Failed Less Invasive Lumbar Spine Surgery as a Predictor of Subsequent Fusion Outcomes

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October 2, 2013

International Orthopaedics
Attn. Marko Pecina, M.D.

Dear Dr. Pecina:

Enclosed please find our manuscript for Orthopedics entitled "*Failed Less Invasive Lumbar Surgery as a Predictor of Subsequent Fusion Outcomes*."

This manuscript was authored by, Douglas Gillard DC, Donald Corenman MD, and Grant Dornan, MS, from the Steadman Philippon Research Institute and Steadman Clinic.

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Each of the authors represents that they have read and approved the final manuscript.

If you have any questions or concerns, please do not hesitate to contact us at the following address:

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Sincerely,

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ABSTRACT: (250/250)

Purpose: It is not uncommon for patients to undergo less invasive spine surgery (LISS) prior to succumbing to lumbar fusion; however, the effect of failed LISS on subsequent fusion outcomes is relatively unknown. The aim of this study was to test the hypothesis that patients who suffered failed LISS would afford inferior subsequent fusion outcomes when compared to patients who did not have prior LISS.

Methods: After IRB approval, registry from a spine surgeon was queried for consecutive patients who underwent fusion for intractable low back pain. The qualifying 47 patients were enrolled and split into two groups based upon a history for prior LISS: a prior surgery group (PSG) and a non-prior surgery group (nPSG).

Results: Typical postoperative outcome questionnaires, which were available in 80.9% of the patients (38/47) at an average time point of 40.4 months (Range, 13.5—66.1 months), were comparatively analyzed and failed to demonstrate significant difference between the groups: PSG v. nPSG: ODI—14.6 ± 10.9 vs. 17.2 ± 19.4 (P=0.60); SF12-PCS—10.9 ± 11.0 vs. 8.7± 12.4 (p=0.59); and bNRS—3.0 (range -2 to 7) vs. 2.0 (range -3 to 8) (p=0.91). Patient satisfaction, return to work rates, perioperative complications, success of fusion and rate of revision surgery were also not different.

Conclusions: Although limited by size and retrospective design, the results of this rare investigation suggest that patients who experience a failed LISS prior to undergoing fusion will not suffer inferior fusion outcomes when compared to patients who did not undergo prior LISS.

INTRODUCTION:

Low back pain (LBP) is a common and perplexing problem in our society that has been demonstrated to effect between 67% and 84% of its members at least once during their lifetime.[1,2] Although the majority of LBP occurrence is self-limiting,[3] approximately 10% of those affected will not recover and develop chronic LBP (cLBP).[4] Estimated economic losses for this condition approaches $90 billion per year[5] and it remains the most costly category of disability claims within industrialized nations.[6]

For those affected with cLBP, a variety of surgical solutions exist which have varying degrees of invasiveness. The least invasive of these surgical techniques is a group of minimally-invasive procedures, which may be collectively called disc decompression/repair techniques (DDRTs). Such techniques include chemonucleolysis,[7] percutaneous nucleoplasty,[8,9] percutaneous laser lumbar discectomy,[10] ozone therapy,[11] intradiscal electrothermal therapy (IDET™),[12] percutaneous laser annuloplasty,[13] selective endoscopic discectomy (SED™),[14] and disc biacuplasty (DBP).[15] In terms of increasing invasiveness, DDRTs are followed by the more traditional decompressive surgeries, such as discectomy, laminectomy, and foraminotomy, and then by the different lumbar fusion techniques (fusion).

There are times when a patient with cLBP may be offered fusion by one surgeon and a less invasive spine surgery (LISS) by another, which presents a perplexing problem: which surgery should be tried first? Simple logic may dictate that the LISS should be tried first; however, the potential failure of that procedure and its effects upon subsequent fusion success at the same level must also be considered.

The astute patient and/or primary care physician may turn to the medical literature to investigate the effect of a failed prior LISS on subsequent fusion outcomes; however, perhaps surprisingly, very few investigations have specifically studied at this issue. In fact, a recent search of MEDLINE, the Cochrane Database, and Healthstar revealed only two limited studies on subject,[16,17] and none of these compared important variables such as patient satisfaction and return to work (RTW). Therefore, the objective of this study was to test the hypothesis that patients who suffered a failed LISS prior to undergoing subsequent fusion at the same level would afford inferior fusion outcomes, which were defined as perioperative complications, rate of revision surgery, clinical outcomes, and fusion success, patient satisfaction, and RTW.

METHODS:

Inclusion and Exclusion Criteria:

With IRB approval, the registry from a single spine surgeon was queried for patients over the age of 18 who had undergone transforaminal lumbar interbody fusion (TLIF) between January 2006 and July 2012, and were at least 12 months status-post fusion for the treatment of chronic intractable low back pain which had failed at least six months of nonsurgical care. Exclusion criteria included greater than 2-levels of involvement; prior lumbar fusion at any level; and a preoperative (preop) diagnosis of infection, tumor, fracture, or pathology.

Data Gathering:

The medical records from 55 consecutive patients were independently analyzed and compared against the inclusion/exclusion criteria; 47 met the criteria and were enrolled into the study. All data was gathered and analyzed by a doctor not associated with patient care (DMG). Collected data included details of the prior lumbar spine surgery, typical patient demographics, and fusion outcomes.

The Surgical Procedure:

All patients underwent either a single or double-level TLIF by the senior author, which was augmented by posterolateral fusion, Texas Scottish Rite Hospital (TSRH™) posterior pedicle screw-rod instrumentation (Medtronic Sofamor Danek, Memphis, TN), and a Boomerang™ polyetheretherketone (PEEK) interbody device (Medtronic Sofamor Danek, Memphis, TN). The generalities of this surgical procedure have been previously described[18] and will not be presented in this paper. Additionally, in order to eliminate the need for iliac crest autograft and its associated morbidity[19] as well as reduce the chances of pseudoarthrosis,[20] the osteobiologic recombinant human bone morphogenetic protien-2 (BMP-2) (Medtronic Sofamor Danek, Memphis, TN) was employed in an off-labeled manner within the disc space, facet joint regions, and intertransverse fusion beds. At each level of fusion, a large kit II of BMP-2 was employed, which contained a dosage of 12 mg of BMP-2 at the standard concentration of 1.5 mg/ml.

Outcome Assessment Tools:

Clinical outcomes were assessed via typical patient-completed outcome questionnaires (PCOQs), which included the Oswestry Disability Index (ODI), a 0-10 point numeric rating scale for back pain (bNRS) (10= worst imaginable pain), the physical component summary score of the 12-item Short Form Health Survey (SF12-PCS), a 0-10 point patient satisfaction instrument (10 = complete satisfaction), and a 0-4 point RTW instrument designed to assess the patient's ability to return to their postoperative (postop) work (0= unable to return at all, 4= return without limitations).

Group Creation:

From the 47 patients who were enrolled into the study, two groups were created based upon whether or not there was past history of a failed LISS prior to TLIF at the same level: a prior surgery group (PSG) and a non-prior surgery group (nPSG).

Success of Fusion: As part of the standard of care, all patients underwent computerized axial tomography (CT) between 4-7 weeks status-post, in order to assess fusion status. For patients who were slow to fuse, follow-up CT and/or x-rays were employed as far out as necessary. A successful fusion was defined as at least a single full thickness cortical strut crossing the disc space, and cortical bone within at least one of the two facet joint regions and intertransverse fusion beds.

Statistical Analysis:

Statistical analysis of the demographic and surgical outcome data of both groups were performed with IBM SPSS Statistics for windows, version 20.0. Armonk, NY: IBM Corp. All continuous demographic variables, baseline outcome scores, and outcome improvement scores were found to be normally distributed, which allowed for parametric testing. bNRS, patient satisfaction, return to work, and all postoperative outcome measures were not assumed to be normally distributed and tested with nonparametric methodology. Possible predictors of clinical outcomes included demographics as well as pre-op variables, while post-op improvement in PCOQs was used as response variables. Independent samples t-tests, and Mann-Whitney U tests were used to compare continuous variables between groups, while Fisher's Exact Test was used to compare prevalence of dichotomous variables between groups.

Pearson Correlations were used to investigate the relationship between continuous predictors and clinical outcomes.

RESULTS:

Of the 47 patients who met the initial entry criteria, 38 (80.9%) successfully completed postop PCOQs at an average time point of 40.4 months (Range, 13.5— 66.1 months) and were split into two groups: the PSG (N= 15) and the nPSG (N= 23). Data from each group was comparatively analyzed, and the type of prior surgery in the PSG group is described in Table 1.

Demographic and Baseline Outcome Questionnaire Data Analysis:

There was no difference between the groups with regard to demographic variables (Table 2); however, preoperative (baseline) PCOQs scores demonstrated that patients in the PSG had significantly lower SF12-PCS scores (lower = more disabled) when compared to the nPSG (p= 0.035). (Table 3). All patients in both groups had subjective complaints of low back pain greater than lower extremity pain before the fusion. With regard to the PSG group, such complaints carried back to the time of their failed LISS.

Complications:

There were no significant differences between the groups, with regard to the success of fusion (pseudoarthrosis), perioperative complications, or rate of revision surgery (p= 0.55). (Table 4) Noteworthy was the fact that both revision surgeries in the PSG occurred in patients who had previously undergone the IDET procedure. Perioperative complications included one case of deep hematoma in the PSG, one intraoperative pedicle screw failure secondary to osteoporotic bone in the nPSG, and one superficial seroma in the nPSG. There were no cases of pseudoarthrosis in either group.

Patient-Completed Outcome Questionnaire Results:

Both groups demonstrated significant improvement from baseline on all PCOQs (P <0.001); however, this improvement was not statistically different between the groups (P>0.59). (Table 5) Patient satisfaction and RTW data also failed to reveal any significant difference between the groups (P>0.32). (Table 5)

In the PSG, the average interval between the LISP and TLIF was 46.1 Months (Range, 0.1—113.9) and the specific procedures were as follows: discectomy (n=10), laminectomy (n=3) and DVRTs (n=2 [both IDET procedures]).

With regard to the discovery of perineural fibrosis, there was no difference between the groups: PSG (4/15, 26.7%) vs. the nPSG (1/23, 4.3%) (p= 0.0685). Furthermore, as a group (n=5), the clinical outcomes of those affected with perineural fibrosis were not statistically different from those not affected (n=33)(P>0.23).

DISCUSSION:

For patients who suffer chronic intractable low back pain, selecting the appropriate surgical procedure is not without challenge, for there are often different surgical techniques available for the same diagnosis, with varying degrees of invasiveness. For example, a patient who suffers a recurrent lumbar disc herniation may have two treatment options available: a repeat discectomy or the more invasive fusion. Although logic would dictate that the least invasive procedure (i.e. the discectomy) should be tried first, what effect, if any, would a failure of that procedure have on fusion outcomes at the same level? Surprisingly, research into this important question is extremely limited.

In 1994, Jenkins et al.[16] published the results of their investigation which studied prognostic factors of lumbar fusion, one of which included the effect of a failed LISS. After undergoing a posterolateral fusion, 234 patients were followed for an average of 11.1 months and clinical outcomes were assessed. The criteria employed for a "poor clinical outcome" were either the need for revision surgery or a failure of subjective improvement. Although the authors noted that there was a significant relationship between failed LISP and fusion outcomes, they failed to report whether this relationship was positive or negative.

In 2013, Kalb et al.[17] published the results of their investigation into the influence of common preoperative factors, which included failed LISS, on surgical complications and clinical outcomes following anterior lumbar interbody fusion (ALIF). Although their paper was not directly comparable to ours (they allowed in patients with prior LISS at levels other than the level of fusion), of the 90 patients who suffered failed LISS before undergoing ALIF, statistical analysis revealed these prior surgeries were not a negative predictor of clinical outcomes or surgical complications. However, the study was limited by a 11 months follow-up, and no typical preoperative PCOQs (they chose to access clinical outcomes with the Prolo scale, which is controversial and has not been thoroughly validated for use in lumbar spine surgery) .[21]

In a comprehensive retrospective comparative investigation, we created two groups of patients from the registry of a single spine surgeon, all in whom had underwent TLIF for the treatment of chronic back pain: a group that had previously undergone LISS (PSG, N= 15) and a group that did not (nPSG, N= 23). Records were independently reviewed and postop PCOQ data, which was collected at an average time-point of 40.4 months, were analyzed which revealed no significant difference between the groups with regard to any of the fusion outcomes: perioperative complications (p=1.0), rate of revision surgery (p= 0.55), failure to fuse (there were no pseudoarthroses), and clinical outcomes (P >0.32).

Patients in the PGS did have significantly worse SF12-PCS at baseline; the significance of this finding is unknown. All other preoperative PCOQs were not statistically different at baseline.

It was also interesting that intraoperative findings of perineural fibrosis were not statistically different between the two groups: (PSG, 4/15, 26.7%; nPSG, 1/23, 4.3%); however, this finding was most likely due to the extremely small group sizes.

Another interesting finding was that the two patients who necessitated revision surgery in the PSG, happen to be the only two patients who had underwent prior failed IDET. The significance of this finding is unknown.

Our study was limited by its retrospective design, small cohort, and relatively homogeneously diagnosed patients. However, to the best of our knowledge, it is the most comprehensive study to date that investigates the important question of what effect does a failed LISS have on subsequent fusion outcomes?

CONCLUSIONS:

The results of our investigation, which refuted our hypothesis, suggested that undergoing a less invasive surgical procedure at the same level of subsequent TLIF, has no effect on fusion outcomes. A larger study with a more heterogeneously diagnosed group of patients is needed to confirm these results.

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Table 1: Type of Previous Failed Surgery		
Type of Surgery	**Number of Patients N=**	**Relative frequency (%) Total Cohort, N= 38**
Microdiscectomy	10	26.3%
Laminectomy	3	7.9%
Intradiscal electrothermography	2	5.3%
Total	15	39.5%

Table 2: Patient Demographics

Demographics:	Prior Surgery Group (n=15) mean value (SD)	Non-Prior Surgery Group (n=23) mean value (SD)	P-value
Age at Surgery	43.1 years (10.6)	45.6 years (11.9)	0.52
Gender (M vs. F)	10/5	12/11	0.51
BMI	25.4 (3.5)	23.8 (2.7)	0.11
Level of Surgery (1 vs. 2)	11/4	11/12	0.29
Depression	6	10	0.74
Smoking Past History	10	11	0.33
Litigation involvement^	6	6	1.0

^Patients who were involved with either the Workers Compensation or Personal Injury systems.

Table 3: Baseline Outcome Questionnaire Scores

Outcome Questionnaire	Prior Surgery Group	Non-Prior Surgery Group	P-value
Oswestry Disability Index (ODI)	39.2	37.7	*0.76
12-Item Short Form Health Survey PCS (SF12-PCS)	31.3	36.8	***0.035**
Numeric Rating Scale – Low Back Pain (bNRS) (0-10 scale)	5.2	4.7	^0.53

*Calculated via two-tailed t-test assuming normal distribution.
^Calculated via the Mann-Whitney U test.

Table 4: Patient Revision Surgeries

Reason	Prior Surgery Group (n=15)	Non-Prior Surgery Group (n=23)	Time Point (months status post TLIF)	P-value for total group difference
Posterior Instrumentation Removal	1*	0	16	N/A
Cage extrusion decompression	1*	0	2	N/A
Adjacent level TLIF for adjacent level disease	0	1	4	N/A
Total	2	1	NA's	P= 0.55
Prevalence	13.3%, 2/15	4.3%, 1/23	N/A	N/A

*Failed surgery prior to fusion was IDET.

Table 5: Clinical Outcome Questionnaires

Questionnaire	Prior Surgery Group (n=15) Mean Point Improvement [range]	Non-Prior Surgery Group (n=23) Mean Point Improvement [range]	P-value for group difference
Oswestry Disability Index	14.6 [-6 – +28]	17.2 [-9 – +62]	0.60
12-Item Short Form Health Survey (physical component score)	10.9 [-6.9 – +30.9]	8.7 [-12.2 – +29.3]	0.59
Numeric Rating Scale (0-10, Low Back Pain)	2.3 [-2 – +7]	2.0 [-3 – +8]	*0.91
	Prior Surgery Group (N= 15) Postop Scores [range]	Non-Prior Surgery Group (N= 23 Postop Scores [range]	P-value for group difference
Patient Satisfaction (0-10, 10 = complete satisfaction)	7.5 [1 – 10]	9.0 [2 – 10]	*0.32
Return to Work (0-4, 4 = complete return w/o restriction)	3.0 [0 – 4]	4.0 [0 – 4]	*0.40

*Calculated via the Mann-Whitney U test.