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Concurrent Use of Lumbar Total Disc Arthroplasty and Anterior Lumbar Interbody Fusion: The Lumbar Hybrid Procedure for the Treatment of Multilevel Symptomatic Degenerative Disc Disease

A Prospective Study

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Study Design. A prospective study.

Objective. The aim of this study was to evaluate clinical and patient outcomes post combined total disc arthroplasty (TDA) and anterior lumbar interbody fusion (ALIF), known as hybrid surgery for the treatment of multilevel symptomatic degenerative disc disease (DDD).

Summary of Background Data. Class I studies comparing the treatment of one-level lumbar DDD with TDA and ALIF have confirmed the effectiveness of those treatments through clinical and patient outcomes. Although the success of single-level disease is well documented, the evidence relating to the treatment of multilevel DDD with these modalities is emerging. With the evolution of the TDA technology, a combined approach to multilevel disease has developed in the form of the hybrid procedure.

Methods. A total of 617 patients underwent hybrid surgery for chronic back pain between July 1998 and February 2012. Visual Analog Pain Scale for the back and leg were recorded along with the Oswestry Disability Index and Roland Morris Disability Questionnaire.

Results. Both statistically and clinically significant ($p < 0.005$) reductions were seen in back and leg pain, which were sustained for at least 8 years postsurgery. In addition, significant improvements ($P < 0.001$) in self-rated disability and function were also maintained for at least 8 years. Patient satisfaction was rated as good or excellent in >90% of cases.

Conclusion. The results of this research indicate that improvements in both back and leg pain and function can be achieved using the hybrid lumbar reconstructive technique.

Key words: arthroplasty, artificial disc, back pain, degenerative disc disease, hybrid procedure, long-term results, lumbar spine, motion preservation, total disc replacement.

Level of Evidence: 4

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Chronic low back pain often occurs as a consequence of degenerative disc disease (DDD) and it is a leading cause of work absenteeism, disability, and quality of life reduction, as well as having a significant impact on societal and health care costs.[1] The pathophysiology of DDD has a complex multifactorial etiology, whereby patients present for surgical management at various stages in the degenerative cycle.[2–4] Often the symptomatic disease involves multiple levels. Symptomatic DDD treated by surgery is a topic of debate among surgeons, insurers, and government agencies with regard to its merits over nonsurgical treatments. Fritzell *et al*,[5] with the Swedish Lumbar Spine Study Group, provided the first systematic evidence that fusion for DDD resulted in superior outcomes when compared to nonsurgical treatments. The surgical group had a 33% reduction in back pain score and a

25% decrease in disability, measured using the Oswestry Disability Index (ODI), whereas the nonsurgical group had 7% and 6% reductions, respectively.

A variety of surgical options exist for those who do not respond to conservative treatment, including anterior lumbar interbody fusion (ALIF) and total disc arthroplasty (TDA).[6] A systematic review in 2010 found no clinically relevant differences between TDA and spinal fusions.[7] Its recommendations were for long-term follow-up to evaluate the effectiveness and safety of TDA. A Cochrane review in 2012 found statistically significant differences in back pain and function in favor of TDA over fusion but concluded these differences were not clinically significant.[2] In the authors' opinion, the results of TDA and ALIF, if applied appropriately, should yield similar results as stabilizing the motion segment, the former dynamically and the latter statically. However, treating multilevel DDD by TDA or ALIF in isolation of each other creates secondary problems. In regards to TDA, increased facet joint stress and arthrosis have been reported, as well as rotational instabilities that result in coronal plain deformity.[8] Multilevel DDD treated by ALIF can result in adjacent motion segment disease, above and below the fused level, and increased nonunion rates.[9] A solution to these issues can be found in combining the technologies in a hybrid procedure, wherein the potential side effects can be reduced and the beneficial effects optimized. The rationale for the hybrid technique is that the ALIF provides stability at an unstable degenerated lumbar segment, whereas the TDA allows for motion preservation, which is not achievable with traditional fusion.[10] The overarching principle of hybrid surgery is to utilize an evidence-based model to match the pathology of a given motion segment to appropriate technology.

There is considerable evidence on the benefits of hybrid surgery, with studies demonstrating the maintenance of preoperative range of motion, postoperative decreases in back pain, and self-rated disability and function and low complication rates, with some studies having no requirement for revision or reoperation.[11–13] The hybrid technique has shown significantly greater improvements in both Visual Analogue Scale (VAS) back pain and disability scores, when compared to a standalone ALIF.[14] Despite early short-term clinical success, minimal longitudinal data following the hybrid approach are available. Given this lack of long-term information, the purpose of this study is to provide long-term follow-up of patients with symptomatic multilevel DDD who underwent a hybrid ALIF and TDA procedure, while demonstrating how much pain reduction and functional improvement can be achieved and how long the effect lasts.

MATERIALS AND METHODS

The 617 patients were treated with lumbar hybrid surgery between July 1998 and February 2012 and recruited to participate in this study at the time of surgery. All participants suffered chronic low back pain (>12 months) and had been unresponsive to nonoperative treatment, including physical therapy and rehabilitation programs. A diagnosis of multilevel discogenic axial low back pain, with or without radicular pain, was established through clinical history, clinical examination, and diagnostic imaging and testing, which included a combination of standing lumbar radiographs, magnetic resonance imaging, and provocative discography with postdiscography fine cut CT scan. In patients with radicular symptoms, electrophysiological studies were performed to confirm the presence or absence of radiculopathy. In patients with complex vascular anatomy, a CT angiogram was obtained. Surgery was offered to patients whose history and clinical findings were consistent with both findings from imaging and concordant provocative tests and whose pain was interfering with social, recreation, and employment opportunities. All procedures were performed by a single surgeon.

Contraindications to surgery included active infection, tumors, significant scoliosis (>20°), and pregnancy. Obesity and involvement in workers' compensation or other litigation were regarded as relative contraindications, whereas surgery was not offered in the presence of overt psychological derangement or maladaptive pain behavior. Surgery was performed via a midline rectus split with a left- or right-sided retroperitoneal approach. A number of TDA prostheses were utilized through the study and the ALIF involved PEEK cages, either with integrated cage and screw systems or with a cage and plate with screws combination. Recombinant human bone morphogentic protein–2 (rhBMP-2), INFUSE Bone Graft (Medtronic Inc, Memphis, TN) was used in all ALIFs. The change in prostheses was because of availability and surgeon preference at the time of surgery.

Participants were required to complete an ODI and Roland Morris Disability Questionnaire (RMDQ) before and at regular intervals postsurgery, along with a self-rated indication of pain using a VAS for back and leg pain. Patient satisfaction was assessed with a four-scale written questionnaire (excellent, good, satisfactory, and poor). These outcomes were recorded postsurgery at 3, 6, and 12 months and yearly thereafter. The outcome questionnaires were analyzed by an independent research team.

As to be expected, there was some loss to follow-up, with a total loss to follow-up of 25%. However, it is noted that 82.8% of those lost to follow-up reported a patient satisfaction score of either excellent or good at the last point of follow-up and also that the majority of patients were lost at the 12- to 24-month stage. This study was approved by the University Human Research Ethics Committee (0000015881) and all participants were free to withdraw at any stage.

Statistical Analysis

Statistical analysis was conducted using the IBM Statistical Package for the Social Sciences (SPSS version 23) software and R version 3.2.5. The VAS for back and leg pain, ODI, and RMDQ continuous outcomes were analyzed both as measured and as change from baseline (before surgery) for the multiple time-points from 3 to 120 months. The raw outcomes were skewed and therefore, medians and interquartile range (IQR) were computed to obtain summary

TABLE 1. Summary Statistics for VAS Outcomes for Back and Leg Pain Over Time

VAS† Outcome				Change From Baseline			
Time Post-surgery, mo	*n*	Median	IQR	*n*	Median Difference‡	95% CI	*P*§
Back pain							
0 Baseline	601	74.0	60.0–86.0				
3	592	15.0	5.0–33.0	583	50.0	47.5–52.5	<0.001*
6	573	10.0	3.0–24.5	564	55.0	52.5–57.5	<0.001*
12	574	9.0	0.0–22.0	565	56.0	53.0–58.0	<0.001*
24	444	8.0	1.0–25.8	435	54.0	51.0–57.0	<0.001*
36	349	9.0	1.0–32.0	340	53.0	49.5–56.0	<0.001*
48	273	9.0	2.0–35.0	263	48.5	44.5–52.5	<0.001*
60	173	9.0	1.0–31.0	164	51.0	45.5–56.5	<0.001*
72	109	10.0	2.0–34.5	99	52.0	45.5–57.5	<0.001*
84	77	11.0	2.5–41.0	69	51.5	43.5–58.5	<0.001*
96	32	14.5	3.3–42.8	22	47.5	35.5–59.5	<0.001*
108	12	22.0	10.3–67.5	4			
120	9	20.0	4.5–64.5	2			
Leg pain							
0 baseline	594	51.0	14.0–80.0				
3	589	4.0	0.0–26.0	573	32.0	28.5–35.5	<0.001*
6	572	1.0	0.0–15.0	557	37.5	34.5–40.5	<0.001*
12	570	1.0	0.0–12.3	555	37.5	34.5–41.0	<0.001*
24	446	2.0	0.0–10.3	433	37.0	33.5 to 40.5	<0.001*
36	348	2.0	0.0–15.0	333	38.0	34.0–41.5	<0.001*
48	275	3.0	0.0–14.0	261	39.5	34.5–43.5	<0.001*
60	174	3.0	0.0–19.0	162	40.5	34.5–46.5	<0.001*
72	110	4.0	0.0–24.3	97	42.5	35.0–49.5	<0.001*
84	78	3.0	0.0–31.0	67	35.5	24.0 to 44.5	<0.001*
96	32	6.0	0.3–15.0	20	46.0	25.5–65.5	0.004*
108	12	10.0	1.0–62.3	4			
120	9	4.0	2.5–60.0	2			

CI indicates confidence interval; IQR, interquartile range; VAS, The Visual Analogue Scale.

**Statistically significant at the 0.005 level.*

†The VAS is scored on a 0 (no pain) to 100 (worst imaginable pain) scale.

‡The median difference is the Hodges-Lehmann estimate. A positive median difference indicates an improvement or reduction in pain score from baseline (before surgery).

§The P value is the result of the sign test. Significance is achieved when $P < 0.005$ using Bonferroni correction, as applied to multiple comparisons.

statistics. The change from baseline scores for ODI and RMDQ followed a normal distribution and therefore the mean differences from baseline were tested using paired *t* tests. The change from baseline scores for both VAS measures displayed skewness, which was not improved by transformations. Hence, the median difference (Hodges-Lehmann estimate) and the corresponding 95% confidence intervals were calculated, as well as the *P* value obtained from the sign test. To account for multiplicity, the reference *P* value of 0.05 was adjusted according to the number of comparisons being made, using Bonferroni correction.

Graphical representations of median changes in leg and back pain VAS and mean change in ODI and RMDQ with 95% CI were plotted, along with their corresponding minimum clinically important difference (MCID). Previous research has found the MCID for back pain VAS to be 12,[15] leg pain VAS to be 16,[15] a 10-point change on the ODI,[2] and a change of 5 points on the RMDQ.[2]

RESULTS

In total, 617 patients with a mean age (standard deviation) of 52.9 (11.1) years were used in this study. The median follow-up time was 36 months (IQR 24–60 months). Table 1 shows the summary statistics for VAS outcomes for back and leg pain and their differences from baseline, along with *P* values. The results for pairwise differences are reported up to 96 months when the sample size was still sufficiently large to enable valid conclusions to be made.

A statistically significant difference can be seen at all follow-up points up to 96 months post-surgery when compared to baseline (from $P < 0.001$ to $P = 0.004$).

Table 2 displays the summary statistics for both the ODI and RMDQ. Statistically significant improvements in both

TABLE 2. Summary Statistics for ODI and RMDQ Outcomes Over Time

Disability Outcome				Change From Baseline			
Time Post-surgery, mo	*n*	Median	IQR	*n*	Mean Difference†	95% CI	*P*‡
ODI§							
0 Baseline	601	44.0	34.0–54.0				
3	590	16.0	6.0–26.0	582	25.8	24.2–27.4	<0.001*
6	575	8.0	2.0–20.0	566	31.7	30.3–33.1	<0.001*
12	573	8.0	0.0–20.0	564	32.2	30.7–33.7	<0.001*
24	445	8.0	0.0–20.0	436	31.3	29.7–32.9	<0.001*
36	349	10.0	0.0–23.0	340	29.3	27.3–31.3	<0.001*
48	275	8.0	0.0–24.0	264	28.6	26.5–30.8	<0.001*
60	171	6.0	0.0–22.0	161	30.3	27.3–33.3	<0.001*
72	106	8.5	0.0–22.8	95	30.9	27.1–34.6	<0.001*
84	77	12.0	2.0–29.0	68	26.6	21.4–31.8	<0.001*
96	32	12.0	0.0–26.0	21	27.1	16.4–37.9	<0.001*
108	12	28.5	11.0–41.5	3			
120	9	16.0	1.0–40.0	1			
RMDQ‖							
0 baseline	601	16.0	13.0–19.0				
3	589	4.0	1.0–8.0	581	10.4	9.9–10.9	<0.001*
6	571	1.0	0.0–5.0	562	12.4	11.9–12.9	<0.001*
12	572	1.0	0.0–5.0	563	12.7	12.2–13.2	<0.001*
24	445	1.0	0.0–4.0	436	12.8	12.2–13.3	<0.001*
36	346	1.0	0.0–5.0	338	12.0	11.3–12.6	<0.001*
48	277	1.0	0.0–4.0	267	12.0	11.3–12.8	<0.001*
60	172	1.0	0.0–6.0	162	12.5	11.4–13.5	<0.001*
72	108	1.0	0.0–6.0	97	12.6	11.3–13.8	<0.001*
84	77	1.0	0.0–6.0	68	12.4	10.9–13.9	<0.001*
96	32	1.0	0.0–10.8	21	12.1	9.0–15.3	<0.001*
108	12	8.0	0.3–13.0	3			
120	9	6.0	0.0–15.5	1			

CI indicates confidence interval; IQR, interquartile range; ODI, Oswestry Disability Index; RMDQ, Roland Morris Disability Questionnaire.

**Statistically significant at the 0.005 level.*

†A positive mean difference indicates an improvement or reduction in disability index from baseline (before surgery).

‡The P value is the result of the paired t-test. Significance is achieved when $P < 0.005$ using Bonferroni correction, as applied to multiple comparisons.

§The ODI is scored on a 0 (none) to 100 (worst) disability.

‖The Roland-Morris Disability Questionnaires (RMDQ) are scored on a 0 (none) to 24 (worst) disability.

measures can be seen at each time point up to 96 months post-surgery when compared to baseline ($P < 0.001$). The initial presurgery ODI median of 44 decreased by 63.6% after 3 months to a median post-surgery score of 16. The score of 16 after 3 months can be interpreted as being minimal disability with this outcome measure.[16] Likewise, the RMDQ initial measurement of 16 decreased postsurgery by 75% to 4, a score which can be interpreted as no disability.[17] The results from 6 to 96 months' follow-up were significantly lower than the initial measurement and still classed as being of no disability (RMDQ = 1.0).

Figures 1(A, B) and 2(A, B) are graphical representations of the differences from baseline for back and leg pain VAS and the ODI and RMDQ outcome measures over time. The relevant MCID for each outcome is also displayed for reference. All of the profiles showed an improvement in pain or function that is well above the corresponding MCID.

Results of the pooled patient satisfaction questionnaires for the entire follow-up period are displayed in Table 3 below. Patient satisfaction is seen to be good or excellent in 90% of cases throughout the follow-up period up to 108 months, with only 2% expressing a poor level of satisfaction (Figure 3).

DISCUSSION

The purpose of this study was to provide long-term follow-up of patients' pain and function for an evidenced-based approach to modern anterior spine surgery for chronic back pain, utilizing a hybrid surgical technique. The results of this research indicate that improvements in both back and leg pain and function can be achieved using this surgical technique. Likewise, levels of patient satisfaction post-surgery appear to be higher than previously published post both fusion and TDA alone. Class 1[6,18,19] results for single-level

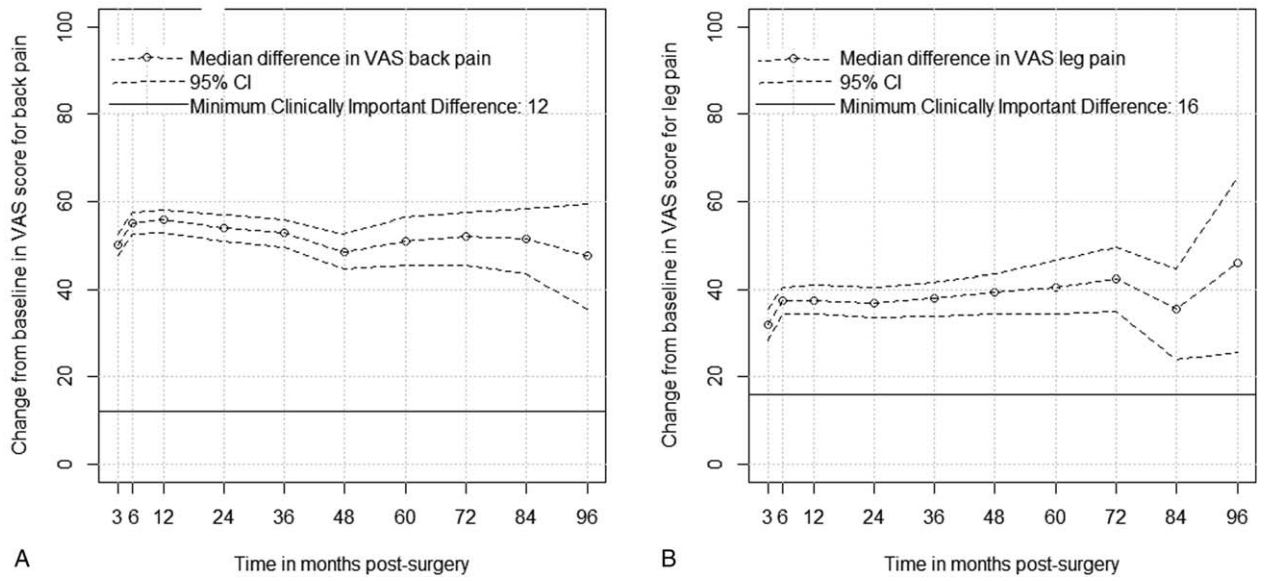

Figure 1. Profile of median difference between pre- and post-surgery over time, and 95% confidence intervals for VAS back (**A**) and leg pain (**B**) scores in 617 patients. VAS indicates Visual Analog Pain Scale.

TDA have been published, validating safety and efficacy[20]; however, there is a suggestion that multiple-level TDA may have poorer outcomes,[21] often related to facet arthritis and segmental instability.[8] This highlights the concept of constraint and has therefore impacted the evolution of design of the implants.[22] Technological and biological solutions for ALIF have shown good clinical outcomes and high fusion rates.[23] However, a higher incidence of adjacent motion segment disease with fusion is a consideration.[24] These factors are the reasons why hybrid surgery evolved. Aunoble *et al*,[25] in a prospective study on 47 hybrid patients, noted a mean reduction in ODI of 24.9 points (53% improvement) at 2 years' follow-up. The VAS back was 64.6% improved. They concluded that hybrid surgery was a viable alternative to multilevel TDA or fusion. Hoff *et al*[11] reported results of a randomized trial of hybrid construct compared with pedicle screw and trans-lumbar interbody cages with a mean of 37 months' follow-up. The hybrid group was associated with lower VAS scores, a low complication rate, better lordosis, and improved motion.

The clinical outcomes of this study compare favorably against previous studies and have shown significant

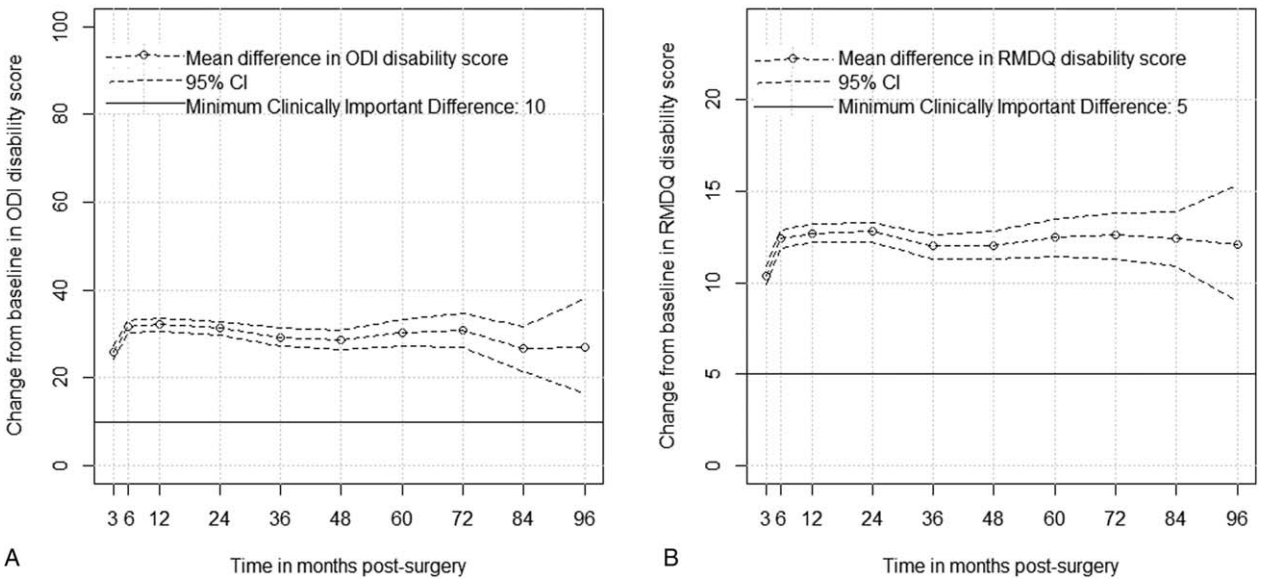

Figure 2. Profile of mean difference between pre- and post-surgery over time, and 95% confidence intervals for ODI (**A**) and RMDQ disability scores (**B**) in 617 patients. ODI indicates Oswestry Disability Index; RMDQ, Roland Morris Disability Questionnaire.

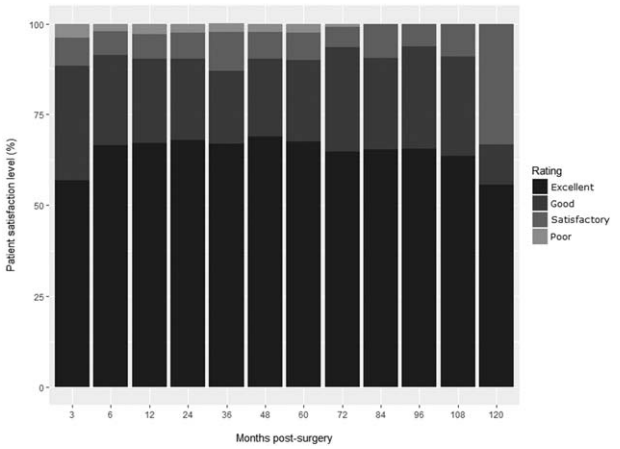

Figure 3. Results of the patient satisfaction questionnaire during the duration of follow-up (N = 617).

improvements in back pain, disability, and quality of life. At all time frames measured throughout this study, the mean difference in ODI score is above the MCID of 10, >15, which is considered clinical success, and also >18.8, which is considered to be substantial clinical benefit.[25,26] The improvements in the ODI, which are maintained for at least 8 years, build on previously published results utilizing this surgical technique. Other studies using the same procedure have shown decrease in back pain VAS from 7.0 to 2.5 at 24 months[27] and 7.4 to 3.73[11] on a 10-point scale, similar to the 74 to 8-point change on a 0 to 100 scale in this study. Other research has demonstrated maintenance of significant improvements in back pain maintained to 34 and 37 months.[11,28]

Changes of 47.42 points have been seen in TDA studies over 24 months, comparable to the 54.0 change in this study. Both of these numbers are lower than Garcia's study in which improvements of 61 to 67 were seen at 24 months.[28] Another study stated mean back pain VAS scores decreased by 3.59 points from 6.93 to 3.34 on a 10-point scale after 24 months, a similar decrease to the postoperative result (using a 100-point scale) in this study.[29] Again, at all time points in this study, the reduction in VAS back pain is >12, suggested to be the MCID.

The significant improvements in leg pain postsurgery are maintained in this study up to 96 months postsurgery. The original concept of TDA was to treat back pain; however, leg pain secondary to neural compression can be treated equally or better. Previous studies have shown decreases in leg pain from 4.1 to 2.5, similar to the 37-point median change using a 100-point scale in this study.[25] Results from other studies report pain using a VAS, but do not clarify whether it is back or leg pain.[6,18,30] Studies using a TDA without fusion have found variable results with no significant differences in leg pain at 12 and 24 months postsurgery, in some,[31] and significant improvements only after 12 months, in others.[19] One study demonstrated decreases in leg pain after 24 months from 5.51 to 2.42 using a 10-point VAS scale, which compares well to the results of this study.[29]

TABLE 3. Summary Statistics for Patient Satisfaction Ratings (Excellent/Good) Over Time

Time Post-surgery, mo	Total, n	Excellent/Good, n (%)
3	572	506 (88.4)
6	561	512 (91.3)
12	555	501 (90.3)
24	436	394 (90.4)
36	344	299 (87.0)
48	270	244 (90.4)
60	170	153 (90.0)
72	108	101 (93.5)
84	75	68 (90.6)
96	32	30 (93.7)
108	11	10 (90.9)
120	9	6 (66.7)

Patient satisfaction appears to be higher, utilizing hybrid surgery when compared to a fusion or TDA alone. Patient satisfaction has previously been reported at 82% for TDA patients, compared to 69% for spinal fusion patients at 24 months post-operation.[2] Other studies have reported satisfaction of patients post-TDA surgery ranging from 88% to 90%.[28,30] At the same time point with 436 respondents, 90.4% of patients in this study recorded either an excellent (n = 296, 67.9%) or good (n = 98, 22.5%) level of satisfaction, with only 7.1% (n = 31) of patients recording satisfactory and 2.5% (n = 11) having a poor level of satisfaction. The satisfaction of patients in this study is also higher >88% at 24 months reported in the study by Yue *et al*,[32] utilizing the same hybrid technique, and comparable to 95.7 satisfaction rate in the Chen *et al*'s study.[13]

There are limitations to the present study that need to be acknowledged. Not all patients experienced leg pain preoperatively and, therefore, their baseline score would be zero. In this case, the IQR rather than the median would provide more useful information. The very wide IQR of 14 to 80 at baseline (Table 1) indicates that 25% of the patients scored <14 and 25% >80. There are two possible scenarios: those who did not have any leg pain at baseline (who may or may not continue scoring zero at follow-up) and those who have some pain to severe pain (who are expected to show a great improvement after surgery). As the analyses considered all patients as a homogeneous group, this difference at baseline might explain why the improvement in leg pain is generally lower than for back pain.

CONCLUSION

There is strong evidence of statistically and clinically significant reduction in back and leg pain for patients undergoing hybrid surgery for chronic low back pain. This improvement in pain is sustained for at least 8 years. Significant improvements are also seen in self-rated physical disability and function, also maintained for at least 8 years. The results

of this study suggest TDA with ALIF is a suitable option for patients suffering chronic back and leg pain secondary to multilevel DDD when conservative management fails.

➢ Key Points

- ❑ Hybrid surgery provides stability at an unstable degenerated lumbar segment while still allowing for motion preservation at the adjacent level.
- ❑ Both statistically and clinically significant benefits can be achieved with hybrid surgery, with results maintained for at least 8 years post-surgery.
- ❑ Patient satisfaction is rated as good or excellent in >90% of cases.

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