Rates of Achieving Meaningful Outcomes After Undergoing Minimally-Invasive Far Lateral Tubular Decompression

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Abstract

Purpose: To evaluate rates of achieving meaningful outcomes among patients undergoing far lateral tubular decompression (FLTD) for neuroforaminal stenosis. Traditional midline approaches are ineffective in treating isolated neuroforaminal stenosis. Direct decompression via a far lateral approach offers a minimally invasive, facet-sparing surgery with minimal surgical dissection.

Methods: Patients who underwent FLTD between January 2014 and January 2019 for isolated foraminal stenosis were included. The study collected patient demographics, perioperative data, and pre- and postoperative patient-reported outcomes (PROs). The study calculated thresholds for achieving minimal clinically important difference (MCID) on each PRO and performed logistic regression analysis to identify predictors of achieving meaningful clinical outcomes and clinical failure.

Results: 64 patients were included with a 2-year follow-up. The analysis showed improvement in each PRO over the 2-year period ($p < 0.001$ for all). 90.2% of patients achieved MCID for at least one PRO, with the VAS leg pain having the highest achievement rate at 79.7%. During the follow-up period, 17.2% required additional surgery. Increased severity of preoperative symptoms was associated with a greater likelihood of achieving MCID in all three PROs ($p < 0.05$, each). The presence of spondylolisthesis was associated with decreased odds of achieving MCID by ODI ($p = 0.04$). Increased operative time was associated with increased odds of achieving MCID by ODI ($p = 0.03$). No variables were associated with revision surgery.

Conclusions: FLTD is an effective treatment option for direct decompression of foraminal and extra foraminal stenosis in well-indicated patients. Most patients achieved MCID two years from surgery, with more severe symptoms having a greater likelihood of improvement, particularly with radicular pain. Further research should be performed on patients with spondylolisthesis to prescribe treatment resulting in maximal benefit.

Level of Evidence: 4

Key Points

- Far lateral tubular decompression (FLTD) is an effective and minimally invasive surgical option for treating symptomatic neuroforaminal stenosis in the lumbar spine.
- The majority of patients (90.2%) achieved minimal clinically important difference (MCID) on at least one patient-reported outcome (PRO) measure two years after FLTD surgery, with improvement in all three PROs over the two-year period.
- Patients with more severe preoperative symptoms had a greater likelihood of achieving meaningful improvement, particularly in regards to radicular pain, and further research should be conducted on patients with spondylolisthesis to determine optimal treatment strategies.

Introduction

It is estimated that 8–26% of patients suffer leg pain from neuroforaminal stenosis, where osseous and hypertrophy of the ligamentum flavum result in compression of the exiting nerve root.[1, 2] Over the past two decades, the introduction of interbody devices have allowed for indirect decompression of the neural elements via segmental distraction.[3–5] Trends in recent years reflect the growing popularity of interbody fusions from either anterior, posterior, or lateral approaches.[6, 7] Isolated foraminal and extraforaminal stenosis is uncommon;[8] however, the far lateral approach offers direct access to this pathology with preservation of midline musculature and facet joints.[9] Additionally, in patients without unstable spondylolisthesis, this approach obviates the need for fusion procedures that carry the risk of increased blood loss, risk of adjacent segment disease and pseudoarthrosis, and increased healthcare resource utilization.[10]

Patient reported outcomes (PROs) increasingly provide clinicians with an assessment of the impact of surgical interventions amid the current trend of value-based healthcare. Despite utilization of these measures, it is not always clear whether statistically significant improvements in these measures correlate with meaningful recovery for patients.[11] As such, the minimum clinically important difference (MCID) index has been increasingly utilized. Utilization of MCID is rapidly growing in a multitude of specialties to indicate successful improvement of patient subjective symptoms with surgery.[12–14] Calculation of this threshold score for a specific population may be performed through distribution or anchor-based approaches.[15, 16]

The purpose of this study was to evaluate rates of achieving MCID at 2-year minimum follow-up among patients who underwent FLTD for symptomatic neuroforaminal stenosis. Factors associated with MCID were evaluated with the hypothesis that patients with more severe preoperative symptoms will have a greater likelihood of achieving this threshold value of improvement.

Materials and Methods

Patient Enrollment

After Institutional Review Board approval (IRB), data was collected from all patients that underwent a single level (either unilateral or bilateral) FLTD by a single surgeon between January 2014 through January 2019. Inclusion criteria were patients ≥ 18 years of age with symptomatic foraminal stenosis, from either disc herniation or degenerative disc disease, who underwent elective index FLTD from January, 2014, to January, 2019. Patient selection for surgery was based on preoperative evaluation by the senior author and included persistence of neurologic symptoms or signs after at four weeks of failed conservative treatment, absence of dynamic instability on flexion/extension radiographs, and preoperative magnetic resonance imaging confirming neuroforaminal stenosis likely to respond to FLTD. Of note, patients with low grade spondylolisthesis with absence of unstable features (facet effusions, instability on flexion/extension) were eligible to undergo a direct decompression procedure alone, Study exclusion criteria included patients without a 2-year follow up, non-elective cases, and patients undergoing multi-level decompression.

Surgical Technique

All surgeries were performed by the senior author (T.J.O). Surgical technique has been described in previously published reports[17, 18] with the exception of the addition of oblique "Scottie dog" view fluoroscopy to approach the neuroforamen from a more lateral approach than described by Yamada et al (Fig. 1).[17] An oblique radiograph was used to localize the superior articular facet. Using this radiograph, the same trajectory was used as the radiograph beam to mark the incision. A METRx™ 18mm tubular retractor (Medtronic, Dublin, Ireland) was docked to the superior articular process. After burring the superolateral portion of the inferior vertebra's superior facet, the neuroforamen was exposed. For all cases, a video microscope was used and all patients were placed prone on a spine Jackson table. Using an oblique approach prevents the need for total resection of the pars interarticularis (Fig. 2).[19]

Outcome Measures

Functional score and pain measures were collected during office visits preoperatively and postoperatively via a standardized telephone script (Appendix 1). The questionnaires assigned included the Oswestry Disability Index (ODI),[20] and leg and low back pain Visual Analogue Scale (VAS)[21]. In order to quantify the clinical significance of outcome achievement, we applied the principles of MCID as defined for functional PROMs. Prior work has proposed that MCID be considered a minimum target for achieving meaningful clinical outcomes.[22] ODI, and VAS pain threshold scores for achieving MCID at 2-year follow-up was determined by calculating the ½ standard deviation of the change in each functional score over the 2-year time period as described in the literature.[23–26]

Statistical Analysis

All statistical analysis was performed using RStudio (2021.09.1, Boston, MA). Data was confirmed to have met parametric statistical assumptions prior to analysis. Independent samples t-test was used to compare the difference in pre- and postoperative PROs. Preoperative variables evaluated in the analysis included demographic, radiographic, and preoperative functional outcomes. A stepwise backward and forward propagation multivariate logistic regression model was used for multivariate analysis. All statistical tests were two-tailed, and the statistical difference was established at a two-sided α level of 0.05 ($p < 0.05$). Averages are reported as mean +/- standard deviation unless stated otherwise.

Results

Patient Population and Perioperative Data

A total of 64 patients with minimum 2-year follow-up and were included in the final analysis. Patient demographics are listed in Table 1. The mean age and BMI were 67.8 ± 12.0 years and 29.9 ± 61.1 kg/m^2, respectively. 62 patients (97%) underwent unilateral decompression via the far lateral approach, while the remaining 2 patients underwent bilateral decompression via bilateral far lateral approaches. Two patients had 2 levels addressed during surgery. The mean operative time was 102 ± 37 minutes (Table 1). Intraoperatively, 6.3% (4/62) of patients were found to have concomitantly have a synovial cyst, 6.3% (4/62) had adjacent segment degeneration, and 17.2% (11/62) had additional sources of possible nerve compression noted. There were no intraoperative complications reported, and most patients were discharged the same day as surgery with three patients (4.7%) requiring an overnight stay for pain control. Nine procedures (14%) were performed at L3/4, 21 were performed at L4/5 (33%), and 36 were performed at L5/S1 (56%).

Table 1
Patient Demographics

	Patients (N = 64)
Demographics	
Age (years ± SD)	67.8 ± 12.0
BMI (kg/m^2 ± SD)	29.9 ± 6.1
Male	42 (65%)
Smoking Status	
Never smoker	28 (44%)
Former	27 (42%)
Current	9 (14%)
Comorbidities	
Diabetes	15 (23%)
History of MI	14 (22%)
Congestive Heart Failure	4 (6%)
Peripheral vascular disease	2 (6%)
Cerebrovascular disease	1 (2%)
Dementia	0
Chronic Pulmonary Disease	2 (6%)
Liver Disease	0
Kidney Disease	0
Approach	
Unilateral	62 (97%)
Bilateral	2 (3%)
Levels of Surgery	
L3/4	9 (14%)
L4/5	21 (33%)
L5/S1	36 (56%)

BMI: Body Mass Index; MI: Myocardial infarction; SD: Standard Deviation

	Patients (N = 64)
Number of Levels of Surgery	
1	60 (94%)
2	2 (6%)
Operative Time (mins ± SD)	102.4 ± 37.3
Length of Stay (days ± SD)	0.74 ± 0.96
BMI: Body Mass Index; MI: Myocardial infarction; SD: Standard Deviation	

Patient Reported Outcomes and Rates of Achieving Meaningful Outcomes

There was a statistically significant improvement across all functional scores including VAS Back pain (6.0 + 2.9 vs 3.8 + 2.9; $p < 0.001$), VAS Leg pain (7.7 + 2.1 vs 2.9 + 3.1; $p < 0.001$), and ODI (51.1 + 19.3 vs 29.4 + 18.7; $p < 0.001$) from baseline to 2-year follow-up (Fig. 3).

MCID was calculated by way of the distribution method. The VAS back pain, VAS leg pain, and ODI threshold values for achieving MCID were 1.63, 1.70, and 12.3, respectively. Of all the MCID thresholds, VAS leg pain had the highest achievement rate at 79.7%, followed by ODI at 76.6% and VAS back pain at 59.4%. A total of 58 (90.5%) patients achieved MCID on at least one threshold score. Over the course of the 2-year follow-up, 17% (11/64) of patients underwent revision surgery with nine patients undergoing decompression via a central approach and two patients undergoing a transforaminal lumbar interbody fusion (TLIF). One TLIF patient had progressive degeneration of her degenerative scoliotic curve with recurrent radiculopathy and the other also had recurrent radiculopathy of the same extremity after a period of relief. Of the preoperative variables, a higher preoperative patient reported outcome was associated with a greater likelihood of achieving the MCID of the respective PRO. Presence of spondylolisthesis was associated with decreased odds of achieving MCID by ODI (OR: 0.62, CI: 0.41–0.92; p: 0.018) Increased operative time was associated with greater likelihood of achieving MCID by ODI (OR: 1.04, CI: 1.00-1.08; p: 0.026). (Table 2). A multivariate logistic regression did not demonstrate any variables associated with revision surgery.

Table 2

Multivariate Logistic Regression For Factors Associated with Revision Surgery and Achieving Patient Reported Outcomes MCID

	p-value	Odd’s Ratio	95% CI
Revision			
Age	0.202	0.96	0.91, 1.02
BMI	0.840	0.90	0.86, 1.12
Gender	0.669	1.42	0.28, 7.13
Smoking status	0.869	1.05	0.57, 1.94
Diabetes	0.370	0.35	0.03, 3.49
History of MI	0.584	0.59	0.09, 3.93
Spondylolisthesis	0.118	1.28	0.94, 1.75
Cobb angle	0.894	1.01	0.93, 1.09
Bilateral	0.993	3.04E-7	N.S.
Operative time	0.687	0.99	0.98, 1.02
MCID VAS-B			
Age	0.264	0.969	0.91, 1.02
BMI	0.124	0.906	0.80, 1.03
Gender	0.181	2.92	0.61, 14.16
Smoking status	0.999	1.00	0.55, 1.82
Diabetes	0.223	2.87	0.53, 15.74
History of MI	0.609	0.67	0.14, 3.17
Spondylolisthesis	0.031	0.67	0.47, 0.96
Cobb angle	0.357	0.97	0.90, 1.04
Bilateral	0.290	0.18	0.01, 4.35
Operative time	0.556	1.01	0.99, 1.03
Pre-op VAS-b	< 0.01w*	1.85	1.32, 2.59

VAS: Visual Analog Scale; MI: Myocardial Infarction

*Indicates Significant Value

	p-value	Odd's Ratio	95% CI
MCID VAS-L			
Age	0.193	0.96	0.90, 1.02
BMI	0.256	0.93	0.82, 1.06
Gender	0.646	1.52	0.26, 8.91
Smoking status	0.604	1.17	0.64, 2.15
Diabetes	0.640	1.58	0.23, 10.71
Hx MI	0.125	6.70	0.59, 76.39
Spondylolisthesis	0.988	1.00	0.74, 1.36
Cobb angle	0.382	1.06	0.93, 1.22
Bilateral	0.993	N.S.	N.S.
Operative time	0.959	1.00	0.98, 1.02
Pre-op VAS-b	< 0.01*	1.89	1.17, 3.04
MCID ODI			
Age	0.895	1.00	0.95, 1.07
BMI	0.186	1.11	0.95, 1.31
Gender	0.454	1.85	0.37, 9.18
Smoking status	0.528	1.22	0.65, 2.29
Diabetes	0.578	1.72	0.25, 11.72
Hx MI	0.985	0.98	0.17, 5.85
Spondylolisthesis	0.018	0.62	0.41, 0.92
Cobb angle	0.457	1.04	0.93, 1.15
Bilateral	0.994	N.S.	N.S.
Operative time	0.026	1.04	1.00, 1.08
Pre-op ODI	0.041*	1.05	1.00, 1.10
VAS: Visual Analog Scale; MI: Myocardial Infarction			
*Indicates Significant Value			

Discussion

Findings of the present study demonstrate that direct surgical decompression of the neuroforamina is an effective choice for treatment of lumbar foraminal or extraforaminal stenosis. Addressing this pathology is difficult through traditional midline approaches. Through the far lateral approach, the exiting nerve root may be directly visualized and decompressed. Additionally, an MIS technique was utilized to minimize extensive dissection and destabilization of the facet joints. Over 90% of patients passed the MCID threshold for at least one reported outcome, while nearly 80% of patients achieved the MCID for treatment of leg pain, which would suggest effective decompression of the foramina. Of note, the presence of spondylolisthesis did decrease the odds of achieving MCID by ODI, however, this trend was not observed in any other metrics, nor was it associated with need for revision surgery. Still, this may reflect a limitation of clinical benefit to direct decompression in these patients. The findings of the present study highlight the effectiveness of direct decompression of the neural foramina via the far lateral approach and determination of the MCID threshold value for this population.

Open procedures are increasingly under scrutiny for their higher rates of muscle atrophy and damage to native architecture and subsequent post-operative instability. Both open and minimally invasive far lateral approaches have been described.[27] The open technique utilizes the Wiltse interval, however, it also requires manual retraction of the multifidus medially, thorough hemostasis from dissection of paraspinal musculature, and a larger incision.[27] The surgical technique utilized in the present study utilizes the reproducible lumbar oblique radiograph to dock on the superior articular facet. An additional advantage is that the planned incision is independent of soft tissue depth and the same technique can be used in patients of variable body habitus. An FLTD approach spares total resection of the pars interarticularis, therefore maintaining spinal stability and foregoing a spinal fusion.[28] No study exists comparing open versus MIS techniques for the far lateral approach as this approach is uncommon, however, a recent study from the Quality Outcomes Database demonstrated shorter length of stay in the MIS group, yet higher satisfaction in the open group.[29] Potential benefits to MIS include shorter length of stay, decreased blood loss, decreased postoperative narcotic requirement, decreased rate of infection, and decreased potential for facet instability, although, MIS has been criticized for its steep learning curve and possibility of incomplete decompression due to limited fields of view, which potentially may affect patient reported outcomes.[30–33] MIS spine cases were also criticized for higher rates of dural tears with subsequent CSF leak in earlier studies, but more recent studies have challenged this conclusion[34, 35] In the present study, there were no intraoperative complication noted and 95% of patients left the same day.

The present study is the first to describe MCID values for FLTD. There remains no consensus on MCID values in the spine literature despite a lengthy history of literature[36, 37] This is primarily because this metric has not been externally validated for different regions or pathologies. It cannot be assumed that patients receiving treatment for a select pathology in one part of the world will quantify their improvement in symptoms like patients of different symptomology and region. Creation of MCID values for this specific population allows for comparison to others and may later be validated externally. Interestingly, our MCID cutoff of 12.3 is higher than that reported in the literature ranging from 5–10 via the distribution method.[15, 38–41] This stricter cutoff is likely due to the increased variability in outcome scores due to the limited sample size; yet, 90% of patients still achieved this score on at least one metric and nearly 80% achieved this score on the VAS leg pain. Correlation to the anchor-based method may also be utilized in the future to determine the optimal method of reporting.

The presence of spondylolisthesis was found to be associated with decreased likelihood of achieving the ODI MCID. However, there was no relation of the presence of spondylolisthesis toward need for revision surgery, fusion surgery, or achievement of MCID by other metrics. Further study is required to determine whether these patients may benefit more from alternative procedures. Recent years have seen the evolution of interbody devices providing indirect decompression of the neural foramen.[42] Interbody cages may be used to expand the cross-sectional area of the neural foramen by 25% in lateral interbody devices,[43] and up to 67% with anterior interbody devices.[44] Certainly, in patients with low grade spondylolisthesis with a collapsed disc space, interbody fusions may be an attractive option that avoids meticulous direct decompression of the nerve root. However, this decompression is variable, and their clinical utility is dependent on the degree of disc space collapse and the degree of spondylolisthesis. For example, Schuler et al. demonstrated that patients with collapsed disc spaces (< 5mm) tended to have earlier and greater improvements in outcome scores.[45] Alternatively, patients with foraminal disc herniations would require discectomy via the far lateral approach. Indications for these procedures are continuously evolving and high-quality comparative studies are useful in determining the optimal management technique. Still, FLTD is an effective procedure for treatment of foraminal stenosis and a useful tool in the spine surgeon's repertoire.

The present study must be viewed with its limitations. This is a retrospective study from one academic medical center with an analysis of in-house surgical data from the senior author (TJO). Larger, multicenter studies are required to externally validate these results. Additionally, follow-up data in this study was limited 2 years. Another limitation is inherent in the distribution method of MCID calculation, as this is specific to this population and requires external validation.[46] Although, the calculated MCID was relatively high and may demonstrate stricter values due to the limited sample size. Additionally, there exists selection bias in patients receiving FLTD as specific indications are still debated, and treatment algorithms may vary between surgeons.

Conclusion

In well-indicated patients, FLTD should remain in a spine surgeon's arsenal to perform direct decompression of foraminal and extra foraminal stenosis. A large majority of patients achieved MCID two years from surgery. Patients with more severe symptoms had a greater likelihood of achieving meaningful improvement. Further research should be performed on patients with spondylolisthesis to prescribe treatment resulting in maximal benefit.

Declarations

- Ethics approval and consent to participate: After Institutional Review Board approval (IRB) was acquired for all patients.

- Consent for publication: we consent for publication
- Availability of data and material: data is available upon reasonable request
- Competing interests: not applicable
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- Authors' contributions: AB, AG, EB, EM, ZK, MJ contributed to conception, design, writing, statistics, review drafting. TJ contributed to review and drafting and conception and supervision.
- Acknowledgements: not applicable
- All experimental protocols were approved by a named institutional and/or licensing committee. Informed consent was obtained from all subjects and/or their legal guardian(s).
- Availability of Data and Materials: The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Figures

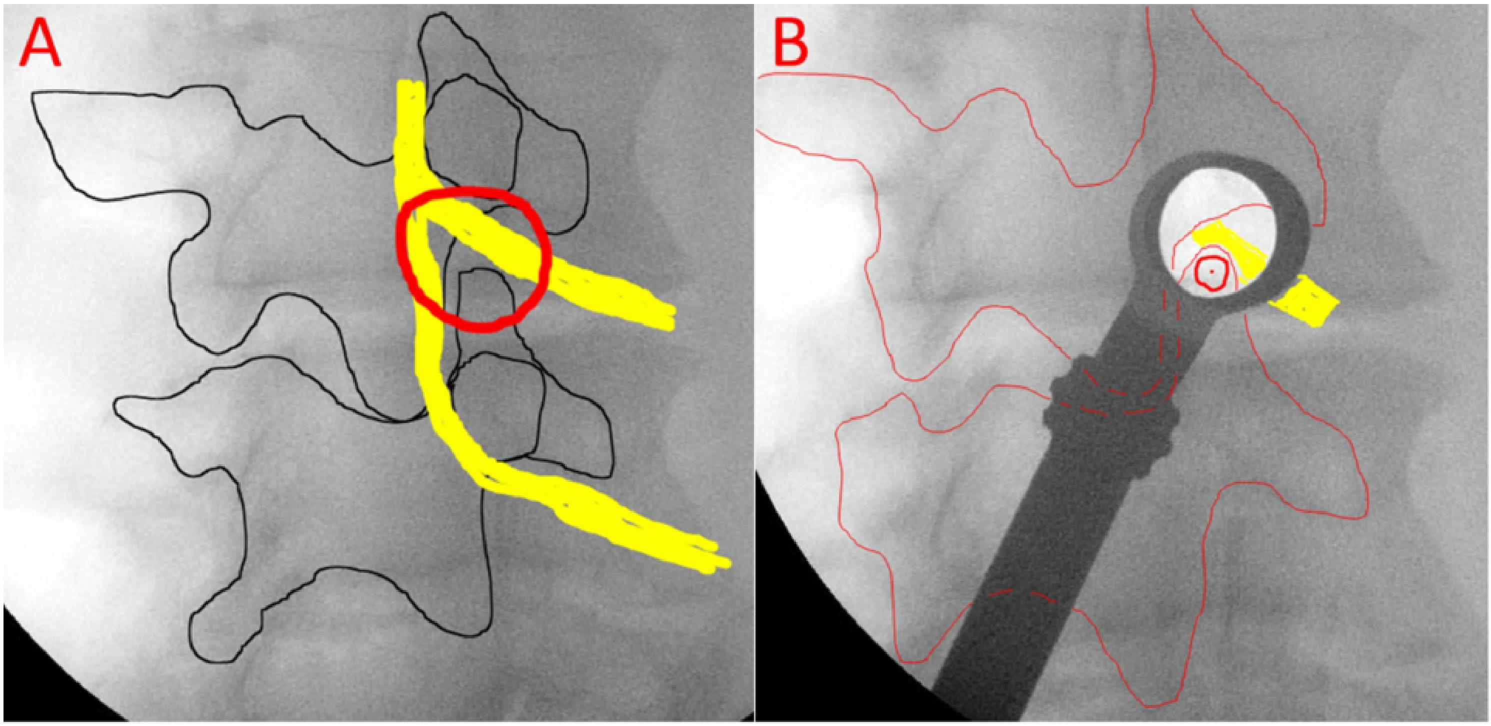

Figure 1

Fluoroscopic, intraoperative radiographs of the “scottie dog” view with neuroforamen and illustrated nerves (A) and tubular retractor docking at the superior articular facet (B) (adapted from Knio et al.).[19]

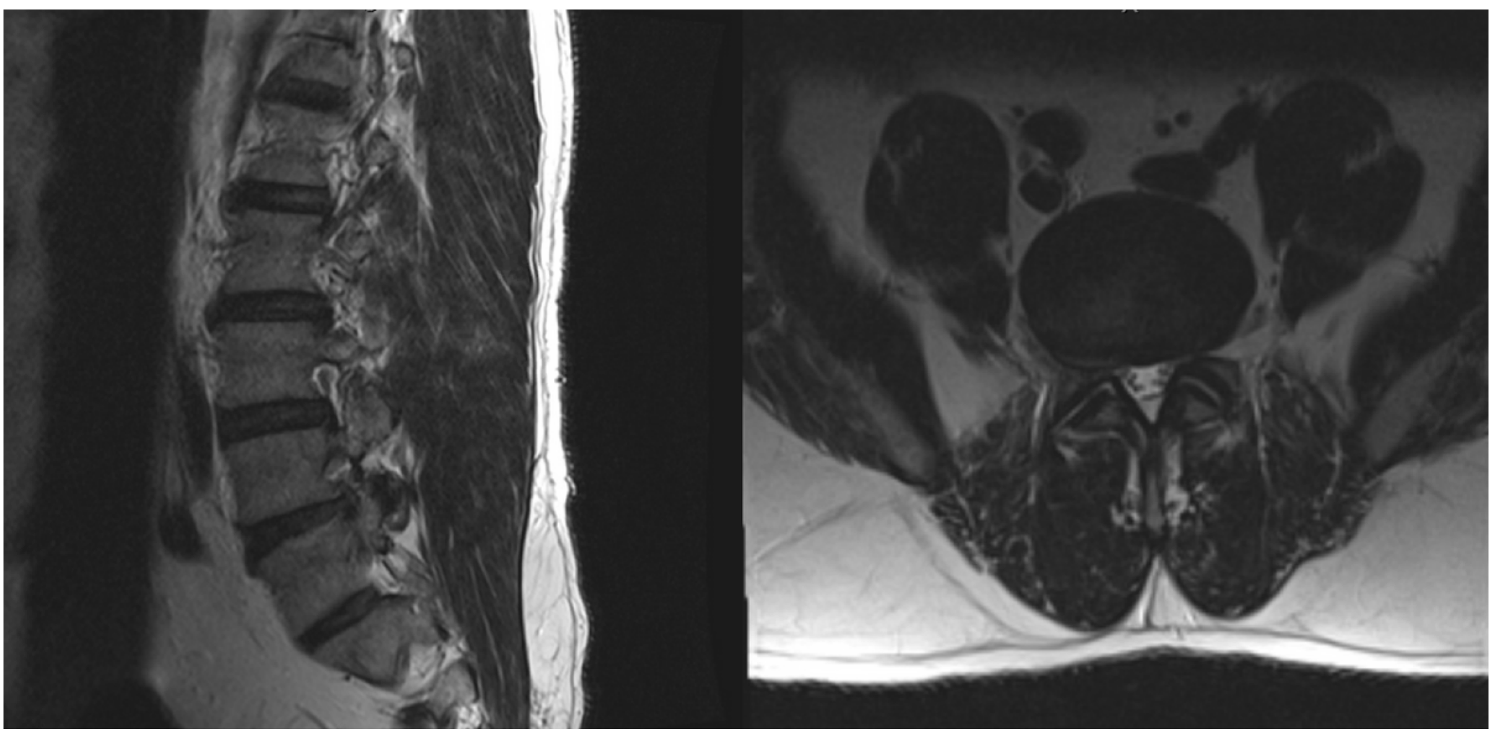

Figure 2

T2-weighted MRI sequence of a sample patient’s axial view of L4/5 left-sided neuroforaminal narrowing (A) and sagittal view (B) of the same left neuroforamen with moderate to severe narrowing. This patient underwent a left L5-S1 FLTD.

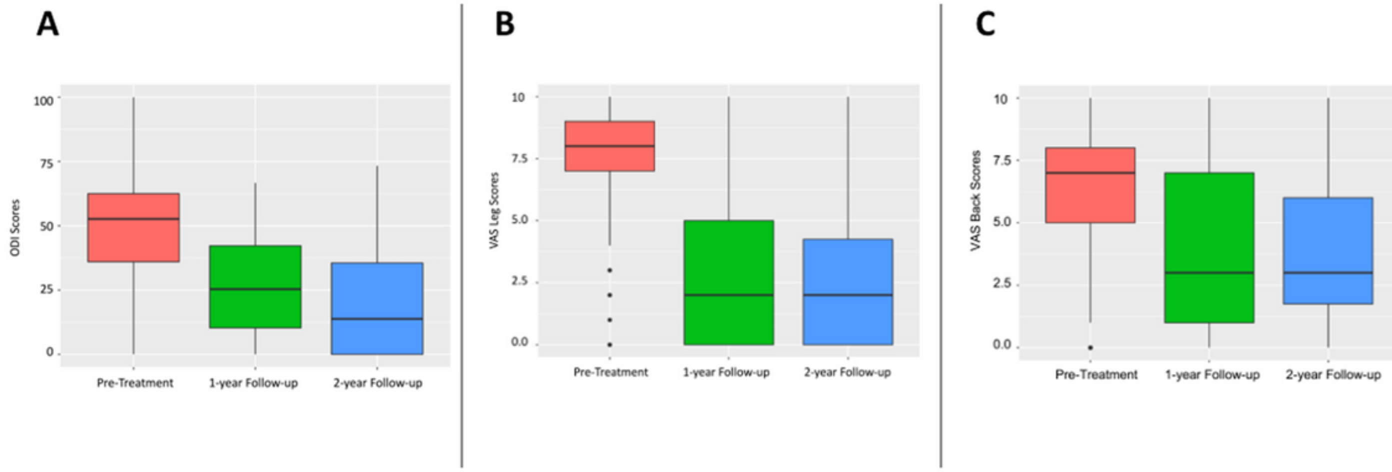

Figure 3

ODI (A), VAS Leg Pain (B), and VAS Back Pain (C) scores at pre-treatment, 1-year follow-up, and 2-year follow-up levels.