Mean 5-Year Follow-Up Results of a Facet Replacement Device in the Treatment of Lumbar Spinal Stenosis and Degenerative Spondylolisthesis

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■ OBJECTIVE: **Flexible stabilization has been utilized to maintain spinal mobility in patients with early-stage lumbar spinal stenosis (LSS). Previous literature has not yet established any nonfusion solution as a viable treatment option for patients with severe posterior degeneration of the lumbar spine. This feasibility study evaluates the mean 5-year outcomes of patients treated with the Total Posterior Spine System (TOPS) facet replacement system in the surgical management of lumbar spinal stenosis and degenerative spondylolisthesis.**

■ METHODS: **Ten patients (2 men, 8 women, mean age: 59.6 years) were enrolled into a non-randomized prospective clinical study. Patients were evaluated with standing anteroposterior, lateral, flexion and extension radiographs and magnetic resonance imaging scans, back and leg pain visual analog scale scores, Oswestry Disability Index, Zurich Claudication Questionnaire and the SF-36 questionnaires, preoperatively, 6 months, 1 year, 2 years, and latest follow-up at a mean of 5 years postoperatively (range: 55–74 months). Flexion and extension standing lumbar spine radiographs were obtained at 2 years to assess range of motion at the stabilized segment.**

■ RESULTS: **The clinical outcome scores for the cohort improved significantly across all scoring systems. Radiographs at 2 years did not reveal any loss of position or loosening of metal work. There were 2 incidental durotomies and no failures at 5 years, with no patient requiring revision surgery.**

■ CONCLUSIONS: **The TOPS implant maintains clinical improvement and motion in the surgical management of LSS and spondylolisthesis, suggesting that it can be considered an option for these indications.**

INTRODUCTION

Lumbar spinal stenosis is a common cause of disability in the elderly population.[1,2] Initially described by Verbiest[3] and Kirkaldy-Willis et al.,[4] it is the end stage of a degenerative pathway initiated by disc dehydration and collapse leading to increased stress transfer to the facet joints and osteophyte formation. The subsequent hypertrophy of the ligamentum flavum and facet joints reduce the space in the canal compressing the cauda equina.[3,4] By this stage the patient presents with back pain and neurogenic claudication which may consist of weakness, numbness, and fatigue arising in the back and radiating into the buttocks, thigh, or lower leg on mobilization. In many patients, degenerative spondylolisthesis occurs, which causes translation of one vertebral body over another, worsening the narrowing of the canal and leading to segmental instability and nerve root impingement.

Key words
- Degenerative spondylolisthesis
- Dynamic/flexible stabilization
- Facet replacement
- Neurogenic claudication
- Spinal stenosis
- TOPS

Abbreviations and Acronyms
ANOVA: Analysis of variance
MCS: Mental component score
MRI: Magnetic resonance imaging
ODI: Oswestry Disability Index
PCS: Physical component score
PcU: Polycarbonate urethane
RCT: Randomized controlled trial
TOPS: Total Posterior Spine
VAS: Visual analog scale
ZCQ: Zurich Claudication Questionnaire

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Treatment is initially conservative and, where the symptoms worsen, activities of daily living are not achievable, and conservative treatments fail, then surgical intervention can be performed to relieve radiating symptoms and neurogenic claudication.[5,6] Surgical intervention attempts to relieve pressure on the dura and nerve roots by excising bony and ligamentous overgrowth elements, and may involve a decompression (while preserving stability), or a decompression and fusion (where instability is present).[7,8]

Unfortunately, a simple decompression of the lumbar spine, while being a shorter procedure associated with less blood loss and shorter hospital stay, does not allow for a more extensive decompression as it risks instability, whereas decompression and fusion leads to reduced mobility, potential adjacent segment disease and increased rate of complications.[7-13] Although both decompression and decompression with fusion have been shown to improve leg pain, various authors have presented differing results with regards to pain relief, outcomes, and patient satisfaction.[14-16]

Several authors have attempted to find an alternative to fusion in a bid to avoid the complications that can occur by preserving motion while enhancing stability using different systems at the affected segment.[17-19] Our clinical trial was performed as a feasibility study to evaluate the outcomes of the Total Posterior Spine System (TOPS System, Premia Spine, Israel) implant. This implant recreates the normal function of the facet joint by guiding, supporting, and limiting the movement of the spinal segment to a similar extent as the facet joint. It is pedicle based, and while allowing wide decompression, recreates the natural motion of the facet joint and therefore adds an element of stability and motion maintenance at the implanted level. The device offers an additional potential nonfusion surgical solution for patients who require a wide decompression and have a functional lumbar disc and suffering from stenosis- or spondylolistheses-related back pain.

This paper presents the mean 5-year prospective follow-up results of the motion-preserving TOPS System for patients presenting with neurogenic claudication due to lumbar spine stenosis and grade I spondylolisthesis. Our hypothesis was that the use of the implant would clinically benefit the patients, in terms of pain and disability, by allowing wide decompression while maintaining stabilization and a normal range of motion.

METHODS

A prospective clinical study was planned to assess the long-term function of the implant and was intended to include 10 patients based on the authors' experience. The primary endpoint was defined as device failure or malfunction. Ten patients (8 women and 2 men) were enrolled into the non-randomized prospective clinical study during an 18-month period (May 2014 to December 2015), after approval by the regional ethics committee (13/LO/1771, NRES Committee). The primary indication was neurogenic claudication of more than 6 months duration due to spinal stenosis with/without single-level grade 1 degenerative spondylolisthesis at the L3 to L5 levels. All patients had failed conservative treatment for 6 months and were keen for an operative solution if possible. Those patients who fit the inclusion criteria and provided informed consent were included in the study.

Inclusion Criteria

All patients presenting with back pain and neurogenic claudication were assessed further with standing anteroposterior, lateral, flexion and extension lumbar spine radiographs and a magnetic resonance imaging (MRI) scan. Spinal stenosis with a grade I spondylolisthesis were acceptable.

Exclusion Criteria

Patients at risk of osteoporosis were evaluated with a DEXA scan and those with a T score lower than −1.5 standard deviation were

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
■ Age 40 to 75 years (male or female)	■ Back or non-radicular pain of unknown etiology
■ Patients with moderate to severe lumbar spinal stenosis at a single level between L3 and L5 with radiologic evidence on CT, MRI, plain radiographs and myelography	■ Lytic or > grade 2 spondylolisthesis
■ At least 6 months of failed conservative treatment prior to surgery (physiotherapy, anti-inflammatory medication, epidural/facet injection therapy)	■ Allergy to titanium and/or polyurethane
■ Up to one prior surgery without instrumentation at any vertebral level limited to the following: IDET (intradiscal electrothermal therapy), laminotomy, foraminotomy, discectomy (that occurred at least three years ago without recurrence of herniation)	■ Previous fusion surgery at any lumbar vertebral level with/without instrumentation/requires supplemental interbody support
■ Lower back pain and/or sciatica with or without spinal claudication	■ Clinically compromised vertebral bodies due to neoplastic, metabolic, traumatic or infectious pathology
■ Oswestry disability index (ODI) % score of at least 40/100 at baseline	■ Scoliosis of > 10°
■ Visual analog scale (VAS) leg pain score of at least 40/100	■ Paget disease, osteomalacia, osteogenesis imperfecta, thyroid/parathyroid gland disorder, DEXA scan T score less than or equal to −1.5, active hepatitis, AIDS or HIV, rheumatoid arthritis, TB, morbidly obese, pregnant, cauda equina syndrome, arterial disease of legs, peripheral neuropathy, sustained pathological fractures of vertebrae or hip.
■ Psychologically, mentally, and physically be able to comply with clinical protocol	■ Patient has insulin-dependent diabetes mellitus, takes anticoagulation, life expectancy < 3 years, >3 Waddell signs or is involved in active spinal litigation

Figure 1. TOPS device including pedicle screws. (Image - Premia Spine)

excluded. Other contraindications for posterior arthroplasty were disc herniation or discogenic back pain, previous surgery at affected levels, scoliosis greater than 10°, or isthmic spondylolisthesis. Table 1 lists the inclusion and exclusion criteria.

Patients included into the trial were evaluated and prospective data collected using a visual analog scale (VAS) for back and leg pain, the Oswestry Disability Index (ODI) questionnaire, SF-36 health survey preoperatively and the Zurich Claudication Questionnaire (ZCQ) at the preoperative stage, at 6 weeks, 3 months, 6 months, 1 year, 2 years and latest follow-up postoperatively.[20-23] The Satisfaction scores of the ZCQ were performed from 6 months postoperatively to latest follow-up (mean of 5 years).

Radiographs (including flexion and extension views) were obtained preoperatively and at immediate postoperative, 3 months, 6 months, 1 year, and 2 years when possible. They were assessed by an independent consulting radiologist for implant failures, screw loosening, or breakage. Motion preservation was assessed by measuring the Cobb angle between the superior and inferior endplates of the stabilized segment on standing neutral lateral as well as lateral flexion and extension radiographs. Follow-up MRI or computed tomography were obtained only if patients had any symptoms such as back pain or radicular pain. Degenerative changes at adjacent levels were evaluated.

Implant Design

The TOPS System is designed to stabilize and preserve motion at the affected segment, allowing radical decompression of the segment with removal of the facet joints and a thorough bilateral foraminal decompression for patients undergoing surgery for degenerative spondylolisthesis and lumbar spinal stenosis.

The TOPS device is a unitary implant comprising 2 titanium plates with an interlocking flexible articulating core and a circumferential polyurethane elastomer cover. Its metal arms connect horizontally to 4 polyaxial pedicle screws (Figure 1). The device is implanted after a total laminectomy, facetectomy, and resection of the pars interarticularis.

The device recreates the function of the facet by allowing physiologic motion in flexion, extension, lateral bending, and axial rotation (Figure 2). The articulating surfaces are covered with a polycarbonate urethane (PcU) component with the moving parts of the implant being sealed within a PcU boot. The boot resists motion and therefore imitates the elastic properties of the facet capsule and posterior ligaments. It also creates a closed compartment to contain possible wear debris. The PcU boot incorporates a polyether ether ketone ribbon that acts as a restraint for excessive flexion of the motion segment, thus preventing the dislocation of the articulating surfaces under extreme loads. The TOPS System therefore mechanically resists translation and shear forces. The biomechanical and kinematic characteristics of the TOPS device were studied in vitro.[24,25] Metal arms project laterally from the titanium plates for anchorage of the implant to the spine via polyaxial pedicle screws. The pedicle screws are blasted with calcium phosphate particles, leaving a roughened titanium surface for bone integration.[26]

The TOPS implant has been studied in an earlier trial by Anekstein et al. but the current trial used a modified implant design which is 30 percent smaller as compared to the previous implant.[26]

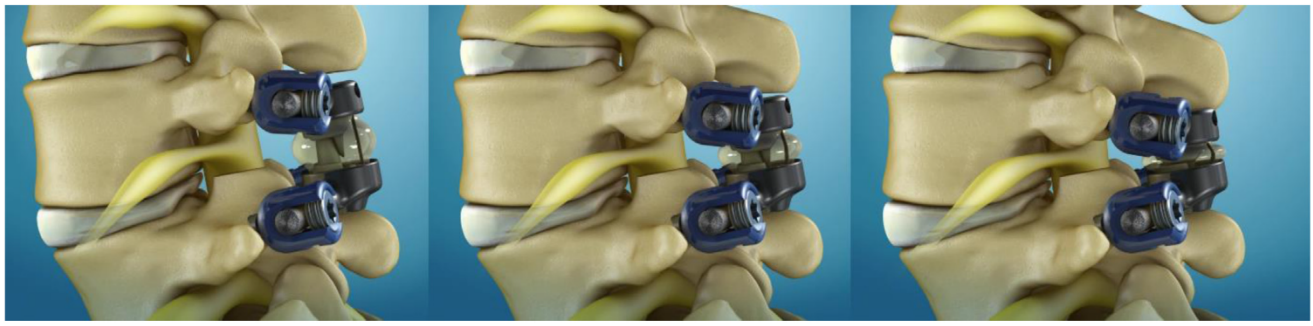

Figure 2. The TOPS implant in situ in different spinal positions. (Image - Premia Spine)

Surgical Technique

The patient is placed prone in a neutral lordotic position. An appropriate midline skin incision is made. Standard subperiosteal approach is used to reveal the posterior elements of the spine. A laminectomy, facetectomy, and resection of the pars interarticularis is then carried out. Following the thorough decompression, a trial template is used to confirm adequacy of bone excision for subsequent prosthesis implantation. The pedicle screw entry points are then identified and prepared. Intraoperative fluoroscopy may be used as required.

A pendulum-type guide is used to ensure that the screw trajectory in the axial plane remains within the range of the polyaxial tulip-head screws relative to the geometry of the implant's 4 arms. The pedicles are then instrumented with the TOPS cannulated screws. A 3-part alignment gauge is used to adjust the dorsal height of the pedicle screws so that they are in the same coronal plane and to determine the correct implant size.

The appropriate size TOPS device is then prepared for implantation by injecting 1.7 mL of sterile saline through a small port in the implant to fill the central boot. The prosthesis is then implanted and secured to the screw heads by set screws, which are tightened to the appropriate torque force. Final biplanar fluoroscopic confirmation of the device position and screws is obtained. A suction drain is inserted as decided by the operating surgeon. The wound is then closed in layers. Patients were mobilized on the first day after surgery with no requirement for brace support and with no activity restrictions needed and discharged when safe.

Statistical Analysis

Data analysis was performed using the repeated-measures 1-way Analysis of Variance (ANOVA) test such that each postoperative interval was evaluated separately for the VAS scores (back pain, left and right leg pain), ODI, SF-36 (Physical Component Score [PCS] and Mental Component Score [MCS]) and the ZCQ (Symptom Severity Scale [SSS], Physical Function Scale [PFS], and Patient Satisfaction to Treatment Scale [postoperative only]). A paired t test was used to analyze the range of motion data. All statistical analysis was performed using GraphPad Instat version 3 (Graphpad Software, La Jolla, CA) with a P value of < 0.05 considered to be significant.[27] This paper follows CONSORT statement guidelines.[28]

RESULTS

All 10 patients (M:F = 2:8) with a mean age of 59.6 years (range: 51–71 years) underwent surgery at the involved level (3 patients at L3/L4 and 7 patients at L4/L5). Two patients presented with grade I spondylolisthesis and the remaining with spinal stenosis. Mean blood loss was 268.8 mL (range: 100–500 mL) with a mean operative time of 121.4 minutes (range: 85–143 minutes). The mean length of stay was 5.2 days (range: 2–15 days).

There was no loss to follow-up and all 10 patients were followed up with clinic visits and/or phone questionnaires for a mean of 5 years (range: 55–74 months). One patient's data were irretrievably lost for preoperative scoring but this patient was followed up as part of the study.

Table 2 lists the clinical outcome scores measured throughout the follow up period. All VAS scores improved significantly with

Table 2. Analysis of Clinical Outcome Parameters

	Preoperative Mean	Interval Mean	*P* Value
VAS back pain	7.1		
		Six months – 1.4	<0.001
		12 months – 0.8	<0.001
		24 months – 0.7	<0.001
		Latest f/u – 1.6	<0.001
VAS left leg pain	7.3		
		Six months – 1.0	<0.001
		12 months – 0.1	<0.001
		24 months – 0.4	<0.001
		Latest f/u – 0.3	<0.001
VAS right leg pain	4.7		
		Six months– 1.3	<0.05
		12 months– 0.1	<0.01
		24 months– 0.4	<0.01
		Latest f/u – 1.1	<0.05
ODI	51.6		
		Six months – 14.4	<0.001
		12 months – 6.8	<0.001
		24 months – 5.3	<0.001
		Latest f/u – 8.4	<0.001
SF-36 PCS	27.9		
		Six months – 69.1	<0.001
		12 months – 73	<0.001
		24 months – 81.9	<0.001
		Latest f/u – 79.8	<0.001
SF-36 MCS	48.7		
		Six months – 81.6	<0.001
		12 months – 87.9	<0.001
		24 months – 76.6	<0.01
		Latest f/u – 85.3	<0.001
ZCQ SSS	59.4		
		Six months – 34.3	<0.001
		12 months – 29.8	<0.001
		24 months – 28.2	<0.001
		Latest f/u – 31.8	<0.001
ZCQ PFS	63.9		
		Six months – 32.8	<0.001
		12 months – 28.9	<0.001
		24 months – 27.2	<0.001
		Latest f/u – 31.7	<0.001

Continues

Table 2. Continued

	Preoperative Mean	Interval Mean	*P* Value
ZCQ Satisfaction scores		6 months — 29.6	
		12 months — 27.8	>0.05
		24 months — 26.4	>0.05
		Latest f/u — 25.5	>0.05

f/u, follow up; VAS, visual analog scale; ODI, Oswestry disability index; PCS, physical component summary; MCS, mental component summary; ZCQ, Zurich claudication questionnaire; SSS, symptom severity scale; PFS, physical function scale.

VAS back pain score showing a fall from a mean of 7.1 to 0.7 at 2 years but rising to 1.6 at 5 years (repeated-measures ANOVA, $P \leq 0.0001$), VAS left leg pain score falling from a mean of 7.3 at the preoperative stage to 0.3 at final mean (repeated-measures ANOVA $P \leq 0.0001$), and VAS right leg pain score being a mean of 4.7 at the preoperative stage to 1.1 at final analysis (repeated-measures ANOVA $P \leq 0.0016$).

The analysis of the ODI scores revealed a preoperative mean score of 51.6 to a final mean of 8.4 (repeated-measures ANOVA $P \leq 0.0001$).

The analysis of the SF-36 PCS revealed a preoperative mean score of 27.9 to a final mean of 79.8 (repeated-measures ANOVA $P \leq 0.0001$) and of the SF-36 MCS showed a preoperative mean score of 48.7 to a final mean of 85.3 (repeated-measures ANOVA $P \leq 0.0001$).

The analysis of the ZCQ SSS revealed a preoperative mean score of 59.4 to a final mean of 31.8 (repeated-measures ANOVA $P \leq 0.0001$), of the ZCQ PFS revealed a preoperative mean score of 63.9 to a final mean of 31.7 (repeated-measures ANOVA $P \leq 0.0001$), and the ZCQ satisfaction scores showed a 6-month mean score of 29.6 to a final mean of 25.5 (repeated-measures ANOVA $P = 0.2351$).

The analysis of range of motion of the stabilized segment revealed a mean neutral angle of 19° (range: 4°—32°), mean flexion angle of 15° (range: 4°—29°) (2-tailed paired t test $P = 0.0059$), mean extension angle of 23° (range: 13°—39°) (2-tailed paired t test $P = 0.0023$), and a mean arc of motion of 9° (range: 3°—14°) (2-tailed paired t test $P = 0.0040$) (**Table 3**). Radiographs at 2 years did not reveal any loss of position or loosening of metal work and revealed continued mobility of the stabilized segment (**Figure 3**).

There were no failures at 5 years with no notable increase in pain or disability. There were 2 incidental durotomies in patients who had significant stenosis. One of these patients underwent a wound exploration for possible wound complications and a change of implant bearings was performed as a precaution due to a sterile discharge. Further dural repair was not necessary and the wound subsequently settled. Otherwise, no patient required any revision spinal surgery.

DISCUSSION

The TOPS System is pedicle screw-based system that is designed to provide posterior stabilization, facet replacement, and motion maintenance in all directions. It was developed as an alternative to fusion surgery for patients with moderate to severe spinal stenosis and degenerative spondylolisthesis by replacing the posterior elements of the spine following decompression surgery.[25]

The device allows flexion, extension, lateral bending, and axial rotation but prevents further sagittal translation (further deterioration in the spondylolisthesis).[29] The study by Wilke et al. showed that this implant stabilizes and preserves near normal physiological range of movement.[25] Previous studies on pedicle screw devices have shown that cyclical loading leads to screw loosening.[17] Myers et al. showed that the load sharing design of the TOPS device reduces this risk.[24] Our results support this view as we have seen no case of screw loosening in this study.

The device aims to provide a functional replacement to the facet joint and allows a wider decompression with reduced risk of consequent instability. However, by design, the device does not replace the intervertebral disc and is therefore limited to the treatment of facet degeneration and spinal stenosis. Pathologies such as predominant disc degeneration are better addressed with spinal fusion.

It should be noted that the scores in our patients were significantly improved. The slight reduction seen in some scores in our patients were attributed to other conditions such as hip and knee osteoarthritis, lung conditions, and social issues causing pain and emotional distress. The ZCQ patient satisfaction scores revealed high satisfaction rates right from the early postoperative stage and remained so at the final analysis. Eight out of 10 patients scored 100% for the ZCQ satisfaction questionnaire.

Previously published randomized controlled trials (RCTs), such as the Coflex interlaminar stabilization device (Paradigm Spine, LLC, Wurmlingen, Germany) RCT[30] and the SLIP study,[31] revealed a substantial improvement in the fusion control arms. However, the implant used in our study differs vastly in its mechanical and stabilizing advantages when compared with the implants used in those trials. The improvements in the clinical outcome scores observed in this study suggest that for this group of patients, the procedure offered similar advantages to fusion without its possible complications.

Table 3. Analysis of Range of Motion of Replaced Segment

n = 10	Neutral Angle (°)	Flexion Angle (°)	Extension Angle (°)	Range of Motion (°)
Mean (°)	19	15	23	9
Range (°) (±SD)	4—32 (±9)	4—29 (±8)	13—39 (±8)	3—14 (±3)
P Value		0.0059	0.0023	0.0040

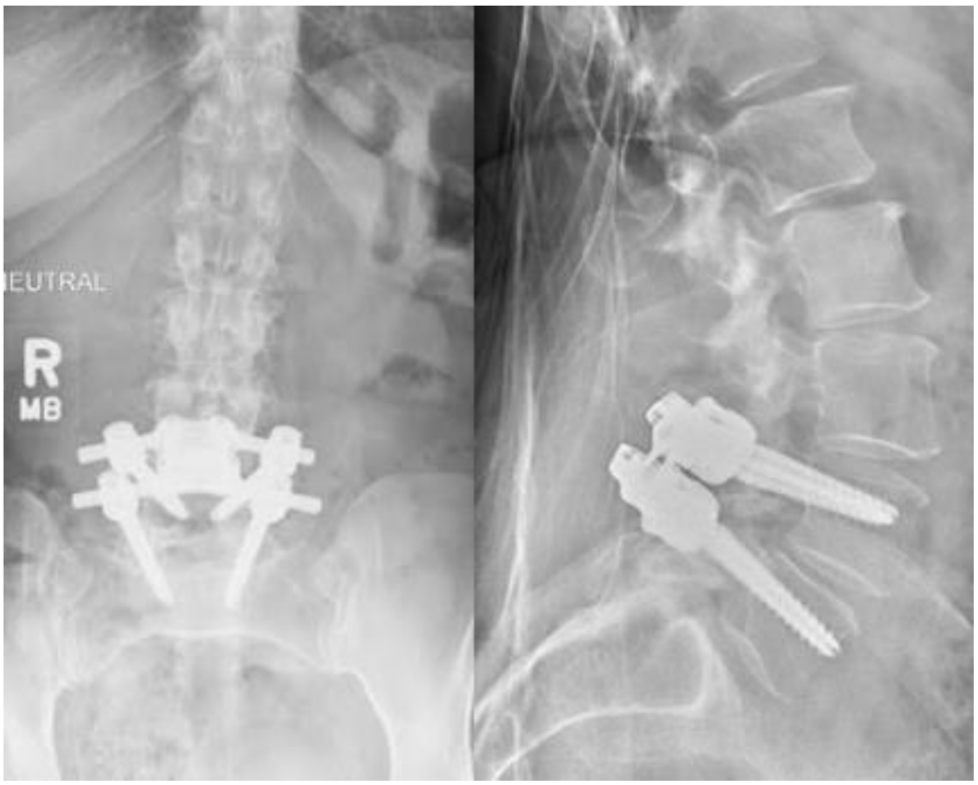

Figure 3. Postoperative radiographs. (*Left*) Standing anteroposterior. (*Right*) Standing lateral.

Our study period is too short to discuss adjacent segment degeneration, but similar studies have shown that dynamic stabilization systems can prevent adjacent segment degeneration while maintaining motion at the operated segment whereas adjacent segment degeneration has been shown start presenting as early as 2 years after spinal fusion.[17,18,32]

Overall, there was a high degree of patient satisfaction with the results achieved by the procedure with a marked reduction in symptoms both for back and leg pain. The mean range of motion achieved was comparable to radiographic studies on lumbar motion.[33]

The limitations of our study were the small numbers and the medium duration of follow-up.

The strict inclusion criteria aimed to represent patients who were symptomatic enough to warrant intervention but however were on the average too young to undergo fusion surgery. Further randomized controlled studies are required to validate these findings on a greater number of patients and explore the clinical impact of the device on patients with additional indications and conditions.

CONCLUSIONS

The TOPS System provided a useful and effective treatment to 10 patients presenting with lumbar spinal stenosis and low-grade spondylolisthesis, by complementing the spinal decompression with a non-fusion solution for patient back pain. At 5 years postoperation, there is a high degree of patient satisfaction with no implant failures and no patient requiring further spinal surgery. Further randomized controlled studies are required to validate these findings.

REFERENCES

1. Atlas SJ, Delitto A. Spinal stenosis: surgical versus nonsurgical treatment. *Clin Orthop Relat Res*. 2006; 443:198-207.

2. Otani K, Kikuchi S, Yabuki S, et al. Lumbar spinal stenosis has a negative impact on quality of life compared with other comorbidities: an epidemiological cross-sectional study of 1862 community-dwelling individuals. *Sci World J*. 2013;2013:590652.

3. Verbiest H. Pathomorphologic aspects of developmental lumbar stenosis. *Orthop Clin North Am*. 1975;6:177-196.

4. Kirkaldy-Willis WH, Wedge JH, Yong-Hing K, Reilly J. Pathology and pathogenesis of lumbar spondylosis and stenosis. *Spine (Phila Pa 1976)*. 1978;3:319-328.

5. Parker SL, Godil SS, Mendenhall SK, Zuckerman SL, Shau DN, Mcgirt MJ. Two-year comprehensive medical management of degenerative lumbar spine disease (lumbar

spondylolisthesis, stenosis, or disc herniation): a value analysis of cost, pain, disability, and quality of life. Clinical article. *J Neurosurg Spine*. 2014;21:143-149.

6. Matsunaga S, Ijiri K, Hayashi K. Nonsurgically managed patients with degenerative spondylolisthesis: a 10- to 18-year follow-up study. *J Neurosurg*. 2000;93(2 suppl):194-198.

7. Ulrich NH, Burgstaller JM, Pichierri G, et al. Decompression surgery alone versus decompression plus fusion in symptomatic lumbar spinal stenosis. *Spine (Phila Pa 1976)*. 2017;42:E1077-E1086.

8. Donnarumma P, Tarantino R, Nigro L, et al. Decompression versus decompression and fusion for degenerative lumbar stenosis: analysis of the factors influencing the outcome of back pain and disability. *J Spine Surg*. 2016;2:52-58.

9. Aihara T, Toyone T, Aoki Y, et al. Surgical management of degenerative lumbar spondylolisthesis. *J Musculoskelet Res*. 2012;15:1-11.

10. Eck J, Humphreys S, Hodges S. Adjacent-segment degeneration after lumbar fusion: a review of clinical, biomechanical, and radiologic studies. *Am J Orthop*. 1999;28:336-340.

11. Lee CK. Accelerated degeneration of the segment adjacent to a lumbar fusion. *Spine (Phila Pa 1976)*. 1988;13:375-377.

12. Schlegel JD, Smith JA, Schleusener RL. Lumbar motion segment pathology adjacent to thoracolumbar, lumbar, and lumbosacral fusions. *Spine (Phila Pa 1976)*. 1996;21:970-981.

13. Kornblum MB, Fischgrund JS, Herkowitz HN, Abraham DA, Berkower DL, Ditkoff JS. Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective long-term study comparing fusion and pseudarthrosis. *Spine (Phila Pa 1976)*. 2004;29:726-733.

14. Malmivaara A, Slätis P, Heliövaara M, et al. Surgical or nonoperative treatment for lumbar spinal stenosis? A randomized controlled trial. *Spine (Phila Pa 1976)*. 2007;32:1-8.

15. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. 2008;358:794-810.

16. Ghogawala Z, Benzel EC, Amin-Hanjani S, et al. Prospective outcomes evaluation after decompression with or without instrumented fusion for lumbar stenosis and degenerative grade I spondylolisthesis. *J Neurosurg Spine*. 2004;1:267-272.

17. Stoll TM, Dubois G, Schwarzenbach O. The dynamic neutralization system for the spine: a multicenter study of a novel non-fusion system. *Eur Spine J*. 2002;11(suppl 2):170-179.

18. Wild A, Jaeger M, Bushe C, Raab P, Krauspe R. Biomechanical analysis of Graf's dynamic spine stabilisation system ex vivo. *Biomed Tech*. 2001;46:290-294.

19. Marsh GDJ, Mahir S, Leyte A. A prospective randomised controlled trial to assess the efficacy of dynamic stabilisation of the lumbar spine with the Wallis ligament. *Eur Spine J*. 2014;23:2156-2160.

20. Scott J, Huskisson EC. Graphic representation of pain. *Pain*. 1976;2:185-195.

21. Fairbank JCT, Pynsent PB. The Oswestry Disability Index. *Spine (Phila Pa 1976)*. 2000;25:2940-2953.

22. Hays RD, Sherbourne CD, Mazel RM. The Rand 36-item health survey 1.0. *Health Econ*. 1993;2:217-227.

23. Stucki G, Daltroy L, Liang MH, Lipson SJ, Fossel AH, Katz JN. Measurement properties of a self-administered outcome measure in lumbar spinal stenosis. *Spine (Phila Pa 1976)*. 1996;21:796-803.

24. Meyers K, Tauber M, Sudin Y, et al. Use of instrumented pedicle screws to evaluate load sharing in posterior dynamic stabilization systems. *Spine J*. 2008;8:926-932.

25. Wilke HJ, Schmidt H, Werner K, Schmölz W, Drumm J. Biomechanical evaluation of a new total posterior-element replacement system. *Spine (Phila Pa 1976)*. 2006;31:2790-2796.

26. Anekstein Y, Floman Y, Smorgick Y, Rand N, Millgram M, Mirovsky Y. Seven years follow-up for total lumbar facet joint replacement (TOPS) in the management of lumbar spinal stenosis and degenerative spondylolisthesis. *Eur Spine J*. 2015;24:2306-2314.

27. Instat GraphPad. *Instat GraphPad version 3.00 for Windows*. 2003. Available at: https://www.graphpad.com/scientific-software/instat/. Accessed June 28, 2021.

28. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:698-702.

29. Potvin J, McGill RN S. Trunk muscle and lumbar ligament contributions. *Spine (Phila Pa 1976)*. 1991;16:1099-1107.

30. Ghogawala Z, Dziura J, Butler WE, et al. Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis. *N Engl J Med*. 2016;374:1424-1434.

31. Musacchio MJ, Lauryssen C, Davis RJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. *Int J Spine Surg*. 2015;10:1-10.

32. Okuda S, Nagamoto Y, Matsumoto T, Sugiura T, Takahashi Y, Iwasaki M. Adjacent segment disease after single segment posterior lumbar interbody fusion for degenerative spondylolisthesis. *Spine (Phila Pa 1976)*. 2018;43:E1384-E1388.

33. Hayes MA, Howard TC, Gruel CR, Kopta JA. Roentgenographic evaluation of lumbar spine flexion-extension in asymptomatic individuals. *Spine (Phila Pa 1976)*. 1989;14:327-331.

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