) and Bilateral group (6.5%) with $p = 0.04$. [7] In Liu *et al.* retrospective study of 215 patients with 4 years follow-up period showed a statistically significant higher rates of cage migration in Unilateral group in comparison to the bilateral group ($p < 0.005$) [9]; This higher cage migration rate leads to more instability and the stress of asymmetry after the unilateral fixation, While in Liang *et al.* study showed much lower rate of cage migration (5.9%) in the unilateral group versus the bilateral group with no statistical significance [10].

Other complications include dural tear which occurred in 1 patient of Group A in our study (3.33%) and 1 patient in Group B (3.33%); In Shen *et al.* study two patients of Group A (6%) and one patient in group B (3%) had dural tear with no statistical significance [11]. Wound infection affected two patients in Group A (6.7%) and 2 patients (6.7%) in Group B in our study while in other studies as Xue *et al.* study showed 3 cases in Group 1 – Unilateral (9%) and 2 cases in Group 2 - Bilateral (6%) with no statistical significance as well [1]. Regarding System failure (broken screws or rods); Our study showed 2 cases in Group A (6.7%) of system failure in comparison to 1 case (3.3%) in

Group B with no statistical significance, in Xue *et al.* study 3 cases (9) in Group 1 (Unilateral) had system failure in comparison to 1 case (3%) of system failure in Group 2 (Bilateral) with no statistical significance [12].

Conclusion

Regarding the clinical outcome in this study; there was a statistical significance better VAS for low back pain and lower limb pain for bilateral group than unilateral probably due to less complications; the functional outcome showed better results in the bilateral group versus unilateral group; while other studies agreed that the clinical and functional outcome is better in the bilateral group; most of them did not find a statistical significance in contrast to our study. There is a statistical significance that the bilateral pedicle screw fixation has better results versus unilateral approach regarding complication rates specially cage migration percentages.

Limitations

The follow-up period is limited to 6 months and should be increased to better assess radiological and clinical outcomes; also adding more lumbar pathologies to better compare both approaches; Finally, the number of patients should be further increased in the upcoming studies for better comparison.

Strength

The comparison for a single level lumbar spondylolisthesis gives a more concise results in this specific pathology; also have a prospective study gives more accurate results and outcomes.

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