

Hybrid construct for two levels disc disease in lumbar spine

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Abstract Prospective study. To study the validity of Hybrid construction (Anterior Lumbar Interbody Fusion) ALIF at one level and total disc arthroplasty (TDA) at adjacent, for two levels disc disease in lumbar spine as surgical strategy. With growing evidence that fusion constructs in the treatment of degenerative disc disease (DDD) 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 two-level DDD by combining the advantages of a single-level ALIF with those of a single-level arthroplasty. 42 patients (25 females and 17 males) underwent Hybrid fusion and had a median follow-up of 26.3 months. The primary functional outcomes were assessed before and after surgery with Oswestry Disability Index and the visual analogue score of the back and legs. Patients were divided into four groups according to the percentage improvement between preop and postop ODI scores. A total of 42 patients underwent a hybrid fusion as follows: 35 L5-S1 ALIF/L4-5 prosthesis, 3 L4-5 ALIF/L3-4 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. At 2-years clinical outcomes, mean reduction in ODI is 24.9 points (53.0% improvement compared to preop ODI). The visual analogue score for the back is 64.6% improvement. At 2-year clinical outcomes, Hybrid fusion is a viable surgical alternative for the treatment of two-level DDD in comparison with two-level TDA and with two-level fusion.

Keywords Total disc arthroplasty · Anterior lumbar interbody fusion · Lumbar spine · Degenerative disc disease · Hybrid construct · Lumbar fusion

Introduction

Low 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. [2] Anterior lumbar interbody fusion (ALIF) with bone morphogenic protein (BMP) in a randomised prospective study as an alternative for 360° arthrodesis provides excellent outcomes without lumbar muscular trauma [3, 4]. While fusion has been demonstrated to reduce pain and improve disability scores, concerns persist over the long-term consequences of a rigid fusion on the remaining free levels. These include accelerated disc degeneration and less frequently, spondylolisthesis. [5]. This process, also known as adjacent-level disease (ALD), often occurs at the level adjacent to the fusion. Although controversy over the true aetiology of ALD continues (iatrogenic versus natural degenerative process) the surgeon must recognise

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that longer fusion constructs carry increased risk for poor outcome [6–9].

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) [10]. 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 [11, 12]. Despite encouraging early and intermediate term results of single-level total disc arthroplasty reported in the literature [13–20], there is growing evidence that two-level arthroplasty does not fare as well [20]. Hybrid fusion is an attempt to address two-level degenerative disc disease (DDD) by combining the advantages of a single-level anterior lumbar interbody fusion (ALIF) with those of a single-level arthroplasty.

L5-S1 and L4-5 are the most common segments affected in degenerative lumbar disease. In our experience, we have found that in patients with two-level lumbar disease, the inferior segment often shows signs of advanced facet arthropathy, whereas the above segment is limited mostly to degenerative disc disease. This finding led to the idea of hybrid constructs comprising of an ALIF at the bottom and prosthesis at the top (Fig. 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 series of 42 hybrid fusions. Our findings reveal that hybrid fusion is

an effective alternative for the treatment of two-level disease.

Methods

Patient evaluation

A prospective study of 80 patients who underwent hybrid fusions between February 2003 and November 2007 was conducted. Of these, 42 patients (25 females and 17 males) operated between February 2003 and March 2006 were followed-up for at least 2 years (range, 21–50 months). Each patient presented with at least two-level DDD (Fig. 2) and at least 1 year of refractory back pain despite exhausting all conventional forms of conservative treatment. Thirty-three (78.6%) patients presented with referred, non-systematised leg pain. This is not to be confused with a true radiculopathy where the symptoms indicate 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 the absence of Modic changes, a discogram was performed. In this series 20 patients (47.6%) had discograms to assist with the diagnosis. Criteria for total disc arthroplasty included no evidence of gross instability (e.g. absence of listhesis), good posterior musculature (>75% muscle/fat distribution), and facets with little or no

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

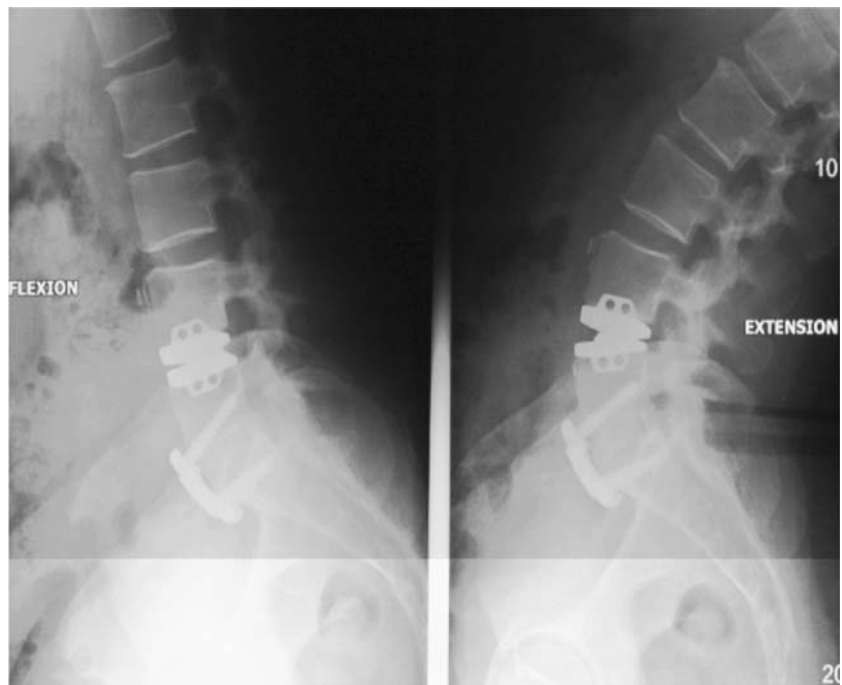




Fig. 2 MRI showing L4-L5 and L5-S1 degenerative disc disease

sign of arthrosis. Facet injections were administered in cases where the source of pain was not clear.

Surgical technique

All patients underwent a hybrid fusion, an ALIF at one level and a total disc arthroplasty (TDA) at the other (Fig. 3) using a left anterior retroperitoneal approach via a pfannenstiell incision. Each patient was placed in the supine position with his/her 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. The ureter and hypogastric plexus were mobilised and retracted to the right during the exposure of the 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 visualisation [21]. An incisional drain was placed in all patients before closure.

All implants were Medtronic (Memphis USA) devices. We used the Maverick disc prosthesis and for the ALIF construct we used a Pyramid plate, a Perimeter cage filled with BMP (Inductos).



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

Outcome measurement

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

Radiographic assessment

Preoperative and postoperative radiographs (full spine) were obtained in all patients including standing AP, lateral, flexion and extension films. A preop lumbar MRI and angio-MRI was obtained in all patients. Several spinal parameters were measured including pelvic incidence, pelvic tilt, sacral slope and regional lumbar lordosis using Optispine® software (Optimage Lyon, France). (Figs. 2, 4).



Fig. 4 Preoperative MRI angiogram to indicate the position of the major blood vessels relative to the L4-L5 and L5-S1 disc space

Statistical analysis

Statistical analyses were performed using SPSS version 13.0, significance of outcome between matched data sets was calculated using a paired Student *t* test. The significance was defined as *p* value < 0.05.

Results

Demographics

A total of 42 patients underwent a hybrid fusion as follows: 35 L5-S1 ALIF/L4-5 prosthesis, 3 L4-5 ALIF/L3-4 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 at 6 months, 12 months and 2 years except for one patient who was not present at the 12-month follow-up visit. The median follow-up was 26.3 months (range, 21–50 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). Postoperative Oswestry scores were obtained 6, 12, and 24 months postop. Excluding local injections, 24 patients (57.1%) had prior lumbar procedures. Eleven (26.2%) patients had at least one prior discectomy, ten (23.8%) underwent at least one nucleotomy, and nine (21.4%) had at least one treatment of facet rhizolysis. One patient had a bilateral L4 and L5 nerve root decompression and another underwent an L5 isthmic repair for a Grade I spondylolisthesis. (Table 1). Sixteen (42.9%) patients had no prior lumbar surgeries. The

Table 1 Prior lumbar procedures

	Discectomy	Nucleolysis	Facet rhizolysis	Other
Number of patients	11 (26.2%)	10 (23.8%)	9 (21.4%)	2 (5%)

mean operating time was 2.5 h (range, 1.75–4 h) and mean blood loss was 100 cc (range, 50 cc–300 cc).

Clinical outcome

Oswestry disability index

The clinical outcomes are summarised on Tables 2, 3, 4, and 5. 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 2-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.

Patients were further classified according to the extent 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 from 19 to 24 (45.2 to 57.1%) between the 6-month and 2-year follow-up. Moreover, 24% of 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.

Visual analogue score back

The visual analogue score for the back is presented in Table 4. All 42 patients in this study presented with low back pain with a mean preop VAS back of 7.0 (SD: 1.4). The mean VAS back decreased to 3.1 (SD: 2.3) at the 6-month follow-up, a mean reduction of 3.9 (improvement of 55.7%). The VAS back continued to decrease at each following visits to a mean of 2.5 (SD: 2.2) at 24 months, or a mean reduction of 4.5 (improvement of 64.6%). These results are significant too (*p* < 0.05).

Visual analogue score legs

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

Table 2 Oswestry disability index (ODI)

	Mean preop ODI	Mean postop ODI	Percentage change
6 months	47.0 ± 9.62 (30.0–72.0)	26.3 ± 13.9 (2.0–52.0)	44.7% ($p = 1.1 \text{ e-}11$)
12 months*		22.8 ± 14.7 (0.0–54.0)	51.1% ($p = 6.6 \text{ e-}12$)
24 months		22.1 ± 16.5 (0.0–62.0)	53.2% ($p = 6.4 \text{ e-}11$)

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

	Poor (<−25%)	Unchanged (>−25% < 25%)	Good (>25% < 50%)	Excellent (>50%)
6 months (%)	0.0	28.6	26.2	45.2
1 year (%)	0.0	21.9	26.8	51.2
2 years (%)	2.3	16.7	23.8	57.1

Table 4 Visual analogue score for back pain (VAS BACK)

	VAS back preop	VAS back postop	% improvement
6 months	7.0 ± 1.4 (3.0–9.0)	3.1 ± 2.3 (0.0–8.0)	55.7% ($p = 3.2 \text{ e-}11$)
1 year		2.9 ± 2.0 (0.0–7.0)	58.8% ($p = 9.2 \text{ e-}12$)
2 years		2.5 ± 2.2 (0.0–8.0)	64.6% ($p = 1.9 \text{ e-}14$)

2.2:) at preop to 2.7 (SD: 3.0) at 6 months, tapering off at 2.5 (SD:2.2) at the 1- and 2-year visits (improvement of 29.0%). P value is below 5% and results are also significant.

Two 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. The other patient presented with a non-radicular buttock/thigh pain after an L4-5ALIF/L3-4 prosthesis hybrid.

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 42 patients, 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. There were no complications such as retrograde ejaculation, hematomas, vessel injuries, nor were there ureteral injuries. No patients presented with new onset of neurological deficits. No deaths occurred.

Device-related complications

No device related complications were observed.

Outcome-related complications

One patient required a second operation after an L4-5 ALIF/L3-4 prosthesis hybrid. After failing 18 months of

Table 5 Visual analogue score for leg pain (VAS LEGS)^b

	VAS leg preop	VAS leg postop	% improvement
6 months	4.1 ± 2.2 (1.0–8.0)	2.7 ± 3.0 (0.0–10.0)	34.1% ($p = 0.037$)
1 year ^a		2.5 ± 2.9 (0.0–8.0)	39.0% ($p = 0.014$)
2 years		2.5 ± 2.5 (0.0–9.0)	39.0% ($p = 0.004$)

^a One patient was not present for the 12-month follow-up visit

^b 33 of 42 patients presented with preop leg pain. Calculations are based on those 33 patients

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 with near-complete resolution of her sciatica. Although the L5-S1 disc space appeared healthy on MRI, it seems that this level decompensated after placement of a hybrid construct superiorly.

Discussion

Fusion has been the gold standard in the treatment of back pain due to degenerative spine disease [2]. 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 [2–4, 21–26]. 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 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 [13].

In recent years 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 post-fusion conditions associated with poor outcome. [27, 28] As demonstrated by Le Huec et al. [29, 30] the motion level above a disc prosthesis presented a diminished lordotic curvature and the general shape of the spine had a better equilibrium according to the Roussouly classification. For 2 level TDA, however, there is an elevated risk for facet joint arthropathy [31]. A healthy posture is one that distributes gravity with the highest biomechanical efficiency and economises the recruitment of postural muscles [32, 33].

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 favourably with fusion. [12, 13, 19, 20, 34, 35] 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. [13–20, 34–36] Although one-level TDA has demonstrated good clinical outcome, two or more level TDA constructs have been less impressive. Siepe showed deterioration in postoperative results in both ODI and VAS for two-level TDA [20]. In their series, the reduction in mean VAS back was 2.9 and reduction in mean ODI was 20%. Our own multi-level TDA experiences agree with these findings. Given the findings above, a hybrid fusion can be a preferable alternative that offers a compromise between a two-level TDA and two-level fusion.

The clinical outcomes of this series of 42 hybrid fusions compare favourably to those for one-level TDA and stand-alone ALIF (see above). At two-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 two-level TDA [20]. Mean reduction in VAS leg was 1.5 (37.9% improvement) at 2 years. This improvement, however modest, 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 four patients

(9.5%). Known complications such as abdominal hematomas, infections, vessel injury, ureteral injury, retrograde ejaculation, and intestinal injuries did not occur [21, 22]. The low rate of complications can best be explained by the senior author's extensive experience in anterior lumbar approach prior to performing hybrid fusions. We agree with other authors that the placement of TDA is very challenging and in inexperienced hands can lead to a catastrophic situation. The assistance of a general or vascular surgeon to provide the approach is strongly recommended.

Conclusion

Hybrid construction is a viable surgical alternative for the treatment of two-level DDD. Clinical outcome after 2 years is very favourable to two-level TDA and to two-level fusion. By introducing motion preservation at one level, post-fusion conditions such as adjacent-level disc disease may be minimised. Long-term follow-ups are necessary to confirm this.

Key points

- Hybrid construction is surgical strategy for two-level disc disease in lumbar spine (Anterior fusion ALIF at one level and Total Disc Arthroplasty TDA at adjacent).
- Hybrid fusion is an attempt to address two-level DDD by combining the advantages of a single-level ALIF with those of a single-level disc arthroplasty.
- A left-leg sympathectomy syndrome was noted in four patients (9.5%).
- In 2-year follow-up, Oswestry Disability Index and the visual analogue score indicate the validity of Hybrid construction for two-level disc disease in lumbar spine.

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