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Original Research Article

Clinical And Radiological Outcome Of Minimally Invasive Unilateral Pedicle Screw Stabilization Versus Minimally Invasive Bilateral Pedicle Screw Stabilization For TLIF Procedures In Degenerative Single Level Lumbar Spine Diseases: A Randomized Controlled Trial

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ABSTRACT

Objectives: To compare Clinical outcome of degenerative lumbar single level spine diseases treated by minimally invasive unilateral pedicle screw stabilization versus minimally invasive bilateral pedicle screws stabilization for TLIF procedures assessed by VAS, ODI SCORE AND SF 36 and to compare the radiological outcome by Beck index, fusion index, vertebral alignment, proper placement of cage. To compare intraoperative blood loss, duration of surgery, length of hospital stays between the mentioned two groups.
Materials and Methods: A total of 30 patients were randomized into two groups. Group 1 underwent minimally invasive unilateral pedicle screw stabilization -TLIF (15patients) and group 2 underwent minimally invasive bilateral pedicle stabilization -TLIF (15 patients) from the period between July 2020 to July 2022 and were followed up for mean duration of 18 months. Degenerative lumbar single level involvement with spinal canal stenosis grade 2, 3 and spondylolisthesis grade 1, 2 were involved. Clinical assessment was measured with visual analogue score (VAS score), Oswestry disability index (ODI) Score and Short form health survey -36 (SF36). Radiological assessment was done with Briedwell interbody fusion index, placement of cage. And were followed up at 3 months,6 months, 12 months and 18 months after surgery.
Results: The mean Age (Years) was 52.73 ± 11.92. Out of 30 participants 15 (50.0%) had Group: MISS- U/L instrumentation –TLIF. 15 (50.0%) of the participants had Group: MISS - B/L instrumentation TLIF. Majority of them were l4-l5 involvement. There was a significant difference between the 2 groups in terms of Duration of Surgery (Minutes) (W = 0.000, p = <0.001) and intraoperative blood loss (W = 3.500, p = <0.001), with the median Duration of Surgery (Minutes) being highest in the Group: B/L TLIF group. With the median Blood Loss (mL) being highest in the Group: B/L TLIF group. There was statistically significant improvement in the trend of VAS Score, ODI score, SF-36 over time in each group after surgery but there were no statistically significant changes between these 2 groups. There were no statistically significant changes in terms of fusion and cobbs' angle between these 2 groups.
Conclusion: MISS TLIF with unilateral pedicle screw fixation in a single level degenerative

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disc diseases is similar to bilateral pedicle screw fixation with added advantages of shorter operative time, lesser intraoperative blood loss, similar days of hospital stay, no statistical significant difference in post operative changes in VAS score, ODI score, SF 36 score, briedwell fusion index, cobbs angle when compared to bilateral pedicle screw instrumentation leading to early mobilization, easy rehabilitation and return to activities of daily living.

Keywords: Degenerative lumbar spine diseases, minimally invasive TLIF, minimally invasive unilateral pedicle screw stabilization, minimally invasive bilateral pedicle screw stabilization, spinal canal stenosis, spondylolisthesis, adjacent segment degeneration.

Introduction

Various lumbar fusion procedures are available to treat different pathological spinal disorders which include spinal canal stenosis, lumbar spinal deformities and instabilities. Major goal is to achieve good fusion, stable spinal segments with maintained good disc height and vertebral alignment, thus reliving the pressure on exiting and traversing nerve roots [1].

Various fusion procedures are currently followed like posterolateral vertebral body fusion, PLIF, TLIF, OLIF, ALIF [1]. Hams *et al*, first used TLIF in 1980s and he has explained advantages of TLIF over PLIF [2]. TLIF has unilateral exposure, decreased neural retraction, decreased potential neurological injury, better maintenance of lumbar lordosis. Thus, TLIF has become a safe and gold standard technique in achieving lumbar fusion.

With advanced imaging guiding technology with fluoroscope and navigation minimally invasive TLIF was developed. It was first described by Foley *et al*. In 2003 and has become increasingly popular method for lumbar arthrodesis [3]. Pedicle screw and rod system is widely accepted and used to achieve more stable and rigid fixation in the patients undergoing fusion surgeries. However due to excessive rigidity of the system, this instrumentation is also suspected to cause decreased mineral content in the fixed area and degeneration of adjacent segments. [1, 4, 5]. To reduce this rigidity numerous clinical and biomechanical studies are performed to find the ideal construct. Favourable results were reported for lumbar fusion in combination with unilateral instrumentation system [5-8]. Goel *et al*. has showed difference in the rigidity between unilateral and bilateral system [9]. Unilateral instrumentation system reduces the motion in flexion extension, lateral bending and axial movements relatively less when compared to bilateral instrumentation TLIF.

Few studies in the literature has shown bilateral pedicle screws instrumentation offer significantly more stability than unilateral pedicle screw instrumentation [9-16]. So controversy exists between unilateral and bilateral pedicle screw stabilisation for TLIF.

Hence this study is conducted to know clinical and radiological outcome of minimally invasive unilateral instrumentation versus minimally invasive bilateral pedicle screw instrumentation for TLIF procedures in single level lumbar spinal segment diseases.

Materials and Methods

Patient characteristics

After the approval of ethical committee, a series of 30 patients from July 2020 to July 2022 were randomly divided into two groups by chit method. Group 1 underwent minimally invasive unilateral pedicle screw stabilization for TLIF procedures for a single level degenerative lumbar spine diseases and group 2 underwent minimally invasive bilateral pedicle instrumentation for TLIF procedures for a single level degenerative lumbar spine disease. All patients were conservatively treated for 9 months before they underwent surgical procedures. Inclusion criteria were lumbar Spinal canal diameter less than 9mm, Spondylolisthesis grade I and grade II, Spinal canal stenosis with severe neurological claudication and radiculopathy, Age less than 70 years and Patient who were willing for minimal invasive TLIF surgery with unilateral or bilateral pedicle screw stabilization giving

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informed written consent. Exclusion criteria were Traumatic or pathological vertebral fracture, multiple level involvement, Grade III/IV spondylolisthesis / spondyloptosis, Severe medical co-morbidities and Age more than 70 years.

Surgical technique
Patient positioning

Patient positioned prone over Wilson frame. Image intensifier was used to identify the desired level of lumbar vertebrae involved.

Patient position over Wilson frame

Minimal invasive - TLIF technique: The procedure was carried out in two steps:

1. Decompression, discectomy with cage insertion for interbody fusion in which surgical access obtained using a tubular retraction system
2. Percutaneous pedicle screw insertion [17]

The side of the approach was decided preoperatively based on the radicular symptom's location. After the patient is draped, a 22-gauge spinal needle is inserted into the skin, directly over the disc space of interest. A 2.5-cm skin incision is centred over this point, approximately 4 to 5 cm lateral to the midline. Haemostasis is achieved with electrocautery. Under c-arm guidance, a K-wire is inserted lateral-to-medial trajectory through the incision toward the facet complex. The wire is passed only through the fascia and muscle to avoid the risk of inadvertent neurological injury or Dural puncture. Serial dilators are passed over the wire creating a muscle-splitting surgical channel. The appropriate-length tubular retractor 22 or 26-mm-diameter is passed over the dilators and centred over the facet joint. Depending on the surgeon's preference, the procedure can be performed using an operating microscope or loop magnification. Total facetectomy is performed using bayoneted osteotomes or the high-speed drill.[18] Decompression was achieved by removing the ligamentum flavum and synovium in piecemeal fashion using Kerrison instruments exposing the exiting and traversing nerve roots. Through the tubular retractor ipsilateral discectomy is done [18]. The interspace is then distracted using a 2.5-cm skin incision on the contralateral side, centred over the interspace, and percutaneous screws and a rod are placed to distract the interspace and temporarily maintain the distracted position. Once the optimal interspace distraction has been achieved, endplate preparation is done using curettes and endplate scrapers. cartilaginous endplate is removed, and the bone endplates are decorticated but left structurally intact [18]. Contralateral decompression is done by wanding technique through the same ipsilateral incision. autologous bone graft which was obtained from removed facet was packed in the anterior 1/3rd of the disc space, then an appropriate size cage was put. percutaneous Screws and rods were placed on both sides in bilateral pedicle screws stabilization group and on only one side in unilateral pedicle screws stabilization group patients and then compression applied across the cage.

Assessment of results

Demographic data of age, sex, preoperative diagnosis, level of lumbar spine involvement was collected from both the groups. Intraoperative blood loss, duration of surgery, duration of hospital stay was also compared between two groups. Patients were asked to follow up at 3

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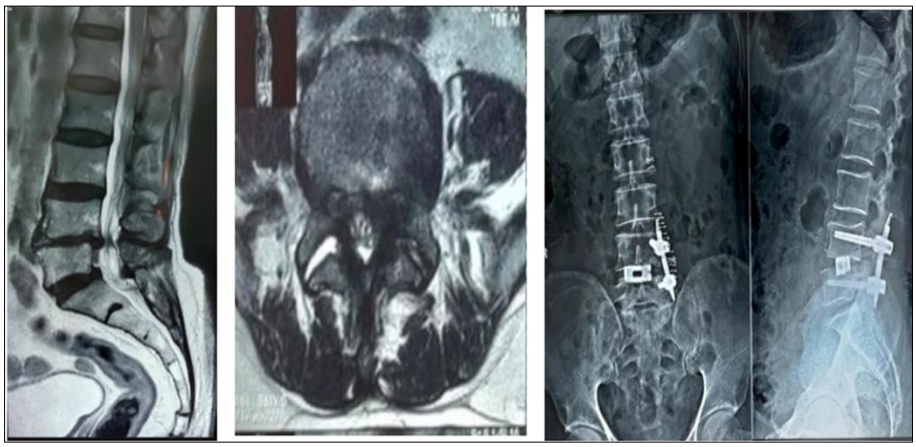
months, 6 months, 12 months, and 18 months. Clinical outcome of degenerative lumbar spine disease treated by minimally invasive unilateral and bilateral pedicle screws stabilization with TLIF assessed by VAS, ODI SCORE AND SF 36 scores and radiological outcome was assessed by Briedwell fusion index, vertebral alignment, proper placement of cage.

Statistical analysis

Demographic data- age, sex, diagnosis, level of involvement, duration of surgery, duration of hospital stay was compared by skewness of data, Shapiro – wilk test. and their respective association compared by Wilcoxon- Mann- Whitney test. clinical assessment by VAS, ODI and SF 36 scores and radiological assessment of cobbs angle and fusion index were assessed by non-parametric test Wilcoxon- Mann- Whitney test. Friedman test was used to compare within each group.



Case 1: A 56 year male patient who is a driver by occupation complaining of pain in lowerback and radiating to the left lower limb since 7 months

Case 2: 45 years female patient with L4-L5 spondylolisthesis

Results

15 (50.0%) of the participants had Group: U/L TLIF. 15 (50.0%) of the participants had Group: B/L TLIF.

The mean Age (Years) was 52.73 ± 11.92. 6 (20.0%) of the participants had Age: 31-40 Years. 7 (23.3%) of the participants had Age: 41-50 Years. 10 (33.3%) of the participants had Age: 51-60 Years. 5 (16.7%) of the participants had Age: 61-70 Years. 2 (6.7%) of the participants had Age: 71-80 Years.

17 (56.7%) of the participants had Gender: Male. 13 (43.3%) of the participants had Gender: Female.

18 (60.0%) of the participants had Diagnosis: Spinal Canal Stenosis. 12 (40.0%) of the participants had Diagnosis: Spondylolisthesis.

1 (3.3%) of the participants had Level: L2-L3. 3 (10.0%) of the participants had Level: L3-

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L4. 15 (50.0%) of the participants had Level: L4-L5. 11 (36.7%) of the participants had Level: L5-S1.
The mean Duration of Surgery (Minutes) was 153.67 ± 28.22

. Summary of Basic Details

Basic Details	Mean ± SD || Median (IQR) || Min-Max || Frequency (%)
Group	
U/L TLIF	15 (50.0%)
B/L TLIF	15 (50.0%)
Age (Years)	52.73 ± 11.92 || 55.50 (42.50-60.00) || 34.00 - 78.00
Age	
31-40 Years	6 (20.0%)
41-50 Years	7 (23.3%)
51-60 Years	10 (33.3%)
61-70 Years	5 (16.7%)
71-80 Years	2 (6.7%)
Gender	
Male	17 (56.7%)
Female	13 (43.3%)
Diagnosis	
Spinal Canal Stenosis	18 (60.0%)
Spondylolisthesis	12 (40.0%)
Level	
L2-L3	1 (3.3%)
L3-L4	3 (10.0%)
L4-L5	15 (50.0%)
L5-S1	11 (36.7%)
Duration of Surgery (Minutes)	153.67 ± 28.22 || 150.00 (122.50-180.00) || 120.00 - 200.00

Table 1: Association between 'Group' and 'Duration of Surgery (Minutes)'

Duration of Surgery (Minutes)	Group		Wilcoxon-Mann-Whitney U Test	
	U/L TLIF	B/L TLIF	W	p value
Mean (SD)	128.00 (9.41)	179.33 (12.23)	0.000	<0.001
Median (IQR)	120 (120-140)	180 (170-185)		
Min - Max	120 - 140	160 - 200		

The Duration of Surgery (Minutes) in the Group: U/L TLIF ranged from 120 - 140. The Duration of Surgery (Minutes) in the Group: B/L TLIF ranged from 160 - 200.
There was a significant difference between the 2 groups in terms of Duration of Surgery (Minutes) (W = 0.000, p = <0.001), with the median Duration of Surgery (Minutes) being highest in the Group: B/L TLIF group

Table 2: Association between 'Group' and 'Blood Loss (mL)'

Blood Loss (mL)	Group		Wilcoxon-Mann-Whitney U Test	
	U/L TLIF	B/L TLIF	W	p value
Mean (SD)	296.67 (39.94)	436.67 (39.94)	3.500	<0.001
Median (IQR)	300 (275-300)	450 (400-450)		
Min - Max	250 - 400	400 - 500		

There was a significant difference between the 2 groups in terms of Blood Loss (mL) (W = 3.500, p = <0.001), with the median Blood Loss (mL) being highest in the Group: B/L TLIF group.

Comparison of the two Groups in Terms of change in VAS Score over time

In Group: U/L TLIF, the mean VAS Score decreased from a maximum of 7.47 at the pre-Operative timepoint to a minimum of 1.33 at the 18 Months time point. This change was

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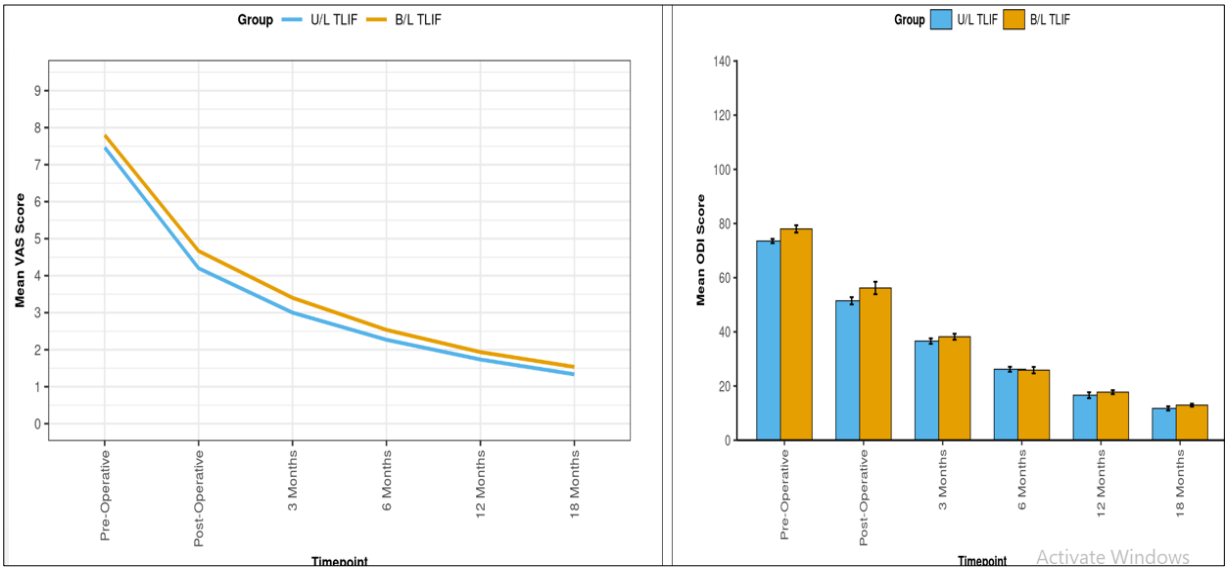
statistically significant (Friedman Test: $\chi 2 = 71.9$, p = <0.001).
In Group: B/L TLIF, the mean VAS Score decreased from a maximum of 7.80 at the pre-Operative timepoint to a minimum of 1.53 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2 = 72.5$, p = <0.001).
The overall change in VAS Score over time was compared in the two groups using the Generalized Estimating Equations method. There was no significant difference in the trend of VAS Score over time between the two groups



Comparison of the two Groups in Terms of change in ODI Score over time

In Group: U/L TLIF, the mean ODI Score decreased from a maximum of 73.53 at the pre-Operative timepoint to a minimum of 11.73 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2 = 74.9$, p = <0.001).
In Group: B/L TLIF, the mean ODI Score decreased from a maximum of 78.00 at the pre-Operative timepoint to a minimum of 12.93 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2 = 74.9$, p = <0.001).
The overall change in ODI Score over time was compared in the two groups using the Generalized Estimating Equations method. There was no significant difference in the trend of ODI Score over time between the two groups.
Comparison of the two Groups in Terms of change in SF-36 over time
The two groups did not differ in terms of SF-36 at any of the timepoints.
In Group: U/L TLIF, the mean SF-36 decreased from a maximum of 84.87 at the pre-Operative timepoint to a minimum of 15.67 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2 = 75.0$, p = <0.001).
In Group: B/L TLIF, the mean SF-36 decreased from a maximum of 83.87 at the pre-Operative timepoint to a minimum of 15.60 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2 = 75.0$, p = <0.001).
The overall change in SF-36 over time was compared in the two groups using the Generalized Estimating Equations method. There was no significant difference in the trend of SF-36 over time between the two groups.

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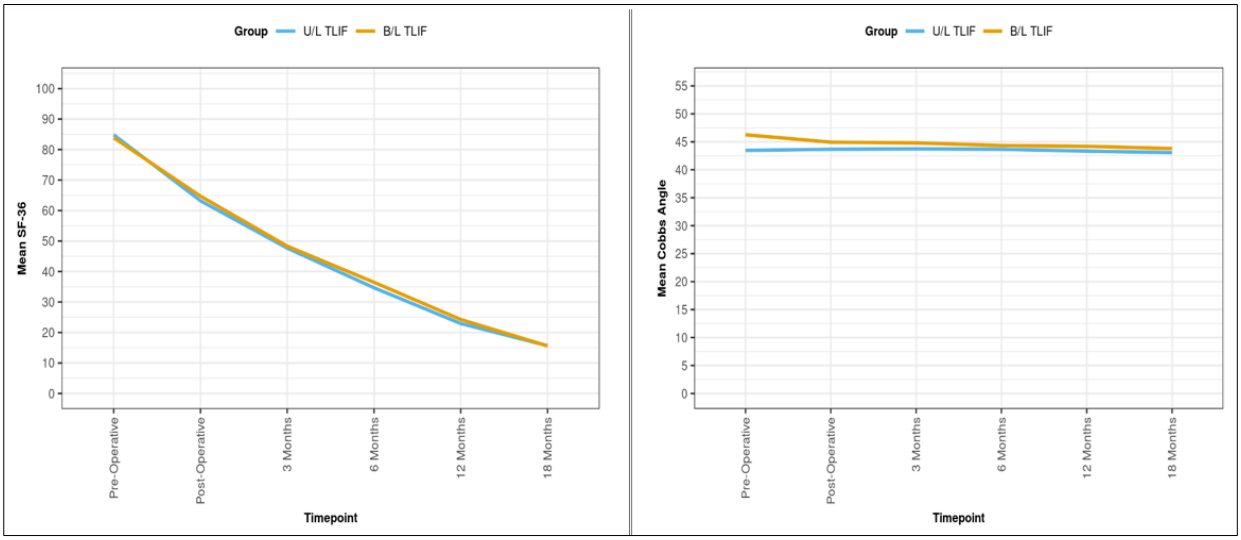

Comparison of the two Groups in Terms of change in Cobbs Angle over time
The two groups did not differ in terms of Cobbs Angle at any of the timepoints.
In Group: U/L TLIF, the mean Cobbs Angle increased from 43.47 at the pre-Operative timepoint to a maximum of 43.73 at the 3 Months timepoint, and then decreased to 43.07 at the 18 Months timepoint. This change was not statistically significant (Friedman Test: $\chi 2$ = 6.6, p = 0.253).
In Group: B/L TLIF, the mean Cobbs Angle decreased from a maximum of 46.27 at the pre-Operative timepoint to a minimum of 43.80 at the 18 Months timepoint. This change was statistically significant (Friedman Test: $\chi 2$ = 13.6, p = 0.019).
The overall change in Cobbs Angle over time was compared in the two groups using the Generalized Estimating Equations method. There was no significant difference in the trend of Cobbs Angle over time between the two groups.

Discussion

In 1982, Sir Harms *et al.* [1] introduced the technique transforaminal lumbar interbody fusion (TLIF). The TLIF procedure reduces the chances of neural retraction thus reducing the risk of potential complications like Dural tears and neurological injury [2, 19]. However, TLIF has an added advantage of preservation of contralateral interlaminar area which can be used as graft [2, 10]. Standard TLIF which is performed with bilateral Pedicle screw fixation has rigid fixation and excellent clinical outcomes [10-12, 19, 20]
Foley *et al.* in 2003, introduced the technique of minimally invasive TLIF [3]. Since then it has become an increasingly popular method of lumbar arthrodesis.conventional TLIF is associated with significant muscle stripping with neural and dural sac retraction that can adversely affect both short- and long term patient outcomes [3]. Minimally invasive lumbar fusion is performed via a muscle-dilating approach and significantly diminishes the iatrogenic soft tissue injury, intraoperative blood loss, duration of hospital stays and postoperative pain and aids for early rehabilitation and early return to daily activities [18, 21]
The pedicle screw and rod system is the widely accepted and practiced to achieve the most stable fixation in patients undergoing fusion surgery [4, 13, 22]. However, due to the excessive rigidity of the system, this instrumentation is also suspected to cause degeneration of adjacent segments [4, 13, 23, 24]. To reduce this rigidity, numerous clinical and biomechanical studies are performed to find the ideal construct [9, 14, 22, 25, 26]. Theoretically, the unilateral fixation is less rigid but stable enough to provide the native segmental stability which might prevent the adjacent segment from early degeneration. Toyone *et al.* [27] observed a lower incidence of adjacent segment degeneration in PLIF with unilateral pedicle screw fixation than that in PLIF with bilateral pedicle screw fixation during a 5 years of follow-up. Favourable results

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were reported for lumbar fusion in combination with a unilateral instrumentation system. Goel *et al*. demonstrated a difference in rigidity between the unilateral and bilateral instrumentation in their study suggesting that Unilateral instrumentation reduces the motion in flexion-extension, lateral bending and axial movements by 40%, 13% and 9%, respectively while in bilateral instrumentation reducing by 70%, 65% and 65% [9]. Kasai *et al*. showed that unilateral instrumentation offers only uneven fixation and this results in dispersion of rigidity depending on the direction of bending and rotation [25]. Schleicher *et al*. conducted a study testing unilateral, bilateral pedicle screws and facet stabilising systems with TLIF and concluded that bilateral pedicle screw instrumentation offers significantly more stability than unilateral pedicle screw instrumentation in the majority of test modes. However, they concluded that all tested stabilization methods could achieve at least the stability of the native segment [14].

Though less rigid biomechanically, unilateral fixation in TLIF may be sufficient for achieving native segmental stability and radiographic fusion and satisfactory clinical outcomes. However there are numerous studies showing that TLIF with unilateral Pedicle screw fixation obtained favourable clinical results and recommended it as an option for appropriately selected patients [4, 6, 7, 13, 15, 16, 25, 28-30]. However there are some reported cases of pedicle screw loosening and malposition, cage migration, postoperative scoliosis, non-union in patients undergoing unilateral pedicle fixation with MISS TLIF.

There are some retrospective studies showing that the inadvertent use of a bullet-shaped cage, undersized cage and the presence of scoliotic curvature were possible risk factors for cage migration [28]. In MIS-TLIF technique with the use of tubular retractor, it may impose restriction on the cage size and location, potentially increasing the risk of cage migration [15]. However, it can be avoided using interlaminar distractor or pedicle screw in the distracted manner.

Nonunion can be due to Less biomechanical stability in unilateral instrumentation. Union is defined as when there is a bony trabecular continuity between adjacent segments, less than 4-degrees of mobility between the segments on dynamic X-Rays, and an intact implant system. Non-union is defined as a visible gap, graft collapse and motion of greater than 4 degrees [31].

Risk of postoperative scoliosis in the unilateral group can be due to the difference in biomechanical properties. However, Choi found that the patients with postoperative scoliosis had a similar fusion rate and clinical result as the patients without scoliosis [15]. But the radiological outcomes were mostly obtained from short term follow-up. Further larger size RCT with longer follow up period and more systematic reviews are still needed to confirm these results.

In our study there were 2 cases of superficial surgical site infection (1 in miss u/l pedicle instrumentation system and 1 in miss b/l pedicle instrumentation system) which were treated conservatively with antibiotics and regular dressings. 1 case of recurrent low back pain in patient who underwent miss TLIF with unilateral pedicle screw stabilization which was treated conservatively. There were no complications in view of cage related problems (cage migration), stability related problems (adjacent segment degeneration, post op scoliosis).

In our study, group MISS TLIF with unilateral pedicle screw fixation had shorter operative time, less intraoperative blood loss, similar days of hospital stay, no statistical significant difference in post operative changes in VAS score, ODI score, SF 36 score, bridwell fusion index, cobbs angle leading to early mobilization, easy rehabilitation and return to activities of daily living as compared to the patients in group undergoing MISS TLIF with bilateral pedicle screw fixation.The main limitation of our study was small sample size, and need long duration of follow up over years.

Conclusion

MISS TLIF with unilateral pedicle screw fixation in a single level degenerative disc diseases is similar to bilateral pedicle screw fixation with added advantages of shorter operative time, less intraoperative blood loss, similar days of hospital stay, no statistical significant difference in

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post operative changes in VAS score, ODI score, SF 36 score, bridwell fusion index, cobbs angle leading to early mobilization, easy rehabilitation and return to activities of daily living.

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