

# CLINICAL AND RADIOLOGICAL OUTCOMES OF THE DEPUY SPINE ANTERIOR LUMBAR PLATE: A PRELIMINARY REPORT

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## INTRODUCTION

Anterior lumbar interbody fusion (ALIF) is frequently performed in the context of discogenic back pain or spondylolisthesis. The rationale of ALIF is to remove a potential pain generator and obliterate the movement of a painful segment<sup>1</sup>. Medium and long term clinical outcomes<sup>2,3</sup> appear satisfactory and ten and 20 year MRI assessments<sup>4,5</sup> after ALIF suggest the procedure itself does not lead to adjacent level disc degeneration. Fusion rates for stand-alone anterior cage average 50%, while this improves to 90% with the addition of pedicle screws<sup>6,7</sup>. However, posterior instrumentation adds significant potential morbidity. This study evaluates supplemental anterior plate fixation to an ALIF procedure as a way to stabilize the spine and avoid posterior surgery in lumbar interbody fusions.

The plate used in this study (Figure 1) was developed specifically for the low lumbar and lumbosacral spine. Made of titanium and low in profile, the plate has angled tabs to facilitate screw insertion through entry points in the anterior vertebral rims, thereby reducing the vessel retraction required at the L5/S1 and L4/L5 levels. Locking of the screws to the tabs was achieved with a split bushing.

## METHODS

Fifty-one patients with disabling low back pain who were considered suitable for anterior lumbar fusion were prospectively recruited to participate in the study. Diagnoses included disk disruption, central disk herniation, degenerative spondylolisthesis and lytic spondylolisthesis (Table 1). In most cases the pain source had been confirmed by lumbar discography. Patients with osteoporosis were excluded. Eleven patients had fusion performed at 2 levels. All had an ALIF performed through an anterior retroperitoneal approach. An interbody spacer packed with autogenous bone graft obtained from the anterior iliac crest was inserted and additional fixation was obtained by the insertion of the DePuy Spine anterior lumbar plate held in place with 4 locking screws. In addition to peri-operative data, clinical outcomes evaluated include the Low Back Outcome Score (LBOS), the Oswestry Disability Index (ODI), visual analogue scale pain scores (VAS), and the SF-36 score. Radiological assessment included plain x-rays at 3 months and thin-section CT scans at 6, 12 and 24 months. The primary radiological



**Figure 1**  
The anterior lumbar plate (precursor to AEGIS™ Anterior Lumbar Plate) used in this study. Note the angled tabs that facilitate screw entry through the anterior vertebral rims.

outcome measure was union, defined as CT scan evidence of continuous bony trabeculae joining adjacent vertebral bodies.

Statistical analysis was performed using paired Student's t-Test for sample means.

Demographics (51 Patients)	
Males	19
Females	32
Age	47 (27-64)
Weight	80.7 kg (57-115)
Level	
L2-3	1
L4-5	22
L5-S1	17
L4-5 and L5-S1	11
Diagnosis (62 Levels)	
Disk Disruption	45
Central Disk Herniation	4
Degenerative Spondylolisthesis	11
Lytic Spondylolisthesis	2

**Table 1**  
Demographic and surgical data.

## TECHNIQUE

A left-sided retroperitoneal muscle sparing approach<sup>8</sup> was performed to expose the anterior and antero-lateral annulus at the target level(s). The approach involved a transverse skin incision, vertical division of the left anterior rectus sheath and lateral retraction of the left rectus abdominis muscle. The retroperitoneal space was entered distal to the free border of the posterior rectus sheath. The L5/S1 disc was exposed distal to the bifurcation of the inferior vena cava (IVC). Anterior exposure of the L4/L5 annulus was achieved by retraction of the left common iliac vessels and IVC after the ascending lumbar vein and/or the L4 segmental vessels were coagulated or clipped and divided.

An interbody spacer packed with morselized autogenous iliac crest bone was inserted after disk space clearance, restoration of disc space height and endplate preparation<sup>8</sup>.

The attachment of annulus to the anterior vertebral rims was cleared with diathermy. After sizing, the plate was held in position (as close to the midline as vessel retraction allowed), screw tracts were prepared in the vertebrae with an awl and 30 mm screws were inserted and firmly locked to the plate. The entry point for screw insertion was through the cortical bone of the anterior vertebral rims. Antero-posterior and lateral fluoroscopy images were taken to verify implant positioning and screw length. Additional bone graft was then inserted on either side of the plate and where possible between the plate and the cage.

## RESULTS

Of 51 patients included in the study, 41 (51 levels) have completed one year of follow-up and 11 (12 levels) have completed 2 years of follow-up. The cohort includes 19 males and 32 females, with an average age of 47 years old (range 27-64). Mean operative time was 175 minutes, and mean blood loss less than 300 ml, including both 1 and 2 level surgeries.

At 12 months post surgery, there is a statistically significant improvement in the VAS (7.6 to 3.8;  $p < 0.001$ ) and the LBOS (18 to 35,  $p < 0.001$ ). At 24 months, there is an improvement in the ODI (49 to 32%,  $p = 0.02$ ), as well as the mental (44 to 53,  $p = 0.02$ ) and physical (28 to 36,  $p = 0.03$ ) components of the SF-36.

Unequivocal extensive bony union was demonstrated on hard copies of thin section CT reconstructions in 42 of 47 levels (89%) at 12 months, with an additional 5 levels (11%) demonstrating evidence of locked pseudoarthrosis. Four levels had incomplete radiographic data and were not available for review. At 24 months, 11/12 (91%) levels available for review with a digital high definition (DICOM) viewer were fused, with 1/12 (9%) assessed as a locked pseudoarthrosis.<sup>9</sup>

No patient needed spinal re-operation after the index procedure. Four patients had a small intra-operative puncture of the left common iliac vein that required a suture. One patient had a post-operative pulmonary embolism. Two patients were found to have minor screw back-out at the 3 month radiographic assessment that was less than 1mm and which remained unchanged on subsequent CT assessment at 6 and 12 months. Screw breakage without back-out and without plate displacement was detected on radiographs at 3 months in one large male patient with cage subsidence. The patient had a satisfactory clinical outcome.

Complications	
Pulmonary embolism	1
Peritoneal tear	2
Urinary tract infections	2
Puncture of left common iliac vein	4
Minor screw back-out < 1mm	2
Screw breakage	1

## DISCUSSION

This study has demonstrated that the DePuy Spine anterior lumbar plate is a device that can be safely implanted, with minimal peri-operative morbidity.

Satisfactory clinical outcomes and a high radiological union rate were obtained at 2 years, with an increase in fusion rates when compared with anterior spacer alone. Whereas in an earlier series<sup>8</sup> we experienced a significant re-operation rate for failure of fusion with stand-alone ALIF (without internal fixation), there have been no cases of re-operation in the current study.

The definition and evaluation of fusion after ALIF remains a controversial topic. Thin-section CT with sagittal and coronal reconstructions is considered the best non-invasive way to assess fusion. However the discrepancy between the assessment of digital images of fusion using hard copies and those seen with a DICOM viewer further highlights the difficulty fusion assessment poses.

No major complications related to the anterior instrumentation have been encountered in this series of 51 consecutive patients. However, in view of the two instances of minor screw back-out and the single case of screw breakage, modifications to the plate design were recommended. These design changes included increasing the plate thickness, increasing the

screw diameter and replacing the split bushings with positive cam locks. All of these changes were implemented in the AEGIS™ Anterior Lumbar Plate System prior to commercial release (Figure 2).

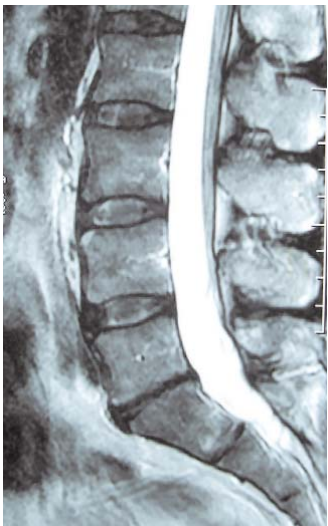
We consider the avoidance of the morbidity associated with posterior lumbar fusion surgery a major advantage of ALIF. The demonstrated safety and the promising short term clinical and radiological results of anterior lumbar plate fixation with ALIF warrant its continued use and evaluation.



**Figure 2**  
**AEGIS™ Anterior Lumbar Plate System.**

### CASE EXAMPLE

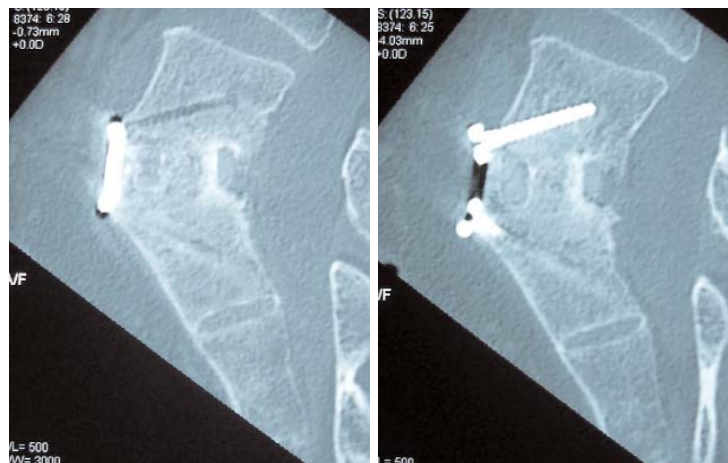
L5-S1 disk disruption in a 56 year old male with mechanical back pain unresponsive to non-operative treatment and with a concordant discogram.



**Figure 3a**  
Note the loss of disk height on the pre-operative sagittal T2-weighted MRI image.



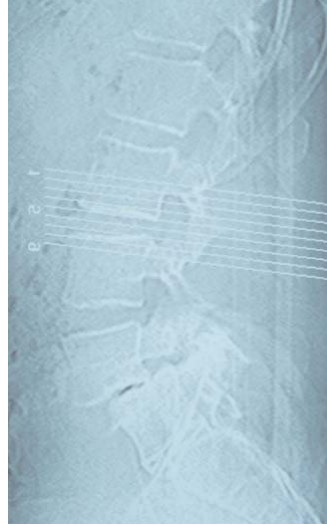
**Figure 3b and 3c**  
Post-operative AP and lateral radiographs at 3 months showing implant position and restoration of disk height.



**Figure 3d and 3e**  
Sagittal CT-scan images taken 12 months post-operatively showing solid bony union and preservation of alignment.

## CASE EXAMPLE

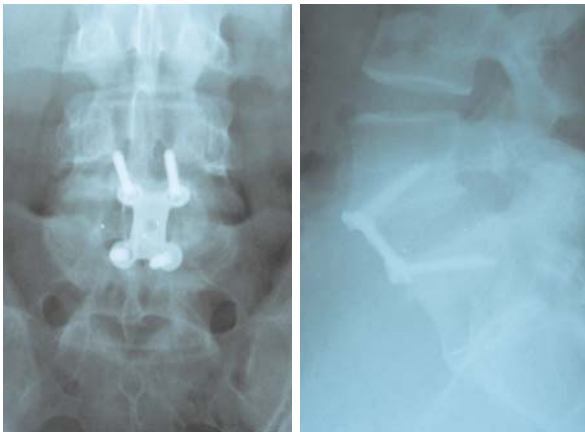
Isthmic spondylolisthesis at the functional lumbosacral level  
in a 43 year old male with a transitional vertebra.



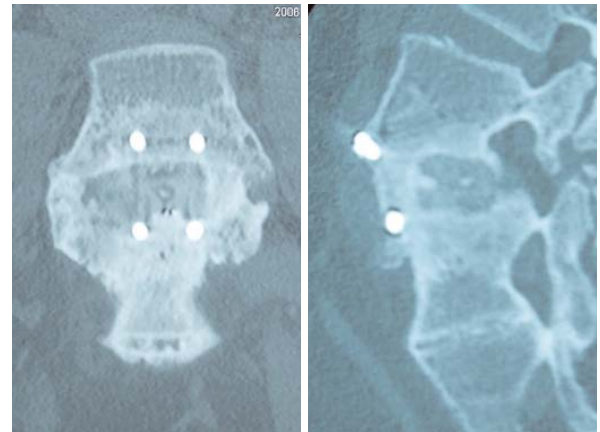
**Figure 4a**  
Preoperative CT-scan  
scout view showing  
the lumbosacral lytic  
spondylolisthesis.



**Figure 4b**  
Pre-operative  
sagittal T2-weighted  
MRI image



**Figure 4c and 4d**  
Post-operative AP and lateral radiographs at 3 months  
showing implant positioning, partial reduction of the  
spondylolisthesis and restoration of disk height.



**Figure 4e and 4f**  
Sagittal and coronal CT-scan images at 2 years  
showing bony consolidation antero-laterally.

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