The concurrent use of lumbar total disc arthroplasty and anterior lumbar interbody fusion: The lumbar hybrid procedure for the treatment of multi-level symptomatic degenerative disc disease a prospective study

Scott-Young, Matthew; McEntee, Laurence; Schram, Ben; Rathbone, Evelyne; Hing, Wayne; Nielsen, David

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Title: The concurrent use of lumbar total disc arthroplasty and anterior lumbar interbody fusion: the lumbar hybrid procedure for the treatment of multi-level symptomatic degenerative disc disease- a prospective study

Running Title: Long term follow up of lumbar hybrid surgery

Authors:

Matthew Scott-Young (MSSB, FRACS, FAOrthA.) [1,2]

Laurence McEntee (MBChB., BHB, FRACS.) [1,2]

Ben Schram (B.Ex.Sci., DPhty., PhD.)[2]

Evelyne Rathbone (MSc) [2]

Wayne Hing (DPhys, MSc, OMT, PhD)[2]

David Nielsen (BBiomedSc., MBBS)[1]

[1] Gold Coast Spine, Gold Coast, QLD AUSTRALIA 4229

[2] Faculty of Health Science & Medicine, Bond University, Gold Coast, QLD AUSTRALIA 4229

Corresponding Author:

Dr Ben Schram, Faculty of Health Science and Medicine, Bond University

Fax: (07) 5595 3522 **Phone:** (07) 5595 5828 **Email:** bschram@bond.edu.au.

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ABSTRACT

Study Design: A prospective study

Objective: The aim of this paper is 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 multi-level 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. While the success of single level disease is well documented, the evidence relating to the treatment of multi-level DDD with these modalities is emerging. With the evolution of the TDA technology, a combined approach to multi-level 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 (VAS) for the back and leg were recorded along with the Oswestry Disability Index (ODI) and Roland Morris Disability Questionnaire (RMDQ).

Results: Both statistically and clinically significant ($p<0.005$) reductions were seen in back and leg pain, which was sustained for at least 8 years post-surgery. 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 at *good* or *excellent* in over 90% of cases.

Conclusions: 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 Points:

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

INTRODUCTION

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 aetiology, 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 amongst surgeons, insurers and government agencies with regards to its merits over non-surgical 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 non-surgical 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), whilst the non-surgical 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 favour 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 multi-level 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] Multi-level DDD treated by ALIF can result in adjacent motion segment disease, above and below the fused level, and increased non-union rates.[9] A solution to these issues can be found in combining the technologies in a hybrid procedure, where 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, while the TDA allows for motion preservation, which is not achievable with traditional fusion.[10] The overarching principle of hybrid surgery is to utilise 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 pre-operative range of motion, post-operative decreases in back pain and self-rated disability and function and low complication rates, with some studies having no requirement for revision or re-operation.[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 multi-level 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 non-operative treatment, including physical therapy and rehabilitation programs. A diagnosis of multi-level 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, MRI, and provocative discography with post-discography 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 (>20deg), and pregnancy. Obesity and involvement in workers' compensation or other litigation were regarded as relative contraindications, while 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, USA) was used in all ALIFs. The change in prostheses was due to availability and surgeon preference at the time of surgery.

Participants were required to complete an ODI and Roland Morris Disability Questionnaire (RMDQ) prior to and at regular intervals post-surgery, 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 post-surgery 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 lost 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 (prior to surgery) for the multiple time-points from 3 to 120 months. The raw outcomes were skewed and therefore, medians and IQR were computed to obtain summary 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 (SD) 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 1 here *****

Table 2 displays the summary statistics for both the ODI and RMDQ. Statistically significant improvements in both measures can be seen at each time point up to 96 months post-surgery when compared to baseline ($p<0.001$). The initial pre-surgery ODI median of 44 decreased by 63.6% after three 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 post-surgery by 75% to 4, a score which can be interpreted as no disability.[17] The results from 6 to 96 months follow up was significantly lower than the initial measurement and still classed as being of no disability (RMDQ = 1.0).

*****Table 2 here*****

Figures 1 & 2 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.

*****Figures 1 & 2 here *****

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).

*****Table 3 here*****

*****Figure 3 here*****

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, utilising 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 TDA have been published, validating safety and efficacy;[20] however, there is a suggestion 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 favourably against previous studies and have shown significant 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, above 15, which is considered clinical success and also above 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 utilising this surgical technique. Other studies using the same procedure have shown decrease in back pain VAS from 7.0 – 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 0-100 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 61-67 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 post-operative 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 above 12, suggested to be the MCID.

The significant improvements in leg pain post-surgery are maintained in this study up to 96 months post-surgery. 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 post-surgery, in some,[31] and significant improvements only after 12 months, in others.[19] One study demonstrated decreases in leg pain after 24 months from 5.51-2.42 using a 10 point VAS scale, which compares well to the results of this study.[29]

Patient satisfaction appears to be higher, utilising 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 than the 88% at 24 months reported in the study by Yue *et al*[32], utilising the same hybrid technique, and comparable to 95.7 satisfaction rate in the Chen *et al's* study.[13]

There are limitations to the current 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 below 14 and 25% above 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 multi-level DDD when conservative management fails.

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TABLES

Table 1. Summary statistics for VAS outcomes for back and leg pain over time

	VAS[1] outcome			Change from baseline			
Time (months) post-surgery	***n***	**Median**	**IQR**	***n***	**Median difference[2]**	**95% CI**	***p*-value[3]**
Back pain							
0 baseline	601	74.0	60.0-86.0				
3	592	15.0	5.0-33.0	583	50.0	47.5 to 52.5	<0.001*
6	573	10.0	3.0-24.5	564	55.0	52.5 to 57.5	<0.001*
12	574	9.0	0.0-22.0	565	56.0	53.0 to 58.0	<0.001*
24	444	8.0	1.0-25.8	435	54.0	51.0 to 57.0	<0.001*
36	349	9.0	1.0-32.0	340	53.0	49.5 to 56.0	<0.001*
48	273	9.0	2.0-35.0	263	48.5	44.5 to 52.5	<0.001*
60	173	9.0	1.0-31.0	164	51.0	45.5 to 56.5	<0.001*
72	109	10.0	2.0-34.5	99	52.0	45.5 to 57.5	<0.001*
84	77	11.0	2.5-41.0	69	51.5	43.5 to 58.5	<0.001*
96	32	14.5	3.3-42.8	22	47.5	35.5 to 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 to 35.5	<0.001*
6	572	1.0	0.0-15.0	557	37.5	34.5 to 40.5	<0.001*
12	570	1.0	0.0-12.3	555	37.5	34.5 to 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 to 41.5	<0.001*
48	275	3.0	0.0-14.0	261	39.5	34.5 to 43.5	<0.001*
60	174	3.0	0.0-19.0	162	40.5	34.5 to 46.5	<0.001*
72	110	4.0	0.0-24.3	97	42.5	35.0 to 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 to 65.5	0.004*
108	12	10.0	1.0-62.3	4			
120	9	4.0	2.5-60.0	2			

[1]The Visual Analogue Scale (VAS) is scored on a 0 (no pain) to 100 (worst imaginable pain) scale.
[2]The median difference is the Hodges-Lehmann estimate. A positive median difference indicates an improvement or reduction in pain score from baseline (prior to surgery).
[3]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.
*Statistically significant at the 0.005 level.

Table 2. Summary statistics for ODI and RMDQ outcomes over time

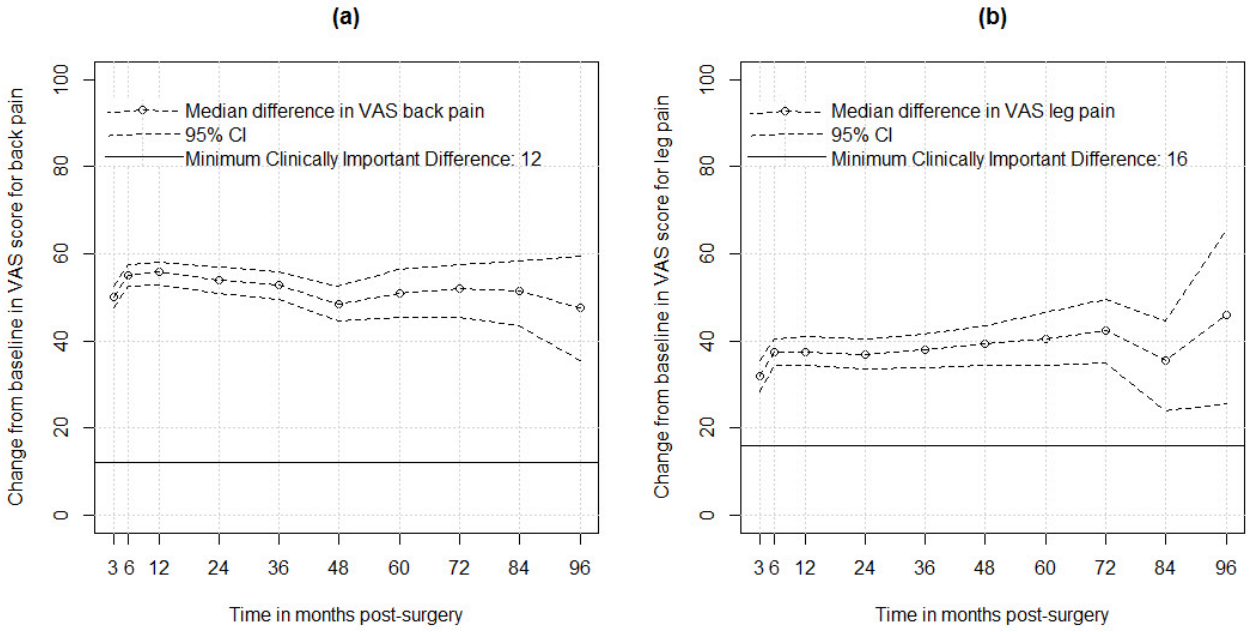
	Disability outcome			**Change from baseline**			
Time (months) post-surgery	***n***	**Median**	**IQR**	***n***	**Mean difference[2]**	**95% CI**	***p*-value[3]**
ODI[1]							
0 baseline	601	44.0	34.0-54.0				
3	590	16.0	6.0-26.0	582	25.8	24.2 to 27.4	<0.001*
6	575	8.0	2.0-20.0	566	31.7	30.3 to 33.1	<0.001*
12	573	8.0	0.0-20.0	564	32.2	30.7 to 33.7	<0.001*
24	445	8.0	0.0-20.0	436	31.3	29.7 to 32.9	<0.001*
36	349	10.0	0.0-23.0	340	29.3	27.3 to 31.3	<0.001*
48	275	8.0	0.0-24.0	264	28.6	26.5 to 30.8	<0.001*
60	171	6.0	0.0-22.0	161	30.3	27.3 to 33.3	<0.001*
72	106	8.5	0.0-22.8	95	30.9	27.1 to 34.6	<0.001*
84	77	12.0	2.0-29.0	68	26.6	21.4 to 31.8	<0.001*
96	32	12.0	0.0-26.0	21	27.1	16.4 to 37.9	<0.001*
108	12	28.5	11.0-41.5	3			
120	9	16.0	1.0-40.0	1			
RMDQ[4]							
0 baseline	601	16.0	13.0-19.0				
3	589	4.0	1.0-8.0	581	10.4	9.9 to 10.9	<0.001*
6	571	1.0	0.0-5.0	562	12.4	11.9 to 12.9	<0.001*
12	572	1.0	0.0-5.0	563	12.7	12.2 to 13.2	<0.001*
24	445	1.0	0.0-4.0	436	12.8	12.2 to 13.3	<0.001*
36	346	1.0	0.0-5.0	338	12.0	11.3 to 12.6	<0.001*
48	277	1.0	0.0-4.0	267	12.0	11.3 to 12.8	<0.001*
60	172	1.0	0.0-6.0	162	12.5	11.4 to 13.5	<0.001*
72	108	1.0	0.0-6.0	97	12.6	11.3 to 13.8	<0.001*
84	77	1.0	0.0-6.0	68	12.4	10.9 to 13.9	<0.001*
96	32	1.0	0.0-10.8	21	12.1	9.0 to 15.3	<0.001*

108	12	8.0	0.3-13.0	3
120	9	6.0	0.0-15.5	1

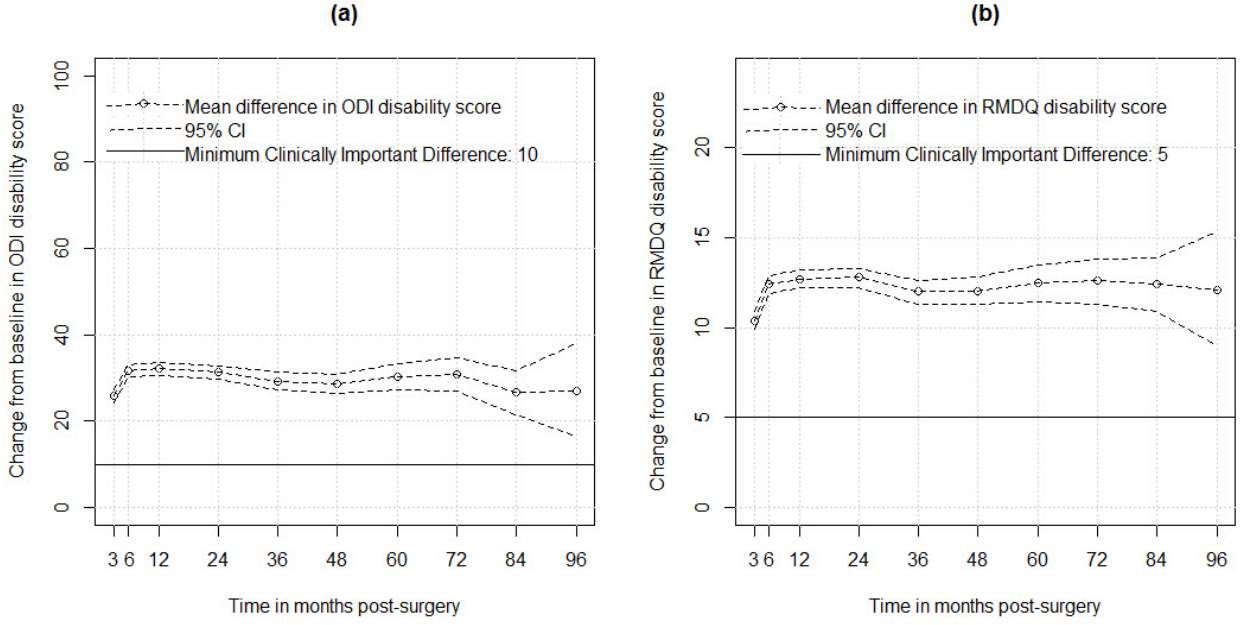
[1]The Oswestry Disability Index (ODI) is scored on a 0 (none) to 100 (worst) disability.
[2]A positive mean difference indicates an improvement or reduction in disability index from baseline (prior to surgery).
[3]The *p*-value is the result of the paired *t*-test. Significance is achieved when $p<0.005$ using Bonferroni correction, as applied to multiple comparisons.
[4]The Roland-Morris Disability Questionnaires (RMDQ) are scored on a 0 (none) to 24 (worst) disability.
*Statistically significant at the 0.005 level.

Table 3: Summary statistics for patient satisfaction ratings (Excellent/Good) over time

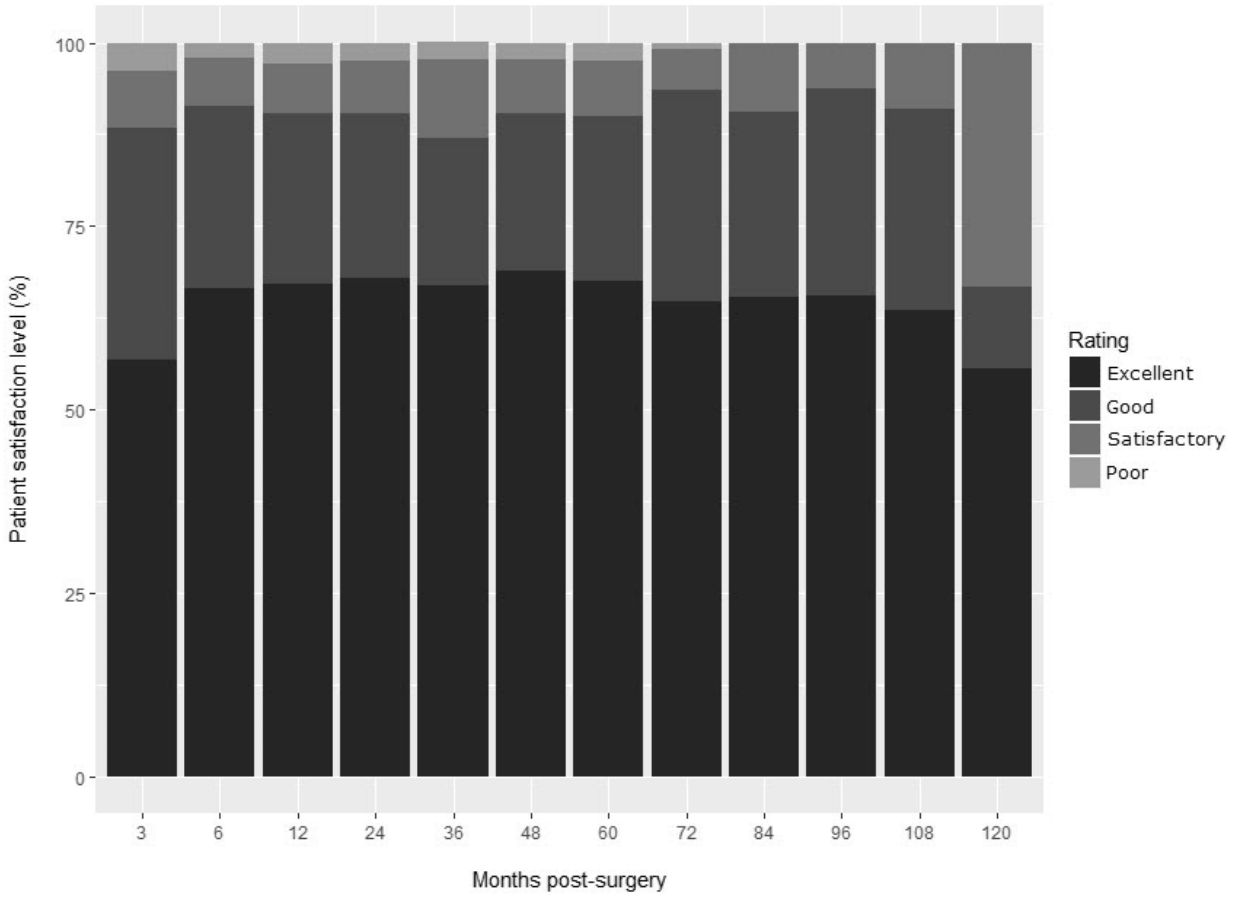
Time (months) post-surgery	*Total n*	Excellent/Good *n* (%)
3	572	506 (88.4)
6	561	512 (91.3)
12	555	501 (90.3)
24	436	394 (90.4)
36	344	299 (87.0)
48	270	244 (90.4)
60	170	153 (90.0)
72	108	101 (93.5)
84	75	68 (90.6)
96	32	30 (93.7)
108	11	10 (90.9)
120	9	6 (66.7)


(a)
Median difference in VAS back pain
95% CI
Minimum Clinically Important Difference: 12
Change from baseline in VAS score for back pain
Time in months post-surgery
(b)
Median difference in VAS leg pain
95% CI
Minimum Clinically Important Difference: 16
Change from baseline in VAS score for leg pain
Time in months post-surgery

369


(a)
Mean difference in ODI disability score
95% CI
Minimum Clinically Important Difference: 10
Change from baseline in ODI disability score
Time in months post-surgery
(b)
Mean difference in RMDQ disability score
95% CI
Minimum Clinically Important Difference: 5
Change from baseline in RMDQ disability score
Time in months post-surgery

370



FIGURES

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.

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.

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