

Posterior Lateral Arthrodesis as a Treatment Option for Lumbar Spinal Stenosis: Safety and Early Clinical Outcomes

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Introduction: Lumbar spinal stenosis (LSS) is a common condition caused by degenerative changes in the lumbar spine with age. LSS is caused by a variety of factors, including degenerative spondylosis and spondylolisthesis. People suffering with LSS experience neurogenic claudication, which causes severe physical limitations, discomfort, and a decrease in quality of life. Less invasive procedures are now being researched to improve the prognosis, success rate, and safety of LSS treatments. Posterior lateral spinal arthrodesis (PLSA) is a new surgical treatment for LSS. This study looks at the procedural and patient safety of PLSA.

Materials and methods: This study is a multicenter retrospective analysis of the safety of PLSA who met the clinical indications for PLSA and underwent the procedure at eight interventional spine practices. Data was collected on demographical information, pre-procedural numeric rating scale score (NRS), post-procedural NRS, and complication reporting. Patients who were included had LSS with or without spondylolisthesis and had failed conservative treatments. A descriptive statistical analysis was performed to report the outcomes. Results were reported as mean and standard deviations for continuous outcomes, and frequency (%) for categorical outcomes.

Results: This retrospective analysis involved 191 patients and 202 PLSA implants. The majority of patients were male Caucasians with a mean age of 69.2 years and a BMI of 31.1. A large majority of implants were placed at the L4-5 level, and the average pre-procedural NRS was 6.3 while the average post-procedural NRS was 3.1, indicating a 50.8% reduction in pain ($p < 0.0001$). Two patients reported complications, but they were unrelated to the device or surgical procedure; no infections, device malfunctions, or migrations were reported in the patient cohort.

Conclusion: Preliminary results with PLSA implants indicate that it is a safe treatment option for patients with moderate LSS who do not respond to conservative management.

Keywords: lumbar spinal stenosis, spondylolisthesis, interspinous fusion, Minuteman, spinal simplicity, posterior lateral spinal arthrodesis

Introduction

Lumbar spinal stenosis (LSS) is frequently caused by degenerative changes in the lumbar spine associated with aging. Multiple factors, such as degenerative spondylosis and spondylolisthesis, can contribute to LSS. Age-related degeneration and protrusion of intervertebral discs can result in increased loading of the posterior vertebral elements. This can lead to the development of posterior vertebral osteophytes, facet hypertrophy, synovial facet cysts, and ligamentum flavum hypertrophy, which can ultimately result in spinal stenosis.¹ In addition, degenerative spondylolisthesis can

cause LSS by fracturing the pars interarticularis, which leads to vertebral instability and forward translation. This anterior slippage can cause stenosis by narrowing the spinal canal. Patients often experience signs of neurogenic claudication, which include pain when walking or standing excessively, resulting in severe physical limitations. Pain and physical restrictions often result in a substantial decline in quality of life. These restrictions can have negative physical, psychological, and monetary effects on the individual patient, the healthcare system, and society as a whole.^{1,2}

It is thought that between 250,000 and 500,000 people in the United States have symptoms of LSS. With about 70 million Americans over 50 years and an anticipated increase of 18 million in the next decade, it is likely that the incidence of spinal stenosis will rise.³ Based on the Framingham Study, in the United States as age increases, the prevalence of acquired relative and absolute stenosis also increases. Specifically, in the 60–69 year old age group, the prevalence of relative and absolute acquired stenosis rises to 47.2% and 19.4%, respectively.⁴

LSS treatment options range from physical therapy, medications, and epidural steroid injections to substantial open surgical decompression of the lumbar spine, with or without fusion or instrumentation. The efficacy of these treatments depends on the degree of the stenosis, the presence or absence of neurologic impairments, the comorbidities present, and the timing of intervention.⁵ However, the expenses of these treatments can vary substantially. In the early stages of LSS or in patients with few symptoms, conservative therapies, which are less expensive, can be effective.^{5,6} Nonetheless, these therapies are typically repeated because their effects are often temporary. Surgical decompression, if successful, can be a one-time intervention. However, it is considerably more expensive and is reserved for those with moderate or severe symptoms. In addition, it is associated with a significantly higher incidence of complications, which raises the cost of care.⁷ Also, elderly patients with LSS who fail conservative treatment may decline surgery or be deemed “high-risk” for surgery. This leaves these patients either untreated or receiving recurrent epidural steroid injections for short-term relief. However, this may result in consequences associated with steroid use, such as osteoporosis, a worsening of diabetes or hypertension, and greater long-term expenditures.⁸

The development of contemporary minimally invasive procedures to improve the prognosis, success rate, and safety of treatments for LSS is now underway. Posterior lateral spinal arthrodesis (PLSA) is a recent advance in the surgical treatment of LSS. Minuteman (Spinal Simplicity, Overland Park, KS, 66,211) is a device authorized by the United States Food and Drug Administration for the treatment of LSS. This device can specifically be used for patients with LSS with or without mild to moderate misalignment of the lumbar spine (grade 1–2 spondylolisthesis). Although the clinical findings of this technology have not yet been sufficiently documented, it has the potential to become a competitive alternative to other conventional procedures.⁹ This retrospective study examines a cohort of patients who received treatment for LSS with PLSA, and were analyzed for procedural and patient safety.

Methods

Study Design

We conducted a multicenter retrospective study of eight interventional spine practices to determine the safety of PLSA. An IRB waiver was granted to the primary investigator who provided oversight of this study. All patient data collected was de-identified and kept confidential with compliance with Declaration of Helsinki. The process for data mining was reviewed and approved by the legal entities at the local institutions involved in this study.

Inclusion Criteria

Patients who were included in this study met all pre-implant evaluation criteria as described: lumbar spinal stenosis with or without spondylolisthesis. Selected patients who had failed conservative treatments (including physical therapy, medications, injections, and advanced procedures [MILD and ISS]) and were desiring further treatment were considered for PLSA.

Exclusion Criteria

Exclusion criteria included patients (a) Solely experiencing axial back pain, (b) Presence of severe spondylolisthesis classified as grade III to V, (c) patients with scoliosis (d) ankylosed spinal segments, (e) Having a history of vertebral osteoporosis or vertebral fractures, acute pars fractures (f) pregnant patients, (g) patient with chronic pain that also co-occurs frequently with psychiatric disorders such as depression and anxiety.

Data Collection

Demographical data, pre-procedural numeric rating scale score (NRS), post-procedural NRS, and complication reporting was collected by each individual site and entered into a secure database created by the corresponding author to maintain confidentiality. NRS data was systematically gathered, with particular attention to the patient's lower back pain and the presence of neurogenic claudication symptoms and graded based on their current level of pain while being examined. All patient data was anonymized. The study included a total of 191 patients who met the clinical criteria for PLSA and underwent a novel PLSA procedure (Minuteman). All patients were included if they had at least one post-implantation follow-up visit. The data from the last clinic visit was used in the manuscript. Data was extracted from the medical record and included age, sex, race, body mass index (BMI), opioid use, history of prior spinal cord stimulator implantation, history of prior minimally invasive lumbar decompression (MILD) or interspinous spacer implantation (ISS), history of prior open lumbar spine surgery, date of PLSA, date of last follow-up, and complications with specific detailing.

Implant Procedure

The patients underwent a microtubular minimally invasive spine fusion via a posterior lateral approach. This technique involves a one-inch incision on the side of the body, then using a Steinmann pin to obtain a radiological placement just above the interlaminar line. A series of microtubular introducers are employed to direct a sheath to the area just lateral to the interspinous space, at which time a measurement rasp is used to open the space and take a measurement. At least 8 millimeters of space must be created to implant the device, which has a function of interspinous retraction, vertebral stabilization and eventual posterior arthrodesis by the addition of bone growth hormonal factors. Patients are usually discharged within an hour of surgery. An example of pre op and post op imaging can be seen in [Figures 1 and 2](#). A diagram for surgical technique can be seen in [Figure 3](#).

Statistical Analysis

A descriptive statistical analysis was performed to report the outcomes. Results were reported as mean and standard deviations for continuous outcomes, and frequency (%) for categorical outcomes. Treatment effects were analyzed using paired *t*-tests with a significance level (α) of 0.05. All analyses were performed using SPSS (IBM SPSS Statistics for Windows, Version 21.0; Armonk, NY: IBM Corp.).

Results

A total of 191 patients encompassing 202 implants were included in this retrospective review. Demographical data is shown in [Table 1](#). The mean age was 69.2 ± 11.4 years. Ninety-eight patients were male (51.3%). The majority (87.4%) of patients were Caucasian ($n=167$). The mean BMI was 31.1 ± 6.2 . Thirty patients (15.7%) had previously undergone MILD or ISS placement for LSS. Fourteen patients (7.3%) had previously undergone open lumbar spine surgery. In regards to pre-procedural opioid use, 48 patients (25.1%) were on chronic opioids with an average oral morphine equivalent (OME) dosage of 31.2 ± 26.3 .

There were a total of 202 PLSA implants. The majority of implants were performed at L4-5 ($n=140$; 69.3%). The mean time between PLSA implantation and last follow-up was 108.5 ± 126 days. The mean pre-procedural NRS was 6.3 ± 2.4 , and the mean post-procedural NRS was 3.1 ± 2.5 (50.8% pain improvement, $p < 0.0001$). Eleven patients (5.8%) had two PLSA devices implanted with the most common levels being L3-4 and L4-5 ($n=6$; 54.6%) ([Table 2](#)).

Two patients had a reported complication after the implant procedure ([Table 3](#)). Neither of the complications were related to the device or the surgical procedure. One patient experienced constipation and urinary retention following the

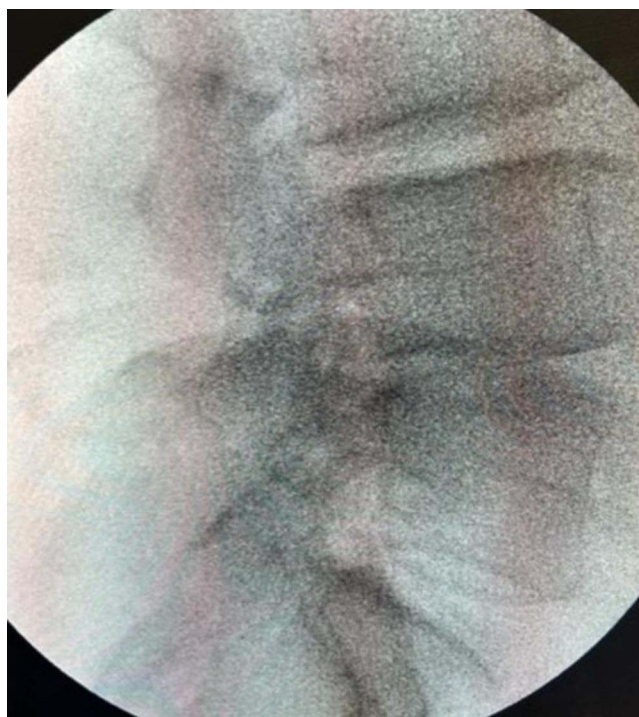


Figure 1 Pre-Op, Lateral, L4/L5, Angular Instability.

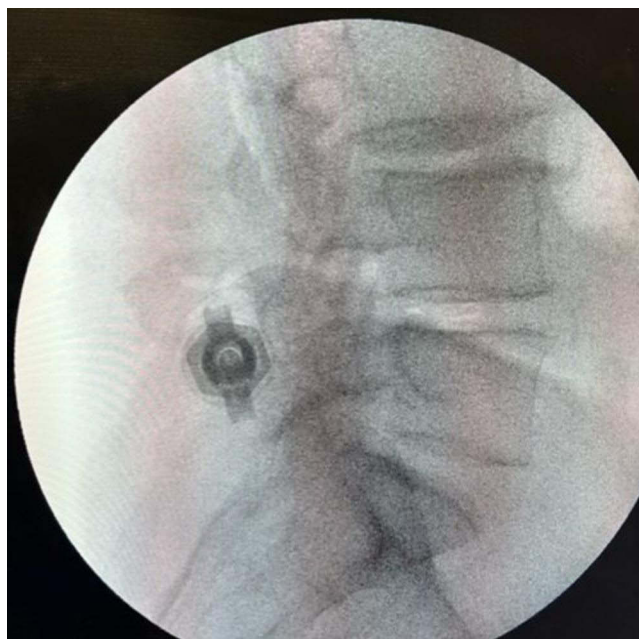


Figure 2 Post-Op, Lateral, L4/L5, foraminal height restored, disc height restored.

implantation surgery which required an emergency room visit. He was discharged home the same day. Of note, the patient did have a history of benign prostatic hyperplasia. The second patient had a hypertensive crisis in the post-anesthesia care unit and was admitted for three days afterwards for cardiac work-up. Neither patient had previously undergone prior LSS advanced treatments or open surgical procedures, and neither patient was on chronic opioids at the

MINIMALLY INVASIVE LATERAL APPROACH (SURGICAL TECHNIQUE)



Figure 3 Flowchart describing the surgical process and technique.

Table 1 Baseline Clinical and Demographic Variables of Included Patients

Variable	Mean±SD or n (%)
Age (years)	69.2 ± 11.4
Sex, Female	93 (48.7%)
Sex, Male	98 (51.3%)
BMI (kg/m ²)	31.1 ± 6.2
History of Prior LSS Advanced Procedures (ie MILD and ISS)	30 (15.7%)
History of Prior Open Lumbar Spine Surgery	14 (7.3%)
Chronic opioid use at time of implantation	48 (25.1%)
Mean OME at time of implantation for patients taking chronic opioids	31.2 ± 26.3
Mean follow-up time between implantation and last follow-up (days)	108.5 ± 126

Abbreviations: BMI, body mass index; ISS, interspinous spacer; LSS, lumbar spinal stenosis; MILD, minimally invasive lumbar decompression; OME, oral morphine equivalents.

Table 2 Procedural Details of Included Patients

Procedural Details	n (%)
Total PLSA implants	202
Procedural levels	
T12-L1	1 (0.5%)
L1-2	3 (1.5%)
L2-3	9 (4.5%)
L3-4	47 (23.3%)
L4-5	140 (69.3%)
L5-S1	2 (1%)
Total number of patients with two level implants	11 (5.4%)
Procedural levels in patients with two level implants	
L1-3	2 (18.2%)
L2-4	2 (54.5%)
L3-5	6 (3%)
L4-S1	1 (9.1%)

Abbreviation: PLSA, posterior lateral spinal arthrodesis.

Table 3 Reported Complications in the Patient Cohort

Patients	Complication	Admission to Hospital?	Long-Term Sequelae
Patient 1	Constipation and urinary retention following the implantation surgery, which required an emergency room visit	No	None
Patient 2	Hypertensive crisis in the post-anesthesia care unit following the implantation surgery	Yes, for three days while undergoing cardiac work-up	None

time of the surgery. Notably, there were no reported infections, device malfunctions, or device migrations in the patient cohort.

Discussion

Minimally invasive procedures for vertebral canal stenosis surgery are being developed. One of the new minimally invasive procedures that has been developed is PLSA (Minuteman). The FDA has authorized this device for the treatment of LSS, and it has several potential advantages over conventional procedures. This device has the benefit of requiring minimal dissection of soft tissue and shortened operative times compared to conventional open surgery, resulting no requirement for post-operative hospital stay and decreased risk of complications.¹⁰ However, additional research was required to assess the safety of PLSA.

To determine the safety and effectiveness of PLSA, a multicenter retrospective study was conducted at eight interventional spine practices. The study included a total of 191 patients who underwent the PLSA procedure for the treatment of LSS. The primary aim of this study was to evaluate the safety of PLSA and determine its effectiveness in reducing pain in patients with LSS. The results of the study demonstrated that PLSA is a safe and effective treatment option for patients with LSS who have failed conservative management and, in some cases, had previously undergone other minimally invasive procedures or open surgical decompression. Our results demonstrated a low overall complication rate of 1.0% (2/191), with no reported complications related to the device or the surgical procedure itself. Only two patients reported complications following the PLSA procedure, and neither of these complications were related to the device or the surgical technique. One patient had constipation and urinary retention, necessitating a visit to the emergency room, while the other had a hypertensive crisis in the post-anesthesia care unit, necessitating a three-day admission for cardiac work-up. Importantly, no infections, device malfunctions, or device migrations were reported in the patient cohort, demonstrating the safety of PLSA.

Given the low complication rate observed in this study, PLSA may be a viable alternative to more invasive open surgical interventions for LSS. This is particularly relevant for elderly patients or those with significant comorbidities, who may be deemed high-risk for more extensive surgery. In addition, there is a biomechanical increase in the surface area of the spinal canal once this device is placed, in some cases this negates the need for a more invasive open decompression.¹¹ In a study conducted by Proietti et al it was found that the complication rate in patients receiving surgery for lumbar stenosis was 14.77% with a higher incidence of major complications in the fusion group. In this study patients being treated for spondylolisthesis had a complication rate of 25.7%.¹² In a prospective study conducted by Reis et al, 23% of patients experienced complications after undergoing spine surgery. Surgical site infection was the most common, accounting for 9% of cases. The risk of complications was higher among patients who underwent spine instrumentation compared to non-instrumented surgery (33% vs 22%).¹³ A recent prospective study analyzed 526 patients who underwent spinal surgery, examining clinical characteristics, comorbidities, surgical management, and outcomes. The overall postoperative complication rate was 26%, with revision surgery required in 12% of cases within 30 postoperative days.¹⁴ When compared with our data, it suggests that PLSA may be a safer alternative to lumbar decompression or fusion surgeries in patients with LSS with or without grade 1–2 spondylolisthesis.

LSS surgery aims to decompress the spinal canal while maintaining stability. Fusion is sometimes necessary, but it increases costs and risks. Patients undergo diagnostic tests before surgery to ensure they can withstand the operation. Surgical treatments have higher financial costs than nonoperative care, with costs not including follow-up care, skilled nursing facilities, physical therapy, and revision surgery. Lumbar laminectomy has an average hospital charge of \$23,724, while laminectomy with fusion has a higher cost due to increased hospital stay, implant costs, and potential complications.^{15,16} Complex and simple fusion procedures have varying complication rates, hospital stays, and costs, with discharged patients often requiring nursing or rehabilitation homes. Between 8% and 10% of patients require revision surgery, with risks increasing based on the number of levels involved.¹⁷ The cost of revision fusion includes surgery, outpatient resource utilization, and indirect costs, such as missed work.

A recent study conducted by Skoblar et al aimed to prospectively evaluate the radiographic fusion outcomes in patients who underwent PLSA. A total of 43 patients, representing 69 treated levels, underwent a follow-up CT scan at a mean follow-up time of 459 days after surgery. The fusion success, assessed by independent radiologists using a novel

grading scale, was achieved in 92.8% of the evaluated levels.¹⁸ Additionally, a biomechanical study aimed to compare the segmental multidirectional stability and maintenance of foraminal distraction provided by PLSA when compared with commonly used pedicle screw and facet screw posterior fixation constructs combined with lumbar interbody cages.¹⁹ The study found no significant differences between the different posterior implants combined with lateral lumbar interbody cages. Furthermore, all posterior fixation devices including the stand-alone PLSA effectively maintained neuroforaminal distraction during flexion and extension.¹⁹ When compared to lumbar laminectomy with or without fusion, PLSA may offer a cost-effective option for patients who have failed conservative treatments and are seeking further intervention when compared to lumbar laminectomy or fusion. However, further research is needed to compare the cost-effectiveness of PLSA with other surgical treatments for LSS.

This study also found a statistically significant reduction in pain levels post-procedure, with the mean pre-procedural NRS score of 6.3 ± 2.4 decreasing to 3.1 ± 2.5 post-procedure ($p < 0.0001$), resulting in a 50.8% pain improvement. This reduction in pain levels suggests that Posterior Lateral Arthrodesis (PLSA) may offer an effective treatment option for patients with Lumbar Spinal Stenosis (LSS) who have not experienced relief from conservative therapies.

To comprehensively assess the impact of PLSA on patient functional outcomes, further research is warranted. It is essential to acknowledge certain limitations in this study, including its retrospective design and the relatively short follow-up period. Future studies should adopt a prospective approach to evaluate the safety and effectiveness of PLSA, incorporating longer-term follow-up data to better understand the enduring effects of this procedure. These studies should consider measuring factors such as pain-related disability, improvements in quality of life, and claudication distance.

Furthermore, conducting comparative studies between PLSA and other surgical or conservative treatments for LSS would provide valuable insights into determining the optimal treatment strategy for patients with varying degrees of symptom severity and comorbidities. This approach could help tailor treatment choices to individual patient needs and enhance our understanding of the most effective interventions for LSS.

Conclusion

In conclusion, our findings suggest that PLSA is a safe treatment option for patients with LSS. The low complication rate observed in this study supports the use of PLSA as an alternative to more invasive surgical interventions, particularly in elderly or high-risk patients. Further research is needed to confirm these findings and to compare the cost-effectiveness and long-term outcomes of PLSA with other treatment options for LSS.

Ethics Statement

This study was approved by the internal review committee at Thomas Health/Saint Francis Hospital, Charleston, WV. This committee waived the need to obtain consent for the collection, analysis and publication of the retrospectively obtained and deidentified data for this study.

Disclosure

Ashley Bailey-Classen MD: Speaker's Bureau for Medtronic. Consultant for Nevro and Biotronik. Medical Advisory Board for Spinal Simplicity.

Usman Latif MD: Consultant, Speaker, and Advisory Board for Spinal Simplicity. Consultant for Omnia Medical. Consultant, Speaker, and Advisory Board for Nevro. Consultant and Speaker for Nalu Medical. Consultant and Speaker for Vertos. Consultant for Hydrocision. Consultant and Advisory Board for Informed Consent. Investigator and Funded Research for Mainstay Medical.

Nomen Azeem MD: Related: Consultant to Spinal Simplicity. Unrelated: Consultant to Abbott, Medtronic, Biotronik, Vertos, Vivex, Ethos Labs, Painteq. Funded Research: Painteq, Vivex, Ethos Labs Minor equity: Spinal Simplicity.

Douglas Beall MD: Consultant: Medtronic, Spineology, Merit Medical, Johnson & Johnson, IZI, Techlamed, Peterson Enterprises, Medical Metrics, Avanos, Boston Scientific, Sollis Pharmaceuticals, Simplify Medical, Stryker, Lenoss Medical, Spine BioPharma, Piramal, ReGelTec, Nanofuse, Spinal Simplicity, Pain Theory, Spark Biomedical, Micron Medical Corp, Bronx Medical, Smart Soft, Tissue Tech, RayShield, Stayble, Thermaquil, Vivex, Stratus Medical, Genesys, Abbott, Eliquence, SetBone Medical, Amber Implants, Cerapedics, Neurovaxis, Varian Medical Systems,

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Chad Stephens: Teaching consultant and medical advisory board from Spinal Simplicity, outside the submitted work.

Larry Khoo MD: Related: Spinal simplicity: speaker, consultant, and minor shareholder. Unrelated: Consultant: Aesculap Spine, Globus Medical, Nuvasive. Spine, SeaSpine, Zimmer Spine, Choice Spine, Camber Spine, Burst Biologics, Augmedics, Spineguard, Amplify Spine, Medtronic Midas Rex, Carevature Spine.

Timothy Deer: Related: Consultant to Spinal Simplicity Unrelated: Consultant to SPR, Nalu, Mainstay, Consultant to Abbott, Saluda, Painteq, Spinal Simplicity; Funded Research: Boston Scientific, Abbott, SPR, Mainstay Minor equity: Ethos, Spintera, Cornorloc, Painteq, Spinal Simplicity, Saluda.

The authors report no other conflicts of interest in this work.

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