Original Study

A prospective clinical study comparing MI-TLIF with unilateral versus bilateral transpedicular fixation in low grade lumbar spondylolisthesis

José-Antonio Soriano-Sánchez[1], Javier Quillo-Olvera[2], Sergio Soriano-Solis[1], Miroslava-Elizabeth Soriano-Lopez[1], Claudia-Angélica Covarrubias-Rosas[3], Javier Quillo-Reséndiz[2], Carlos-Francisco Gutiérrez-Partida[1], Manuel Rodríguez-García[1]

[1]Soriano Institute of Minimally Invasive Spine Surgery at ABC Hospital, Neurological Center, Santa Fe Campus, Mexico City, Mexico; [2]The Brain and Spine Care Center, Hospital Star Medica Querétaro, Blvd, Bernardo Quintana Arrioja Nº 4060 Col, San Pablo, Querétaro, Mexico; [3]Research Department, Anahuac Querétaro University, School of Medicine, Querétaro City, Mexico

Correspondence to: Javier Quillo-Olvera, MD. The Brain and Spine Care Center, Hospital Star Medica Querétaro, Blvd, Bernardo Quintana Arrioja Nº 4060 Col, San Pablo, ZIP: 76125 Querétaro City, Mexico. Email: neuroqomd@gmail.com.

Background: Minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) has become one of the standard techniques for approaching ipsilateral decompression, anterior column fusion, and posterior stabilization. This procedure is usually accompanied by the placement of bilateral transpedicular screws in the corresponding segment. The purpose of this study was to evaluate the clinical efficacy of unilateral screw fixation compared with bilateral fixation in patients diagnosed with low-grade symptomatic lumbar spondylolisthesis who underwent an MI-TLIF technique.

Methods: A prospective and comparative study was performed in 67 patients with grade 1 symptomatic lumbar spondylolisthesis. The sample was allocated on both unilateral fixation group (n=33) and bilateral fixation group (n=34). Clinical outcomes were evaluated using Oswestry Disability Index (ODI), visual analogue scale (VAS) for leg and back pain, and Short Form 36 Health Survey (SF-36), preoperatively, and at 1, 3, 6, and 12 months postoperatively. Changes over time and differences between the groups were analyzed. Statistical analyses included: Friedman test, Student's *t*-test and Mann-Whitney's U. A two-tailed P value of <0.05 was considered significant.

Results: During 1-year of evaluation there were no significant clinical differences between both groups.

Conclusions: Patients with grade 1 symptomatic lumbar spondylolisthesis treated with MI-TLIF with unilateral screw fixation had similar clinical results than those treated with bilateral fixation at 12 months postoperatively.

Keywords: Transpedicular screw fixation; minimally invasive transforaminal lumbar interbody fusion (MI-TLIF); surgical procedures; spine surgery

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Introduction

Transforaminal lumbar interbody fusion (TLIF) was initially described by Harms and Rolinger in 1982 (1). It has become one of the standard techniques for the decompression of the ipsilateral foramen and a proper interbody fusion. This technique offers the anatomical advantage of not requiring a great retraction of the thecal sac and its contents. High fusion rates have been reported. Clinical outcomes comparable to those obtained with posterolateral fusion (PLF) and posterior lumbar interbody fusion (PLIF) have been described. This procedure is usually accompanied by the placement of bilateral transpedicular screws in the

Table 1 Baseline characteristics of groups

Characteristic	Unilateral fixation group	Bilateral fixation group	P
n	33	34	*
Age†	52 (±16.51)	57.38 (±14.23)	0.274
Sex‡			
Female	16(45.7%)	19 (54.3%)	0.544
Male	17(53.1%)	15 (46.9%)	0.544
No. of operated levels‡			
1	20 (60.61%)	14 (41.18%)	*
2	11 (33.33%)	15 (44.18%)	*
3	1 (3.03%)	5 (14.71%)	*
Radiculopathy‡	31 (93.9%)	27 (79.4%)	0.081
PreOp Oswestry†	47.33 (±22.34)	45.08 (±17.35)	0.842
PreOp VAS leg pain§	8 (2.0)	6.5 (4.0)	0.003
PreOp VAS back pain§	8 (2.0)	9 (2.0)	0.933
PreOp SF-36§	44.44 (21.26)	46.82 (11.38)	0.251

†, values expressed as mean (± SD); ‡, n (%), §, median (IQR); *, not applicable.

Table 2 Side of radiculopathy

Side	Unilateral fixation group	Bilateral fixation group	P
Right	12 (50%)	12 (50%)	
Left	19 (55.9%)	15 (44.1%)	0.198
N/A	2 (22.2%)	7 (77.8%)	

Values expressed as n (%).

corresponding segment; this results in immediate rigid segment stabilization that will last while fusion takes places (2-4). Some authors have demonstrated that excessive stiffness of such a construct can jeopardize the fusion process due to graft resorption that is in hand due to lack of stress against end plates (5-7). Scientific evidence in the literature has demonstrated that unilateral transpedicular screw fixation, after fusion, produces radiological results comparable with bilateral fixation: this is done at a lower cost because less amount of implants are used (8-12). Minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) was initially described by Foley (13). It has similar radiographic fusion rates than open TLIF and a tendency to yield better clinical results in the immediate postoperative period (14). Some authors have demonstrated that unilateral transpedicular screw fixation is as effective as bilateral screw fixation after MI-TLIF (15,16).

We sought to evaluate the clinical efficacy of unilateral compared with bilateral transpedicular screw fixation after MI-TLIF technique in patients with low-grade symptomatic lumbar spondylolisthesis (Meyerding grade I, II). The main outcome measure was obtained with Oswestry Disability Index (ODI) at 12 months.

Methods

Study characteristics and patient population

A prospective and comparative cohort study was performed in 67 patients with low-grade symptomatic lumbar spondylolisthesis (Meyerding grade I, II) with facetary joint pain. The study was carried-out from May 1, 2012 to May 1, 2015. An institutional approval for this study was obtained. All patients were diagnosed with lumbar spondylolisthesis utilizing dynamic X-ray imaging (flexion-extension) and clinical axial pain. All patients were operated by the same surgeon. We excluded patients with previous spine surgery, tumors, metastases, spine infection, and rejection to participate in the present study. Patients were allocated to unilateral fixation group (n=33) and bilateral fixation group (n=34). Allocation of patients in groups was performed by consecutive sampling. Patients were assigned to a group during the initial visit. One-hundred percent of follow-up was achieved. Baseline characteristics of both groups are presented in *Table 1*. Side of radiculopathy was similar in both groups prior to surgery, *Table 2*. Operated segments ranged from L2-L3 to L5-S1. Patients were subjected from 1 to 3 operated levels. The median age of the patients was 59 [29–81] years old. The sample by sex was 35 female patients (52.2%) and 32 male patients (47.8%). Radiculopathy was diagnosed in 58 patients (86.6%) and no diagnosed in 9 patients (13.4%).

Surgical technique

With the patient in prone position under general anesthesia, use of continuous neurophysiologic monitoring, and acquisition of intensified fluoroscopy images with C-arm, surgical approach was performed on the most symptomatic

Table 3 Changes in outcome variables, unilateral fixation group

Variable	PreOp	PostOp				Δ**	P*
		1 mo.	3 mos.	6 mos.	12 mos.		
ODI†	47.33 (±22.34)	28.5 (±9.42)	21.83(±8.63)	15.67(±8.35)	11.5 (±8.14)	–35.83	<0.001
VAS leg pain§	8 (2.0)	2.5 (3.0)	2 (3.0)	1 (2.0)	1 (2.0)	–7	<0.001
VAS back pain§	8 (2.0)	3.5 (4.0)	3 (4.0)	2 (3.0)	1.5 (4.0)	–6.5	<0.001
SF-36§	44.44 (21.26)	52.39 (2.50)	49.89 (13.37)	53.62 (23.73)	62.25 (17.28)	+17.81	0.004

†, values expressed as mean (± SD); §, median (IQR); **, change from PreOp to 12 mos.; *, Friedman test; mo, month; mos., months.

Table 4 Changes in outcome variables; bilateral fixation group

Variable	PreOp	PostOp				Δ**	P*
		1 mo.	3 mos.	6 mos.	12 mos.		
ODI†	45.08 (±17.35)	21.42 (±15.38)	12.5 (±7.13)	9.92 (±5.39)	9.82 (±4.93)	–35.26	<0.001
VAS leg pain§	6.5 (4.0)	0.5 (1.0)	0(1)	0(0)	0(0)	–6.5	<0.001
VAS back pain§	9 (2.0)	3 (1.0)	2 (2.0)	1 (1.0)	1 (2.0)	–8	<0.001
SF-36§	46.82 (11.38)	60.56 (13.41)	60.56 (9.06)	60.56 (23.75)	60.56 (23.75)	+13.74	0.004

†, values expressed as mean (± SD); §, median (IQR); **, change from PreOp to 12 mos.; *, Friedman test; mo, month; mos., months.

side. Progressive tubular retractors were used. Minimally invasive surgical procedure was performed through an 18 mm diameter working cannula. After a complete lateral facetectomy, discectomy, and end-plates, preparation was performed and bone graft was delivered in the lumbar intersomatic space. A rectangular bullet-nose cage was inserted. Cannulated transpedicular screws were placed afterwards.

Outcomes

Clinical outcomes were evaluated using the ODI, visual analogue scale (VAS) for leg and back pain, and short form 36 health survey (SF-36), preoperatively and at 1, 3, 6 and 12 months postoperatively. Disability at 12 months postoperatively was measured using the ODI as the main outcome measure. Change over time and differences between groups were analyzed.

Statistical analysis

Variables were tested for normality. Parametric variables were expressed as mean (standard deviation), non-parametric as median (interquartile range). Categorical variables were described as absolute and relative frequencies. Overall change over time for repeated measures was analyzed with Friedman test. Comparison between groups was carried out with a Student's *t*-test and Mann-Whitney's U for parametric and non-parametric variables, respectively. Effect sizes were calculated between group analyses for parametric variables with Cohen's d. Analyses, graphs, and tables were performed with R Statistical Software V.3.1.0 (R Foundation for Statistical Computing, Vienna, Austria) and Microsoft Excel 2010. A two-tailed P value of <0.05 was considered significant.

Results

Baseline values and change over time

Along the evaluated period of 12 months, the unilateral fixation group had a diminution for the four clinical outcomes scales used: ODI (P<0.001), VAS leg pain (P<0.001), VAS back pain (P<0.001), and SF-36 (P=0.004), *Tables 3,4*. In the bilateral fixation group we also observed a decrease in the values of the same clinical scales: ODI

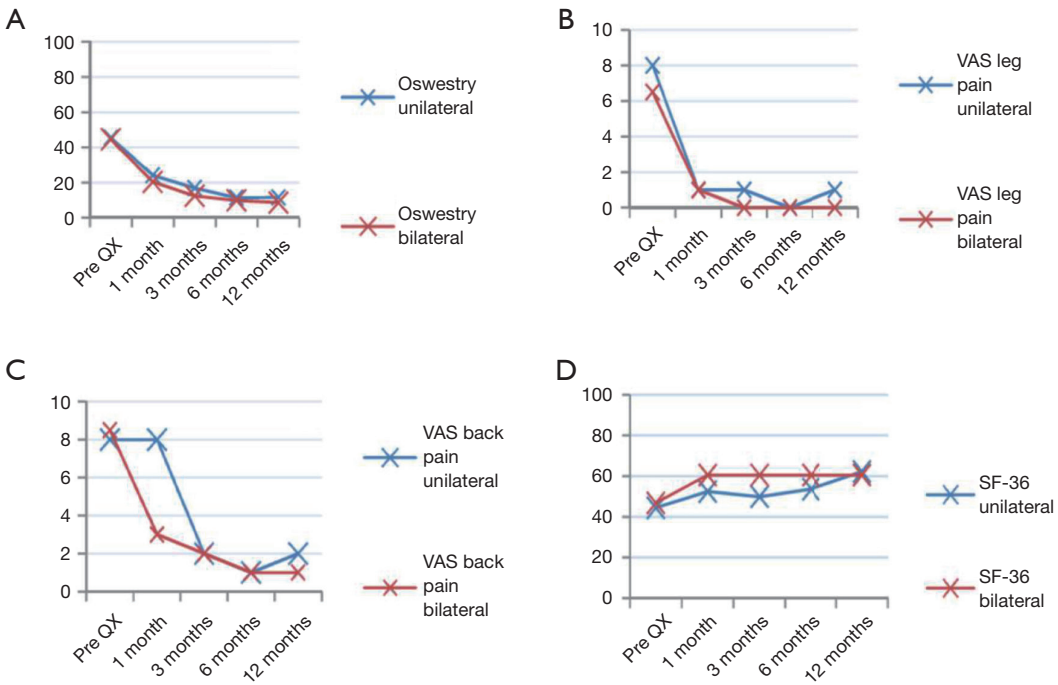

Figure 1 Comparison charts among groups regarding change over time. (A) Oswestry Disability Index (ODI); (B) visual analogue scale (VAS) for leg pain; (C) VAS for back pain; (D) short Form 36 Health Survey (SF-36).

(P<0.001) (*Figure 1A*), VAS leg pain (P<0.001) (*Figure 1B*), VAS back pain (P<0.001) (*Figure 1C*), and SF-36 (P=0.004) (*Figure 1D*).

Comparisons between groups

ODI was similar preoperatively (P=0.842) and so kept at 1 (P=0.210), 6 (P=0.466), and 12 months (P=0.189); at month 3, unilateral fixed group scored 9.33 points higher than the bilateral fixation group (P=0.023). VAS leg pain. Patients in the unilateral fixation group had an initial pain 1.5 VAS points higher than the bilateral group (P=0.003). At 1-month there was no significant difference (P=0.158). At 3, 6 and 12 months, the unilateral fixation group remained with 2 (P=0.013), 1 (P<0.001) and 1 (P<0.001) VAS points higher respectively than the bilateral fixation group. *VAS back pain*. Baseline VAS score was similar between groups (P=0.933), and thus maintained in the following evaluations at 1 (P=0.131), 3 (P=0.994), 6 (P=0.493) and 12 months (P=0.314). SF-36 values were alike between groups before surgery (P=0.251) and so continued to be at 1 (P=0.369), 6 (P=0.626) and 12 months (P=0.121); at month 3 patients in the unilateral fixation group had 10.67 less points (P=0.006) than the patients in the bilateral fixation group, *Table 5*.

Discussion

TLIF is a standard surgical option for patients with isthmic spondylolisthesis and axial pain. Screw fixation accompanies this procedure to provide stability. Bilateral screw fixation was first introduced but further research has demonstrated that unilateral screw fixation is a good option for maintaining stability of the spine. In 1992, Kabins reported similar clinical and radiographic fusion results between unilateral (16 patients) and bilateral (20 patients) procedures in a retrospective series of 36 patients with isolate L4–L5 fusions (8). In 2000, Suk designed a prospective study with 87 patients to compare bilateral with unilateral pedicle screw fixation in one or two fused segments (9). The conclusion was that unilateral is as effective as bilateral screw fixation in all items evaluated: blood loss, operating time, duration of hospital stay, clinical outcomes, complication rates and medical expenses. Recently, Xue compared clinical and radiographic outcomes of 37 patients fixed with unilateral pedicle screws and 43 patients fixed bilaterally; the study was carried-out with randomized methodology concluding that TLIF with unilateral transpedicular screw fixation is

Table 5 Comparison between groups

Measured	Unilateral fixation group	Bilateral fixation group	Difference	ES	P*
ODI[†]					
PreOp	47.33 (±22.34)	45.08 (±17.35)	2.25	0.059	0.842
1 mo.	28.5 (±9.42)	21.42 (±15.38)	7.08	0.267	0.210
3 mos.	21.83 (±8.63)	12.5 (±7.13)	9.33	0.501	0.023
6 mos.	15.67 (±8.35)	9.92 (±5.39)	5.75	0.379	0.466
12 mos.	11.5 (±8.14)	9.82 (±4.93)	1.68	0.124	0.189
VAS leg pain[§**]					
PreOp	8 (2.0)	6.5 (4.0)	1.5	NA	0.003
1 mo.	2.5 (3.0)	0.5 (1.0)	2	NA	0.158
3 mos.	2 (3.0)	0 (1.0)	2	NA	0.013
6 mos.	1 (2.0)	0 (0)	1	NA	<0.001
12 mos.	1 (2.0)	0 (0)	1	NA	<0.001
VAS back pain[§**]					
PreOp	8 (2.0)	9 (2.0)	–1	NA	0.933
1 mo.	3.5 (4.0)	3 (1.0)	0.5	NA	0.131
3 mos.	3 (4.0)	2 (2.0)	1	NA	0.994
6 mos.	2 (3.0)	1 (1.0)	1	NA	0.493
12 mos.	1.5 (4.0)	1 (2.0)	0.5	NA	0.314
SF-36[§]					
PreOp	44.44 (21.26)	46.82 (11.38)	–2.38	NA	0.251
1 mo.	52.39 (2.50)	60.56 (13.41)	–8.17	NA	0.369
3 mos.	49.89 (13.37)	60.56 (9.06)	–10.67	NA	0.006
6 mos.	53.62 (23.73)	60.56 (23.75)	–6.94	NA	0.626
12 mos.	62.25 (17.28)	60.56 (23.75)	1.69	NA	0.121

[†], values expressed as mean (± SD); [§], median (IQR); ES, effect size; *, student's *t*-test/Mann-Whitney's U; **, all differences are less than 3 VAS points, NA, not applicable, VAS, visual analogue scale.

a viable treatment option with better results in terms of operative time, blood loss, and hospital stay for single level disease (12). It is clear that in *in-vitro* models, the rigidity obtained by a bilateral fixation is superior than unilateral. Nevertheless, it has been demonstrated that the absence of certain degree of movement can yield to a fusion failure (7). In our study we found similar results between both groups treated, specially one year after surgery. MI-TLIF with unilateral transpedicular screw fixation is an excellent surgical option to treat patients with low-grade symptomatic lumbar spondylolisthesis (Meyerding grade I, II) and diarthrosis with facetary joint pain. We appreciate that VAS leg pain remained slightly higher in unilateral fixation group compared to the bilateral group. However, this can be explained because unilateral group patients had higher scores indicated in the preoperatively VAS leg pain score. *Figure 1B* depicts the decrease of radicular pain in both groups evaluated. We also consider that a difference below 3 points in a VAS pain scale might not be clinically significative due to subjective appreciation of pain. We

calculated effect sizes for differences between groups for the only parametric variable: ODI. In the *Table 5*, there are some statistically significant differences among VAS for back and leg scores. However, those differences are very minute (1-2 VAS points); this is a clear case where a statistically significant difference does not represent a meaningful clinical difference. Disability was the main outcome measured. It was evaluated at 1 year after surgical procedure in both groups. Upon the two group comparison, the difference found in the last ODI evaluation at 12 months was 1.68 points which translates to no clinical significance between unilateral and bilateral fixation groups. Although this is not a cost-effectiveness study, it is evident that MI-TLIF with unilateral screw fixation requires less hardware which in turn results in less cost. Finally, the main limitation of this study was the non-randomized nature by itself. Important strengths were that all patients were operated by the same surgeon and that there was a homogenous nature of the sample.

Conclusions

In conclusion, our statistical analysis demonstrated that patients with low-grade symptomatic lumbar spondylolisthesis (Meyerding grade I, II) treated with MI-TLIF with unilateral transpedicular screw fixation had similar clinical results than those treated with bilateral at 12 months postoperatively.

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None.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Informed Consent: The approval for this work has the number ISCCVM201602, and the informed consent of each patient within the study.

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