

Case Series of 11 Patients Operated with Axial-LIF Technique in a Single Center in Mexico

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Abstract

Introduction: Since the earliest description of spinal fusion in 1911 and later by Dr. Fred H. Albee, it has become one of the most commonly performed procedures by orthopedist and neurosurgeons. The spinal fusion is now used to treat a variety of indications, such as traumatic injuries, deformities, primary and secondary tumors, infections and degenerative conditions of the spine. The risk of iatrogenic injury during traditional anterior, posterior, and transforaminal open fusion surgery is significant. The axial lumbar interbody fusion (Axia-LIF) is a minimal invasive technique which uses the retroperitoneum-presacral anatomical corridor to fuse the lumbar vertebral bodies L4-L5-S1 avoiding manipulation of the annular ligament, paravertebral muscles and facet joints. **Methods:** In this retrospective series, we report all the cases made in the Centro Medico Naval in México City in two years. A total of eleven patients with degenerative disc disease and spondylolisthesis underwent Axia-LIF one or two level systems with a 36 months clinical and radiographic follow-up. The outcomes included Oswestry Disability Index (ODI) score and leg/back pain severity. Radiographic outcome was evaluated with dynamics and orthogonal x-ray, as well as lumbosacral tomography scan to evaluate fusion status. **Results:** Nine patients underwent Axia-LIF one level system (L5-S1) and the rest two levels system (L4-S1). Ten patients were fixated with transpedicular percutaneous screws and one with facets joints screws. No intra-operative complications were reported. The mean back pain severity improved 57% in 12 months, and the mean leg pain severity improved 50% in

the same time ($P < 0.001$). Mean ODI scores improved 58%, from $60\% \pm 16\%$ at baseline to $25\% \pm 8\%$ at twelve months ($P < 0.001$). At one year, a patient developed pseudoarthrosis that required posterolateral arthrodesis with transpedicular percutaneous screws. At 36 months monitoring, 100% patients presented a total interbody fusion in the tomography scans. At final follow-up, mean ODI score improved 73% ($16\% \pm 5\%$; $P < 0.001$). Conclusion: The Axial Lumbar Interbody Fusion has demonstrated to be a safe treatment for the degenerative disc disease L5-S1 and L4-S1. The patients who underwent one or two level Axia-LIF showed an improvement in ODI and back/leg pain severity scores, with no intraoperative complications. The use of this technique and its indications are still in controversy; nevertheless, its use has increased as for pathologies such as spondylitis, scoliosis, patients with residual pain with previous surgeries. We recommended complementary pedicular fixation to avoid complications and improved interbody fusion.

Keywords

Spine Surgery, Axial-LIF Procedure, Axial-LIF, CMN 20 de Noviembre, Spinal Fusion, Centro Médico Naval

1. Introduction

Since the earliest description of spinal fusion in 1911 and later by Dr. Fred H. Albee, it has become one of the most commonly performed procedures by orthopedist and neurosurgeons [1]. The spinal fusion is now used to treat a variety of indications such as traumatic injuries, deformities, primary and secondary tumors, infections and degenerative conditions of the spine [2]. The risk of iatrogenic injury during traditional anterior, posterior, and transforaminal open fusion surgery is significant. The axial lumbar interbody fusion (Axia-LIF) is a minimal invasive technique which uses the retroperitoneumpresacral anatomical corridor to fuse the lumbar vertebral bodies L4-L5-S1 avoiding manipulation of the annular ligament, paravertebral muscles and facet joints [3]. The spine surgery is base in known principles: alignment, stability, understanding the cause and maintaining or restoring function [4]. The standard open spine surgery requires big incisions, with several muscle dissections to approach the spine, as a consequence it brings great scars, denervated muscles and devascularized areas, causing muscle atrophy, chronic pain and disability to the patient [5]. All this translates into high costs for the health system. The minimal invasive approach to the spine minimizes the risk of open spine surgery achieving the same goal and allows preserving surrounding structures and function, avoiding the muscles atrophy [6]. In 2006, Ozgur and Pimenta *et al.* described a novel technique that limited the risk of muscular, radicular and dura mater injuries of posterior and lateral techniques, visceral and vascular injuries for anterior approach [7].

The advantages of this technique over the others are the preservation of the annular ligament, no dissection in the paravertebral muscles and a percutaneous

corridor without neural structures [8] [9] [10].

The objective of this study is to report the clinical and radiological outcome of the Axia-LIF technique, in the first series of cases reported in Mexico.

2. Methods

The present study reports the first cases made in Mexico, in the Navy Medical Center of Mexico City in two years. A total of eleven patients with degenerative disc disease and spondylolisthesis underwent Axia-LIF one or two levels system, seven women and four men; with 36 months clinical and radiographic follow up. Nine cases were placed one level system (L5-S1) and two cases two level system (L4-L5-S1). Outcomes included Oswestry Disability Index (ODI) score and leg/back pain severity. Radiological outcome were evaluated with dynamics and orthogonal x-ray, as well as lumbosacral tomography scan to evaluate fusion status of the arthrodesis at 3, 6, 12, 24 and 36 months. The present work has been guided by the ethical standards established globally such as the Declaration of Helsinki, the Declaration of Geneva of the World Medical Association, so that the best for the patient is considered, subordinating the knowledge and conscience of the physician must be subordinated to the fulfillment of that duty, the main purpose of research is to understand the causes, evolution and effects of diseases and to improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Medical research is subject to ethical standards that serve to promote and ensure respect for all human beings and to protect their health and individual rights.

Although the primary objective of medical research is to generate new knowledge, this objective should never take precedence over the rights and interests of the individual research subject.

3. Technique

First, the patient must undergo intestinal cleansing. In the operative room (OR), the patient has to be placed in prone position and proceeds to perform neurophysiological monitoring. Then the “C” arm of the fluoroscope is place towards the patient to get lateral and AP projections. A 2 cm incision is made in the lower part to the left paracoccygeal notch, to then proceed to perform the arthrodesis technique as it is described by Morotta *et al.* (the detailed description of the surgical technique is beyond de aim of the article) [11].

4. Results

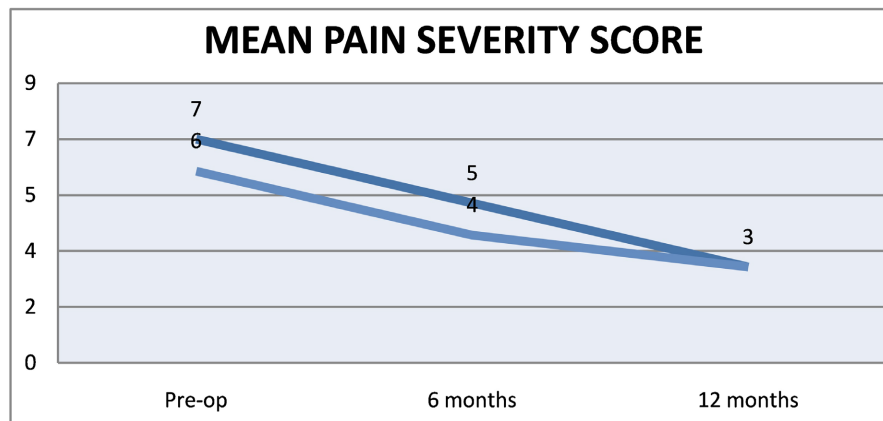
Eleven patients underwent surgery; Nine underwent a single level arthrodesis (L5-S1) and the other two patients a two-level arthrodesis (L4-S1). Ten patients were placed percutaneous pedicular fixation and one of them was placed facet fixation screws. There were no complications related to the approach (**Table 1**).

The mean lumbar/leg pain severity score improve from 7 (lumbar) and 6 (leg) to 3 (for both) in twelve months (**Figure 1**).

Table 1. List and data of each patient.

No.	Age	Gender	Diagnosis	Arthrodesis Level	Complementary Fixation		complications	
					Pedicule	Facet	During surgery	Postsurgery
1	41	m	DDD	1	x		No	No
2	54	m	SL	2	x		No	No
3	47	f	SL	1	x		No	No
4	57	f	DDD	1	x		No	No
5	50	m	DDD	1		x	No	Yes
6	48	m	SL	1	x		No	No
7	59	f	SL	1	x		No	No
8	60	m	SL	1	x		No	No
9	43	m	DDD	2	x		No	No
10	47	m	DDD	1	x		No	No
11	52	f	DDD	1	x		No	No

*DDD: Degenerative Disc Disease; *DLS: Degenerative Lumbar Spondylolisthesis.

**Figure 1.** Mean lumbar/leg pain severity score during the follow-up at 6 and 12 months.

The mean scores for ODI showed an improvement in general. The mean improve from $60\% \pm 16\%$ in the pre-op to $25\% \pm 8\%$ in twelve months (**Figure 2**).

From the total of patients, 10 patients had an adequate interbody fusion at twelve months, 1 patient developed pseudo-arthrosis in which the complementary fixation was made with facet screws, which subsequently required transpedicular fixation with complementary posterolateral arthrodesis.

The total follow up for each patient was 36 months, at the end, 100% completed an adequate intersomatic fusion and a mean ODI's score $16\% + 5\%$ (**Figure 2**). Also the foraminal height was measured, with an increase of more than 15% in all patients bilaterally.

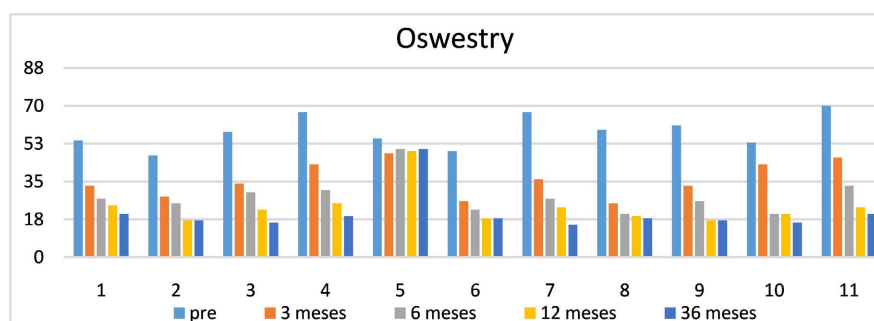


Figure 2. ODI Score for each patient previous surgery and their follow-up to 36 months.

5. Discussion

Biomechanical studies demonstrate the procedure is safe and provides a high rate of clinical success and fusion [12] and the increase in foraminal height of 15% - 20% after the axial LIF procedure [13].

In our study, there is a general tendency in all cases to increase this height by up to 15% bilaterally. Considering the largest dimensions in the 36th month during the follow-up, Pimenta *et al.* reports that some of complications such as pain post-op are more likely to see them from 24 months after surgery, in our casuistry there was no recurrence of pain except in 1 case that the arthrodesis was not achieved immediately [14].

Rates of 91% radiological evidence of stability and anterior fusion of follow up at 17.5 months have been reported [15]. In our study the rate of complete fusion was achieved in 90% of the cases.

Reports indicate a clinical improvement of 57% at 40 months of follow-up when assessing the Oswestry Disability Index (ODI) and pain severity. The results of bone fusion rates in a single level arthrodesis are comparable to conventional open techniques [16]. The mean percentage in ODI score improves 35% from the basal score in our series at 36 months following the surgery.

The indications of the axial LIF technique after its appearance and use have been growing as a viable therapeutic option in scoliosis. It is considered a safe procedure for the correction of this and the sagittal balance [17]. In long scoliosis correction fixation, L4-S1 has been routinely introduced, providing distal arthrodesis and adequate lumbosacral fixation [18].

A single level spondylolisthesis surgery with modification of the Bohlman technique with trans-sacro screw placement has been in use since 2015, reporting symptom improvement with a 2 year follow up, with the advantage of omitting bone grafts [19]. Although a complementary fixation technique was performed in 100% of our patients besides the Axial LIF procedure, we also found a significant improvement in ODI and pain severity scores in all patients, even the one who had pseudo-arthrodesis and required another type of posterolateral fixation during follow up.

Likewise, the indication of revision surgery due to residual pain of pseudoarthrosis in other techniques that require a stronger construct or previous

arthrodesis, results in a valid viable option and has similar fusion rates [20]. In our series, only one patient required posterolateral fixation after presenting pseudo-arthrodesis, but in the end of the follow up (36months) it has an improvement in the ODI and pain severity score. Even if necessary, removal of the previous implant is also technically possible in patients who require it [21].

In our country, the Axial LIF technique began to be used in our center in 2013 as an alternative management for one and two level (L5-S1/L4-S1) degenerative disc disease in well-selected patients in which the anterior and posterior indications were contraindicated, and for our series only two patients with two level disc disease were treated. Although the reports of two treated levels are subject of current study, the best indication to treat 2 levels is still under discussion. The twelve months follow up has a latent improvement, considering that the complications reported are plausible at 24 months with solid arthrodesis only in 22%, decrease in disc height and segmental lordosis gained by procedure [22]. We believe that our results are not very different from those reported in the world literature despite the fact that it is a small series of cases.

According to the existing international bibliography we conclude that the most of the patients presented had radiographic evidence of stable L5-S1 interbody cage placement and fusion at the last follow-up. The percutaneous paracoccygeal approach to the L5-S1 interspace provides a minimally invasive corridor through which discectomy and interbody fusion can safely be performed. It can be used alone or in combination with minimally invasive or traditional open fusion procedures. It may provide an alternative route of access to the L5-S1 interspace in those patients who may have unfavorable anatomy for or contraindications to the traditional open anterior approach to this level.

The results from this study have limitations. Firstly, it is a retrospective study that itself has its own biostatistical limitations. Second, because surgical indication remains a controversial issue, there is a selection bias in patients, so the results are influenced when selecting those patients in whom it is considered that they can have better outcome with this type of technique.

6. Conclusion

Axial Lumbar interbody fusion is a safe and effective procedure in the treatment of DLS, even though it offers a number of potential benefits in the treatment of degenerative disc disease, but the limited existing data doesn't identify an optimal candidate for the procedure. Studies with larger numbers of patients are needed, which may be difficult to achieve given that it is a procedure reserved for patients who are not candidates for traditional or new techniques with wide acceptance by spine surgeons. Since it is a procedure performed on patients who are excluded from other techniques, the number of patients available is considerably reduced, so efforts can be made to increase the confidence of the existing results by conducting multicenter studies with greater standardization in the inclusion criteria. However, the preliminary results and the current information

identify that this technique can be a valid and safe option for patients for whom traditional techniques are not an option.

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Conflicts of Interest

The authors declare that there are no conflicts of interest, no financial support of any kind has been received from any supplier or brand for the realization of this article and will not be obtained in the future.

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