

The First Grade III Lumbar Spondylolisthesis Treated With the Novel 360° Artificial Disc/Artificial Facet Replacement Solution

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ABSTRACT

Background: The incidence of spondylolisthesis increases with age and is more prevalent in women. “High-grade” (above grade II) occurs in 10% to 12% of affected individuals. Patients often present with back pain as well as leg pain, numbness, paresthesias, hamstring tightness, radiculopathy, and neurogenic claudication. If conservative therapy fails, the standard of care is fusion. However, despite its effectiveness in stabilizing the spine, fusion causes biomechanical load transfer to adjacent vertebrae, which can increase the risk of adjacent segment disease and reduce range of motion. These drawbacks are especially problematic for younger, more active patients who wish to maintain a high quality of life. In this report, we describe an innovative 360°, motion-preserving surgical approach utilizing 2 FDA-approved devices, the Prodisc L Artificial Disc Replacement and the Total Posterior Spine System, in an “off-label” investigational manner for the treatment of high-grade spondylolisthesis and associated disc space collapse.

Methods: This case report is part of a multi-institution, Institutional Review Board-approved, prospective cohort trial. Subjective and objective outcomes were collected every 6 to 12 weeks. Patient satisfaction scores as well as patient-reported outcomes included neurologic examination, visual analog scale (VAS) back pain, VAS left leg pain, VAS right leg pain, Patient-Reported Outcomes Measurement Information System (PROMIS), PROMIS physical health, PROMIS mental health, 12-item short form (SF-12), need for repeat surgery, patient’s recommendations pertaining to their surgery, and postoperative radiographic dynamic x-ray images. A 36-year-old man presented to the clinic with complaints of progressive 7 to 8/10 low back pain with pain radiating down his legs bilaterally. The patient reported years of symptoms, only mildly managed with conservative therapy. He had been offered fusion by multiple surgeons. Imaging demonstrated progression of his known L5 to S1 grade II spondylolisthesis with severe disc space collapse to now grade III.

Results: The patient’s Oswestry Disability Index improved from 16 to 2 (87.5%) at 3 months postoperatively. The patient’s VAS score for back, left, and right leg pain was 4.87, 2.41, and 1.51 preoperatively. All VAS scores decreased to 0 by 3 months. The PROMIS physical health score of 14 remained relatively stable at 13 at 3 months. The SF-12 physical and mental component scores improved by 16.7% and 21.23%, respectively. By 6 weeks postoperation, the patient expressed high satisfaction of 8 out of 10, improving to 10 out of 10 by 3 months. Results have been maintained at 9 months.

Conclusion: This case illustrates encouraging early data in support of a 360° arthroplasty concept in the treatment of high-grade spondylolisthesis.

Clinical Relevance: This cutting-edge motion preservation work has the possibility of changing the landscape of spine surgery. The hope is that the technology and methodology provide an option for patients who would otherwise almost unequivocally undergo fusion.

Level of Evidence: 5.

New Technology

Keywords: motion preservation, 360-degree arthroplasty, novel arthroplasty, total disc replacement, artificial facet replacement, lumbar spine

INTRODUCTION

Spondylolisthesis is a spinal condition characterized by the forward slippage of 1 vertebral body over another. There are multiple types of spondylolisthesis affecting individuals of all ages. The lytic type affects younger patients and occurs in up to 4% to 8% of the

population.¹ The acquired or degenerative type commonly affects individuals older than 50 years, with a higher prevalence in older adults and in women.^{2,3} Patients with spondylolisthesis frequently experience back pain but may present with additional symptoms such as leg pain, hamstring tightness, radiculopathy, and neurogenic claudication.^{4,5} The presenting symptoms

can vary along with the severity of spondylolisthesis, typically described using the Meyerding classification.⁶ High-grade cases (grade >II), defined as having greater than 50% slippage, occur in approximately 11.3% of affected individuals.⁶⁻⁸ To manage the symptoms and progression of spondylolisthesis, especially in high-grade cases, surgical intervention is often necessary. Fusion remains the conventional management strategy in these instances.⁹⁻¹⁴ However, despite its effectiveness in stabilizing the spine while simultaneously allowing for decompression of the neural elements, fusion limits the range of motion and biomechanical load transfer to adjacent vertebrae, increasing the risk of adjacent segment disease (ASD).¹⁵⁻¹⁷ These drawbacks can be especially problematic for younger, more active patients who wish to maintain the highest level of function and quality of life. In the setting of severe, symptomatic spondylolisthesis, limited surgical options outside of fusion currently exist. Proponents of arthroplasty and motion preservation are always seeking alternatives. Other than simple decompression for radiculopathy, pars repair in the young, and interlaminar stabilization in low-grade stable slips, lumbar artificial disc replacement (ADR) has been another alternative (in an off-label manner). When compared with fusion, lumbar ADR has demonstrated comparable pain relief and symptomatic improvement while preserving motion at the treated levels.¹⁸⁻²⁰ However, spondylolisthesis and the often corresponding facet arthropathy have traditionally excluded patients from being candidates for lumbar ADR surgery.

Facet arthroplasty has emerged as a dynamic alternative to fusion, demonstrating promising outcomes in the treatment of single-level severe facet arthropathy, lumbar stenosis, and degenerative low-grade spondylolisthesis.^{21,22} Similar to ADR, dynamic stabilization and decompression with facet arthroplasty may yield several advantages over rigid fusions. Facet arthroplasty aims to restore physiological motion after a facetectomy and decompression while also maintaining the spine's natural load distribution to mitigate ASD.^{23,24} Interestingly, facet arthroplasty often requires a relatively healthy disc with good height, thereby limiting its use in the context of severe degenerative disc disease (DDD). Patients with spondylolisthesis will often present with both facet arthropathy and severe DDD, making them a unique challenge for the option of motion preservation. Since each underlying condition is in and of itself a contraindication for the other motion-preserving alternative, this patient population has almost entirely been treated with fusion. Furthermore, no current method

exists to dynamically treat high-grade spondylolisthesis. The development of a surgical construct capable of addressing both pathologies, simultaneously, without fusion, could create a paradigm shift in lumbar spine management.

In this report, we describe a case from a broader, ongoing clinical trial, assessing an innovative 360° motion-preserving lumbar surgical approach utilizing 2 FDA-approved devices, the Prodisc L ADR and the Premia Total Posterior Spine (TOPS) System, “off-label,” in a young man with L5 to S1 grade III spondylolisthesis and associated disc space collapse.

CLINICAL PRESENTATION

A 36-year-old man presented to the clinic with complaints of progressive low back pain and pain radiating down his legs bilaterally. The patient reported years of symptoms, managed with extensive conservative and holistic therapies, but there has been a significant exacerbation of symptoms over the past 6 months. He had been offered fusion by multiple surgeons in the past. The pain, rated at 7 out of 10, was characterized by constant pulling and tightness in the lumbar region, exacerbated by sitting, standing, and walking, and partially alleviated when supine. Prior imaging studies taken 15 months before the operation, including magnetic resonance imaging and radiography, had demonstrated an L5 to S1 grade II spondylolisthesis with severe disc space collapse (Figure 1). Conservative management included physical therapy, pain management-directed injections, nonsteroidal anti-inflammatory drugs, Medrol dose packs, gabapentin, yoga, Pilates, and a personal trainer, all of which had provided initial long-term relief, but their effectiveness diminished. The patient had declined previous recommendations for a fusion. On updated imaging taken 2 weeks before surgery (Figure 2), his anterolisthesis had progressed and was now categorized as a grade III by 2 separate neurosurgeons and the reading radiologist.

On examination, the patient had a body mass index of 26.93. Neurologically, he had preserved strength (5/5) across all extremities, intact sensation to light touch, and a gait stable enough for heel, toe, and tandem walking, though lumbar tension increased with movement. Bilateral L5 radiculopathy was present, and deep tendon reflexes were rated at normal (2+) in the bilateral patellar and Achilles. The patient had negative Babinski and clonus reflexes bilaterally. He had significant pain exacerbation with torso flexion and extension and axial loading.

Given the patient's reluctance toward conventional fusion and his symptomatic and listhesis progression, he was screened for enrollment in a novel, motion-preserving

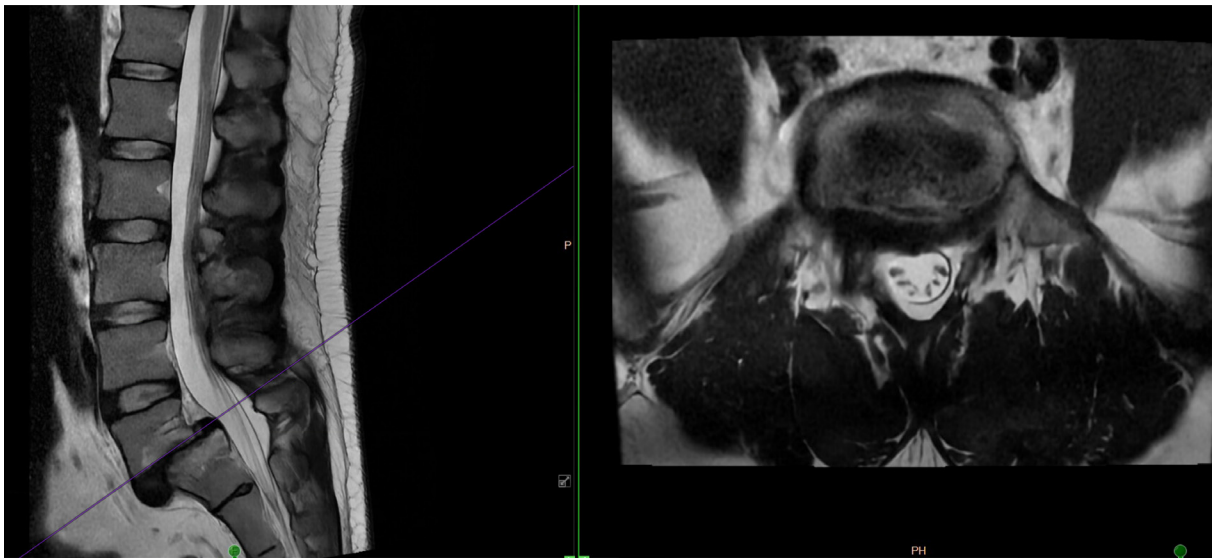


Figure 1. Preoperative sagittal (left) and axial (right) magnetic resonance imaging taken 15 months before the operation demonstrating L5 to S1 grade II spondylolisthesis.

clinical trial, combining 2 FDA-approved devices, the Prodisc L ADR and the Premia TOPS System in an “off-label” investigational manner. The Prodisc L ADR aims to address the lost disc height, while the TOPS device aims to replace the incompetent facets at the same level. Both can (partially) improve the anterolisthesis. The combination potentially affords an otherwise “excluded” patient with a 360° motion-preserving surgical option. After discussing potential risks, uncertainties, and the experimental nature of this procedure, the patient wished to proceed and provided informed consent. The patient formally enrolled in our Institutional Review Board–approved clinical trial.

OPERATIVE INTERVENTION

The operative intervention consisted of 2 stages. The operation took place at an ambulatory surgery center (ASC) with acute postoperative inpatient rehabilitation support. Stage 1 consisted of the anterior L5 to S1 ADR; stage 2 was the posterior artificial facet replacement TOPS procedure. Stage 1 proceeded per standard. The anterior exposure was achieved by a vascular surgeon. Using fluoroscopic guidance, the L5 and S1 vertebral bodies and disc space were identified, and a discectomy was performed to clear the space for the

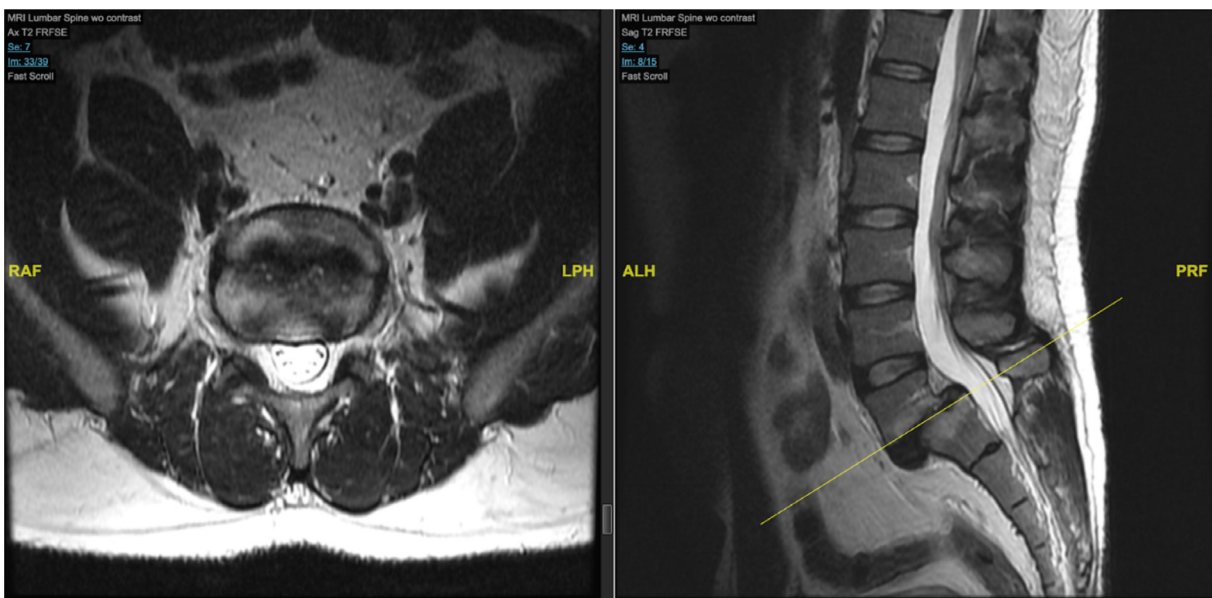


Figure 2. Preoperative axial (left) and sagittal magnetic resonance imaging (right) taken 2 weeks before the operation demonstrating grade III spondylolisthesis.

artificial disc implant. The discectomy was extended laterally with Kerrison rongeurs, and we appreciated the hypermobility of the spinal motion segment and meticulously released the posterior longitudinal ligament to ensure adequate decompression. An artificial disc was selected based on fluoroscopic measurements and prepared. The implant was positioned with fluoroscopic guidance to restore disc height and partially reduce the spondylolisthesis. Stable somatosensory evoked potentials were maintained, no abnormal electromyography activity was appreciated, and final x-ray images confirmed the correct position and placement of the ADR. Once prone, the posterior incision was carried down to the L5 to S1 segment. Pedicle screws were placed bilaterally at L5 to S1, followed by complete laminectomy and bilateral facetectomies. The pars defects were resected, and both the exiting L5 and traversing S1 nerve roots were visualized and decompressed bilaterally. The TOPS implant was filled with saline and sized, then placed and adjusted anteriorly to accommodate the segmental angle and secured with 4 standard set screws. Final imaging confirmed proper positioning with excellent re-alignment of the motion segment. After recovery, the patient was released from the ASC and sent to an inpatient rehabilitation unit per our protocol.

OUTCOMES

Subjective Outcomes

By 6 weeks postoperatively, the patient reported significant improvement in his lower back pain, his primary preoperative complaint. He noted that the pain and numbness in his left leg had significantly improved. He was already able to perform physical activities, such as sports, resuming work, more intense physical training, and strengthening exercises. This early functional recovery was encouraging and was maintained at the 9-month postoperative check.

Objective Outcomes

Objective findings at the 6-week follow-up timepoint were consistent with the patient's subjective improvements. On examination, he remained neurologically intact, although some intermittent left radiculopathy intermittently recurred in the S1 dermatomal distribution. A postoperative computed tomography scan was performed to further assess the source of his left leg symptoms. This was carefully evaluated and found to be unremarkable and reassuring. Per protocol, weight-bearing and dynamic x-ray images obtained at 6 weeks postoperatively (Figure 3) demonstrated intact hardware placement, alignment, and restoration of physiologic



Figure 3. Postoperative dynamic x-ray images: flexion (left) and extension (right) taken 6 weeks postoperatively.

Table. Patient-reported outcomes: preoperative, wound check, 6 weeks postoperative, 3 months, 6 months, and 9 months postoperative.

Outcome Measure	Preoperative	Wound Check	Postoperative Follow-up			
			6 wk	3 mo	6 mo	9 mo
Oswestry Disability Index	16	44	24	2	0	4
VAS back pain	4.87	0.16	0.6	0.0	0.0	0.0
VAS left leg pain	2.41	5.1	1.7	0.0	0.0	0.0
VAS right leg pain	1.51	0.15	0	0.0	0.0	0.0
PROMIS Physical Function	13	13	15	16	16	15
PROMIS Mental Health	14	11	11	13	13	12
SF-12 Physical Component Summary	52.03	-	46.89	60.71	60.23	59.72
SF-12 Mental Component Summary	38.88	-	39.42	47.16	45.42	40.84
Patient satisfaction rating	-	7	8	10	10	10
Repeat surgery?	-	Yes	Yes	Yes	Yes	Yes
Recommend surgery?	-	Yes	Yes	Yes	Yes	Yes

Abbreviations: PROMIS, Patient-Reported Outcomes Measurement Information System; SF-12, 12-item Short Form; VAS, visual analog scale.

motion at the index level. By 3 months after the operation, the patient was completely pain free, and he remained pain free at 9-month follow-up.

Patient-Reported Outcomes

Postoperative patient-reported outcomes (PROs) demonstrated substantial improvements in pain, functional capacity, and overall satisfaction. These were assessed preoperatively and at 1-week, 6-week, 3-month, 6-month, and 9-month postoperative follow-up visits. The Table provides an overview of PRO across validated scales, including the Oswestry Disability Index, visual analog scale (VAS) for back and leg pain, PROMIS Physical Function and Mental Health scores, and SF-12 Physical and Mental Component Summary scores. Patient satisfaction ratings, willingness to recommend the procedure, and the necessity of any repeat surgeries were also captured.

Preoperatively, the patient’s Oswestry Disability Index score was 16, indicating moderate disability

(Figure 4). The score increased to 44 at the 1-week wound check but decreased to 24 by 6 weeks and 0 by 3 months. This was maintained at 6 months postoperatively. VAS score for back pain decreased substantially from 4.87 preoperatively to 0.16 at 1 week. There was a slight increase to 0.6 at 6 weeks (Figure 5). VAS for left leg pain increased to 5.1 at 1 week postoperatively before improving to 1.7 by 6 weeks. Right leg pain improved significantly from 1.51 preoperatively to 0.15 at the initial visit. Remarkably, all VAS scores decreased to 0.0 by the 3-month postoperative follow-up. This was again sustained at the most recent 9-month visit.

The PROMIS Physical Function score initially remained unchanged at 13 (Table) for the wound check. This gradually increased with each subsequent follow-up to 16 at the 6-month follow-up visit. The PROMIS Mental Health score was 14 preoperatively, decreasing to 11 initially but stabilizing to near baseline levels of 13 by 3 months postoperatively. The SF-12 Physical Component Summary score also initially decreased immediately after surgery but improved

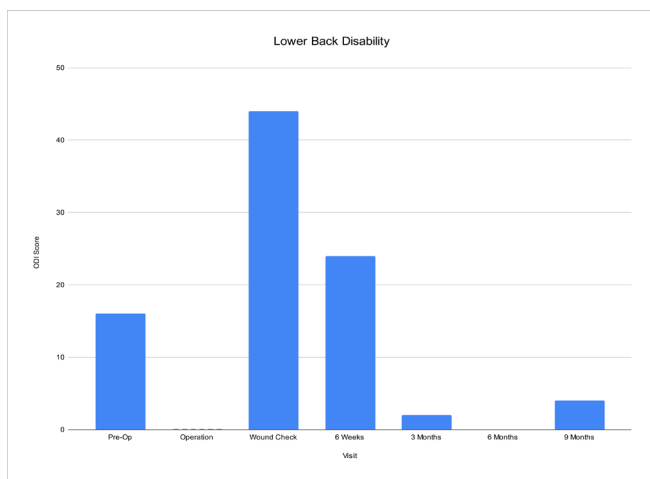


Figure 4. Bar graph showing the patient’s Oswestry Disability Index (ODI) scores across multiple visits. A decreasing trend in ODI scores over time suggests improvement in patient-reported disability levels.

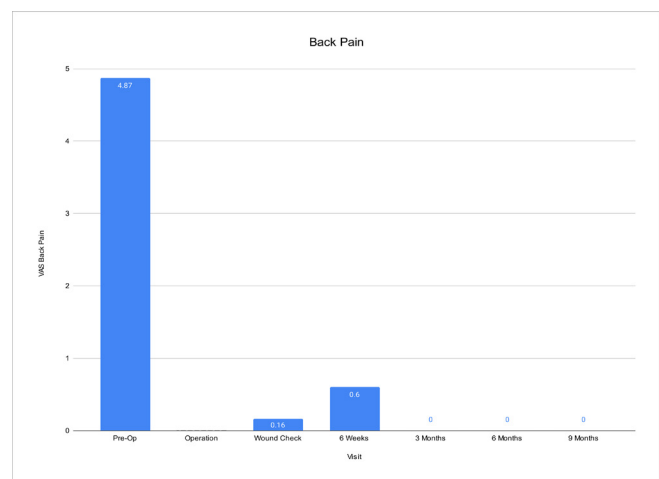


Figure 5. Bar graph depicting visual analog scale (VAS) back pain scores across multiple visits.

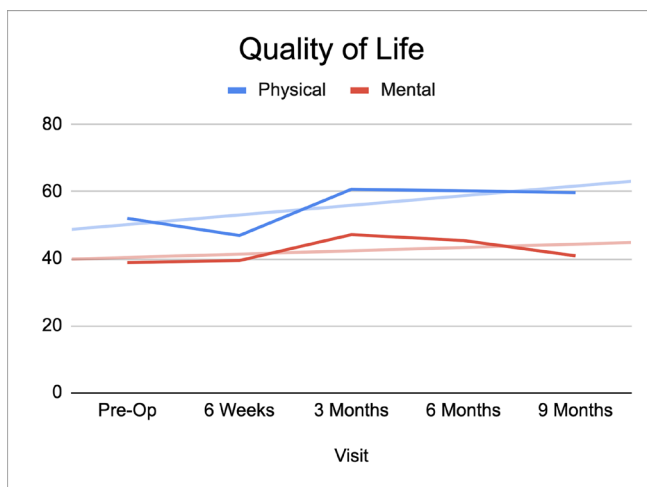


Figure 6. Line graph illustrating 12-item Short Form scores over multiple visits.

notably past baseline by the 3-month follow-up visit (Figure 6). The SF-12 Mental Component Summary score improved at each follow-up appointment until the 3-month visit. These scores were all relatively stable at 6-month follow-up, though they declined slightly at 9-month follow-up.

Patient Satisfaction

By 6 weeks postoperatively, the patient expressed high satisfaction, rating his outcome at 8 out of 10. The patient's satisfaction increased further to 10 out of 10 by 3 months postoperatively, which continued at his 9-month follow-up. He also affirmed at each postoperative visit that he would recommend the procedure to others (Table).

DISCUSSION

To the our knowledge, by combining ADR with TOPS, this case represents the first of its kind “360° motion-preserving arthroplasty” in someone with grade III lumbar spondylolisthesis. It is important to note that this case report is part of a larger, Institutional Review Board–approved, clinician-directed trial with early encouraging results. A notable improvement in the patient's preoperative symptoms, pain relief, analgesic reduction, and early return to activities of daily living and athletics/exercise incites encouragement for this novel construct and warrants further observation and investigation. For younger and active patients, motion preservation may be particularly advantageous by reducing biomechanical stresses on adjacent levels and decreasing the long-term risks associated with fusion. Despite fusion serving as the gold standard for spinal

stability for decades, its limitations and risks are well documented.^{17,25} The increased risk of ASD through the disproportionate displacement of the mechanical load has been widely studied, revealing a multifactorial etiology. Studies indicate that patients undergoing fusion for lumbar spondylolisthesis report high rates of subsequent interventions on adjacent segments, though the natural progression of preexisting disc degeneration remains a factor.^{26,27} Some reports suggest that ASD can manifest as early as 2 years postoperatively, with the incidence increasing over time.^{26,28,29} The use of motion-preserving implants may mitigate the risk of ASD by maintaining a more natural distribution of mechanical load across spinal segments. However, some studies show that although fusion may accelerate radiographic ASD, true symptomatic ASD correlates more strongly with disease progression and aging than fusion itself. This necessitates further study to fully elucidate the nuances that precipitate ASD.^{16,17,25,30} Motion preservation may permit an accelerated return to activities of daily living and even elite-level activity.^{18,31} This benefit may translate into earlier return-to-work and less use of ancillary services and analgesics, imparting an even larger health care economic benefit.^{32–35}

The combination of ADR and TOPS appears to have achieved multifaceted benefits in our early experience, allowing for decompression, disc height restoration, and segmental stability. Each device plays a distinct role in the restoration of function. The ADR maintains disc height with indirect neuroforaminal decompression, as well as partial anterior stabilization and correction of the anterolisthesis, while the TOPS appears to stabilize this correction, providing further posterior stability while allowing for motion after a comprehensive posterior and posterolateral decompression. Theoretically, the 2 devices also create a synergistically stable yet functionally dynamic construct that permits physiological movement without rigid immobilization.

The early favorable outcome in this case suggests the need for further rigorous study. The off-label use of ADR and TOPS, as an alternative to fusion in appropriate cases, is compelling and contributes to a growing body of evidence supporting motion preservation over fusion. Innovations such as the one reported here are necessary to continue to improve patient outcomes from complex spinal pathologies currently treated with traditional methods. As our fusion methods have improved, there has been a paucity of revolutionary surgical methods designed to achieve superior outcomes. However, significant limitations must be acknowledged. While part of a larger prospective clinical trial, this represents an

N-of-1 unique clinical experience, even within the trial cohort (this is the only patient with grade III spondylolisthesis). The data analysis remains in its early stages and has currently only been collected at a single center by 2 surgeons. However, additional surgeons and sites have started to participate. Furthermore, questions remain regarding the long-term durability, functional outcomes, and overall effectiveness of this device combination compared with fusion. Concurrent biomechanics and engineering studies are being conducted.

CONCLUSION

This case demonstrates the potential of the novel 360° arthroplasty as an off-label combination of 2 independently FDA-approved, motion-preserving devices—Prodisc L ADR and Premia’s TOPS—for treating high-grade lumbar spondylolisthesis. The patient’s rapid recovery and functional improvements provide encouraging early data as the field continues to strive toward motion preservation. While this could represent a paradigm shift and significant evolution in how we care for our spine patients, ongoing diligent research is warranted and is underway.

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Funding: The authors received no financial support for the research, authorship, and/or publication of this article.

Declaration of Conflicting Interests:

Jared Ament reports infrequent payments for teaching other surgeons techniques and pearls for the TOPS device from Premia Spine. However, none of the authors received funding related to this work.

Disclosures: Amir Vokshoor reports royalties/licenses from Globus Medical; reports payment for a presentation from Orthofix; was a paid expert witness for a law firm; and is the president and founder of the Institute of Neuro Innovation.

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Published 24 June 2025

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