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Mobility-Maintaining Facet Arthroplasty of the Lumbar Spine With the Second-Generation TOPS System: A Case Series

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BACKGROUND: Lumbar spinal stenosis results from spinal canal narrowing and can lead to pain and dysfunction. Until recently, surgical treatment for lumbar spinal stenosis requiring an extensive decompression, with or without spondylolisthesis, had to balance pain relief with the long-term risks of spinal instability after decompression and adjacent segment disease (ASD) after spinal fusion. Spinal motion-preserving devices aim to reduce the incidence of ASD after posterolateral fusion and consequent need for revision surgery.
OBJECTIVE: To present a single-center experience with a facet replacement implant (TOPS System [TOtal Posterior Spine System], Premia Spine) designed to stabilize the spine and prevent further degeneration while maintaining a normal range of motion (ROM).
METHODS: Seventeen patients received the implant after a laminotomy. Clinical assessments included surgery duration, complication rates, and visual analog score for back pain. Radiographs were used to measure ROM changes from flexion to extension and assess for any repositioning of a degenerative spondylolisthesis and segment lordosis.
RESULTS: The average operative time was 102 minutes. The average visual analog score reduction was 7.5 at 3 months, 6.8 at 12 months, and 6.7 at the longest follow-up (average: 51 months, range: 26-77), demonstrating an average improvement of 81%. The preoperative and postoperative average ROMs were 8.2° and 7.4°, respectively.
CONCLUSION: This series shows that the TOPS System has the potential to relieve back pain and maintain close-to-normal ROM over longer time periods without inducing ASD. The TOPS System is the first to allow the patient to settle into physiological lordosis adjustment thus presenting new treatment possibilities with mobility-maintaining dorsal instrumentation.

KEY WORDS: Dynamic stabilization, Degenerative spondylolisthesis, Spinal stenosis, Facet replacement, TOPS, Case series

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Natural degeneration of the disk and facet joints affects the spine's load-bearing properties[1,2] and changes the orientation of the inferior-to-superior facet joints, leading to cartilage wear, facet joint degeneration, spondylolisthesis,[3] and nerve roots and spinal cord compression.[4] The disk's biochemical and biomechanical integrity becomes compromised and provides diminished shear force resistance, leading to an unstable lumbosacral segment and progression of spondylolisthesis that increases the tension of the facet joint capsule and ligaments and generates pain because of the mechanical instability and local spinal stenosis.[5] Degenerative lumbar spinal stenosis (LSS) manifests itself by a reduced anteroposterior diameter of the spinal canal and narrowing of the lateral recesses and neural foramina because of degenerative processes.

Patients generally present with radicular pain, associated with neurological deficit or neurogenic claudication and potential disability.[6] If conservative treatments fail to restore quality of life, surgical options are available, ranging from minimally invasive laminotomies to implanted instrumentation surgeries.

Until recently, surgical options for moderate-to-severe LSS requiring an extensive decompression, with or without spondylolisthesis, had to balance pain relief with the risk of iatrogenic instability after a broad decompression, partial or complete facet resection, or removal of

ABBREVIATIONS: ASD, adjacent segment disease; **LSS,** lumbar spinal stenosis.

ligaments[7,8] or adjacent segment disease (ASD) after spinal fusion.[9,10]

Motion-preserving devices aim to reduce the incidence of ASD and potential need for revision surgery.[11] Some clinical studies on motion-sparing devices are showing promising outcomes in reducing ASD, although there is less information on outcomes for total facet replacements.

A newer approach to treatment of degenerative spondylolisthesis and LSS is total dorsal arthroplasty of the facet joints: laminotomy and facet resection followed by an implant designed to both stabilize the spine and prevent further degeneration. The TOPS System (TOtal Posterior Spine System, Premia Spine) is a facet replacement implanted after surgical decompression.

We are one of the first centers to use the next-generation TOPS System, a smaller version of the original configuration, manufactured with the same materials and performance specifications. We report on our current use of this device. A cohort of 17 consecutive patients meeting the TOPS indications were implanted and followed for an average duration of 51 months.

METHODS

The TOPS System

The TOPS System includes the TOPS device and the pedicle screws used for its fixation. The device is designed to allow axial rotation, lateral bending, extension and flexion, and block sagittal translation. The device is implanted using a posterior surgical approach to replace the skeletal elements such as the lamina and the facet joints that are diseased and/or removed during the decompression.

The implant is available in various sizes, allowing a 1-level implantation at either the L2-3, L3-4, or L4-5 vertebral level.

The indication for use of the TOPS implant is a grade I degenerative spondylolisthesis with facet degeneration and/or moderate-to-severe spinal stenosis, with a 4-mm minimum intervertebral disk height and without Modic 1 signs of the neighboring vertebral bodies. Serious symptomatic facet arthrosis with vertebral misalignment and without pronounced instability is also an appropriate indication. The TOPS implant can be used alone or in combination with the VersaLink Fixation System (also by Premia Spine): a bilateral titanium lumbar fusion system used with a titanium crossbar designed to connect above or below the TOPS device as a hybrid construct. This combination allows treating different stages of spinal degeneration at multiple adjacent vertebral segments, without the additional stresses generated by a multiple-segment fusion.

The TOPS implant is based on a unique design comprising titanium plates with extending rods attached to pedicle screws. The plate's orientation transverses the spinal column, above and below the resected facet joint, in contrast to typical fixation systems that connect pedicle screws with rods or fixation components oriented longitudinally, or in parallel, to the spinal column. The titanium plates are anchored to one another by an interlocking articulating core sealed within a polycarbonate urethane boot that resists motion in a way mimicking the elastic properties of the native facet capsule and posterior ligaments (Figure 1A). A polyetheretherketone ribbon protects the articulating surfaces from dislocation caused by excessive flexion. When implanted after facet resection and decompression, the device permits ±1.5° axial rotation, ±5° lateral bending, +8° flexion, and -2° extension (Figure 1B), consistent with normal spine properties[12-16] while also inhibiting excessive rotation, bending, extension/flexion, and translation. The system's pedicle screws possess a roughened titanium surface, shown to improve bone implant contact and implant stability.[17]

An in vitro biomechanical investigation using functional cadaver spinal sections demonstrated that the TOPS implant restored near-normal range of motion (ROM) for rotation, lateral bending, flexion, and extension. Intervertebral pressures, measured on the intact specimen before facetectomy and implantation of a TOPS device and afterward, showed similar intervertebral disk pressures.[18]

Major contraindications for use of the TOPS System include isthmic or greater than first-grade degenerative listhesis, scoliosis, clear osteochondroses, osteoporosis, primary diagnosis of diskogenic back pain, or back or leg pain of unknown etiology.

Surgical Technique

To achieve proper device alignment and optimal postimplant ROM, the surgery is performed with patients lying prone to maintain their neutral standing lordosis. Pedicle screws are placed parallel to the craniocaudal axis and symmetrical to the median plane of the spine, ensuring that the vertical distance between pedicle screws is the same on both sides. The TOPS System instrument set includes a pendulum for screw placement with the correct trajectory and a tool to ensure proper screw

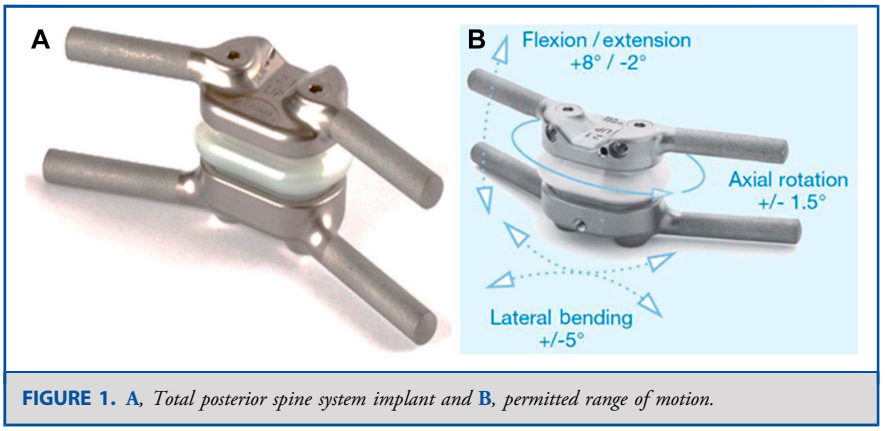

FIGURE 1. **A**, *Total posterior spine system implant and* **B**, *permitted range of motion.*

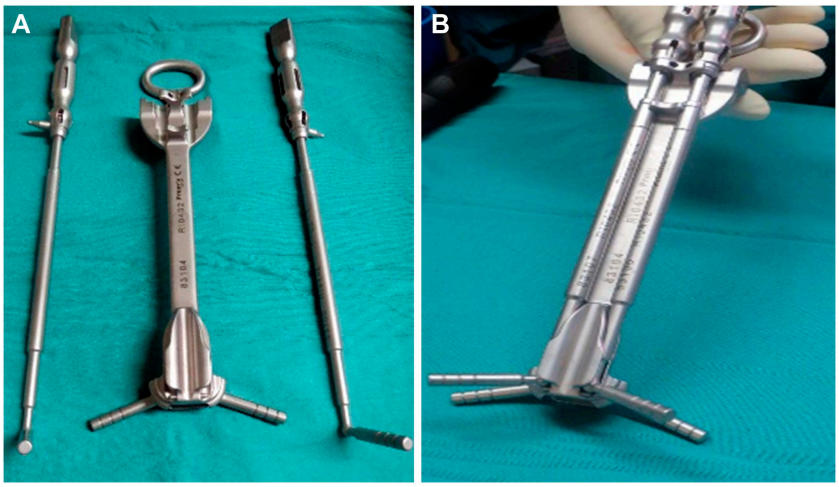

FIGURE 2. *Total posterior spine system implant alignment gauge.* **A**, *Gauge components for implant sizing (left and right superior arms and central implant trailer) and* **B**, *assembled instrument.*

alignment and implant size (Figure 2). Three sizes are available: 21, 30, and 38 mm, chosen based on the vertical distance between pedicle screws.

The laminotomy is performed while maintaining the cranial lamina, followed by the facetectomy. Attempts should be made to preserve the cranial parts of the spinous process. A template implant is used to ensure sufficient space for the device, and if its introduction into the screw heads is difficult, additional bone shaving may be necessary. The implant is prepared in the sterile field by attaching to an insertion tool and filling with 1.7 mL of saline through its filling port. The device is then seated in the pedicle screws. Before the final fixation of the set screws with the torque wrench, the device is centered relative to the neighboring spinous processes. Figure 3 shows an illustration of the spine before the procedure (top), after the facetectomy (middle), and with the implant (bottom). Figure 4 shows the TOPS implant in situ.

Case Series

This prospective study was approved by the Institutional Review Board. All patients who received the second-generation TOPS implant between 2012 and 2016 were evaluated (Table 1). Informed consent to the procedure and use of data was obtained from all patients. The preferred reporting of case series in surgery (PROCESS) guidelines was observed.[19]

Standard clinical assessments collected were length of surgery, intraoperative and postoperative complications, and preoperative and postoperative visual analog scale (VAS) score for low back pain. Standardized flexion/extension x-ray radiographs were used to measure changes in ROM from flexion to extension and assess for any repositioning of a degenerative spondylolisthesis and segment lordosis.

Symptomatic ASD was defined by the occurrence of relevant symptoms at adjacent levels. Operative ASD was defined as symptomatic ASD requiring surgery.

Ethics Approval

This retrospective chart review study involving human participants was in accordance with the ethical standards of the institutional and national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

RESULTS

Seventeen patients were included in the study (age 54-82, 10 female and 7 male). The indication for use of the implant was grade I degenerative spondylolisthesis with relative or absolute spinal canal stenosis in 15 cases, spondylarthrosis with spinal canal stenosis in 1 case, and symptomatic osteoarthritis of the facets in 1 case. Patients were also recruited if the necessary decompression was too extensive for a standard decompression-only (without instrumentation) procedure because of concern for an iatrogenic destabilization.

The TOPS implant was used to replace L4/5 (10 cases), L3/4 (6 cases), and L2/3 (1 case). Because TOPS is indicated for single-level use, instrumented fusion at the adjacent level (Versalink Fixation System, Premia Spine) was used in 4 cases to address multilevel disease. No patient was lost to follow-up. The longest-term follow-up ranged from 26 to 77 months (51 months average).

The average operative time was 102 minutes (range: 60-140).

Outcome measures are summarized in Table 2.

VAS Scores

The average preoperative VAS score, obtained prospectively, was 8.3 (range: 6-10).

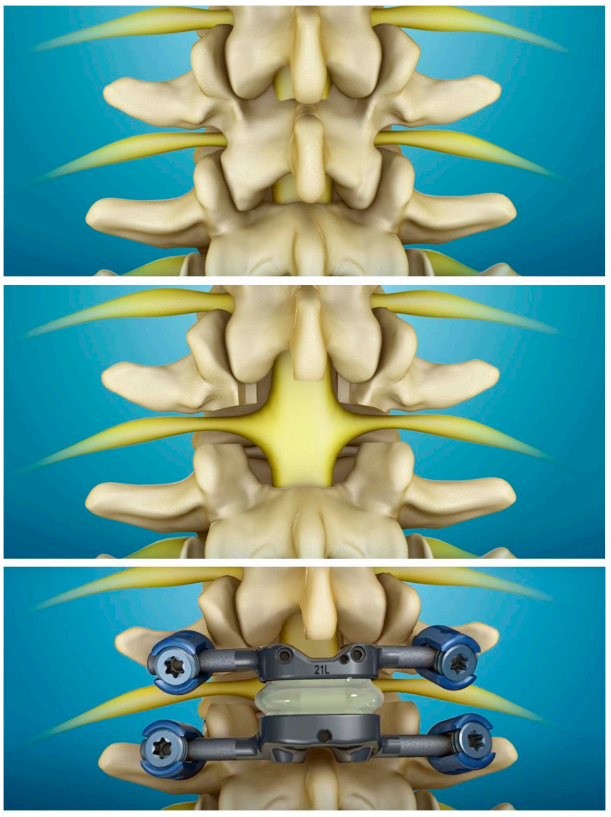

FIGURE 3. *Illustration of the spine before the procedure (top), after the facetectomy (middle), and with the implant (bottom).*

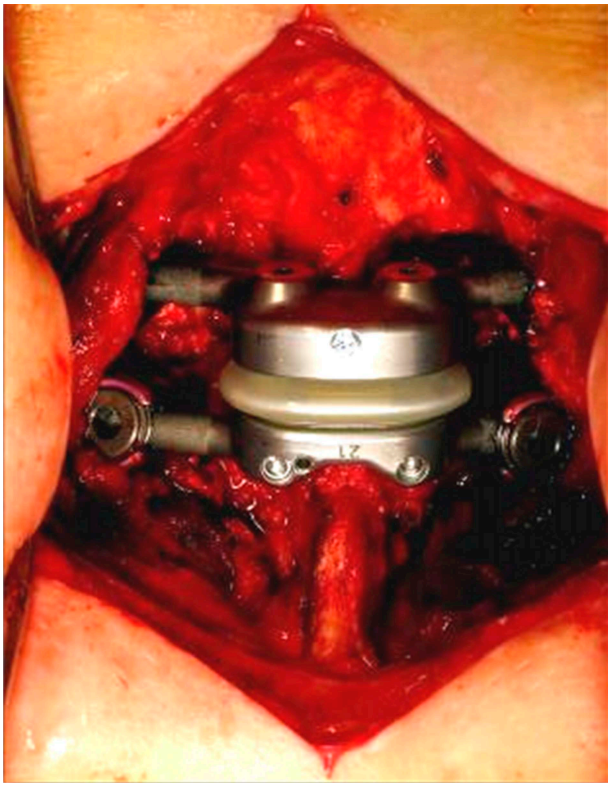

FIGURE 4. *Total posterior spine system implant in situ.*

At 3 months, the average VAS score was 1.0 (range: 0-4; n = 12), with an average reduction of 7.5 (range: 4.5-10) from preoperative score (88% improvement, $P < .01$).

At 12 months, the average VAS score was 1.5 (range: 0-7; n = 17), with an average reduction of 6.8 (range: 1.5-10) from preoperative score (82% improvement, $P < .01$).

At the latest follow-up (average of 51 months, range: 26-77), the average VAS score was 1.6 (range: 0-7, n = 17), with an average reduction of 6.7 points (81% improvement, $P < .01$). Leg pain VAS score was 0.7 (range: 0-3, n = 17), without any case of implant-caused sciatica.

Radiographic Outcomes

Segmental ROM, measured from flexion/extension x-rays, was available for 5 of the 17 patients at the preoperative time point and for all 17 patients at the postoperative time point. The average preoperative ROM was 8.2° (range: 6°-12°) and 7.4° at follow-up (median 7°, range: 1°-12°), as demonstrated in Table 3 and Figure 5.

Figure 6 shows the preoperative imaging scans of a 54-year-old female patient suffering from degenerative spondylolisthesis at L4 with severe local pain after a previous L5/S1 posterior lumbar interbody fusion. Imaging revealed pronounced spondylarthroses, degenerative spondylolisthesis, and severe osteoarthritis with effusion of the L4/5 joints. The patient was treated with TOPS implant insertion at L4/5. At the 2-year follow-up, the patient was pain free with full reduction, improvement of lordosis, and flexion/extension movement of 7° (Figure 7).

Complications

From the time of surgery and up to the long-term follow-up visit, 3 of the 17 patients had clinically noteworthy complications.

1. In 1 patient (no. 10), the radiographic evaluation showed one screw migration, a segmental kyphosis of 6°, a spondylolisthesis of 7 mm, and 9° of segmental mobility. Throughout the entire follow-up period, the patient was pain free. The screw positioning was changed intraoperatively during the alignment process and could have contributed to the screw migration. Despite the initial screw migration, there was no sign of screw loosening at 5 years postoperatively.
2. A patient (no. 13) had an intraoperative dural tear caused during the decompression because of severe scarring. The patient complained of severe radicular pain along with conus syndrome immediately postoperatively. An x-ray with myelography imaging was conducted postoperatively to investigate

TABLE 1. Patient Demographics, Indication for Implant, Implant Size, and Duration of Implant Operation

Patient no.	Sex	Age	Indication	Spinal canal stenosis (or other)	Implant segment	Fusion segment	Implant size	Operation time (min)
1	F	66	DS first grade	Absolute	L4/5	—	30	95
2	F	65	DS first grade	(Spondyloarthrosis)	L4/5	—	30	120
3	F	73	DS first grade	Relative	L3/4	L4/5	30	135
4	M	62	DS first grade	Absolute	L3/4	—	30	85
5	F	59	Ankylosing spondylitis	Absolute	L2/3	—	30	100
6	M	82	DS first grade	Absolute	L4/5	L3/4	30	140
7	F	76	DS first grade	Absolute	L3/4	L4/5	21	135
8	F	54	DS first grade	(Ankylosing spondylitis)	L4/5	—	21	100
9	M	64	DS first grade	Relative	L4/5	—	30	95
10	M	69	DS first grade	Absolute	L3/4	—	21	120
11	M	62	DS first grade	Relative/absolute	L4/5	—	21	64
12	F	74	DS first grade	Absolute	L4/5	—	21	100
13	M	71	DS first grade	Absolute	L4/5	—	21	110
14	F	65	DS first grade	(Instability)	L3/4	—	30	85
15	M	75	DS first grade	Relative	L4/5	—	30	60
16	F	65	DS first grade	Absolute	L4/5	—	21	70
17	F	71	DS first grade	Absolute	L3/4	L4/5	21	130

DS, degenerative spondylolisthesis.

the cause of pain and did not reveal any sign of stenosis or indication that the implant could be cause of the problem. The pain was determined to be emanating from the segment above the TOPS implant and associated with pre-existing degeneration. The pain was successfully relieved with conservative treatment thereafter without the need to re-intervene. The radicular pain disappeared after 4 months, and the bowel and bladder problems disappeared completely after 7 months. At the 77-month follow-up, the patient had no spinal pain or disability and led a physically active lifestyle.

TABLE 2. Outcome Measurements

Variable	Mean value (range)	Difference from baseline
VAS back pain		
Baseline	8.3 (6 to 10, n = 17)	
3 months	1.0 (0 to 4, n = 12)	−7.3 ($P < .001$)
Latest follow-up	1.6 (0 to 7, n = 17)	−6.7 ($P < .001$)
VAS leg pain		
Latest follow-up	0.7 (0 to 3, n = 17)	NA
Mobility		
Baseline	8.2° (6° to 12°, n = 5)	
Latest follow-up	7.4° (1° to 12°, n = 17)	−0.7° ($P = .56$)
Segmental lordosis		
Baseline	6.4° (−1° to 12°, n = 11)	
Latest follow-up	6.6° (−10° to 15°, n = 17)	+0.2° ($P = .84$)

VAS, visual analog scale.

3. In a third case (no. 8), the patient underwent a L3-L5 decompression primary procedure, with a TOPS System implanted at the L4-L5 level. The patient reported hearing sounds from the implant during movement at 39 months postoperatively without associated pain or device failure. At the patient's request—48 months after the original TOPS implantation—the patient was revised to a 2-level L3-L5 fusion as a prophylactic measure to prevent a future requirement for an L3-L4 fusion because of segmental deterioration brought on by the current L4-L5 fusion and the previous decompression.

There were no cases of radiological deterioration at the TOPS segment, symptomatic ASD, or reoperation of either the TOPS segment or an adjacent segment due to pain or disability. There was one case of an intraoperative dural leak which was repaired during the procedure.

DISCUSSION

Outcomes from this single-site experience support a low complication rate with a rapid and sustained reduction in pain. Our experience with standard use of the second-generation TOPS

TABLE 3. Postoperative Range of Motion

ROM postoperatively (°)	1	2	5	6	7	8	9	10	11	12
No. of patients	1	1	2	1	5	1	1	2	1	2

ROM, range of motion.

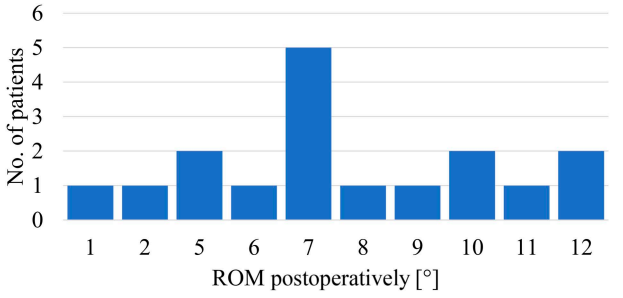

FIGURE 5. *Number of patients by ROM postoperatively (°). ROM, range of motion.*

implant is consistent with what McAfee et al [20] reported in 2007 using the first-generation TOPS implant in a prospective, multicenter, nonrandomized pilot study that enrolled 29 patients. The McAfee study reported excellent 1-year functional outcomes with low surgical morbidity in patients with degenerative spondylolisthesis accompanied by stenosis and back pain. The surgical technique corresponds to the conventional dorsal approach for the use of currently available implants.

A basis for comparison for the observed pain score improvement can be found in a large-scale review of lumbar spinal fusion for degenerative disorders, that reported a three-month improvement in VAS back scores of 67% (from 64 to 21, n = 346) and a 12-month improvement of 66% (from 64 to 22, n = 475).[21] Although the indications are broader in the review article, when using it as a successful outcome reference point for LSS surgery, it is clear that the TOPS System provides substantial relief from LSS symptoms.

In this study, a postoperative near-physiological biomechanical spinal profile was facilitated by implant use. Near-physiological ROM[22] was achieved, with repositioning of a grade 1 spondylolisthesis and physiological lordosis adjustment. These outcomes are supported by an in vitro biomechanical investigation also demonstrating near-normal lateral inclination and rotation.[18] The improved mobility reduces the peak moments on the pedicle screws, potentially improving their long-term durability. Meyers et al [23] found that the motion limitations after implantation of the Dynesys System (Zimmer Spine) resulted in higher torque on the pedicle screws compared with the TOPS System, with increases of up to 56% in flexion/extension and 86% in lateral bending.

This site's experience has been that the TOPS surgical technique allows implantation of the device without complications and minimal "fiddle factor." The average operative time of 102 minutes found in this study is lower than reported durations of 1-level spinal fusion procedures of 142 to 200 minutes.[24-26]

Two complications were device-related (11.7%), but without associated pain or disability: one patient with observed screw migration and another who reported hearing sounds from the implant. Changing of screw position once inserted should be prevented as far as possible. To achieve this objective, we use neuromonitoring in all cases so that an incorrect screw position can be recognized at the time of pedicle screw insertion. A more

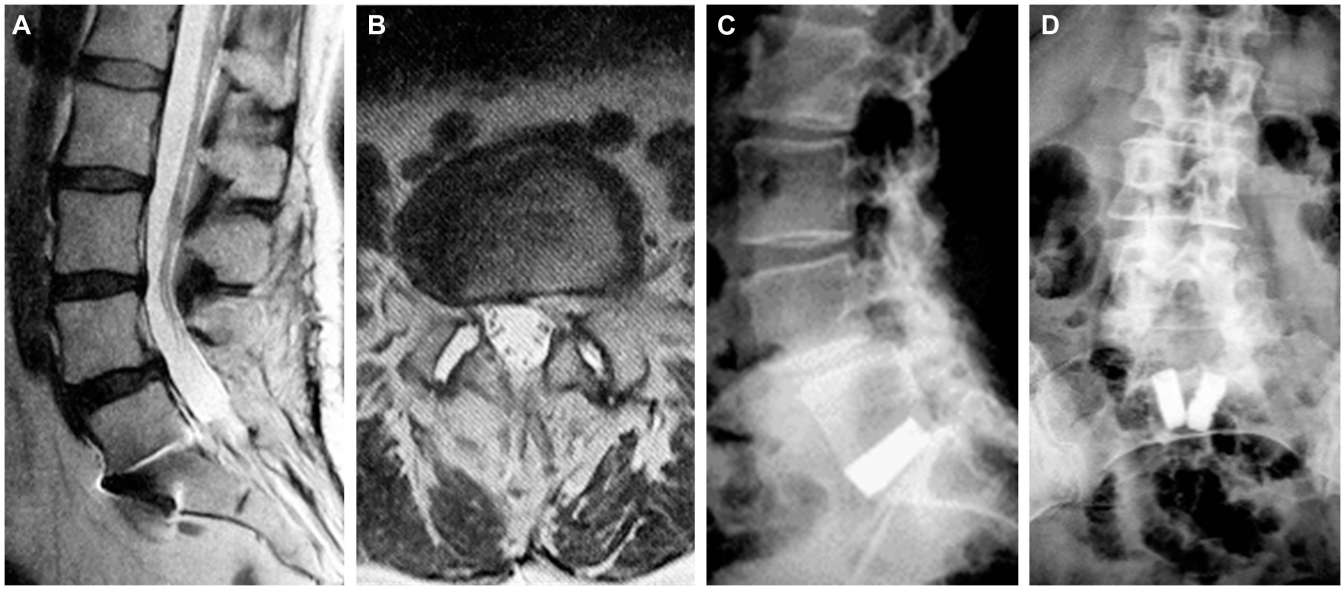

FIGURE 6. *Preoperative imaging of a 54-year-old female patient suffering from degenerative spondylolisthesis at L4 with severe local pain after a previous L5/S1 posterior lumbar interbody fusion. Imaging revealed pronounced spondylarthroses, degenerative spondylolisthesis, and severe osteoarthritis with effusion of the L4/5 joints.* **A**, *Sagittal MRI,* **B**, *axial MRI,* **C**, *sagittal x-ray, and* **D**, *coronal dorsal x-ray.*

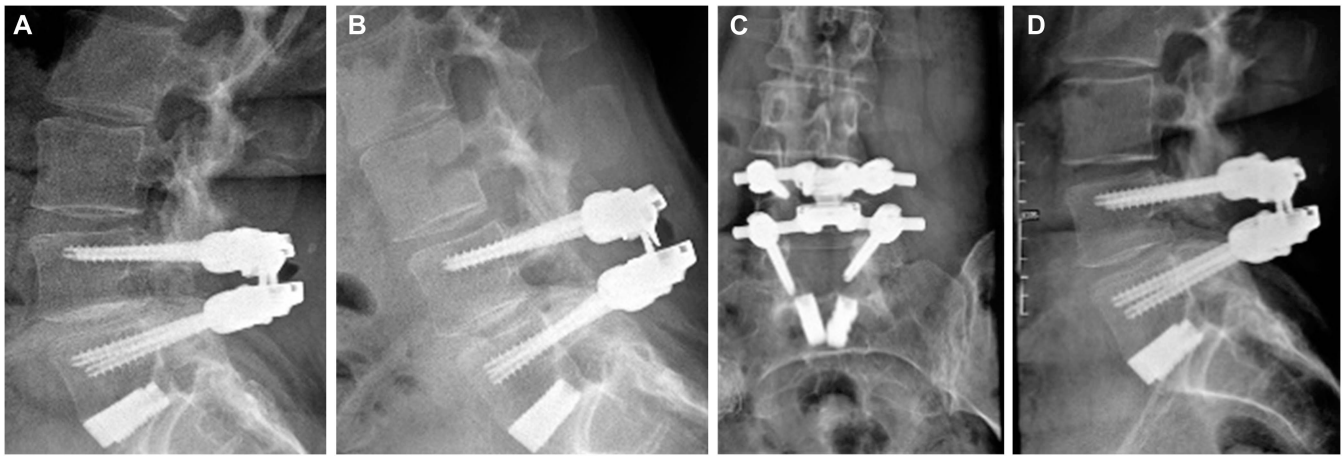

FIGURE 7. *Postoperative imaging of the patient at 2-year follow-up after the insertion of the total posterior spine system implant implant at L4/5. The patient was pain free with full reduction, improvement of lordosis, and flexion/extension movement of 7°.* **A**, *Extension, sagittal view;* **B**, *flexion, sagittal view;* **C**, *standing, coronal dorsal view; and* **D**, *standing, sagittal view.*

accurate complication rate should be calculated based on the results of a larger study.

Limitations

This is a pilot study and, therefore, limited to a relatively small series. A larger, randomized, study is required to validate these findings and compare them with spinal fusion outcomes. Radiographic ASD has not been assessed because the index-level ROM was between 5° and 12° for all but 2 patients, and postoperative pain scores were low, suggesting a low risk of ASD. Although ASD can often appear during the follow-up duration of this study, a 7 to 10-year follow-up will provide better estimation of long-term ASD risks.[27]

The current study suggests that the TOPS System is a beneficial option for treating LSS because of the ease of implantation, rather short operation time, maintenance of segmental mobility and lordosis, and the partial reduction of the spondylolisthesis which occurs upon interoperative facetectomy. A large-scale level 1 Food and Drug Administration Investigational Device Exemption study is being conducted at 40 sites in the United States and may produce further data confirming these findings.

CONCLUSION

The data from this single-site experience of implanting the TOPS system after a laminotomy show that the system has the potential to relieve back pain, maintain a close to normal range of motion over longer periods of time, and not induce adjacent segment degeneration. Moreover, the TOPS System is the first system to allow the patient to settle into physiological lordosis adjustment thus presenting new possibilities for treatment of this condition with mobility-maintaining dorsal instrumentation.

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Disclosures

The authors have no personal, financial, or institutional interest in any of the drugs, materials, or device described in this article.

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COMMENT

Facet disease and facet joint pain is the bugbear for every spine surgeon as we struggle with limited options that include nonoperative therapy and ultimately spinal fusion. The first hip was fused in 1826 but we had to wait almost 100 years for the first synthetic hip arthroplasty n 1923. We are in this transition phase in spine. Instead of a simple hinge joint or a ball and socket, we deal with a tripod structure at 5 connected levels with the complexity level magnified.

This study is a limited cohort series of 17 patients looking at facet joint replacement in the milder end of the spectrum of the disease. Of note, this is a second generation device reflecting that the learning/development process is slow. The results are encouraging, but longer term follow-up will be needed. Just like we have seen with the indications for cervical/lumbar arthroplasty, it won't suit all comers. The study is more proof of concept. More work needs to be done. This study is a step in the right direction.

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