

# Efficacy and safety of minimally invasive axial presacral L5-S1 interbody fusion in the treatment of lumbosacral spine pathology: a retrospective clinical and radiographic analysis

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**Summary.** *Background:* The surgical treatment of degenerative disc disease L5-S1 is considerably controversial. The purpose of this study was to evaluate the radiographic and clinical results of patients treated with AxiaLif<sup>®</sup> Technique (AxiaLif<sup>®</sup>, AMSSGroup, Italy) using a minimally invasive pre-sacral approach. *Methods:* From 2013 to 2018 a total of 52 patients have been treated (12 M, 40 F; mean age 46.3 years). Diagnosis included L5 isthmic spondylolisthesis low-grade dysplasia, primary and secondary degenerative disc disease. 43 patients have been followed for at least 2 years. Fusion assessment was based on plain radiographs and Brantigan fusion criteria at 1, 6, 12 and 24 months after surgery. All patients completed the VAS and ODI at baseline through last follow-up. *Results:* Clinical results showed good pain resolution. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, 77% at 3, 6, 12 and 24 months, respectively ( $p < 0.001$ ). ODI demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points ( $p < 0.001$ ). Complete fusion was demonstrated in 65% of cases, 30% partial fusion and 5% in the absence of bony bridges visible radiographically. We had two major complications, as 1 retroperitoneal hematoma and 1 spondylodiscitis, and one minor complication, as a superficial infection of the surgical wound. *Conclusions:* The surgical treatment of degenerative disc disease at L5-S1 with minimally invasive technique Axialif showed good radiographic and clinical outcomes with an acceptable rate of complications. Moreover, shorter hospitalization and faster functional recovery are adding factors to choice this technique. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Keywords.** degenerative disc disease, axialLIF, pre-sacral approach, fusion L5/S1

## Background

The treatment of debilitating lumbar disc disease with segmental instability is becoming a mayor challenge for surgeons treating spinal disorders. The need to combine fusion with mechanical stabilization has led over the past few decades to the development of various spinal devices. The key of the surgical success of the lumbar fusion is to find the right sagittal balance of the spine; an anterior support to the lumbar spine is often crucial to obtain the target required. This support permits to increase the rate of fusion with sensible reduction of failure of the implants. Although this can be preformed utilizing multiple different techniques, such as an anterior lumbar interbody fusion (ALIF), transforaminal lumbar interbody fusion (TLIF), posterior interbody lumbar fusion (PLIF) and axial interbody fusion (AxiaLif), each has its own set of challenges (1). An axial interbody fusion exploits the natural tissue plane separating the sacrum from the peritoneal contents, and a discectomy, bone grafting, and implantation of an axial-directed cylindrical implant, that can be performed using a 3 cm paracoccygeal minincision. The purpose of this study was to evaluate the radiographic and clinical results of patients treated with AxiaLif device for L5-S1 interbody fusion (AxiaLif®, AMSSGroup, Italy).

## Methods

At our centers from 2013 to 2018 we have treated with interbody fusion at L5-S1 through AxiaLif® Technique (AxiaLif®, AMSSGroup, Italy). The patients cohort is subdivided in 12 males and 40 females, mean age 46.3 years (range 21-67). Diagnosis included L5 isthmic spondylolisthesis low-grade dysplasia, primary degenerative disc disease, disc disease secondary to previous discectomy.

In choosing surgery were excluded patients who had undergone previous abdominal surgery, and patients in whom the anatomical curvature of the sacrum did not allow an ideal passage of the probe. 43 patients have been followed for at least 2 years. All patients were evaluated with plain radiographs (using Brantigan fusion criteria) and dynamic MRI pre-operative,

post-operative radiographs and in some selected cases with CT scan at 1, 6, 12, and 24 months after surgery. In addition, all patients completed the VAS and ODI at baseline through last follow-up. Our work has two main objectives: one is to assess the clinical condition of the patient and the improvement of its painful symptoms and the other is to analyze the degree of fusion of the arthrodesis. The evaluation of the success of fusion at 24 months between the two vertebral segments treated was done through standard radiographs and CT multiplanar. It can often be quite difficult to assess the degree of fusion through the simple x-rays but they are still able to give us some important clues radiographic nonunion such as implant migration, subsidence, or excessive movement of flexion-extension, other indices failure of arthrodesis may be a fracture of the sacrum or the erosion of the vertebral endplates. The CT scan is the gold standard test in the evaluation of the rate of arthrodesis, in fact through the sagittal, axial and coronal reconstructions we can accurately quantify the amount of new bone formation between the somatic endplates of the two adjacent vertebral bodies. Although open surgical exploration remains the standard of care for determination of fusion, it is impractical in most clinical situations. Static radiographs have long been used as a practical method of fusion assessment, but they tend to significantly overestimate the presence of a solid fusion. Dynamic radiographs improve accuracy but limitations include measurement reliability, disagreement on allowable motion, and the two-dimensional nature of radiographs. Ultimately, lack of movement at a fused segment does not confirm fusion. Radiostereometric analysis further improves accuracy; however, methodological demands make it largely impractical for routine use. CT is now widely accepted as the standard for noninvasive assessment of spinal fusion. Fine-cut imaging, multiplanar reconstruction, and metal artifact reduction have increased the ability to assess fusion on CT. However, significant concerns remain regarding the effects of high radiation exposure (2-4)

The radiologic assessment of interbody fusion is an important factor in the evaluation and management of patients after surgery. Accurate detection of an interbody arthrodesis is particularly important in patients who remain symptomatic after surgery when

the need for further intervention is considered. Furthermore, there is a need for a reliable radiologic tool that permits valid comparisons between different techniques and implants used for interbody fusion (5). In all patients enrolled in our study, we analyzed the arthrodesis through plain radiographs in two projections and the projections dynamics, in selected cases, we also run the TC that has allowed us to evaluate in somewhat more detail the degree of fusion between the vertebral bodies in which we performed arthrodesis. The use of plain static standard radiography has been the most commonly method to assess spinal fusion, the most important criteria for establishing fusion is the presence or absence of bridging trabecular bone across the segment (3). Instead, the items that indicated a lack of fusion are represented by graft resorption, implant subsidence or migration, implant integrity and position, and the presence of deformity under physiologic load (6). Although on the one hand the analysis of arthrodesis performed with the standard radiography is easily executable, inexpensive and does not create excessive damage to the patient in terms of accumulation of radiation, of the other in some conditions do not allow us to better analyze the degree fusion between the vertebral bodies as it is not always possible to see the trabecular bone bridges. Have been proposed different classifications for radiographic assessment of arthrodesis such as the classification of Bridwell et al, or that of Newton et al; Blumental and Gill have even compared surgical exploration with the radiograph and showed that only in 69% overall agreement between two methods. Furthermore, Kant et al have also shown that some cases that appeared frankly were not fused to surgical exploration (7-10).

In our study for the evaluation of arthrodesis by standard radiographs we used the classification of Brantigan and Steffee (11,12). As we have said previously, CT remains the most accurate tool to assess the degree of fusion between the two vertebral bodies involved in the fusion process. Computed tomography was used for the first time in the eighties for the evaluation of the arthrodesis. Over the years, techniques are increasingly sophisticated and we were allowed to have images more accurate and reliable information, such as to have very precise on the arthrodesis which is the target of our surgery, able to get a lock the mo-

tion segment. CT gives us several advantages, such as including fine-cut CT with 0.5 to 1-mm slices, helical reconstruction, and artifact reduction. Fusion status was evaluated based on 3-D CT scans and ranked to 5 grades according to the anterior fusion criteria described by Brantigan et al (grades 1 and 2, not fused; grade 3, uncertain; grades 4 and 5, fused). The fusion status was documented, and the consistency among different observers was excellent. Currently, however, there are disputes about whether the CT is the best radiographic method for the evaluation of the arthrodesis: in fact some authors as Fogel et al have shown that radiography and helical CT have equal accuracy in defining the interbody fusion in the lumbar confirmed by surgical exploration (13). These authors suggest that the X-ray would show incontrovertibly the presence of fusion or nonunion and that, therefore, the CT would provide no additional information with respect to the investigation rx standard. In addition there is also saying that you need to have a good CT in order to properly evaluate the merger as it should minimize the artifacts that are produced on the instruments. It should also be underlined the fact that an exam CT exposes the patient to a high number of radiation with the possibility of developing a tumor, in fact a single examination TC corresponds to about 240 standard Rx (14-16).

### **Surgical technique**

The surgical technique studied in this paper is called AxiaLif® Technique (AxiaLif®, AMSSGroup, Italy).

It has been introduced as a minimally invasive surgical technique to perform effective lumbosacral spine arthrodesis without anatomy disruption. AxiaLif device consists of a series of custom-made instruments for remote access to the anterior sacrum. The technique provides percutaneous access to the lumbar spine through the pre-sacral space. Patient is placed prone on a fluoroscopic table after induction of general anesthesia. The gluteal region is sterilely prepped and draped. The para-coccygeal notch is palpated and a 3 cm incision is made lateral to the coccyx. The incision could be done either on the right or on the left,

depending on the choice of the surgeon. After a careful section of the sacro-coccygeus ligament, the mesorectal space is exposed, a blunt trocar is advanced cephalad until the arch of the distal sacrum is encountered. It is then walked under the sacral arch anteriorly and advanced into the pre-sacral space. Biplane fluoroscopy is used to monitor advancement of the trocar. Once in the pre-sacral space the trocar is advanced along the midline anterior sacral surface with fluoroscopic monitoring until the trocar path creates a trajectory into L5. Once the position of the introducer trocar has been confirmed the blunt tip is exchanged for the sharp stylet which is then inserted into the sacrum. The partial discectomy is performed using various cutting-loop devices specifically designed for a trans-sacral approach. The devices are inserted coaxially and rotated to cut and fragment the disc nucleus. A cannula is inserted into the L5-S1 disc space to introduce the bone graft material for fusion. A 7.5-mm diameter drill is inserted through the working sheath and intervertebral space to penetrate directly into the L5 vertebral body. The AxiaLif cage is inserted and engaged into the L5 vertebral body along the predetermined trajectory. After the prosthesis has been fully threaded into the L5 vertebral body, the differential screw pitch mechanism of the device creates distraction across the L5-S1 disc space thereby restoring the height of the disc space, lordosis and increasing foraminal height. At the end of the procedure, an accurate washing of the approach is performed, and an drainage in aspiration way is placed. The second step of the procedure is to lock the L5-S1 facet joint, using 2 percutaneous screws, or percutaneously pedicular screws, to provide solid fusion in a circumferential way.

## Results

All patients before surgery were underwent to a careful clinical examination and were studied their instrumental examinations such as plain and dynamic radiographs, MRI that confirmed the presence of disc disease and degenerative changes at the L5-S1 segment. We excluded patients who had undergone pelvic surgery. The clinical results showed a good resolution of painful symptoms and a good recovery of the quality of

life. VAS back demonstrated an average reduction over baseline of 50%, 57%, 71%, 77% at 3 month, 6 month, 12 month and 24 months, respectively ( $p < 0.001$ ) (Table 1-2 and Table 7). VAS Leg demonstrated an average reduction over baseline of 42%, 58%, 69%, 75% at 3 month, 6 month, 12 month and 24 months, respectively ( $p < 0.001$ ) (Table 3-4 and Table 7). ODI demonstrated an average reduction over baseline of 38%, 51%, 67%, and 72% at the same time points ( $p < 0.001$ ) (Table 5-6-7). There were 27 subjects with 36 month data that demonstrated an average 80% reduction in pain and a sustained reduction in ODI by 73%. Complete fusion was demonstrated in 65% of cases, 30% partial fusion and 5% in the absence of bony bridges visible radiographically (Figure 1a-b,2,3,4a-b). Two major complications: 1 retroperitoneal hematoma, requiring surgical evacuation and 1 spondylodiscitis due to *Staphylococcus aureus*, resulting in the removal of the axial screw and targeted antibiotic therapy, with complete recovery at the end. One minor complication, a superficial infection of the surgical wound, which resolved with antibiotic therapy.

## Discussion

Degenerative disc and facet joint disease of the lumbar spine is common in the ageing population, and is one of the most frequent causes of disability. Degenerative disc disease is characterized by a cascade of events closely linked to each other resulting in a progressive deterioration of the intervertebral disc and severe anatomical changes of spine. In some cases turns out to be paucisintomatic disc degeneration and discogenic pain can be kept under control by medical therapy, in other cases, the structural damage is so severe that you have to act surgically. Currently there are many surgical techniques to treat the various diseases of the lumbosacral spine. Although there are different procedures, fusion still remains the treatment of choice, and in particular, interbody fusion guarantees an excellent anterior column support, a large area of footprint between the vertebral bodies and promotes proper alignment of anatomical structures, while also allowing an indirect decompression of the neural structures (17,18). The ALIF technique enables a complete disk

**Table 1.** VAS Back Mean and SD for 43 pts w/ 2-yr follow-up

Time	Mean	Std. Deviation	N
Pre	7.837	1.2522	43
3mo	3.953	1.9634	43
6mo	3.349	1.7027	43
9mo	2.744	1.5133	43
12mo	2.302	1.3008	43
24mo	1.767	1.3063	43

**Table 2.** VAS Back Mean, SE, and 95% CI for 43 pts w/ 2-yr follow-up

Time	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Pre	7.837	.191	7.452	8.223
3mo	3.953	.299	3.349	4.558
6mo	3.349	.260	2.825	3.873
9mo	2.744	.231	2.278	3.210
12mo	2.302	.198	1.902	2.703
24mo	1.767	.199	1.365	2.169

Note: All VAS Back improvements compared to baseline are highly significant ( $p < 0.001$ )

**Table 3.** VAS Leg Mean and SD for 43 pts w/ 2-yr follow-up

Time	Mean	Std. Deviation	N
Pre	3.674	2.5702	43
3mo	2.140	1.8203	43
6mo	1.535	1.4695	43
9mo	1.581	1.4513	43
12mo	1.140	.9900	43
24mo	.907	.9465	43

**Table 4.** VAS Leg Mean, SE, and 95% CI for 43 pts w/ 2-yr follow-up

Time	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Pre	3.674	.392	2.883	4.465
3mo	2.140	.278	1.579	2.700
6mo	1.535	.224	1.083	1.987
9mo	1.581	.221	1.135	2.028
12mo	1.140	.151	.835	1.444
24mo	.907	.144	.616	1.198

Note: All VAS Leg improvements compared to baseline are highly significant ( $p < 0.001$ )

**Table 5.** ODI Mean and SD for 43 pts w/ 2-yr follow-up

Time	Mean	Std. Deviation	N
Pre	.5019	.13980	43
3mo	.3116	.12726	43
6mo	.2465	.10652	43
9mo	.1984	.09621	43
12mo	.1679	.08294	43
24mo	.1381	.09760	43

**Table 6.** ODI Mean, SE, and 95% CI for 43 pts w/ 2-yr follow-up

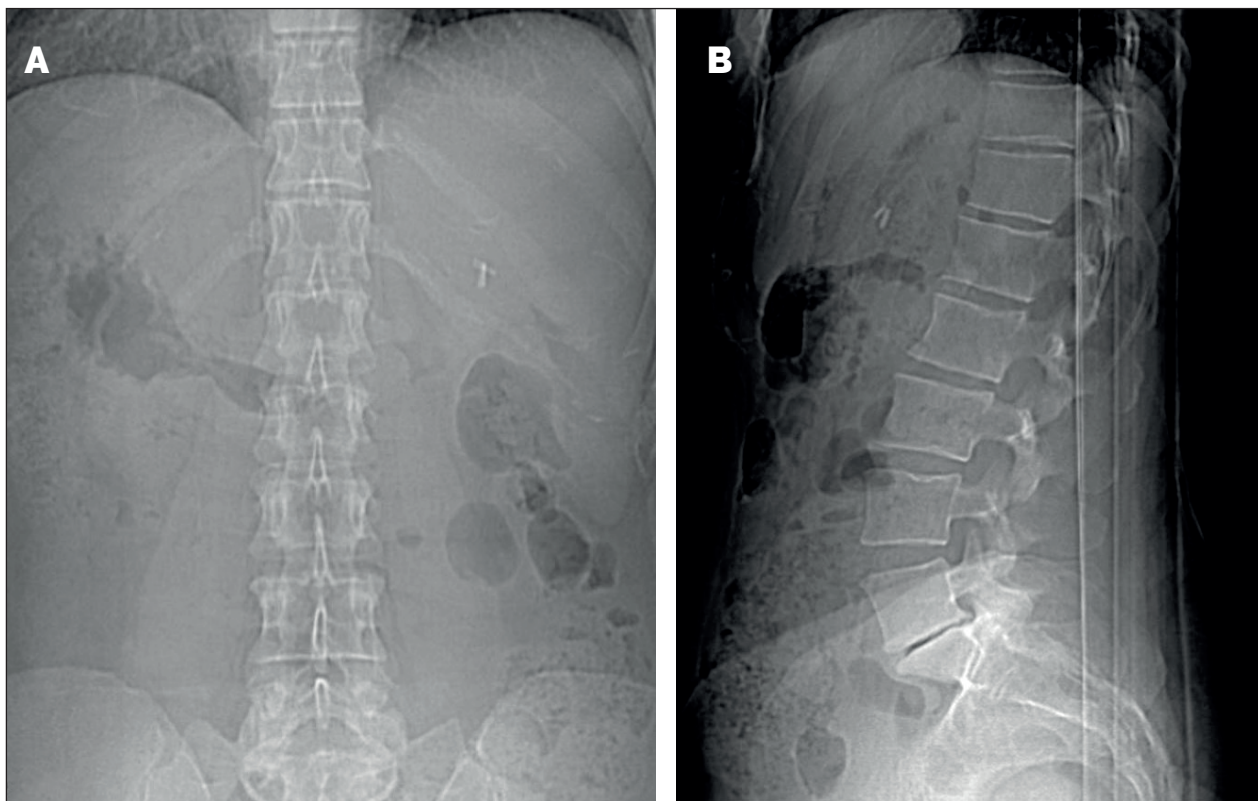
Time	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Pre	.502	.021	.459	.545
3mo	.312	.019	.272	.351
6mo	.247	.016	.214	.279
9mo	.198	.015	.169	.228
12mo	.168	.013	.142	.193
24mo	.138	.015	.108	.168

Note: All ODI improvements compared to baseline are highly significant ( $p < 0.001$ )

**Table 7.** Percent Improvements ODI, VAS Back, VAS Leg

Time	% Improvement		
	ODI	VAS Back	VAS Leg
3mo	38%	50%	42%
6mo	51%	57%	58%
9mo	60%	65%	57%
12mo	67%	71%	69%
24mo	72%	77%	75%

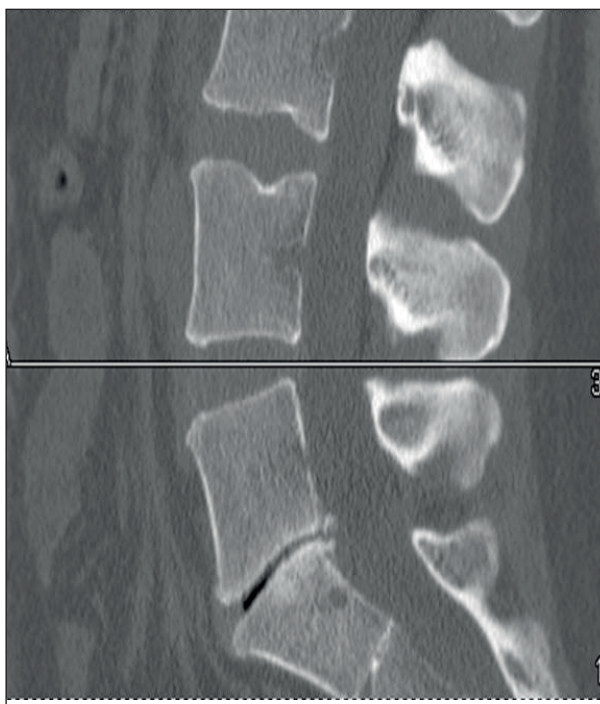
space preparation and significant restoration of foraminal height and lumbar lordosis (19); however, despite fusion rates of the lumbosacral junction of 97.2% (1), there is significant approach-based morbidity from manipulation of the neurovascular structures and abdominal viscera. In fact, the anterior lumbar interbody fusion (ALIF) is burdened by an ileus rate between 3% and 5.44% (20), an overall risk of vascular injury from 1.9% to 4.6% (21), a retrograde ejaculation that occurs at a rate of approximately 2.5% to 8.4% (22). The TLIF technique, although allows lumbosacral fusion rates of 99.2% (1) and eliminates the morbidity of the anterior approach, have also several complica-



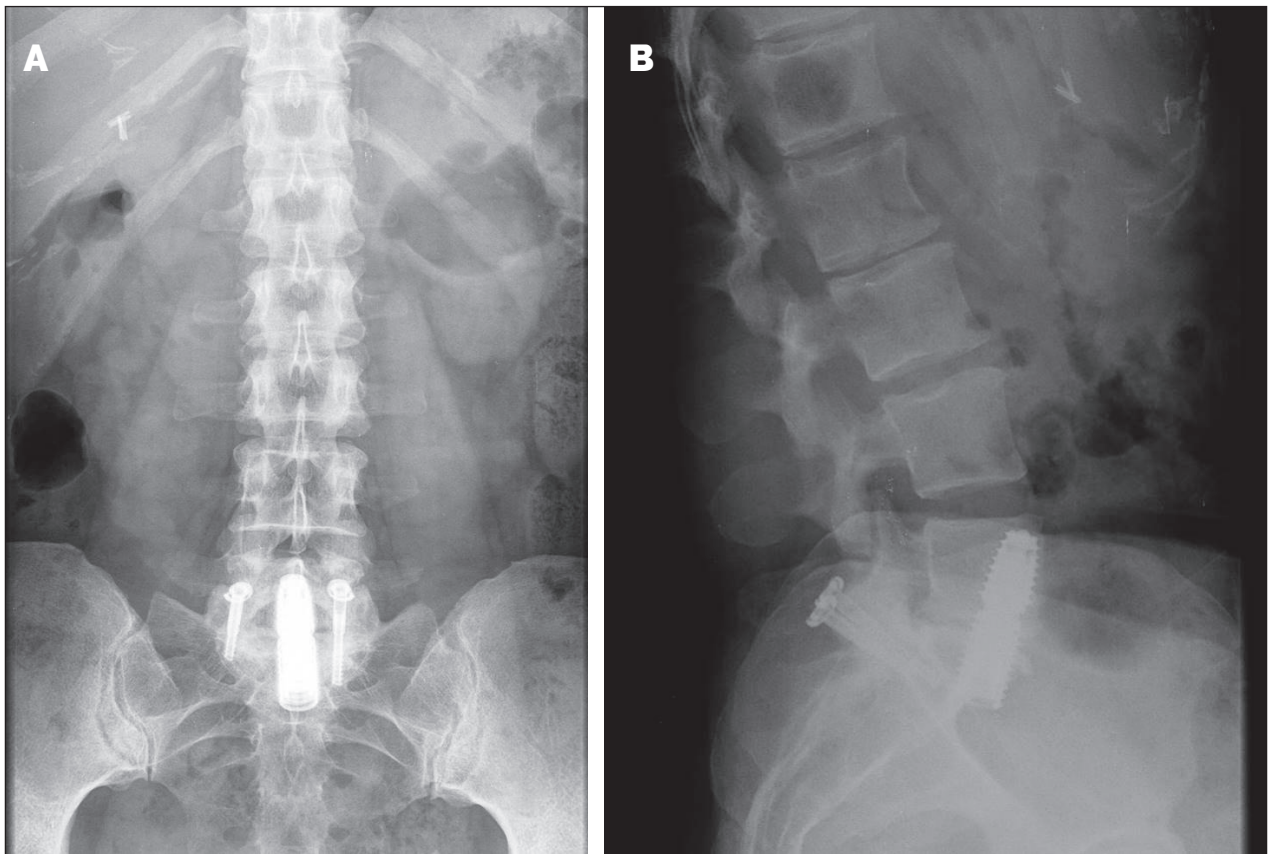
**Figure 1.** AP (a) and Lat (b) radiological views of lumbar spine shows degenerative disc disease L5-S1.



**Figure 2.** MRI sagittal image of lumbar spine shows degenerative disc disease L5-S1.



**Figure 3.** CT sagittal image of lumbar spine shows degenerative disc disease L5-S1.



**Figure 4.** Two years after implant of AxiaLif device AP (a) and Lat (b) radiological views shows L5-S1 interbody solid fusion.

tions, including radicular pain or neurological injury, due to nerve root manipulation, and a decreased ability to restore foraminal height and lumbar lordosis (23). Wong et al. (24) performed a retrospective study of a subgroup of 432 patients who underwent single level fusion using minimally invasive TLIF and observed 58 perioperative complications: 3.7% of durotomy, 1.4% of perioperative infection. The PLIF technique is one of the most traditional lumbar approach worldwide used. This technique has some disadvantages: there may be significant iatrogenic paraspinal injury caused by large incisions, dissections and muscle retraction that can lead to fatty degeneration of them and scarring; it may be difficult to correct coronal balance and to restore lumbar lordosis; in addition there could be an injury of nerve roots due to retraction, causing fibrosis and chronic radiculopathy (25). The Axialif technique is a new mini-invasive alternative to traditional spinal fusion. Schroeder GD et al. (1) in their

systemic review of the literature for the treatment of lumbosacral junction pathology using Axial Interbody Fusion showed overall fusion rates of 90.5%. Gundanna MI et al. (26) in a large case series had an overall complication rate of 1.3% of which 0.6% bowel injury, 0.1% presacral hematoma, 0.1% sacral fracture. In our case series, the Axialif technique showed effective high fusion rates of 95%, acceptable complication rate of 3.8% and an high value of patient satisfaction demonstrated by percent improvements of ODI, VAS Back and VAS Leg (Table 7). It's of paramount importance to address the right anatomical shape of the lumbosacral area for this particular technique. The contraindications are represented by previous surgery on the pelvis, infectious processes, active or high risk of infection, fever or neutrophilic leukocytosis, abnormal anatomy due to local organic malformations, severe osteoporosis which would preclude the success of the technique, suspected or documented metal allergy or

intolerance. The goals of this procedure are to improve neural decompression and primary stability that leads to fusion, thus reducing the risk of iatrogenic neural disorders and other complications. The percutaneous paracoccygeal approach to the L5-S1 interspace provides a minimally invasive path through which discectomy and interbody fusion can safely be performed. In addition to this approach, a posterior fixation (Open or Minimally Invasive Spine Surgery) should be used to increase stability and to provide fusion. The Axialif should be considered as an alternative technique to access the L5-S1 interbody space in those patients who have favorable anatomy or have contraindication to traditional open anterior approach.

## Conclusions

The surgical treatment of disc disease at L5-S1 with minimally invasive technique Axialif has led to good clinical and radiological outcomes. In our opinion, this method can be a good alternative to more aggressive approaches such as either the anterior retroperitoneal or the posterior approaches. In the case series presented, the low rate of complications, the high value of patient satisfaction and the efficacy of radiographic fusion justify the choice of this technique. Moreover, the low rate of complications leads to shorter hospitalization and faster functional recovery.

**Conflict of Interest:** Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Received: 29 September 2020

Accepted: 19 October 2020

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