# Hybrid Surgery: Fusion and Disc Arthroplasty is Superior To Two Disc Arthroplasties in the Lumbar Spine. Randomized Controlled Trial

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#### ABSTRACT

STUDY DESIGN: Prospective study.

**OBJECTIVE**: To study the validity of Hybrid construction (Anterior Lumbar Interbody Fusion) ALIF at one level and (Total Disc Arthroplasty) TDA at the adjacent level for two levels disc disease in the lumbar spine as an alternative surgical strategy compared to two levels disc arthroplasties.

**SUMMARY OF BACKGROUND DATA**: With growing evidence that fusion constructs in the treatment of DDD (Degenerative Disc Disease) may alter sagittal balance and contribute to undesirable complications in the long-term, total disc arthroplasty (TDA) slowly becomes an accepted treatment option for a selected group of patients. Despite encouraging early and intermediate term results of single-level total disc arthroplasty reported in the literature, there is growing evidence that two-level arthroplasty does not fare as well. Hybrid fusion is an attempt to address 2-level DDD by combining the advantages of a single-level ALIF with those of a single-level arthroplasty.

**CONCLUSION:** Clinical outcomes at 2 years show Hybrid fusion to be a viable surgical alternative for the treatment of 2-level DDD in comparison to two-level TDA.

**KEY WORDS**: Anterior lumbar interbody fusion, Degenerative disc disease, Hybrid construct, Lumbar spine, Lumbar fusion, Total disc arthroplasty.

ow back pain occurs in roughly 25% of the working population each year. Not surprisingly, it is the second most common reason for doctor visits(1). Arthrodesis is the established gold standard for the surgical treatment of refractory low back pain due to lumbar degenerative disc disease(9). While fusion has been demonstrated to reduce pain and improve disability scores, concerns persist over the long-term consequences of rigid fusion on the remaining free levels. These include accelerated disc degeneration and less frequently, spondylolisthesis(24). This process, also known as adjacent-level disease (ALD), often occurs at the level adjacent to the fusion. Although controversy over the true etiology of ALD continues (iatrogenic versus natural degenerative process), the surgeon must recognize that longer fusion constructs carry an increased risk for poor outcome(14,27,28,30).

Alternative surgical strategies for two-level disc disease include two-level total disc arthroplasties and hybrid fusions (fusion at one level and arthroplasty at an adjacent level) (5). The rationale behind artificial disc replacement for the treatment of degenerative disc disease is to preserve motion at the affected level. In turn, the excessive strain at the adjacent levels is diminished and in theory, decreases the risk for ALD (12,22). Despite encouraging early and intermediate term results of single-level total disc arthroplasty reported in the literature(10,17,18,29,31,32,34) there is growing evidence that two-level arthroplasty does not fare as well(19). Hybrid fusion is an attempt to address 2-level degenerative disc disease (DDD) by combining the advantages of a singlelevel anterior lumbar interbody fusion (ALIF) with those of a single-level arthroplasty. L5-S1 and L4-5 are by far the most common segments affected in degenerative lumbar disease. We have selected patients with 2-level lumbar disease where the inferior segment shows no signs of advanced facet arthropathy whereas the above segment is limited to degenerative disc disease. Consequently, a hybrid construct comprising an ALIF at the bottom and prosthesis at the top is as appropriate as two level disc prosthesis (Figure 1).

While the use of arthroplasty in combination with fusion has been previously reported, no clinical series on hybrid fusion have been published. In this paper, we present the clinical outcome of a prospective randomized series of 70 patients with a ratio 2/1 for hybrid and two discs prosthesis respectively.

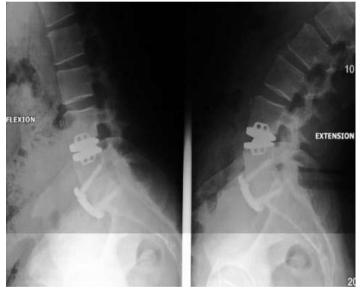


Figure 1: Flexion-extension X-rays of a patient with ALIF of L5-S1 and TDA L4-L5.

# **METHODS**

# Patient Evaluation:

70 patients were included between February 2003 and November 2007. Randomisation was performed with a ratio of two hybrid construct for one two level arthroplasty. All patients were followed-up for at least 2 years (range, 21-50 months). Each patient presented with at least 2level DDD (Figure 2) and at least one year of refractory back pain despite exhausting all conventional forms of conservative treatment. Thirty-three patients presented with referred, non-systematized leg pain. This is not to be confused with a true radiculopathy where the symptoms

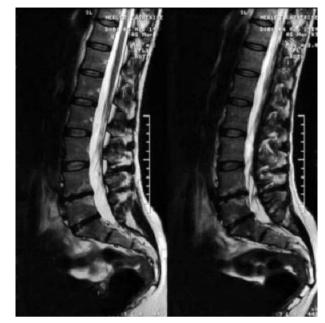


Figure 2: MRI showing L4-L5 and L5-S1 degenerative disc disease.

respect a distinct dermatomal distribution and the patients demonstrate a positive straight-leg raise test. Patients with true lumbar radiculopathies were excluded from this study. The relationship between back pain and DDD was determined by history, physical exam, and the presence of Modic 1 changes at the endplates on MRI. In less clear cases (eg. black discs), a discogram was performed. In this series 20 patients (28.5%) had discograms to assist with the diagnosis. Criteria for total disc arthroplasty included no evidence of gross instability (eg. absence of listhesis), good posterior musculature (>75% muscle/fat distribution), and facets with little or no sign of arthrosis. Facet injections were performed in cases where the source of pain was not clear.

Patients were randomized into two groups: fusion/TDA (group A) and double TDA (group B).

Group A: ALIF at L5S1 and TDA at L4-5 (Figure 3). ALIF was performed using an anterior impacted cage (Union cage or Perimeter cage, Medtronic, Memphis, USA) filled with autologous bone and with anterior plating with the Pyramid® titanium plate (Medtronic, Memphis, USA). The disc arthroplasty at the L4L5 level was performed using a Maverick<sup>®</sup> implant (Medtronic, Memphis, USA), metal and metal ball and socket prosthesis using the AMav design.

Group B: The disc arthroplasty at L5S1 and L4L5 was performed using a Maverick® implant through an anterior retroperitoneal video-assisted approach.



Figure 3: X-ray showing an ALIF of L5-S1 and a TDA L4-L5.

#### **Statistical Analysis:**

Statistical analyses were performed using SPSS version 13.0. A significance of outcome between matched data sets was calculated using the paired Student T-test. The Mann-Whitney U test, and 2 testing were used to assess potential baseline group differences regarding self-assessed and proportional data respectively. ANOVA was used to examine for within–group effects. The Mann-Whitney U test was conducted on score differences from baseline on each follow-up occasion. Statistical significance was set to P < 0.05.

#### Surgical Technique:

All patients underwent a left anterior retroperitoneal approach via a pfannelstein incision. Each patient was placed in the supine position with their legs spread apart and the buttock just off the edge of the bed (French position). This position decreases the pelvic tilt and increases the lumbar lordosis, ensuring excellent placement of the lumbar cage and the lumbar prosthesis. Any slight rotation of the lumbar spine was corrected under fluoroscopy. A combination of blunt dissection and bipolar cautery was used to perform the retroperitoneal dissection. Extreme care was exercised when mobilizing the ureter and hypogastric plexus during the exposure of the L5-S1 disc space. Levels above the sacrolumbar junction were exposed by carefully retracting the aortoiliac junction medially and by ligating the passing segmental vessels. The left ascending lumbar vein was divided as necessary. The sympathetic chain was carefully swept laterally. Specific self-retaining retractors were used to create a working corridor from the abdomen to the spinal column. A video-assisted endoscope was introduced through the left rectus muscles to improve visualization (2). An incisional drain was placed in all patients before closure.

#### **Outcome Measurement:**

All patients were assessed preoperatively and 6 months, 12 months, and 24 months postoperatively. The primary functional outcomes assessed before and after surgery were the Oswestry Disability Index and the visual analogue score of the back and legs. Patients are divided into 4 groups according to the percentage improvement between preop and postop ODI scores. Patients with an improvement of over 50% are considered as having an excellent outcome. Patients with an improvement between 25% and 50% are considered as having a good outcome. Patients with an improvement between -25% to 25% are considered unchanged. Patients with less than -25% change in their ODI are considered having a poor outcome. Postoperative complications were analysed as well. A decrease of more than 2 units on the VAS was considered a significant improvement.

#### Radiographic Assessment:

Preoperative and postoperative radiographs (full standing spine) were obtained in all patients including standing AP, lateral, flexion and extension films. A preop lumbar MRI was obtained in all patients. Several spinal parameters were measured including pelvic incidence, pelvic tilt, sacral slope, and regional lumbar lordosis using Optispine<sup>®</sup> software (Figures 2, 4 and 5).

#### RESULTS

#### **Demographics:**

Group A: a total of 42 patients underwent a hybrid fusion as follows: 35 L5-S1 ALIF/L4-5 prosthesis, 3 L4-5 ALIF/L3-



Figure 4: Radiographic assessment: pelvic incidence, pelvic tilt, sacral slope and regional lumbar lordosis were measured.



Figure 5: Preoperative MRI angiogram to indicate the position of the major blood vessels relative to the L4-L5 and L5-S1 disc space.

4 prosthesis, 2 L5-S1 ALIF/L4-5 prosthesis/L3-4 prosthesis, 1 L5-S1 prosthesis/L4-5 ALIF, and 1 L5-S1 ALIF/L4-5 ALIF/L3-4 prosthesis. All 42 patients were followed up to 2 years and the median follow-up was 26.3 months (range, 22-50 months). There were 25 females and 17 males. The mean age was 43 years (range, 31–60 years) and the mean BMI was 24.4 (range, 18.8 – 30.7). Excluding local injections, twenty-four patients (57.1%) had prior lumbar procedures. Eleven (26.2%) patients had at least one prior discectomy, 10 (23.8%) underwent at least one nucleotomy, and 9 (21.4%) had at least one treatment of facet rhizolysis. One patient had a bilateral L4 and L5 nerve root decompression (Table 1). Sixteen (42.9%) patients had no prior lumbar surgeries. The mean operating time was 2.5 h (range, 1.75 – 3.9 h) and mean blood loss was 100 cc (range, 50 – 300 cc).

Group B: a total of 28 patients underwent two-level disc prosthesis. All 28 patients were followed up to 2 years except one and the median follow-up was 25.2 months (range, 23-53 months). There were 18 females and 10 males. The mean age was 44.5 years (range, 29–59 years) and the mean BMI was 23.7 (range, 19 – 31.2). Excluding local injections, 10 had prior lumbar procedures. 6 patients had one prior discectomy, 5 underwent one nucleotomy, and 4 had facet rhizolysis. (Table 1). The mean operating time was 2.6 h (range, 1.5 - 3.7 h) and mean blood loss was 120 cc (range, 50 - 350 cc).

#### **Clinical Outcome**

#### Oswestry Disability Index

The clinical outcomes are summarized on (Table 2,3,4, and 5).

Group A: Mean preoperative ODI decreased from 47.0 (SD: 9.62) to 26.3 (SD:13.9) (P < 0.001), or a mean reduction of 20.7 (44.0.% improvement), at the 6-month follow-up. Modest improvement continued over the ensuing 18 months with ODI decreasing to 22.1 (SD: 16.5) at the two-year visit, or a mean reduction of 24.9 (53.0% improvement compared to preop ODI). All of these results are significant with P value <0.05.

Group B: Mean preoperative ODI decreased from 48.5 (SD: 9.01) to 30.1 (SD:12,7) (P < 0.001), or a 37.9% improvement), at the 6-month follow-up. Modest improvement continued over the ensuing 18 months with ODI decreasing to 28.1 (SD: 17,1) at the two-year visit, or a 42.1% improvement compared to preop ODI). All of these results are significant with P value <0.05.

Patients were further classified according to the extent

Number of Patients	Discectomy	Nucleolysis	Facet rhizolysis	Other
Group A	11 (26.2%)	10 (23.8%)	9 (21.4%)	2 (5%)
Group B	6	5	4	

Table 1: Prior Lumbar Procedures

#### Table 2: Oswestry Disability Index (ODI)

ODI	Mean Preop ODI	Mean Postop ODI	Percentage Change
Group A			
6 months	17.0.0.62	26.3 ± 13.9 (P<0,001)	44.7% (P<0,001)
24 months	$47.0 \pm 9.62$	22.1 ± 16.5 (P<0,001)	53.2% (P<0,001)
Group B			
6 months	40.5 0.01	30.1 ± 12.7 (P<0,001)	37.9% (P<0,001)
24 months	$48.5 \pm 9.01$	28.1 ± 17.1 (P<0,001)	42.1% (P< 0,001)

Difference between group A and B is significant at 6 months (P< 0.041) and at 24 months (P< 0.045)

of improvement in their ODI. The results are outlined in (Table 3). The number of patients with excellent outcome (or percentage improvement of ODI > 50%) increased in group A from 19 to 24 (45.2% to 57.1%) between the 6-month and two-year follow-up. Moreover, 24% of the patients showed good outcome at 2 years. Inversely, the number of patients with unchanged outcome decreased from 12 to 7 (28.6% to 16.7%). One patient (2.3%) had a poor outcome (worsening of preop ODI > 25%) at 2-year follow-up.

The number of patients with excellent outcome (or percentage improvement of ODI > 50%) increased in group B and was 25% at two-year follow-up. Moreover, 46.42% of patients showed good outcome at 2 years. Inversely, the number of patients with unchanged outcome was 21.42%. Two patients (7.14%) had a poor outcome at 2-year follow-up.

The difference between group A and B was significant at 2 years follow up, even if this does not constitute high significance. This is probably due to the small number of patients.

# Visual Analogue Score Back

The visual analogue score for the back is presented in (Table 4).

Group A: patients presented with low back pain with a mean preop VAS back of 7.0 (SD: 1.4). The mean VAS back decreased to 2.5 (SD: 2.2) at 24 months, or a mean reduction of 4.5 (improvement of 64.6%). These results are significant (P < 0.05).

Group B: mean preop VAS back of 6.9 (SD: 1.3). The mean VAS back decreased to 3.1 (SD: 2.0) at 24 months, or improvement of 55.08%. These results are significant (P < 0.05).

Group A	Poor (< -25%)	Unchanged (>-25% <25%)	Good (>25% < 50%)	Excellent (>50%)
6 months	0.0%	28.6%	26.2%	45.2%
2 years	2.3%	16.7%	23.8%	57.1%
Group B				
6 months	7.14%	-	-	-
2 years	7.14%	21.42%	46.42%	25%

Table 3: Breakdown on clinical outcome based on changes in Oswestry scores

Difference between group A (80,9%) and B 71,42%) for good and excellent results together is significant at 2 years (P< 0.037)

Group A	VAS Back Preop	VAS Back Postop	% improvement
2 years	$7.0 \pm 1.4$	$2.5 \pm 2.2$	64.6% (p=1.9 e-14)
Group B			
2 years	6,9 ± 1.2	3.1 ± 2.0	55.08% (P=3.2 e11)

Table 4: Visual Analogue Score for Back Pain (VAS BACK)

Difference between group A and B is significant at 2 years (P< 0.031)

Difference between group A and B was significant at 2 years follow up, even if this does not constitute high significance. This is probably due to the small number of patients.

## Visual Analogue Score legs

The visual analogue score for the legs is presented in (Table 5).

Group A: 33 of 42 (78.6%) patients presented with some form of referred leg pain at their preop visit. Patients with true radicular symptoms were not included in this study. Improvement in VAS legs was more variable and more modest than that of VAS back. It decreased from 4.1 (SD 2.2:) preop to 2.5 (SD:2.2) at the one-year and 2-year visit (improvement of 29.0%). P value is below 5% and the results are also significant.

One patients with no prior history of leg pain developed new onset of leg pain. Of these, one had a referred L5 pain after an L5-S1 ALIF and L4-5, L3-4 prosthesis.

Group B: Patients with true radicular symptoms were not included in this study. Improvement in VAS legs was more variable. It decreased from 3.9 (SD 2.0:) preop to 2.7 (SD: 3.0) at the one-year and 2-year visit. P value is below 5% and results are also significant.

# Comparison within the groups

VAS back and Oswestry scores were significantly better in group A when compared to group B even if the difference was limited in this short series.

## **COMPLICATIONS**

## **Approach-related Complications:**

Of the approach-related complications, a sympathectomy syndrome affecting the left leg was the most common in this series. Four out of group A, or 9.5%, experienced warmth and dryness of the left lower extremity. This occurs during the exposure of the levels above L5-S1. The placement of the prosthesis requires a wide opening, putting the sympathetic chain on the left side at risk for injury. Two patients in group B experienced warmth and dryness of the left lower extremity. There were no other complications.

# **Device-related Complications:**

No device-related complications were observed.

# **Outcome-related Complications:**

No non-union was established on the last postoperative X Rays. There was no radiolucency surrounding the cage or indirect signs such as screw breakage. No CT scan was performed to assess the fusion. Eight patients underwent an MRI for persisting pain to evaluate adjacent levels. No significant changes were found except in one case. This patient in group A required a second operation after an L4-5 ALIF/L3-4 prosthesis hybrid. After the failure of 18 months of conservative treatment for worsening left L5 pain (including foraminal injections), an L5-S1 decompression and posterior fusion was performed with an excellent outcome. Her past surgical history included a left L5-S1 discectomy several years before her initial visit at our clinic

Table 5: Visual Analogue Score for Leg Pain (VAS	AS LEGS)
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Group A	VAS Leg Preop	VAS Leg Postop	% improvement
2 years	4 1 + 2 2	$2.5 \pm 2.5$	(P=0.004)
Group B			
2 years	$3,9 \pm 2.0$	$2,7 \pm 3,0$	(P=0.003)

Calculations are based on those patients with only preop leg pain.

with near complete resolution of her sciatica. Although the L5-S1 disc space appeared healthy on MRI preoperatively, it is now clear that this level decompensated after placement of a hybrid construct superiorly. In retrospect, a hybrid construct adjacent to a postdiscectomy level might carry a risk for decompensation. Three patients in group B developed an abnormal motion at the level of disc prosthesis. When patients were in flexion on lateral view, one prosthesis was in extension and the other in flexion and the inverse phenomenon was seen in extension. This of course affects the motion and the lumbar lordosis but two had good clinical outcomes and one was unchanged. The load transmission and the position of the prosthesis according to the center of rotation are probably responsible for this strange adaptation.

# DISCUSSION

Fusion has been the gold standard in the treatment of back pain due to degenerative spine disease(9). Fusion is thought to improve back pain by eliminating sources believed to be responsible in back pain including the disc, facet joints, and the neural elements. The clinical outcome of lumbar fusions for the treatment of DDD varies widely in the literature(2,3,7,9,11,25). A meta-analysis comprising 14 studies of instrumented posterolateral fusion combined with an interbody fusion with a minimum of 2-year follow-up revealed a mean reduction in back pain of 49.1 % and a mean decrease in ODI scores of 20.6. In 15 series of stand-alone interbody fusion, the mean decrease in pain was 45.5%, and the mean decrease in ODI scores was 27.9 (10).

In recent , surgeons have begun to shift their strategy in treating DDD from that of fusion to that of motion preservation. There is growing evidence that fusion constructs may alter sagittal balance and contribute to undesirable complications in the long-term. Failed-back syndrome and adjacent disc disease are well-described postfusion conditions associated with a poor outcome(15,16). We believe motion preservation leaves the native sagittal alignment intact, allowing a patient to assume good posture and minimizing poor outcome in appropriate cases (12,19,23,33). A healthy posture is one that distributes gravity with the highest biomechanical efficiency and economizes the recruitment of postural muscles(6,26).

TDA has become a popular motion preservation technique in recent years.

TDA has been used to treat discogenic pain for over 20 years. It has slowly become an accepted treatment option for a selected group of patients. Several studies have now been published and their outcomes compare favorably with fusion(10,13,21,22,29,34). The reduction in mean ODI for single-level TDA has ranged from 24.0 (Prodisc) to 26.0 at 24-month follow-up and reduction of mean VAS back ranges from 4.1 (Charite) to 4.8 at 24-month follow-up (4,10,13,17,18,20,29,31,32,34). Although one-level TDA has demonstrated good clinical outcome, 2 or more level TDA constructs have been less impressive. Siepe showed a deterioration in postoperative results in both ODI and VAS for two-level TDA(18). In their series, the reduction in mean VAS back was 2.9 and reduction in mean ODI was 20%. Our series of 2 level TDA experiences agree with these findings. In contrast, a hybrid fusion can be a preferable alternative that offers a compromise between a 2-level TDA and 2-level fusion. Our series support this concept with a significant difference. A longer series is requested as the difference is not highly significant but the clinical outcomes of the hybrid group compare favorably to those for onelevel TDA and stand-alone ALIF published in the literature. At 2-year follow-up, the mean reduction in ODI was 24.9 and the mean reduction in VAS back was 4.5. This outcome is superior to that of 2-level TDA in our series and in Siepe and Park's series(29). Mean reduction in VAS leg is modest in both groups, but this is welcomed since the goal of surgery was focused on improving back pain and not leg pain.

Rate of complications in this series was low. A left leg sympathectomy syndrome was noted in both groups. Known complications such as abdominal hematomas, infections, vessel injury, ureteral injury, retrograde ejaculation, and intestinal injuries did not occur(2,25). The low rate of complications can best be explained by the senior authors' extensive experience in the anterior lumbar approach prior to performing hybrid fusions or two-level discs. We agree with other authors that the placement of TDA is very challenging and can lead to a difficult situation in inexperienced hands. The assistance of a general or vascular surgeon to provide the approach is strongly recommended in this case.

# CONCLUSION

Hybrid construction is a viable surgical alternative for the treatment of 2-level lumbar DDD. Clinical outcome after 2 years is very favorable to two-level TDA. Postfusion conditions such as adjacent-level disc disease may be minimized by introducing motion preservation at one level. Long-term follow-ups are necessary to confirm this. Analysis of sagittal balance is ongoing and could provide more accurate explanation.

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