

Facet Replacement

The New Motion Treatment Paradigm for Spinal Stenosis and Spondylolisthesis Patients



The TOPS™ System provides an entirely new modality to treat patients with spinal stenosis and spondylolisthesis. TOPS is the first and only FDA-approved facet replacement device with a superiority-to-fusion claim.

A disruptive breakthrough in spinal care, TOPS uniquely addresses the needs of patients, surgeons, caregiving facilities and commercial payers to create a broad win for all stakeholders.

Learn about:

- ✓ [The TOPS™ System](#)
- ✓ [Details on facility reimbursement](#)
- ✓ [Specifics on surgeon reimbursement](#)
- ✓ [Compelling healthcare economics for payers](#)
- ✓ [Clinical evidence supporting the FDA's label of superiority to lumbar fusion](#)
- ✓ [Meaningful patient benefits](#)
- ✓ [Tangible surgeon benefits](#)

The TOPS™ System

The FDA is heralding in a new modality for the treatment of Spinal Stenosis and Degenerative Spondylolisthesis with its PMA approval of the TOPS™ System for Facet Replacement.

The TOPS System is a motion preserving alternative to lumbar fusion. Instead of rigidly fixing two adjacent vertebrae, TOPS recreates normal motion after surgical decompression to eliminate nerve root impingement.

Like an artificial hip or knee, TOPS replicates the posterior spinal column function by providing physiologic motion in flexion, extension, rotation, lateral bending, and sagittal translation. Pre-clinical and clinical data demonstrate the TOPS facet replacement's ability to absorb high forces and reestablish the mechanical integrity of the spine segment.

Breakthrough Device

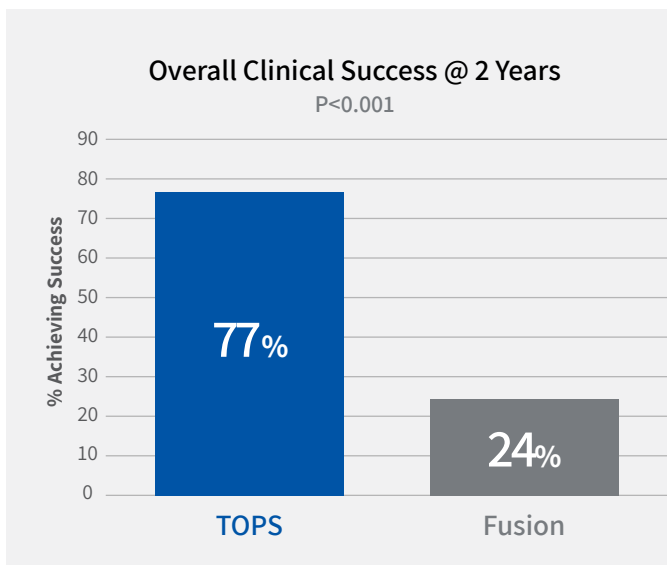
“We are pleased to inform you that your device and proposed indication for use meet the criteria and have been **granted designation as a Breakthrough Device.**”

The Food & Drug Administration, October 26th, 2020

Superior to Fusion

“**The TOPS group demonstrated a clinically meaningful and substantial advantage over the Fusion** control group, with 77% of subjects randomized to the TOPs group achieving composite clinical success, compared to 24% of subjects randomized to the fusion control. Based on these results, the **TOPS System was deemed to be superior to the Fusion** control with respect to composite clinical success while maintaining equivalent safety.”

The Food & Drug Administration, June 15, 2023



The result is
Stability, Mobility, and Durability.

Facility Payment

New Technology Add-On Payment (NTAP) Approved

The TOPS™ System was awarded the prestigious New Technology Add-on Payment (NTAP) by the Centers for Medicare & Medicaid Services (CMS). This is only the 3rd time that CMS has granted an NTAP to a spinal implant. Beginning October 1, 2023, and through September 30, 2026, qualifying TOPS procedures are **eligible for up to \$11,375 in additional reimbursement beyond the DRG.**

All in-patient procedures **involving Medicare and TRICARE** insured patients are eligible for the add-on payment.

Further, CMS recognized the uniqueness of TOPS and awarded new ICD-10-PCS code for facet arthroplasty.

ICD-10-PCS Code	Description	2023 DRG Assignment
XRHB018	Insertion of posterior spinal motion preservation device into lumbar vertebral joint, open approach, New Technology Group 8	518

Note that reimbursement in the inpatient setting for facet arthroplasty compares favorably to fusion before adding the NTAP.

Surgical Treatment	MS-DRG	2023 DRG Relative Wt.	FY 2023 Base Payment
Fusion	460	3.7660	\$23,055
Facet Arthroplasty	518	3.7277	\$22,821

Significant Reprocessing Savings

The TOPS System comes in only a single container saving significant reprocessing costs versus fusion systems that typically come in five or six containers. Further, all TOPS implants are sterile packed to reduce the risk of infections from re-cleaning and reprocessing of exposed fusion implants.



Physician Payment

Existing Temporary Code with CPT-1 Guidance Codes for Payment

Facet arthroplasty is most appropriately described by CPT code 0202T.

As a temporary code, there are no RVU's assigned to this code. Therefore, **when using the T code, physicians are required to perform a crosswalk to assign value to the 0202T code.** As demonstrated in the IDE study, the TOPS procedure requires a similar effort, skill and time investment as a TLIF. Therefore, when advocating for a fair compensation for the TOPS procedure, surgeons can rely on existing CPT codes and RVU's to craft an argument for a payment that reflects:

- ✓ The bony work required for preparing the structural bed for the TOPS device
- ✓ The neural decompression work to relieve the patient of neurogenic claudication
- ✓ The placement of the pedicle screws, including the additional precision in accurate screw trajectory, caudal-cranial positioning, and dorsal alignment
- ✓ The TOPS motion implant sizing and device placement

Recommended Primary CPT Procedure Code

CPT Code	Description
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine

Possible Cross-Walk Utilizing Category I Code

CPT Code	Description
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root [s], [eg, spinal or lateral recess stenosis]) single vertebral segment; lumbar
22840	Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation)(List separately in addition to code for primary procedure)



By: Jared Ament,
MD, MPH

TOPS™ System is a Dominant Solution for Payers versus Traditional Lumbar Fusion

As published in the Journal of Health Economics and Outcomes Research, “A Prospective Study of Lumbar Facet Arthroscopy in the Treatment of Degenerative Spondylolisthesis and Stenosis: Early Cost-Effective Assessment from the Total Posterior Spine System (TOPS) IDE Study” the TOPS System has proven its cost-effectiveness and economic benefit versus TLIF fusion for patients suffering from spondylolisthesis and spinal stenosis.

The data from the prospective randomized study was independently analyzed by Neuronomics, my firm which focuses on healthcare economic analyses. Its findings demonstrate that, **even at a premium of \$4,000 over the cost of a TLIF implant, TOPS still achieves cost-effectiveness at a willingness-to-pay threshold of \$100,000 within one-year after surgery.** Furthermore, TOPS becomes the dominant strategy when data is examined at two years and beyond. From the societal perspective, TOPS is even more highly cost-effective at one year and dominant at two years and beyond.

The paper, concludes that ***TOPS appears to be a highly cost-effective surgical modality compared with TLIF*** as a motion-preserving, non-fusion alternative for the treatment of grade 1 spondylolisthesis with lumbar spinal stenosis. Since the TOPS System yields greater QOL [quality of life] at a lower total cost over time, it deserves serious attention.

Ament JD, Vokshoor A, Badr Y, et al. A prospective study of lumbar facet arthroplasty in the treatment of degenerative spondylolisthesis and stenosis: early cost-effective assessment from the Total Posterior Spine System (TOPS™) IDE study. *JHEOR*. 2022;9(1):82-89. doi:10.36469/jheor.2022.33035



Journal of Health Economics and Outcomes Research

Other Conditions

A Prospective Study of Lumbar Facet Arthroplasty in the Treatment of Degenerative Spondylolisthesis and Stenosis: Early Cost-effective Assessment from the Total Posterior Spine System (TOPS™) IDE Study

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➤ [Supplementary Material](#)

ABSTRACT

Background: Given the increased attention to functional improvement in spine surgery as it relates to motion preservation, activities of daily living, and cost, it is critical to fully understand the healthcare economic impact of new devices being tested in large FDA randomized controlled trials (RCT). The purpose of this analysis was to comprehensively evaluate the cost-effectiveness of the novel Total Posterior Spine System (TOPS™) System investigational device compared with the trial control group, standard transforaminal lumbar interbody fusion (TLIF).

Objective: To evaluate the cost-effectiveness of TOPS™ compared with TLIF.

Methods: The study patient population was extracted from a multicenter RCT with current enrollment at n=121 with complete 1-year follow-up. The primary outcome was cost-effectiveness, expressed as the incremental cost-effectiveness ratio. Secondary outcomes were health-related utility, presented as quality-adjusted life years (QALYs), and cost, calculated in US dollars. Analysis was conducted following Second Panel on Cost-Effectiveness Health and Medicine recommendations. The base case analysis utilized SF-36 survey data from the RCT. Both cost and QALY outcomes were discounted at a yearly rate of 3% to reflect their present value. A cohort Markov model was constructed to analyze perioperative and postoperative costs and QALYs for both TOPS™ and control groups. Scenario, probabilistic, and threshold sensitivity analyses were conducted to determine model discrimination and calibration.

Results: The primary time horizon used to estimate cost and health utility was 2 years after index surgery. From a health system perspective, assuming a 50/50 split between Medicare and private payers, the TOPS™ cohort is cost-effective 2 years postoperatively (\$6158/QALY) compared with control. At 6 years and beyond, TOPS™ becomes dominant, irrespective of payer mix and surgical setting. At willingness-to-pay thresholds of \$100,000/QALY, 63% of all 5000 input parameter simulations favor TOPS, even with a \$4000 upcharge vs TLIF.

Discussion: The novel TOPS™ device is cost-effective compared with TLIF and becomes the dominant economic strategy over time.

Conclusions: In the emerging, rapidly expanding field of value-based medicine, there will be an increased demand for these analyses, ensuring surgeons are empowered to make the best, most sustainable solutions for their patients and society.



By: Stephen
Hochschuler, MD

Facet Replacement, Fusion, or Decompression—only for Spondylolisthesis and Spinal Stenosis

There are several important factors when considering whether facet replacement, lumbar fusion, or decompression is the right solution for degenerative spondylolisthesis and stenosis sufferers. Depending on each patient's situation, one procedure might have benefits over the others.

To Instrument or Not to Instrument. That is the First Question

The first decision is whether instrumentation is necessary. Clinical literature supports “decompression-only” when patient symptoms can be treated without destabilizing the spine segment. Non-instrumented procedures tend to have fewer complications, less blood loss, reduced surgical time, and lower direct costs. But in which indications is there a high likelihood of clinical success without instrumentation? Several studies have looked at pre-operative parameters to anticipate post-operative success. Factors such as disc height, slip angle, slip grade, facet morphology, facet joint fluid, pelvic parameters, age, obesity, the pervasiveness of nerve root impingement, and segmental stability have been assessed to determine for their capacity to predict outcomes.

Decompression vs. Fusion. The Clinical Literature is Inconclusive

There are several clinical studies that compare fusion to decompression in the lumbar spondylolisthesis and stenosis population. The SLIP I study from Dr. Ghogawala et al points to similar ODI improvements in the fusion and decompression-only patients, with a reoperation rate of 34% in the decompression-only arm versus 14% among the fusion cohort at 4 years¹. **Advantage fusion.** However, Drs. Austevoll² and Forsth³ each led European studies out to two and five years, respectively, that found similar clinical outcomes between decompression-only and fusion with higher costs in the instrumentation arm.

Advantage decompression. So, what conclusions can be drawn? The conventional wisdom and consensus among surgeons are that an instrumented fusion should be deployed if a patient suffers from segmental instability or if the decompression potentially introduces an iatrogenic spondylolisthesis.

Comparing Fusion with TOPS

This conclusion is now being reexamined with the introduction of facet replacement. This new instrumented modality raises a new paradigm: the ability to stabilize an unstable spine segment following decompression without rigid fixation. The T^oTal Posterior Spine (TOPS) System differs from traditional fusion. Rather than fusing the adjacent vertebrae together, the TOPS™ System maintains the full function of the motion segment. The TOPS surgery relies on a wide decompression followed by the replacement of the bilateral facet joints with a prosthesis. The motion implant is comprised of two titanium endplates connected by a polycarbonate urethane boot. The internal motion component is made of titanium and polycarbonate urethane articulating parts and an interlocking PEEK woven ribbon, which are attached to the endplates. The construct is anchored to the spine with four standard pedicle screws. The flexible boot and articulating parts allow constrained physiological movement in flexion, extension, lateral bending, and axial rotation, while blocking excessive posterior and anterior sagittal translation.

WATCH: How does it work? TOPS System Animation

The TOPS System represents a new surgical approach that combines the benefits of the two available alternatives, decompression-only and decompression with fusion. Like a fusion, TOPS stabilizes the spinal segment but without sacrificing motion and rigidly fixing the spine. Like decompression, TOPS maintains motion but allows the surgeon to remove all posterior pain generators more thoroughly without the fear of destabilizing the spine segment. The result is a post-operative segment that mimics the natural kinematics of the spine following a complete and wide decompression of the neural elements. The TOPS™ System is indicated for single-level moderate to severe spinal stenosis and up to a Grade I degenerative spondylolisthesis.

Clinical Evidence Supports TOPS' Superiority to Lumbar Fusion

To back its theory with clinical evidence, Premia Spine engaged in a prospective, randomized (2:1) PMA trial at 37 sites throughout the US comparing the TOPS System to a standard transforaminal lumbar interbody fusion (TLIF).

An interim 2022 publication of the IDE results based on 249 subjects (170 TOPS and 79 TLIF) demonstrated a statistically significant higher clinical success rate for TOPS patients compared with the control group (85%

1. Ghogawala Z, Dziura J, Butler WE, et al. Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis. *N Engl J Med.* Apr 14 2016; 374(15):1424–34. doi:10.1056/NEJMoa1508788

2. Austevoll IM, Gjestad R, Solberg T, et al. Comparative Effectiveness of Microdecompression Alone vs Decompression Plus Instrumented Fusion in Lumbar Degenerative Spondylolisthesis. *JAMA Netw Open.* 2020;3(9):e2015015. doi:10.1001/jamanetworkopen.2020.15015

3. Forsth P, et al., A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis, *N Engl J Med.* 2016 Apr 14; 374(15):1413–23. doi: 10.1056/NEJMoa1513721.

versus 64%, respectively). All-in-all, TOPS patients got better faster, and had lower revision rates and less opioid use than the fusion control group.

Ultimately, the TOPS pivotal trial reached 302 patients before closing enrollment. The FDA based its 2023 PMA approval on a subset of 168 patients (115 TOPS, 53 fusion patients) who had reached their two-year follow up at the time of submission.

Premia Spine and the FDA established a composite clinical success (CCS) scoring that consisted of six criteria to reflect the assessment of three stakeholders: patients, surgeons, and radiologists. For each patient, if any of the criteria were not met, the case was considered a failure. The study CCS included: an improvement of 15 points or greater in ODI, an extensive neurologic assessment for new or worsening deficit, reoperation rates, device failure (breakage, disassembly, loosening, and lucency as evaluated by the radiologists), supplemental injections, and the maintenance of motion in TOPS patients or presence of fusion in TLIF patients.

The results were overwhelmingly in favor of the TOPS System. In the approval product label, the FDA said that the “TOPS group demonstrated a clinically meaningful and substantial advantage over the Fusion control group, with 77% of subjects randomized to the TOPS group achieving composite clinical success, compared to 24% of subjects randomized to the fusion control.” Based on these results, the TOPS System was deemed to be superior to the fusion control with respect to composite clinical success while maintaining equivalent safety.

Benefits of TOPS Surgery

For qualified patients, the TOPS System appears to accomplish the same clinical objectives as the traditional fusion surgery in terms of providing nerve decompression, pain relief, and segmental stabilization. There are also additional potential benefits:

- Quicker recovery. When compared to a fusion control group, TOPS subjects demonstrated better recovery at the first post-op visit at six weeks (as measured by ODI, VAS leg, and VAS back improvement from pre-op). The TOPS advantage was maintained, and in fact, widened at each subsequent visit through two years.
- Secondary benefits. When compared to a fusion control group, TOPS patients had lower revision rates and less opioid use than the fusion control group.
- Healthcare economics. TOPS demonstrated greater health benefits at a lower cost of care from the first post-op visit at six weeks through all time points.
- Easy to perform. Easy to revise. The TOPS™ System surgical technique is like an open posterior midline fusion, without the need to manipulate nerve roots to access the anterior disc space. Pedicle screw placement is similar to that of a fusion, albeit a bit more demanding in terms of precision. Time of surgery is the same. A revision to fusion involves removing the set screws and TOPS device, and rotating the screw heads 90 degrees for fusion rods. An interbody is recommended in revision procedure.

Watch: Surgical technique

Benefits of fusion

It is important to note that facet replacement is not for all instrumented spondylolisthesis and stenosis patients. In fact, the success of this modality hinges on sticking to the indications that drove its clinical success and superiority labeling. Fusion will remain the gold standard for:

- Multi-level pathology. Fusion is the solution of choice for patients who require instrumentation at two or more levels. TOPS is indicated for symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5.
- Other pathologies are better served with fusion. Patients with L5-S1 degeneration, with osteoporosis, with concurrent disc herniation, or with an isthmic spondylolisthesis are all better served with rigid fixation.
- Fewer unknown risks. Traditional fusion has been around for decades with abundant data regarding its long-term safety and efficacy of a fusion. While TOPS results thus far are very promising, it is still relatively early in its life cycle with over a decade of long-term follow-up.
- More widely covered by insurance. Gaining coverage for fusion of a grade I spondylolisthesis with spinal stenosis is relatively straightforward. It is too early to know if insurance carriers will cover the TOPS surgery or deem it experimental. The good news for facilities is that TOPS has a CMS New Technology Add-on Payment that will pay up to \$11,375 on top of the DRG starting on October 1, 2023.

Making the decision among decompression-only, traditional fusion and the TOPS System comes down to patient desire and discussing the potential benefits and risks of each alternative.

Ultimately, the treatment of spondylolisthesis and spinal stenosis could spread evenly among the three modalities—fusion, decompression-only, and facet replacement—with each treatment taking its rightful share of the patient population based on their indications and preferences.

4. Coric et al. Prospective randomized controlled multicenter study of posterior lumbar facet arthroplasty for the treatment of spondylolisthesis. *Journal of Neurosurgery*. 2022 Sep 23;38(1):115–125.doi: 10.3171/2022.7.SPINE22536. Print 2023 Jan 1

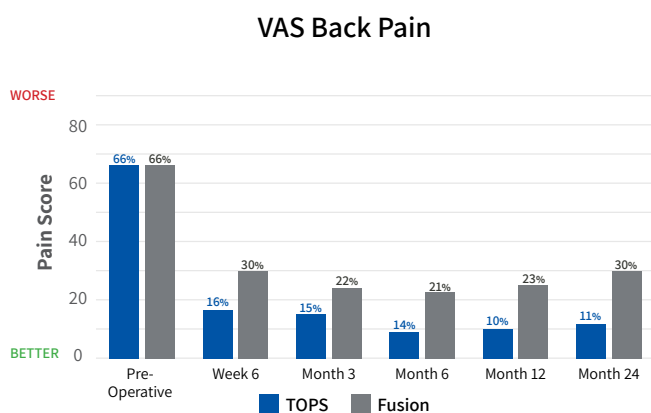
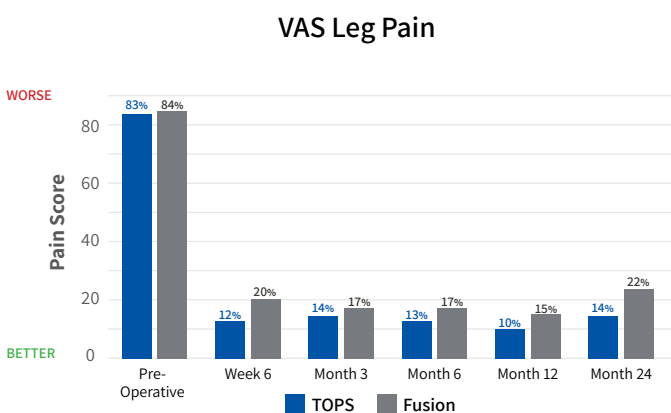
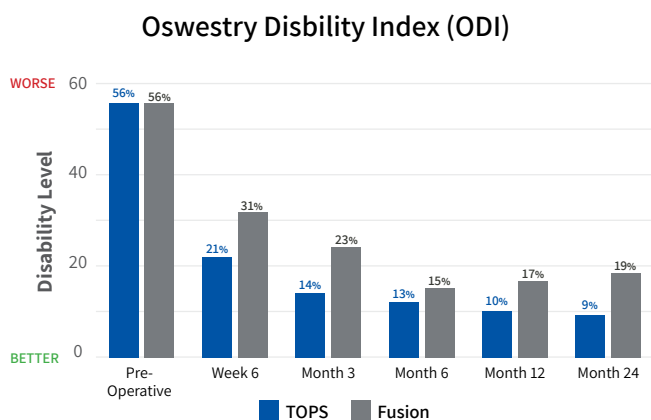
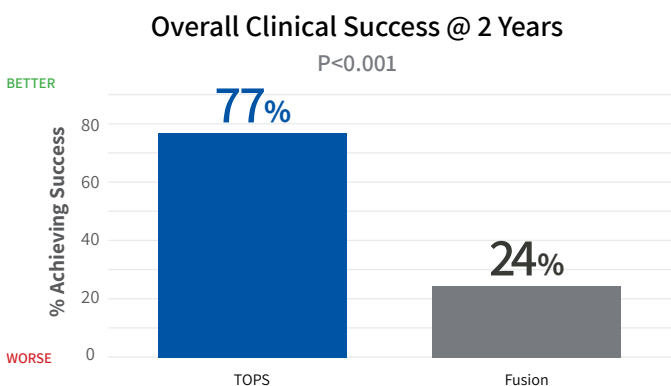
5. TOPS System Summary of Safety and Effectiveness (SSED), FDA

Clinical Data

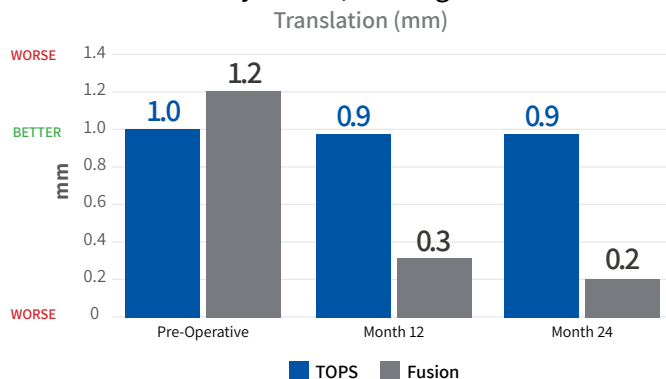
The TOPS System is the **first and only posterior lumbar motion preservation system** with Level I evidence from a prospective randomized study **demonstrating superiority over spinal fusion**.

US IDE Clinical Trial – 2 Year Results - TOPS System demonstrates vs Fusion

- ✓ **Superiority in overall clinical success at 2 years**
- ✓ Greater improvement in overall function
- ✓ Faster relief of symptoms
- ✓ Lower rate of re-operation. Lower rate of post-operative injections. Similar complication rates
- ✓ Longer lasting relieve of symptoms
- ✓ Preservation of motion including physiological translation
- ✓ **Better outcome scores at every time point on leg pain, back pain, and daily function scores**



Summary of Flex/Ex Range of Motion



Clinical Data

The TOPS System was **first implanted in 2005**. The current version of TOPS has been in clinical use for a dozen years. **Several thousand patients have benefitted from the TOPS System.**

Long-Term Clinical Results

Published 5-Year Data

Results from prospective single-center study demonstrate TOPS is safe and effective treatment with excellent long-term results.

Outcomes after 5 years:

- ✓ 84% improvement in disability
- ✓ 96% improvement in leg pain
- ✓ 77% improvement in back pain
- ✓ No reoperations or device failure

Published Case Series

Results from retrospective single-center study with strong results.

Outcomes at mean 51 (26-77) months:

- ✓ 81% average VAS improvement
- ✓ Post-op ROM of 7.4° in flex/ex

Published 11-Year Data

Longer-term results show significant and sustained improvement in all outcomes through 11 years of follow-up.

Outcomes after 11 years:

- ✓ 67% improvement in disability
- ✓ 80% improvement in leg pain
- ✓ 75% improvement in back pain
- ✓ No reoperations or device failure

WORLD NEUROSURGERY ■: E1-E7, ■ 2021

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

Shahnawaz Haleem¹, Awaiz Ahmed², Satish Ganesan³, Stephen F. McGillion⁴, John L. Fowler⁵

OPERATIVE NEUROSURGERY

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

Werner Lack, MD^{1*}

Hans Paul Kutschera, MD²

Josef Krugluger, MD³

JNS SPINE

CLINICAL ARTICLE

Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis

Yossi Smorgick, MD,² Yigal Mirovsky, MD,¹ Yizhar Floman, MD,¹ Nahshon Rand, MD,¹

Patient Benefits

Patients refuse to fuse. They choose to move.

TOPS provides superior clinical outcomes to fusion. This has been proven in the TOPS System FDA study. TOPS outperformed fusion at every time point for key indicators of surgical success: less leg pain, less back pain, and the ability to dramatically improve daily function.

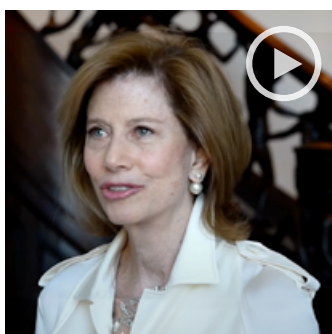
For patient who suffer from:

- ✓ Radiating leg pain
- ✓ Greater leg/buttock pain than backpain
- ✓ Severe pain which starts when walking as little as 100 yards or 2 minutes
- ✓ Pain reduces with sitting, bending forward, or leaning over a cart or bicycle

Hear from patients who experienced the debilitation of spondylolisthesis and spinal stenosis



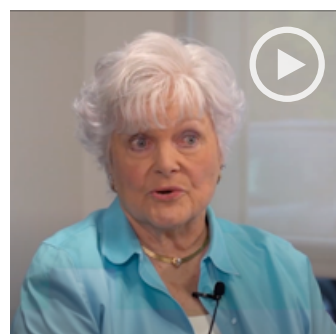
David danced at his son's wedding



Bonnie explains why TOPS surgery was the right decision for her



Keith Thomas's patient review about back pain relief



Virginia Flowers patient testimonial



Marianne Galang's Story



Rick Scarinzi's Story



Margaret's Story



Sarah Garbarino's Story

Surgeon Benefits

A New Technology with a Familiar Feel

The TOPS™ System is a true practice differentiator. It provides surgeons with a **viable third option** to decompression or fusion for patients with spondylolisthesis and spinal stenosis. Further, the system relies on a tried-and-true **pedicle screw surgical technique**. So, there is very **little learning curve**. In fact, in the IDE study, there was no statistical difference in outcomes between an aggregation of all “first patients” versus an aggregation of “all subsequent patients.”

Other benefits of the TOPS System include:

- ✓ **One container:** Simple procedure. Easy for scrub techs to master
- ✓ **Sterile implants:** No reprocessing of implants and reduced risk of infection
- ✓ **Straightforward revision procedure:** Remove set screws. Remove TOPS motion device. Insert a cage.
Rotate the heads 90°. Place fusion rods
- ✓ **Compelling clinical data:** On label from FDA as superior to fusion
- ✓ **Existing CPT-III code:** Describes facet arthroplasty procedure
- ✓ **Independent ISASS study:** Work valuation survey in final stages of processing to reflect peer assessment of facet replacement for crosswalk

TOPS makes the difference in spinal care

- ✓ Motion alternative to lumbar spinal fusion
- ✓ FDA labeled as superior to spinal fusion
- ✓ New Technology Add-on Payment of up to \$11,375 for Medicare eligible procedures