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ORIGINAL PAPER

# Minimally invasive transaxial lumbosacral interbody fusion: a ten year single-centre experience

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**Abstract**
*Purpose* Our aim was to evaluate mid- and long-term results in a cohort of patients who underwent minimally invasive transaxial lumbosacral fixation and to identify clinical and other parameters that can aid in proper patient selection.
*Methods* Over a period of ten years, we assessed 164 patients who had a complete follow-up of a minimum of one year (average 54 months). On follow-up, we recorded clinical status, fusion status, visual analogue scale (VAS), Oswestry Lower Back Pain Disability Index (ODI) scores and patient satisfaction.
*Results* There were no intra- or peri-operative complications. Overall clinical success rate was 73.8 %. Only sex (female), working status (still working), body mass index (BMI) (lower) and presence of Modic II changes (absent) were correlated with a good result.
*Conclusions* Transaxial fixation is a safe, minimally invasive technique that can offer good results in patients with single-level degenerative disc disease (DDD) at the lumbosacral level, with minimal operative risk.

**Keywords** Transaxial · Fusion · Axialif · Discopathy · Back Pain · DDD

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## Introduction

Transaxial lumbosacral fixation (AxiaLIF®) as a minimally invasive technique to obtain fusion of the lumbosacral segment was introduced in 2004 as a novel approach. The technique was widely accepted by a number of surgeons both in the USA and the rest of the world, but due to the economic situation, issues with reimbursement and inadequate management, the company (TranS1 Inc., Wilmington, NC, USA and later Baxano Surgical, Inc., Raleigh, NC, USA) went out of existence. At present, there are efforts to revive the technique. In 2013, we described a six year experience with the technique with a mean follow-up of 21 months [1]. The aim of the study reported here was to present results after a longer follow-up, thereby paying attention to some of the other clinical parameters.

Back pain is an extremely common problem in any modern society and can be the result of degenerative disc disease (DDD). In most cases, the appropriate approach is conservative; in selected cases, operative treatment has been shown to be effective. This only applies to patients having had symptoms for ≥six months and having failed multimodality conservative treatment. Surgery is aimed at providing stability to the affected segment mostly by fusion. Surgical approaches for achieving fusion are traditionally posterior, anterior, transforaminal and extreme lateral. For each approach, there are different risk profiles related to tissues that need to be transversed in order to reach the target area.

Presacral access is a technique using the largely avascular and aneural corridor along the ventral side of the sacrum. Along this corridor, a safe access can be gained to the L5/S1 disc space. With special instruments, the disc space can be cleaned out and fusion can be performed using a special rod (Fig. 1).

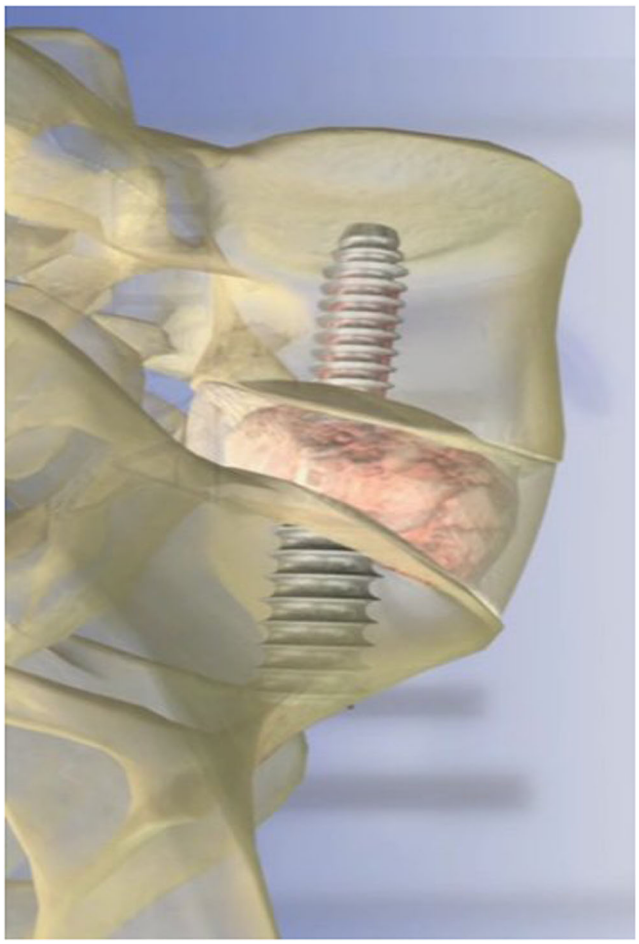

**Fig. 1** Transaxial lumbosacral fixation (AxiaLIF) rod and filling of the disc space

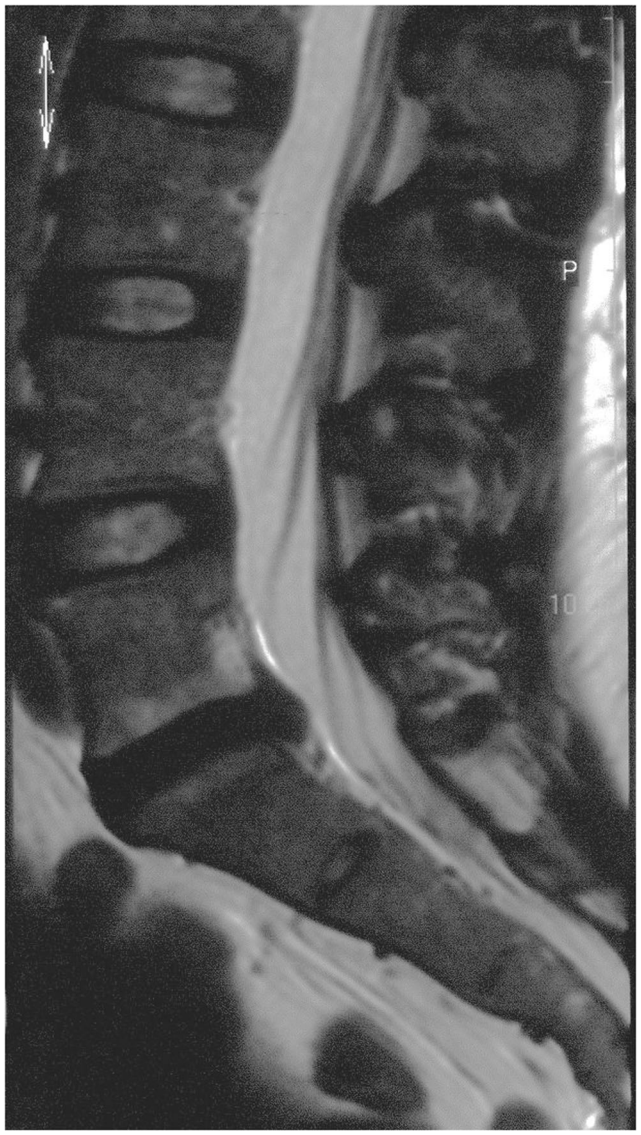

**Fig. 2** Pre-operative sagittal T2-weighted magnetic resonance image (MRI) with black disc, Modic II changes and some herniation at the lumbosacral level

Studies have shown a significant reduction in back pain (63 %), few complications and good fusion rates (87–94 %) [1–4] using this procedure. In this paper, we present results of 164 patients with a minimum follow-up of 12 (average 54 ± 35.28) months.

## Materials and methods

A total of 164 patients with a history of back pain for > six months and radiographically confirmed single-level DDD underwent lumbosacral interbody fusion using the transaxial technique. The minimum follow-up was one year, and in March 2016, there was a final follow-up that recorded virtual analogue scale (VAS) and Oswestry Lower Back Pain Disability Index (ODI) scoring lists, along with a questionnaire including socioeconomic factors and treatment satisfaction. Our research was approved by the Dutch research ethics committee.

Pre-operatively, each patient had a complete physical evaluation including a history of previous treatments. The diagnosis was confirmed by conventional X-rays and magnetic resonance imaging (MRI) (Fig. 2). Whenever feasible, provocative discography followed by anaesthetisation of the disc (Discoblock) was performed. MR images were also studied for abnormalities that could jeopardise the procedure, and Modic changes were recorded [5]. No patient had previous surgery at the index level other than discectomy, and there were no cases of clear instability. Other contraindications were osteoporosis, trauma, extreme obesity and age >80 years.

Patients were predominantly women (65 %), with an average age of 48 ± 9.13 years (25–67). Typically, there was a long history (average 31 ± 34.51 months) of unsuccessfully treated back pain, and in 80 % of patients, nonradicular leg pain was present; five patients (3 %) had previous discectomy at the index level. In 69 cases (the initial period), a stand-alone rod was used; the last 95 cases had additional fixation with transfacet screws. Mean operating time was 36 ± 6.65 min, blood loss was l<00 ml in all cases

**Table 1** Baseline population statistics

| Baseline | No. | Range | Standard deviation | No. analysed (of 164) |
|---|---|---|---|---|
| Nonradicular leg pain | 131 (79.9 %) | - | - | 164 |
| Sex | M = 58 (35.4 %) F = 106 (64.6 %) | - | - | 164 |
| Facet screw fixation | 95 (57.9 %) | - | - | 164 |
| Discectomy before AxiaLIF | 5 (3.1 %) | - | - | 164 |
| Age (years) | 48.09 | 25–67 | 9.13 | 164 |
| History of back pain (months) | 31.47 | 1–120 | 34.51 | 162 |
| Implant length (mm) | 44.77 | 40–60 | 4.27 | 132 |
| Operating time (min) | 35.77 | 24–60 | 6.65 | 132 |
| Hospitalisation (days) | 2.57 | 1–14 | 1.39 | 132 |
| VAS back pain severity | 79.96 | 40–100 | 12.49 | 164 |
| VAS leg pain severity | 43.11 | 0–90 | 30.1 | 164 |
| Oswestry Disability Index | 45.56 | 12–92 | 15.76 | 164 |
| Follow-up (months) | 54.05 | 12–120 | 35.28 | 164 |

*AxiaLIF* transaxial lumbosacral fixation, *VAS* visual analogue scale

and mean hospitalisation was 2.57 ± 1.39 (1–14) days. Baseline patient characteristics are summarised in Table 1.

## Surgical procedure

The operation was performed as described elsewhere [6]. A 2-cm incision was made either midline or just left of the paracoccygeal notch, and blunt finger dissection was used to displace the rectum away from the sacrum. A blunt dissecting instrument was used to carefully dissect the presacral space, advancing in a to-and-fro manner under fluoroscopic guidance and carefully adhering to the midline. A guide pin was docked usually at the S1/2 level. A cannulated drill created a bony channel in the sacrum and provided access to the L5–S1 disc. Cutters were used to extract disc material and to abrade the endplates. Bone graft substitute (one of the following: Actifuse™, Baxter International, Inc., Deerfield, IL, USA; Allomatrix®, Wright Medical Technology, Inc, Arlington, TN, USA; DBX®, Synthes, Inc., West Chester, PA, USA; Tutoplast® 4, Tutogen Medical, Inc, West Paterson, NJ, USA; NANOSTIM™, Medtronic, Inc, Minneapolis, MN, USA) was inserted into the disc space in combination with the bone obtained from drilling. After placing a larger working channel, the AxiaLIF® rod was advanced through the sacrum halfway into the L5 vertebral body. Since there were no cases of accompanying root symptoms in most cases, a nondistracting rod was used. Percutaneous facet screw fixation was added beginning in mid−2008. No other supplemental fixation devices were used in this series.

## Main outcomes and follow-up

All patients were followed up at six weeks and one year. Patients were assessed clinically, and VAS and ODI scores were obtained, as were plain X-ray films. In 123 patients, a computed tomography (CT) scan at one year was performed. In early 2016, patients were interviewed by phone and then completed a follow-up questionnaire. Fusion mass was assessed by independent radiologists with thin-slice (1- to 2-mm) high-resolution CT scan in coronal and sagittal planes at the one year follow-up visit. Fusion status was assessed on a 4-point grading scale as described by Tan et al. [7]; solid fusion was defined as radiographic evidence of bridging bone between L5 and S1 (Fig. 3). Working status, analgesic medication usage, patient satisfaction and additional treatments were determined at each follow-up and at the final interview. VAS (for back and leg pain) and ODI scores were collected as scores ranging from 0 to 100. Continuous data was reported as mean ± standard

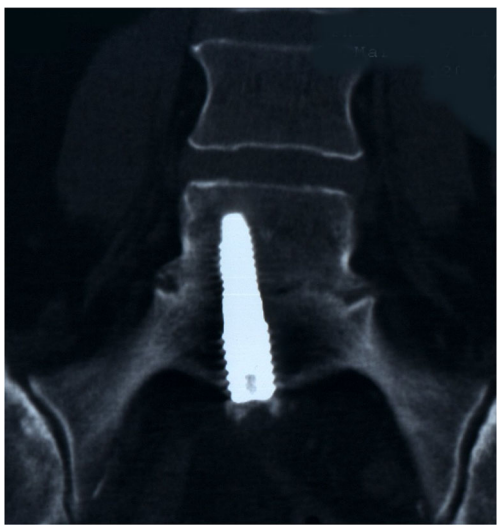

**Fig. 3** Computed tomography (CT) scan after 1 year showing solid fusion of the treated segment

deviation and categorical data as percentages. Change scores for VAS and ODI and the percentage improvement in those scores from pre-operative to last follow-up were calculated. Modic type endplate changes were assessed whenever a pre-operative MRI image was available ($n = 95$). Clinical success was defined as a ≥30 % improvement in the respective score.

### Statistics

Data were analysed using IBM SPSS Statistics V23.0 (SPSS, Chicago, IL, USA) and classified as continuous or categorical, the Shapiro-Wilk test was used to assess normality of distribution, independent or related *t* tests and analysis of variance (ANOVA) with post hoc Bonferroni correction were used for normally distributed data, whereas Mann–Whitney or Wilcoxon and Kruskal–Wallis tests with post hoc Bonferroni correction were used for nonnormally distributed data. Predictors of clinical success and solid fusion were analysed using univariate logistic regression. Significance was set at $P \leq 0.05$.

## Results

There were no intraoperative complications, including vascular, neural, urologic, or bowel injuries. In some cases, light transient paralytic ileus was observed, and in the first postoperative X-rays, some bowel distension was not uncommon. Symptoms did not qualify as complications in any of our patients. In the follow-up period, 24 (14.6 %) patients underwent further surgery, 15 (9.5 %) being at the treated level. Detailed information is listed in Table 2.

Back pain decreased from a mean VAS of 80 ± 12.49 preoperatively to 34 ± 28.74 at the last follow-up ($p < 0.001$), representing a decrease of 57.7 %. Leg pain decreased from a mean VAS of 43 ± 30.10 to 24 ± 29.41 at the last follow-up ($p < 0.001$) representing a decrease of 44.3 %. Mean ODI decreased from 46 ± 15.76 to 19 ± 18.96 ($p < 0.001$), corresponding to a decrease of 58.5 %. Clinical success was achieved in 73.8 % of patients for back pain and in 53.7 % for leg pain. ODI clinical success was 76.8 %.

Before treatment, 31.7 % of patients were fully able to work (or retired, housewife, student, etc.), 25.6 % were limited and 42.7 % were unable to work. At the last follow-up, 67.7 % were fully able to work and 15.2 % in a limited fashion (both $p < 0.001$). At final follow-up, 58.5 % of patients were able to fully discontinue the use of analgesic medication, 19.5 % reported daily use of analgesics, 64.6 % reported satisfaction and 84.2 % would likely or definitely have the procedure again.

The rate of solid fusion at the first year follow-up was 89.4 %. In 8.9 %, fusion status was unclear (no signs of clear bony bridging, but also no signs of loosening). In 1.6 % of cases, there was clear nonunion. Female sex was the only predictor of solid fusion [odds ratio (OR) 0.26; 95 % confidence interval (CI) 0.08–0.84; $p = 0.025$). There was no clear difference in fusion rates between the stand-alone group and patients who had additional facet screw fixation (Table 3).

The correlation of solid fusion and clinical success is not always clear; however, we found no statistical evidence of a difference in ODI change scores in fused compared with nonfused and indeterminately fused patients ($p = 0.20$). However, fusion status did account for important back pain reduction, as fused individuals showed a mean VAS back pain change score of 46 ± 28.3 while nonfused and indeterminately fused patients had a mean change score of 23 ± 20.5 ($p = 0.004$). Table 3 shows that the only predictor of clinical success in ODI reduction was body mass index (BMI) (OR 0.89, 95 % CI 0.81–0.98, $p = 0.019$), with a low BMI being more favourable.

Predictors of clinical success in VAS back pain severity were lower BMI (OR 0.89, 95 % CI 0.81–0.98, $p = 0.015$), higher age (OR 1.04, 95 % CI 1.0–1.09, $p = 0.036$) as well as pre-operative working ability, which had an overall significance of $p = 0.043$. Patients who were able to work fully had an OR of 3.06 (95 % CI 1.25–7.5, $p = 0.015$) and those who were limited in their ability had an OR of 1.78 (95 % CI 0.75–4.21, $p = 0.19$) of achieving clinical success in back pain reduction compared with patients who were unable to work pre-operatively. There was a significant difference in VAS back pain change scores only between patients who were still fully able to work and those who were not able to work at all ($p = 0.018$). Whether or not they could still work in a limited fashion or not at all made no difference ($p = 0.12$). The mean VAS change score was 52 ± 26.34 for fully

**Table 2** Re-operations during the follow-up period

| Type of re-operation | No. re-operations | No. patients | Percentage |
|---|---|---|---|
| Broken facet-screw removal | 1 | 1 | 0.61 % |
| Asymptomatic broken facet screw | 0 | 3 | 1.83 % |
| Additional fixation at index level | 11 | 11 | 6.71 % |
| Fusion at another level | 5 | 5 | 3.05 % |
| Total disc replacement at another level | 3 | 3 | 1.83 % |
| Anterior lumbar interbody fusion at L4/5 | 1 | 1 | 0.61 % |
| Implantation of a neurostimulator and related operations | 8 | 3 | 1.83 % |
| Discectomy at index level | 3 | 2 | 1.22 % |

**Table 3** Univariate baseline predictors of fusion and clinical success (≥30 % improvement)

| Baseline variable | *P* value (solid fusion) | *P* value (clinical success ODI) | *P* value (clinical success VAS back pain) |
|---|---|---|---|
| Sex | 0.025* | 0.17 | 0.16 |
| Duration of back pain | 0.10 | 0.08 | 0.21 |
| Discography | 0.59 | 0.99 | 0.97 |
| Facet screw fixation | 0.19 | 0.26 | 0.74 |
| Back pain severity | 0.22 | 0.93 | 0.49 |
| Working status | 0.66 | 0.45 | 0.043* |
| Age | 0.48 | 0.19 | 0.036* |
| Body mass index | 0.49 | 0.019* | 0.015* |
| Smoking | 0.77 | 0.30 | 0.5 |
| Modic changes | 0.89 | 0.081 | 0.14 |
| Leg pain severity | 0.90 | 0.20 | 0.26 |
| Oswestry Disability Index | 0.99 | 0.88 | 0.42 |

*ODI* Oswestry Lower Back Pain Disability Index, *VAS* visual analogue scale

* $P \leq 0.05$

working patients and 40 ± 29.78 for patients not able to work at all. This significant difference was not present in ODI change scores ($p = 0.41$). Table 4 shows the relationship between VAS and ODI scores and Modic changes. It appears that Modic II is a negative predictor for success.

Discography was performed in 85 (51.8 %) patients. It was considered positive when there was pain on injection of contrast and relief of pain following anaesthetisation, which was the case in 79 (48.1 %) patients. There was no significant correlation between results of discography and clinical success. Smoking history did not lead to any significant differences in either VAS back pain ($p = 0.84$) or ODI ($p = 0.96$) change scores.

## Discussion

This series is the largest single-centre experience with transaxial fusion and also having the longest follow-up. The study shows that the procedure is safe and provides a high rate of clinical success and fusion. Fusion rate in this series was 89.4 %. Although others have reported higher fusion rates with AxiaLIF®, many of those studies assessed fusion status

**Table 4** Effect of Modic changes and pre-operative working ability on visual analogue scale (VAS) and Oswestry Lower Back Pain Disability Index (ODI) change scores

| I<br>Modic-type endplate changes | J | Mean difference (I–J)<br>ODI change score | *P* value | Mean difference (I–J)<br>VAS back pain change score | *P* value |
|---|---|---|---|---|---|
| No Modic changes | Modic type 1 | 2.00 | 1.000 | 1.05 | 1.000 |
| | Modic type 2 | 13.79 | .022* | 10.92 | .53 |
| Modic type 1 | No Modic changes | −2.00 | 1.000 | −1.05 | 1.000 |
| | Modic type 2 | 11.79 | .015* | 9.87 | .40 |
| Modic type 2 | No Modic changes | −13.79 | .022* | −10.92 | .53 |
| | Modic type 1 | −11.79 | .015* | −9.87 | .40 |
| Pre-operative working ability | | | | | |
| Fully able | Limited | .53 | 1.000 | 3.38 | 0.63 |
| | Unable | −3.93 | .85 | 12.45 | 0.018* |
| Limited | Fully able | -.53 | 1.000 | −3.38 | 0.63 |
| | Unable | −4.46 | .76 | 9.07 | 0.12 |
| Unable | Fully able | 3.93 | .85 | −12.45 | 0.018* |
| | Limited | 4.46 | .76 | −9.07 | 0.12 |

* $P \leq 0.05$

exclusively with radiographs or with a combination of CT and radiographs [8, 9]. Discordance in fusion rates assessed with CT and radiographs is well known and is illustrated by the study by Bohinski et al., who reported a fusion rate of 100 % with AxiaLIF® using post-operative radiographs but only 88 % using CT [8]. After accounting for differences in imaging modality, fusion rates reported in our series were comparable with other studies of AxiaLIF®. Even if in our series there was no detectable advantage of additional facet-screw fixation, we believe that stand-alone use is not to be recommended. Placement of facet screws adds little to operating time and does not involve high risks or unacceptable extra costs. Other studies have found that facet-screw fixation can improve fusion rates and accelerate fusion [10, 11]. We used demineralised bone matrix for all patients. The use of bone morphogenetic protein (BMP) instead of only demineralised bone matrix is becoming increasingly popular, with recent studies suggesting that BMP can increase fusion rates and even improve clinical outcomes [12].

In order to make the procedure safe, detailed knowledge of the presacral anatomy is required. Diligent passage of the area is mandatory, since rectal perforation is a possible and serious complication. Gundanna et al. reported a 0.6 % bowel injury rate in patients treated with AxiaLIF®, with 42 % of these perforations due to frank surgeon error or deviations from recommended procedural steps [13]. In our series of 164 patients, no bowel perforations were detected. Mild post-operative ileus can sometimes be encountered, as is the case with all types of spinal fusion [14]. Blunt finger dissection and careful advancement of the dissecting instrument under fluoroscopy are essential. Recently, an inflatable cover has become available, but this was not used in this series. We put much emphasis on proper patient selection, to the nature and possible cause of back pain, as well as to anatomical features that may endanger the patient. We believe this selection is paramount to obtaining a good result. An analysis of the postmarket surveillance experience in >9000 patients treated with AxiaLIF®, including >8000 L5–S1 cases, reported an overall 1.3 % complication rate [6]. In our series, there were no serious complications; 15.8 % of patients required further operative treatment (9.15 % at the index level).

Patient selection is the key to clinical success. Many attempts have been made to identify predicting parameters to aid the process of patient selection. In our study, relevant predictors for clinical success were high age, female sex, low BMI and pre-operative working ability. Much attention has been paid to the predictive value of Modic changes [15–20]. Some studies indicate that Modic type I changes, as an expression of a still-active process, would be the best predictor, but in our study, this was not confirmed. Contrary to some opinions, in our current cohort, the presence of Modic II changes was associated with less reduction in VAS for back pain.

Another much debated test is provocative discography. It has been rated as being useless and valuable [21–24]. Some recent interest has been addressed to the value of disc anaesthetisation [25, 26]. In our study, all patients had discography when feasible, followed by a so-called discoblock as part of the selection process. We found no good correlation between discographic and clinical results.

Our study is limited by it not being randomised. Mean patient follow-up was 54 months, which represents one of the longest follow-up reports following AxiaLIF® surgery, providing insight into long-term clinical and radiographic outcomes and correlating with clinical and other parameters. It is reasonable to assume that the clinical course of a patient with an accomplished fusion will be no different than after fusions obtained by other techniques. It is, however, of interest to see the natural course of DDD as far as other levels are concerned and to evaluate how long a patient can benefit from a single surgery before relapsing into new problems. This study also shows that there are no clear reliable tests to predict fusion results. Patient selection must therefore rely on a combined physical, radiological and psychological evaluation.

Overall, single-level AxiaLIF® is a safe and effective means by which to achieve lumbosacral fusion in patients with symptomatic DDD.

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