Original Study

The outcome of pedicle screw instrumentation removal for ongoing low back pain following posterolateral lumbar fusion

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Background: Our aim was to determine whether patients derived benefit from removal of pedicle screw instrumentation for axial pain without other cause using our surgical technique and patient selection. A secondary aim was to investigate factors that were associated with poorer outcomes for this procedure as well as complication rate in this cohort.

Methods: Theater records from a single spinal surgeon's practice were reviewed to identify patients that had undergone lumbar fusion for discogenic back pain with subsequent pedicle screw instrumentation removal (Expedium, DePuy Synthes) in the preceding 3 years with a minimum of 18 months follow-up. Inclusion criteria were persisting midline axial back pain with computed tomography (CT)–confirmed solid fusion with non-radicular symptoms and nil other potential causes found, e.g., infection. Case note review along with pre- and post-operative Oswestry disability index (ODI) questionnaires and visual analog scores (VAS) were assessed for all patients. Surgical technique included re-use of previous midline posterior incision and the Wiltse approach with removal of implants, confirmation of a solid fusion mass, washout and bone grafting of removal sites.

Results: From 50 consecutive patients who underwent removal of posterolateral instrumentation for an index elective lumbar fusion for discogenic back pain, 34 patients were identified that met the criteria with a mean follow-up of 25 months (range, 18-36 months). The VAS and ODI improved in 22/34 (65%) of participants. The mean cohort VAS score was 6.6 pre-surgery and 4.3 post-surgery (P=0.04). Preoperative and postoperative mean Oswestry disability scores were 64 and 41, respectively (P=0.05). There was a statistically significant difference in the proportion of patients with poorer compared to satisfactory outcomes with regards to compensable status, preoperative grade II opioid use and shorter time between fusion and removal procedure. Complications were one postoperative hematoma and one superficial wound infection, both of which settled without re-operation.

Conclusions: Approximately two thirds of patients were satisfied with removal of instrumentation for treatment of residual low back pain (LBP) following elective lumbar fusion and recorded reduced VAS and grade II opioid use. A subset of patients remained that did not derive benefit and were associated with compensable status, preoperative grade II opioid use and a shorter time between fusion and removal procedure. A prospective cohort study with preoperative diagnostic injections and standardized imaging and microscopic techniques would strengthen future studies. However, this study suggests that removal of instrumentation is safe and provides modest benefit as a palliative procedure for a subset of patients with significant disability from chronic LBP without an underlying cause following lumbar fusion.

Keywords: Lumbar back pain; metal removal; lumbar fusion; outcomes; pedicle screw; instrumentation

Submitted Aug 03, 2015. Accepted for publication Aug 31, 2015.
doi: 10.3978/j.issn.2414-469X.2015.08.02
View this article at: http://dx.doi.org/10.3978/j.issn.2414-469X.2015.08.02

Introduction

Elective lumbar spine fusion surgery for discogenic axial low back pain (LBP) is a commonly performed procedure. In the United States alone, there are over 300,000 lumbar spine fusions performed annually with many performed for this indication (1). However, post-lumbar fusion LBP remains a common problem. There have been many causes of LBP identified following lumbar fusion, such as infection, adjacent segment disease, residual sensitized disc and pseudo-arthrosis, but the differential diagnoses of pain generators also include hardware-related pain. Approximately 15% of patients who undergo reoperation for ongoing LBP following fusion have their symptoms attributed to hardware-related pain (2-4). DePalma and colleagues [2011], investigated the prevalence of hardware-related pain, which was established as a diagnosis of exclusion via a series of local anesthetic injections and neural blockades. The most prevalent site of ongoing post-fusion hardware-related LBP was identified as the sacro-iliac joint, which is generally attributed to stress transfer (5). Alanay and colleagues also affirmed this approach, only making the diagnosis of hardware-related pain after exclusion of other causes and diagnostic anesthetic injections.

Recent studies regarding corrosion and subclinical infection of metalwork have highlighted potential sources of LBP which warrant further investigation and may provide another explanation for the benefit derived from metal removal after imaging confirmed solid fusion (6-8). Studies regarding the outcomes of removal of elective lumbar fusion instrumentation published in the last 15 years are summarised in *Table 1*.

Aside from mechanical impingement, prominence and stress transfer, a major theory of how pain is generated from metal hardware is a host immune reaction to corrosion debris from the metalware. Metal corrosion is a common and, generally, consistent finding (14-16) at hardware retrieval. However, Alanay *et al.* [2007] reported that no corrosion was detected during their study (10). Metalware can corrode via mechanical forces or via bio-corrosion and is also related to the presence of cross-links in the construct (15-19). The metal ions liberated by this corrosion combine with native proteins to form complexes which initiate local host inflammation (20-23). Persistent exposure to these pro-inflammatory complexes can lead to granuloma formation and bursal adherence to the metalware (24,25). However, this does not account for patients with metalwork that does not cause pain and chronic inflammation, a possible hypersensitivity response is thought to be process behind the selectivity. There is a rate of approximately 10-15% metal sensitivity incidence documented in the literature amongst the general population (26).

The primary aim of our study was to assess whether removal of pedicle screw instrumentation following elective lumbar fusion in our cohort was associated with satisfactory outcomes. Secondary outcomes of interest were to identify patient factors that may influence outcomes, the complication profile of the procedure and how our results compared to the existing literature.

A pilot study of patients that underwent pedicle screw removal had been presented at local and national meetings where criticism was directed towards the brevity of follow-up and the heterogeneity in radiological confirmation of fusion. Thus, a longer follow-up and strict inclusion criteria were introduced to strengthen the methodology of the study.

Methods

Inclusion criteria

To evaluate the outcomes of removal of pedicle screw instrumentation for index elective lumbar fusion, our patient cohort was identified from a retrospective review of a spinal surgeon's operative cases where, at the time of latest Oswestry disability index (ODI) questionnaire, subjects would be between 18 months and 3 years post-operatively. Patient case files were then retrieved for correlation to see if inclusion criteria were met.

For inclusion in the study, the following parameters were required to be met for analysis:

(I) All patients required an ODI questionnaire to be documented pre-operatively to be considered further in analysis with a repeated ODI questionnaire with at least 18 months follow-up;

(II) The indication for fusion as the index procedure must have been documented as discogenic back pain with posterolateral fusion with pedicle screw instrumentation. Patients who had index procedures for adult deformity correction or trauma were excluded as were patients who underwent other forms of elective lumbar fusion, as this would introduce further variables which would limit comparison.

(i) Solid fusion documented post-operatively by

Table 1 Summary of previous studies examining ongoing LBP following elective lumbar fusion

Name/year	Cohort	Inclusion criteria	Method assessment	Level of evidence	Outcome [favorable, %]
Wild *et al.* 2003 (9)	45	Tender instrumentation post lumbar fusion in absence of pseudarthrosis	VAS pre- and post-Satisfa wild ion categorized loose *vs.* solid instrumentation	IV	79% overall recommend the surgery, 82% would repeat surgery, 77% consider the surgery a success. Mean VAS 7.5 → 5.5 (P<0.05) More favorable outcome in 'loose' prosthesis group (satisfaction 100% in most categories *vs.* 55-64% for solid)
Alanay *et al.* 2007 (10)	25	Excluded	VAS functional improvement on 5 pts scale Preoperative LA to tender area 20 months FU	IV	Mean VAS halved; 84% patients had functional benefit 40% much better but 0% all better; one superficial infection
Kim *et al.* 2008 (11)	14	Persistent pain and tenderness despite solid fusion	VAS and modified McNab's score, pre- and post-12 month Radiological review	IV	93% excellent or good VAS 6.4 → 2.9 (P<0.0005) 5 degrees change sagittal balance
Stavridis *et al.* 2010 (12)	53	Degenerative or traumatic thoracolumbar instrumentation with tenderness	Interview 6-24 months postop	IV	63% would undergo again 12% complete remission
Salgarello *et al.* 2013 (13)	2	Removal and fat grafting for LBP post elective lumbar fusion	VAS pre- and post-	IV	100% - VAS of 10→2 and 7→1 respectively

LBP, low back pain; VAS, visual analogue scores; LA, local anaesthetic; FU, follow-up.

computed tomography (CT);

(ii) Additional patient inclusion criteria (as assessed by review of correspondence letters for surgical indications) were persistent axial paramidline LBP to palpation with imaging confirmed solid fusion, non-radicular symptoms and no other cause found, e.g., infection;

(iii) Additional exclusion criteria included exchange of metalwork, revision fusion or other therapeutic procedures.

Operative procedure

The routine of the senior surgeon at these cases was to reuse the previous incision and remove the hardware via a posterior approach. There was intra-operative confirmation of a solid fusion mass and debridement and irrigation of corrosion/inflammatory affected tissue, if required. Tissues were sent for culture if there was macroscopic suspicion of infection at the time of operation. Bone grafting to removal sites was undertaken with the theoretical interest of reducing the potential for any empty screw holes to act as stress-risers in the postoperative period. Primary wound closure was undertaken in a standard fashion with an absorbable monofilament to skin and no drain *in situ*.

Follow-up

The senior author undertook routine assessment of patients, initially to assess the state of the soft tissues and wound within the first 6 weeks and then a second assessment at 3 months to assess the short-term outcome from the procedure. The senior author's practice was to review annually but this would vary depending on patient circumstances and requests.

Table 2 Demographic and operative variables for the patient cohort who met inclusion criteria

Demographic and operative variables	
Gender (female)	13/34 (38%)
Mean age in years [range]	49 [31-68]
Compensable status	15/34 (44%)
Mean years post index procedure [range]	4 [3-6]
Mean years post removal procedure [range]	2 [1.5-3]
Number of levels fused	
1	17 (50%)
2	12 (36%)
3	3 (9%)
4	2 (6%)
Level (s) involved	
L2/3	5 (15%)
L3/4	15 (45%)
L4/5	26 (76%)
L5/S1	22 (65%)
Pre-operative grade II opioid use	28/34 (82%)

Outcome measurement

Brief history of ODI: the ODI is an index which has been derived from the Oswestry LBP questionnaire. Fairbank *et al.* in *Physiotherapy*, first published this validated questionnaire in *Physiotherapy*, 1980 (27). The ODI is considered the gold standard for measuring the degree of disability and quality of life in an individual with LBP.

An additional feature of the questionnaire provided in the surgeon's practice was that it enabled measurement of other demographic and operative variables, e.g., age, sex, marital status, number of operations, analgesic regimen, treatment success and satisfaction.

Data analysis

Pre and post-operative data was collected and tabulated by the study investigators. ODI and visual analogue scores (VAS) were then analysed using QI Macros (KnowWare Internation, Denver, CO, USA) with chi-squared analysis via a two-by-two table for patient factors' influence upon outcomes and a paired t-test analysis for statistical significance in the change of VAS and ODI from pre- to post-operatively.

Table 3 Reasons for non-inclusion of patients into analysis from consecutive case series

Reasons for non-inclusion in analysis	N [%]
Fusion assessment by plain radiography only	9/16 [56]
Missing pre- or post-operative ODI outcomes	8/16 [50]
Radicular symptoms from malpositioned or broken screw	2/16 [13]
Culture positive infection at operative site	2/16 [13]
Additional procedures performed	9/16 [56]
Overlap of two or more of above reasons	11/16 [69]

ODI, oswestry disability index.

Results

A consecutive series of 50 patients were identified who had an index posterior lumbar fusion (PLF) procedure and were at least 18 months following removal of pedicle screw instrumentation. However, only 34 of these patients met inclusion criteria. The demographics of the cohort who met inclusion criteria, including age, levels fused in the index procedure and years post index procedure, are demonstrated in *Table 2*. The reasons for non-inclusion of eligible patients are shown in *Table 3*.

The mean follow-up was 25 months (range, 18-36 months). From the 34 patients, 21 were male and 15 were compensable (work-related injury, insurance or litigation claim pending), respectively.

There were two complications, one closed wound hematoma, which resolved with aspiration and without the need for reoperation, and one superficial infection that resolved with a week of oral antibiotics. Subjective outcome, compared to pre-operative scoring, was good or very good in 22/34 (65%) of patients, no different in 8/34 (23%) and worse in 4/34 (12%).

VAS analysis as seen in *Table 4* showed a clinically important and statistically significant improvement in mean VAS (2.3) (P=0.04). ODI improved from a mean pre-operative cohort score of 64 to a post-operative score of 41 with statistical significance (P=0.05). 18 patients (53%) recorded ongoing routine post-operative use of class II opioids compared to 28 of patients pre-operatively (82%).

Patient demographics thought to contribute to worse outcomes were explored. Compensable status and grade II opioid use were statistically different in proportion by chi-square analysis between the cohort of patients who rated their outcome as good or excellent compared to those

Table 4 Pre- and post-operative cohort means and medians for visual analogue score and ODI

	Pre-operative	Post-operative	P value
Mean VAS	6.6	4.3	0.04
Median VAS	7	4	N/A
Mean ODI	64	41	0.05
Median ODI	66	44	N/A

ODI, oswestry disability index; VAS, visual analogue scores.

with neutral or poor results. Specifically, of those patients who recorded neutral or poor outcomes, pre-operative grade II opioid use was found in 12/12 (100%) compared to 16/22 (73%) with good or excellent outcomes, while compensable status was recorded for 9/12 (75%) with neutral or poor results compared to 6/22 (27%) in those with good or excellent outcomes. Other factors, including gender, number of levels instrumented, marital status and smoking were assessed but none of these were found to be significantly different in the cohorts albeit that small patient numbers may have contributed to this finding.

Discussion

In our series, removal of pedicle screw implants in individuals with ongoing LBP following solid fusion for discogenic back pain lead to good or excellent subjective outcome results in approximately 2/3 of patients and did not lead to any significant complications and or reoperations. These findings are consistent with existing literature as depicted in *Table 1*. Overall, there was a statistically significant improvement in VAS for cohorts and the mean improvement was a decrease of 2.3, which is clinically important for this group of patients with challenging pain syndromes. Inconsistent outcomes were observed in compensable patients and those with grade II opioid use pre-operatively.

The strengths of the study are consistency in patient selection and operative technique, as carried out by the senior author and the requirement for CT-confirmed solid fusion. There were defined indications for the index and removal of metalwork procedure in this series and the number of patients is one of the larger cohorts in the existing literature.

The main limitation is that the study is a retrospective review of prospectively collected data from a small cohort. An additional limiting factor of external validity of the results is the non-uniform microbiological tissue sampling, no quantification of corrosion products or serum metal ions and lack of characterization of the 'looseness' of the metalware. However, none of the cases were noted to be macroscopically infected or loose from the operative records. Further, there may be a selection bias that may have affected results given the psychological makeup of the patients consenting for surgery in the face of uncertain results given that the senior author would only offer the procedure as a last resort and, further, discography was not routinely used to confirm the diagnosis of 'discogenic' back pain. Finally, there has been previous literature to suggest isolated posterolateral fusions can have a subset of patients with solid posterior fusion who have persistent LBP which was be reproduced by provocative discography (28) and this may present another uncertainty as to the nature of pain generators.

This study is informative about the relative utility of the procedure for patients who are disabled by their symptoms without another pain generator. Ideally, a larger prospective cohort study with pre-operative diagnostic injections assessing for positive relief of pain around metalwork, microbiological protocols (regarding samples being routinely sent for microscopy and testing for fastidious organisms) and quantification of corrosion (tissue and serum levels) would confirm the results of this study and existing literature. Longer follow-up periods and measurement of adjacent segment disease would also strengthen a conclusion of sustained benefit drawn from subsequent research.

Removal of pedicle screw instrumentation was identified as being a successful operation, with regards to pain reduction and a reduction in routine class II opioid use, in a cohort with a high degree of baseline functional disability.

Conclusions

Removal of instrumentation for treatment of ongoing LBP following elective lumbar fusion for discogenic back pain was identified as a successful operation by two thirds of patients who as a cohort recorded reduced VAS and grade II opioid use. A prospective cohort study with preoperative diagnostic injections and routine testing for micro-organisms and corrosion products would strengthen further studies. Despite limitations, this study suggests that removal of instrumentation remains a safe and palliative option for a subset of patients with significant disability from chronic LBP without an underlying cause following lumbar fusion.

Acknowledgements

Funding: Nil funding was received for this article.

Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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Cite this article as: Zotti MG, Brumby-Rendell OP, McDonald B, Fisher T, Tsimiklis C, Yoon WW, Osti OL. The outcome of pedicle screw instrumentation removal for ongoing low back pain following posterolateral lumbar fusion. J Spine Surg 2015;1(1):50-56. doi: 10.3978/j.issn.2414-469X.2015.08.02

Contributions: (I) Conception and design: OL Osti, MG Zotti, WW Yoon; (II) Administrative support: MG Zotti, OP Brumby-Rendell, B McDonald, C Tsimiklis, T Fisher; (III) Provision of study materials or patients: OL Osti; (IV) Collection and assembly of data: MG Zotti, WW Yoon, OL Osti; (V) Data analysis and interpretation: MG Zotti, OP Brumby-Rendell, B McDonald; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

