TOPS Total Posterior System-Results of an FDA-IDE Trial

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Disclosures related to this talk: None

Personal 20 Year Endeavor

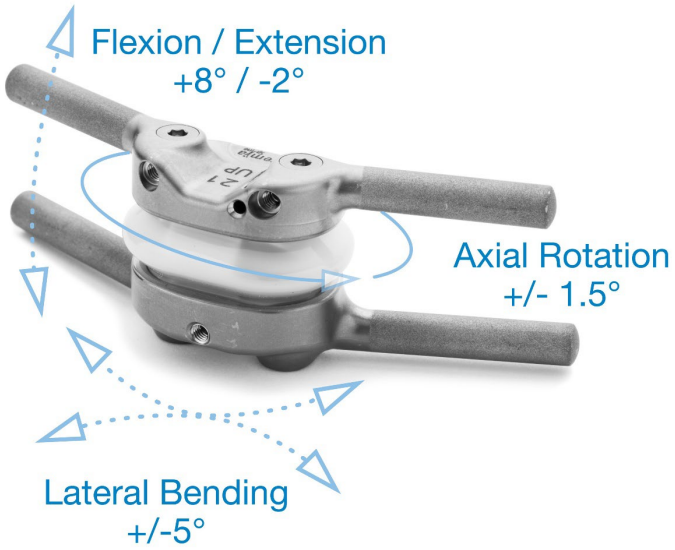
- I find the concept of motion retention appealing
- I understand that the biomechanics involved in maintaining a lifetime of lumbar implant integrity is daunting
- I followed the Charite and subsequent TDR products and haven't found them useful in my practice
- I have followed the posterior devices, incorporated them into my practice and participated in clinical trials

Personal 20 Year Endeavor

- My personal experience prior to TOPS was the Dynesys system.
- This was a pedicle screw-based system with a PCU spacer which was placed under tension.
- The system was very stiff, essentially functioned as a semi-rigid fusion construct.
- Was taken to FDA panel and was not FDA approved, essentially ending the development of similar constructs (Globus, Spine-way, Medtronic)
- Newer systems of posterior systems include Limiflex (tension band placed across posterior spinous processes), TOPS (presented today), and, possibly, Co-Flex.
- The promise of these systems is to allow increased stability without negative influence on adjacent level

Facet Replacement

Where Does It Fit In?



Spondylolisthesis and Spinal Stenosis

- When conservative (non-surgical) care is no longer effective, surgery is the next line of treatment
- The surgical standard of care today is either a decompression, decompression followed by fusion, or decompression with non-fusion instrumentation
- Fusion can be performed with or without instrumentation
- There may be appropriate surgical interventions at various stages of disease (Coflex, Vertiflex, Limiflex) and specific patient populations (further study needed)

Where TOPS™ Fits In

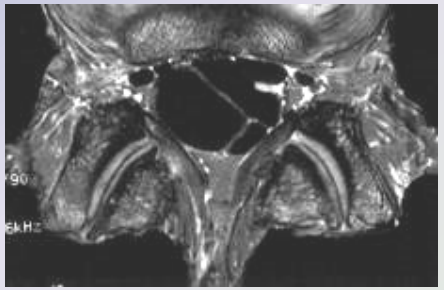
Continuum of segmental degeneration

Disc Degeneration

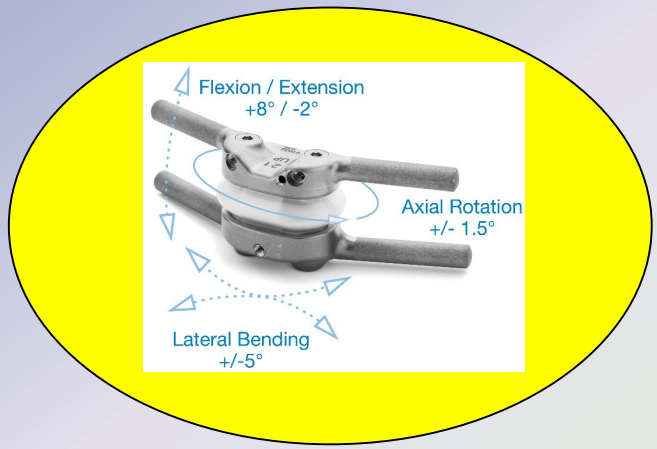
Facet Degeneration

Early Stage

- **Conservative care**
- **Decompression-only**
- **Vertiflex / Coflex**
- **Limiflex**

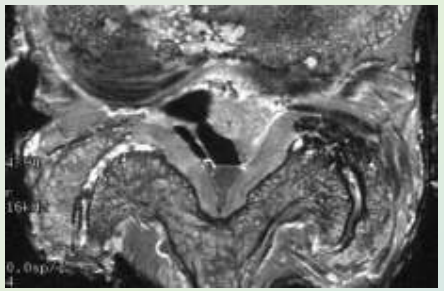


Mild



Late Stage

- **End plate issues with no disc height**
- **Very little segmental motion**
- **Instability**
- **Fusion**

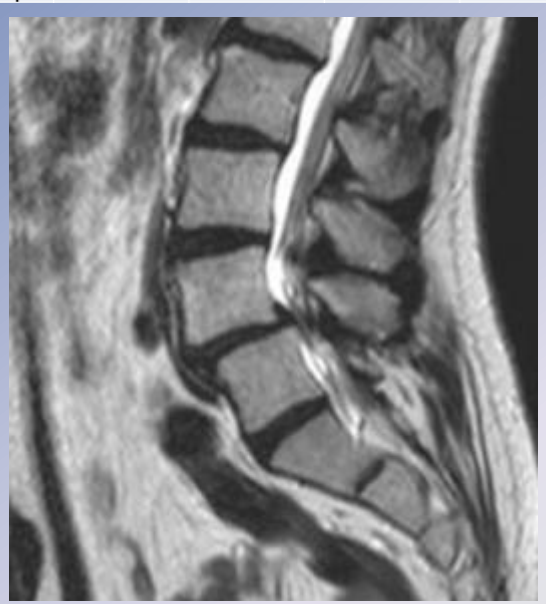


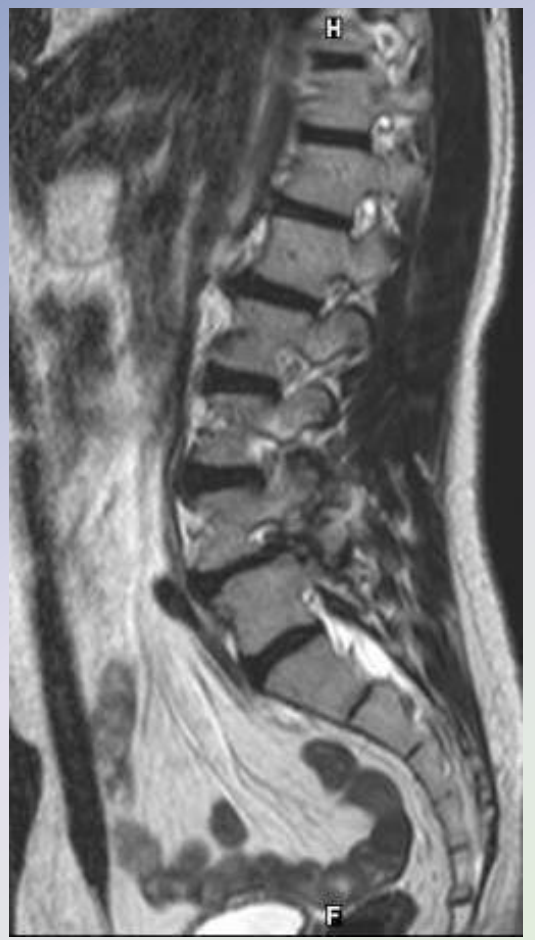
Severe

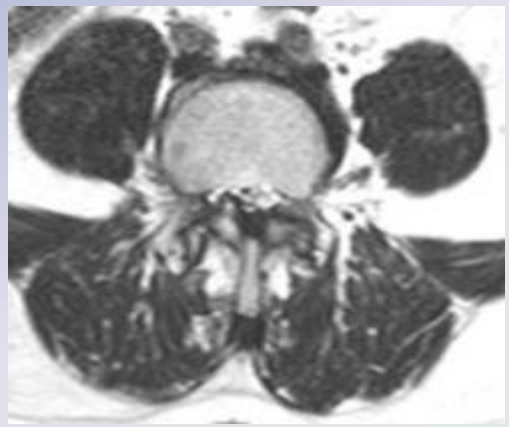
Case Study

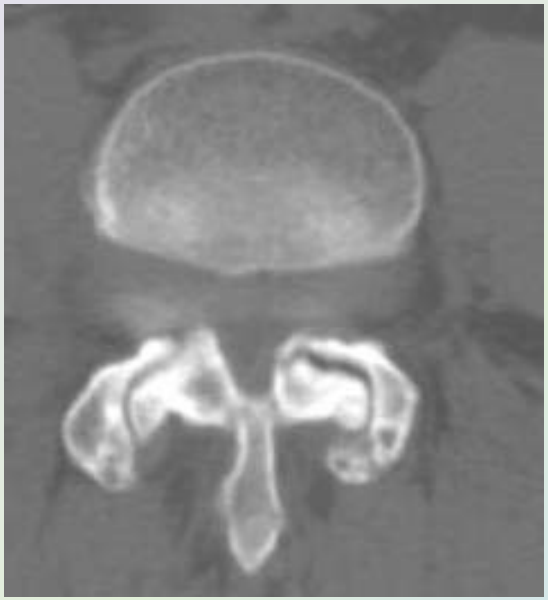
- 52 year-old male with primarily left leg pain, neurogenic claudication and little back pain

Time Period	ODI	VAS Left	VAS Right	VAS Back
Pre-Op	40	100	40	4



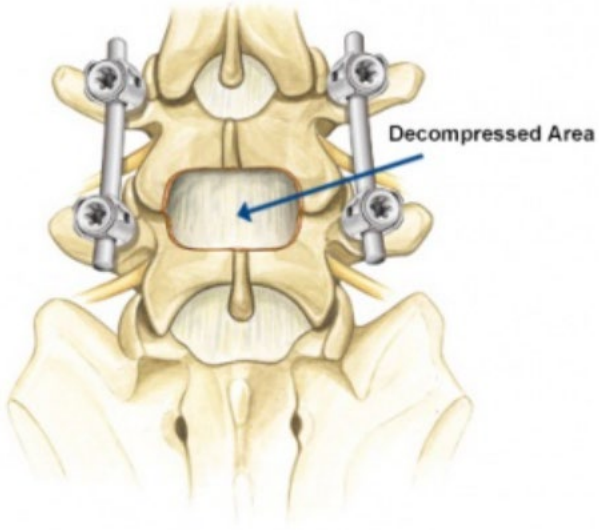






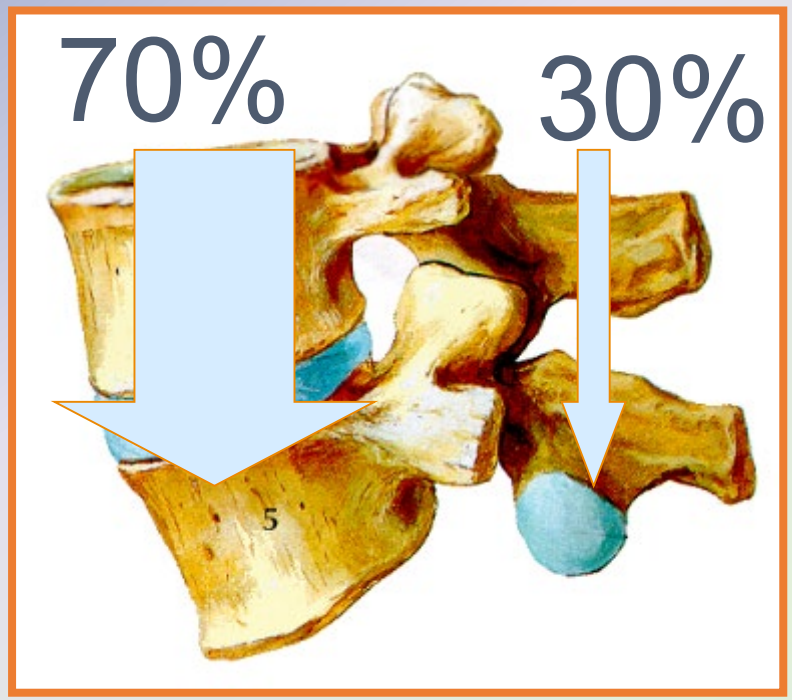
What do you do?

- Decompression
- Fusion (indirect decompression)
- Decompression + Instrumented Fusion
- Decompression + Non-Instrumented Fusion
- Limiflex
- Co-Flex
- Other options??



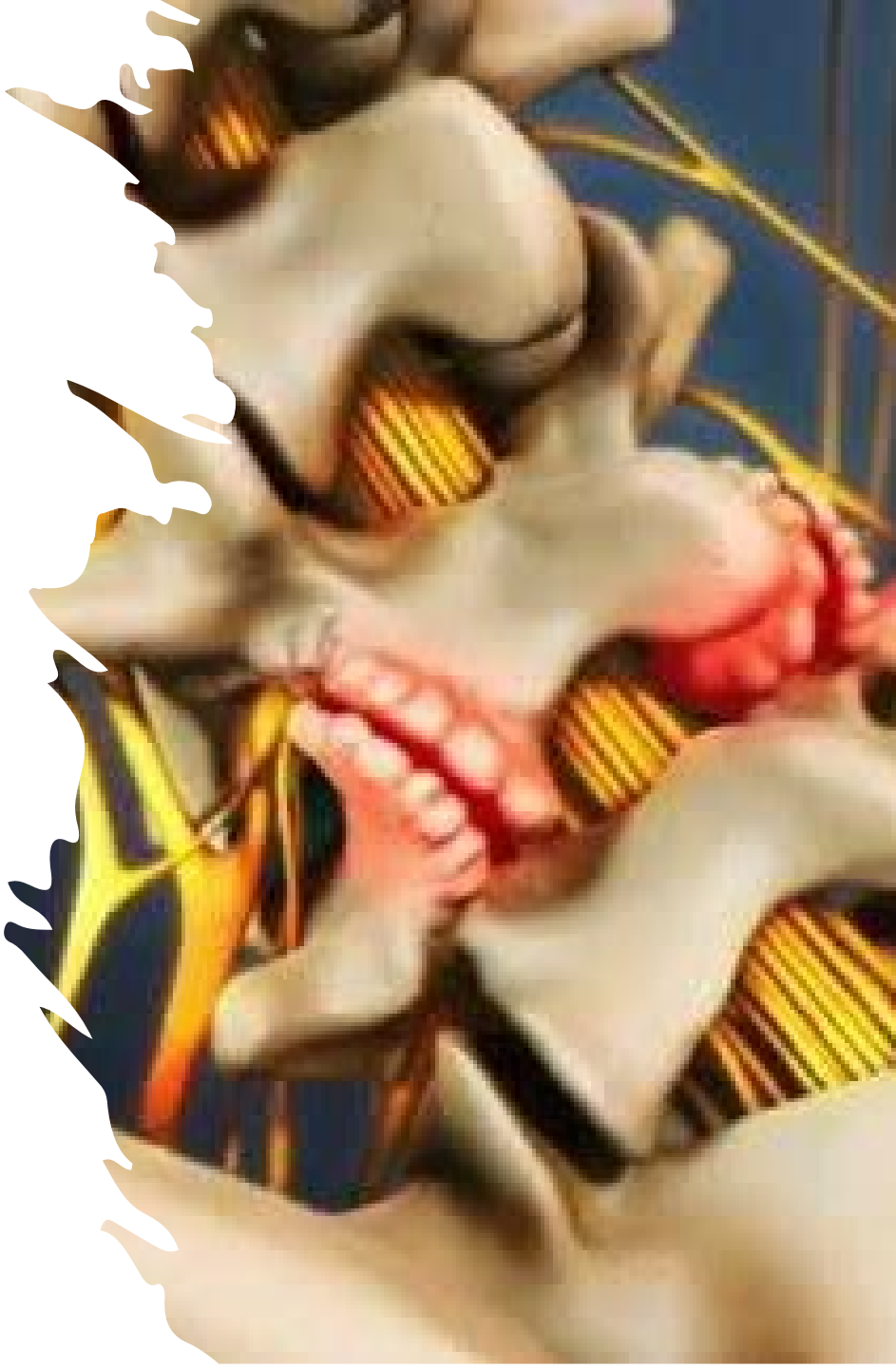
Facet joint function

- The disc carries most of our load, while the facet joints determine the range and quality of our motion
- The facets contain sagittal translation, rotation, flexion, extension, and lateral bending
- Resist shearing motion
- Probably bear more axial load as disc degenerates



How do the facets fail us?

- The degenerative cascade begins with a loss of disc height, that changes the relative positioning of the medial and lateral facet joints, that can lead to abnormal articulation within the facet joints and osteoarthritis.
- Osteoarthritis of the facet joints can contribute to spinal stenosis and spondylolisthesis



SLIP 1 Study for Spondylolisthesis and Stenosis

April 14, 2016

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Laminectomy plus Fusion versus Laminectomy Alone for Lumbar Spondylolisthesis

Zoher Ghogawala, M.D., James Dziura, Ph.D., William E. Butler, M.D., Feng Dai, Ph.D., Norma Terrin, Ph.D., Subu N. Magge, M.D., Jean-Valery C.E. Coumans, M.D., J. Fred Harrington, M.D., Sepideh Amin-Hanjani, M.D., J. Sanford Schwartz, M.D., Volker K.H. Sonntag, M.D., Fred G. Barker, II, M.D., and Edward C. Benzel, M.D.

ABSTRACT

BACKGROUND

The comparative effectiveness of performing instrumented (rigid pedicle screws affixed to titanium alloy rods) lumbar spinal fusion in addition to decompressive laminectomy in patients with symptomatic lumbar grade I degenerative spondylolisthesis with spinal stenosis is unknown.

METHODS

In this randomized, controlled trial, we assigned patients, 50 to 80 years of age, who had stable degenerative spondylolisthesis (degree of spondylolisthesis, 3 to 14 mm) and symptomatic lumbar spinal stenosis to undergo either decompressive laminectomy alone (decompression-alone group) or laminectomy with posterolateral instrumented fusion (fusion group). The primary outcome measure was the change in the physical-component sum-

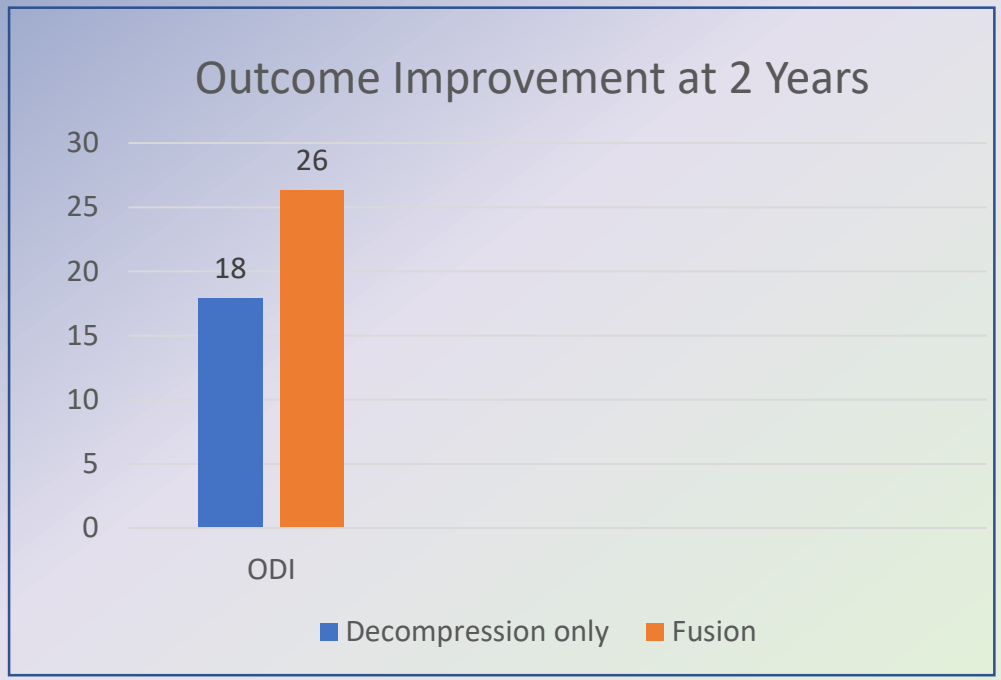
SLIP 1 Study for Spondylolisthesis and Stenosis

CONCLUSIONS

Among patients with degenerative grade I spondylolisthesis, the addition of lumbar spinal fusion to laminectomy was associated with slightly greater but clinically meaningful improvement in overall physical health–related quality of life than laminectomy alone. (Funded by the Jean and David Wallace Foundation and others; SLIP ClinicalTrials.gov number, NCT00109213.)

SLIP 1 Study for Spondylolisthesis and Stenosis

- 59 patients with spondylolisthesis and stenosis at their 2-year follow-up
  - 32 treated with decompression only
  - 27 treated with decompression and fusion



Scandinavian Study

The NEW ENGLAND JOURNAL of MEDICINE

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A Randomized, Controlled Trial of Fusion Surgery for Lumbar Spinal Stenosis

Peter Försth, M.D., Ph.D., Gylfi Ólafsson, M.Sc., Thomas Carlsson, M.D., Anders Frost, M.D., Ph.D., Fredrik Borgström, Ph.D., Peter Fritzell, M.D., Ph.D., Patrik Öhagen, Karl Michaëlsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.

ABSTRACT

BACKGROUND

The efficacy of fusion surgery in addition to decompression surgery in patients who have lumbar spinal stenosis, with or without degenerative spondylolisthesis, has not been substantiated in controlled trials.

METHODS

We randomly assigned 247 patients between 50 and 80 years of age who had lumbar spinal stenosis at one or two adjacent vertebral levels to undergo either decompression surgery plus fusion surgery (fusion group) or decompression surgery alone (decompression-alone group).

From the Department of Surgical Sciences, Division of Orthopedics (P. Försth, T.C., P. Fritzell, K.M., B.S.), and the Uppsala Clinical Research Center (P.Ö., K.M.), Uppsala University, Uppsala, Stockholm Spine Center (P. Försth, A.F.), the Department of Learning, Informatics, Management, and Ethics, Karolinska Institutet (G.Ó., F.B.), and Quantify Research

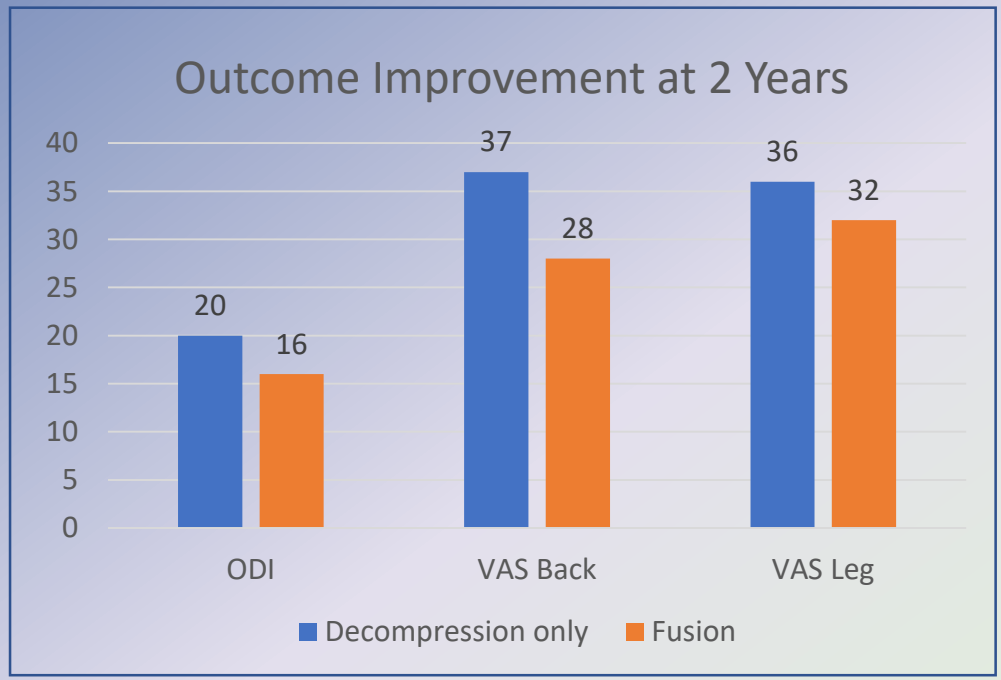
Scandinavian Study

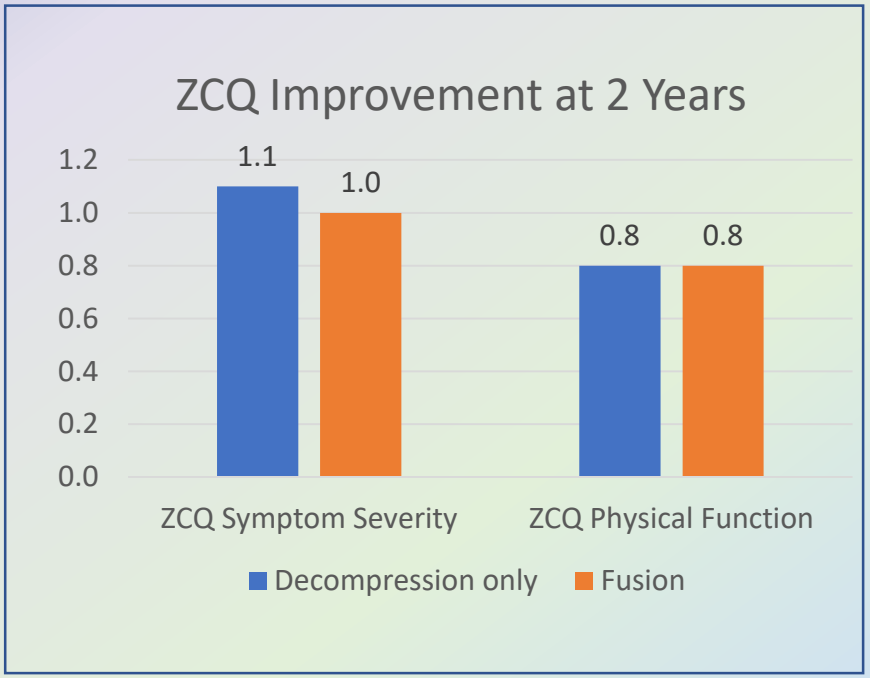
CONCLUSIONS

Among patients with lumbar spinal stenosis, with or without degenerative spondylolisthesis, decompression surgery plus fusion surgery did not result in better clinical outcomes at 2 years and 5 years than did decompression surgery alone. (Funded by an Uppsala institutional Avtal om Läkarutbildning och Forskning [Agreement concerning Cooperation on Medical Education and Research] and others; Swedish Spinal Stenosis Study ClinicalTrials.gov number, NCT01994512.)

Scandinavian Study

- 135 of 247 patients had both spondylolisthesis and stenosis
  - 67 treated with decompression only
  - 68 treated with decompression and fusion





Enter Facet Joint Replacement

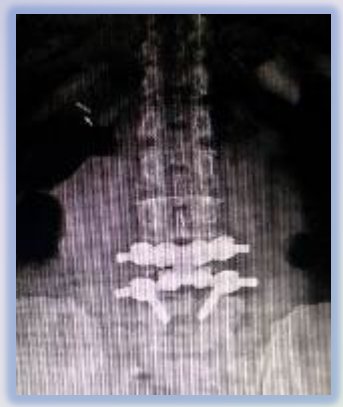
- The Total Posterior Spine (TOPS) System is a lumbar facet arthroplasty device
- The TOPS™ System's novel motion-preserving procedure treats spinal stenosis and degenerative Grade I spondylolisthesis (no spondylolysis)

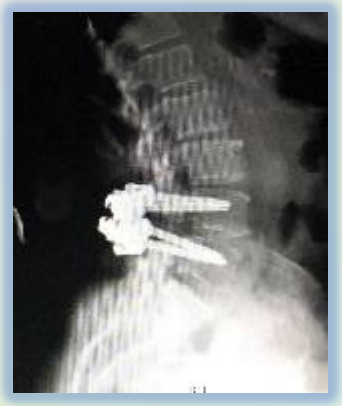
TOPS™ System description

- Pedicle screw-based device that replaces facets and posterior elements
- Titanium construct with polycarbonate urethane (PcU) articulating core
- Allows movement between the plates, simulating physiologic motion
  - Axial rotation, lateral bending, extension, flexion and constrained sagittal translation

TOPS System IDE Study

- 153 subjects enrolled as part of a multi-center (36), prospective, randomized IDE clinical trial
- Study examines patients randomly assigned to facet arthroplasty (TOPS System) with at least 12 months follow-up
- All subjects underwent decompressive laminectomy via mid-line incision at one lumbar level followed by dynamic stabilization with TOPS System
- Primary clinical outcome measures:
  - Oswestry Disability Index (ODI)
  - Visual Analogue Scale (VAS)
  - Re-operation rates

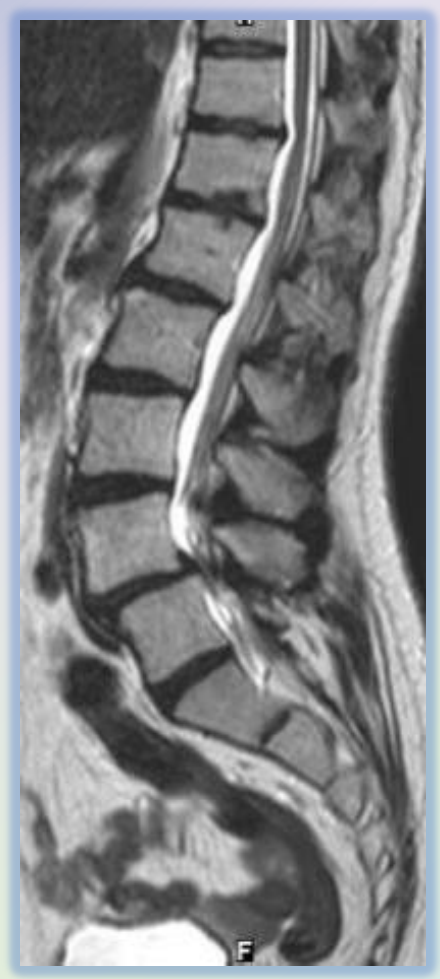




Indications

KEY INCLUSION CRITERIA

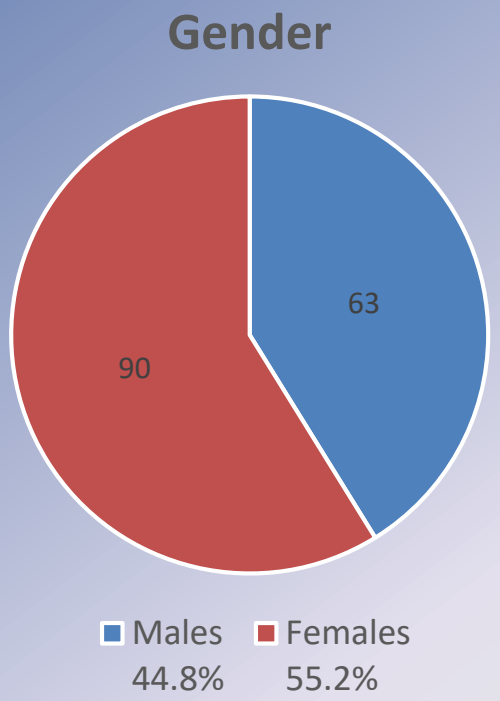
- **Single level pathology** – between L2 – L5
  - At least moderate spinal stenosis, and;
  - Degenerative spondy (up to Grade 1), and;
  - Thickening of ligamentum flavum OR scarring of facet joint capsule
- **Age** – 35 - 80 years old
- **ODI** – at least 40/100 at baseline
- **Leg/Back pain**– predominant leg symptoms versus back symptoms

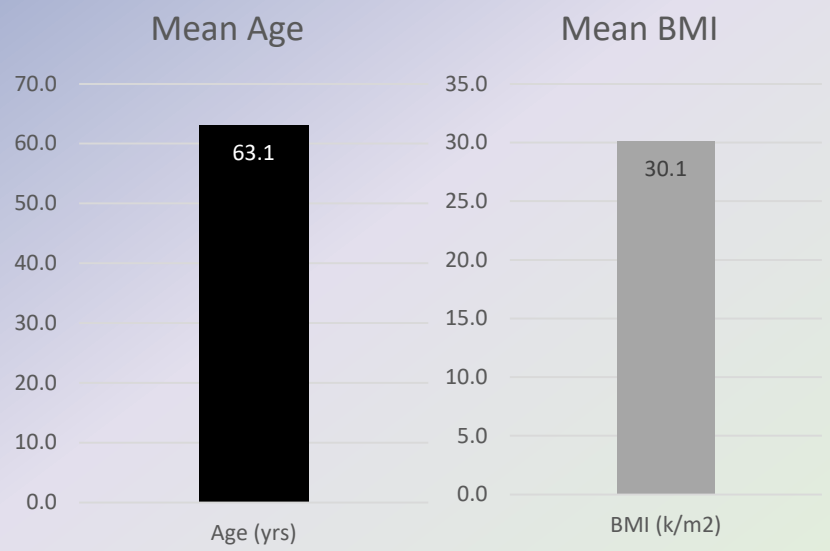


KEY EXCLUSION CRITERIA

- Scoliosis > 10 degrees
- BMI > 40
- More than (1) level involved
- <4mm disc height at index level
- Spondylolithesis > Grade I
- Lytic spondylolisthesis
- Prior surgery at any lumbar level WITH instrumentation
- Prior surgery at adjacent levels WITHOUT instrumentation
- Osteoporosis (DEXA $\leq$ -2.0) – *subjects with SCORE value > 6 must have pre-op DEXA*

TOPS Patient Demographics

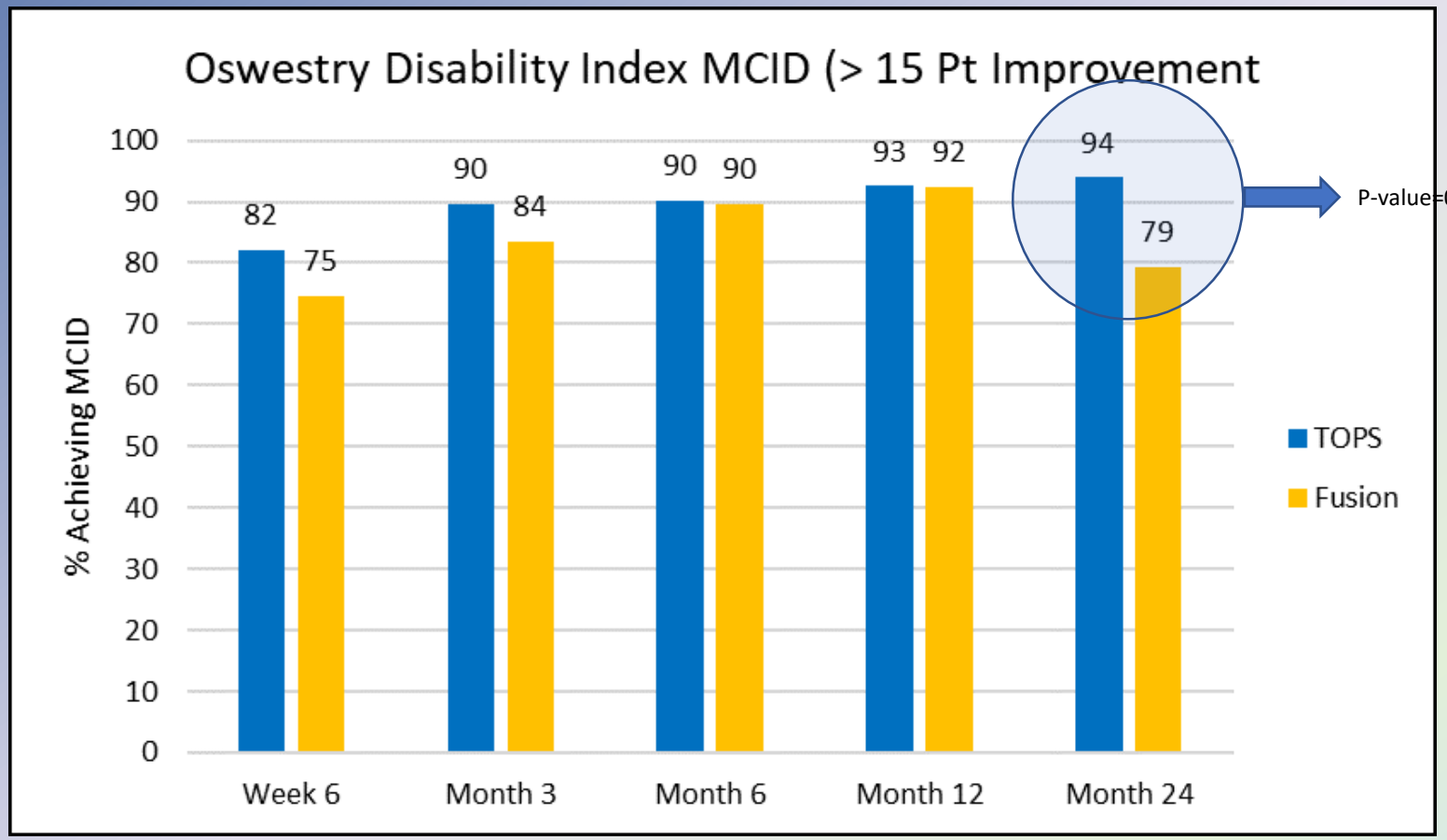




Baseline Demographics

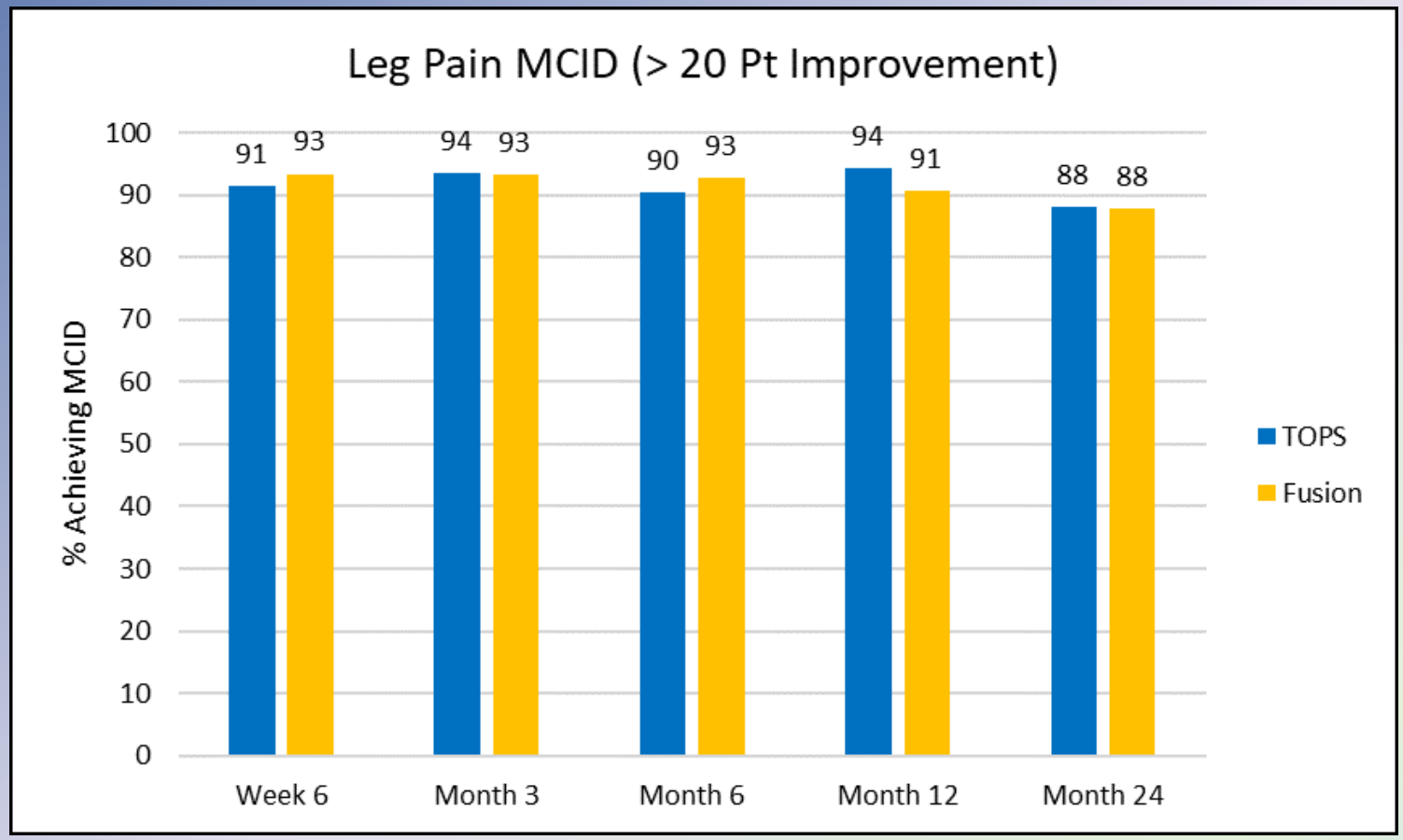
	N	%			
Gender	153				
Male	63	44.8			
Female	90	55.2			
	Mean	**SD**	**Median**	**Min**	**Max**
Age	63.1	8.2	64.0	38.0	79.0
BMI	30.1	4.9	30.0	17.4	39.9

ODI MCID at 24 Months



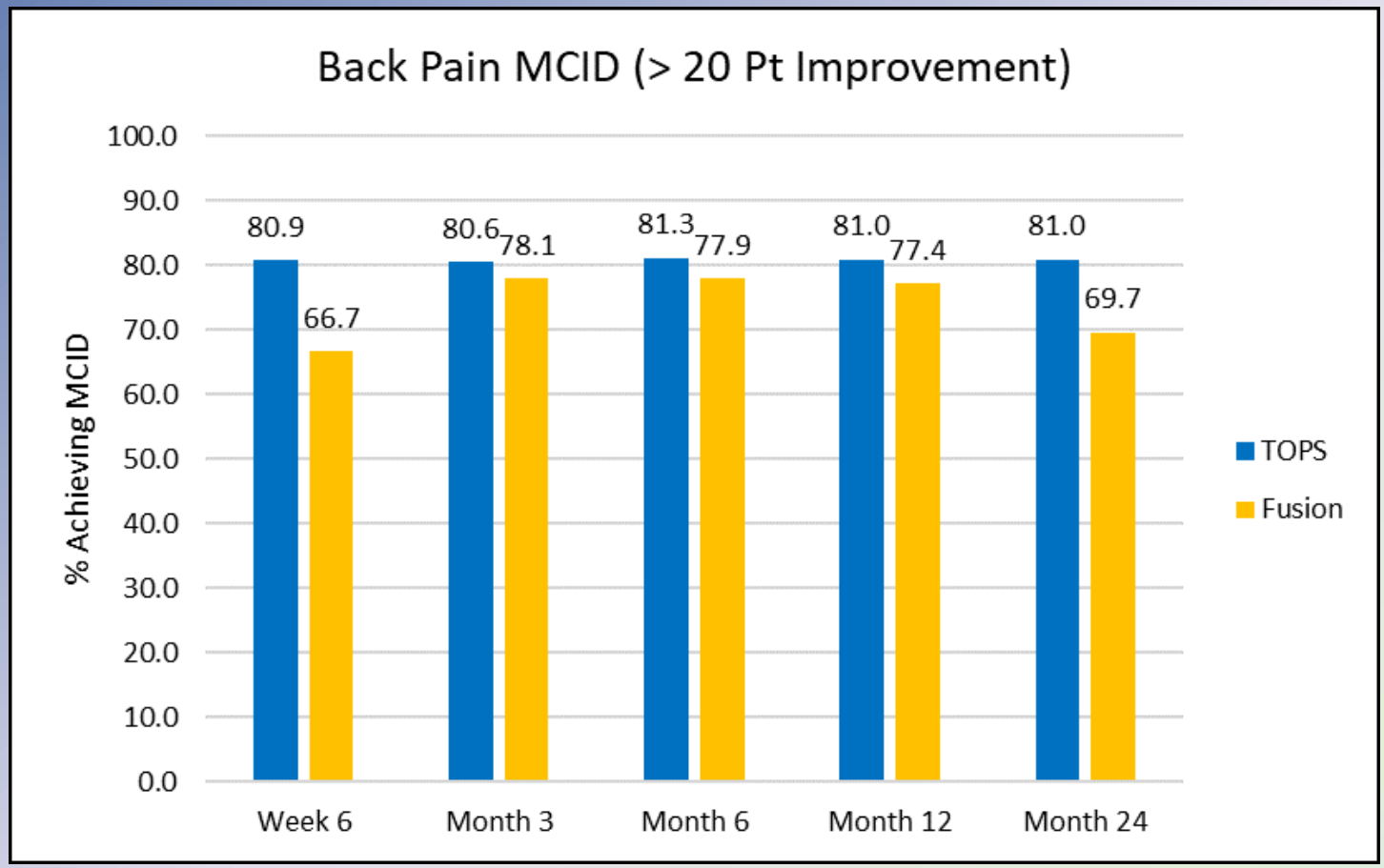
TOPS (N)	163	155	144	122	84
Fusion (N)	75	73	68	53	34

Leg VAS MCID at 24 Months



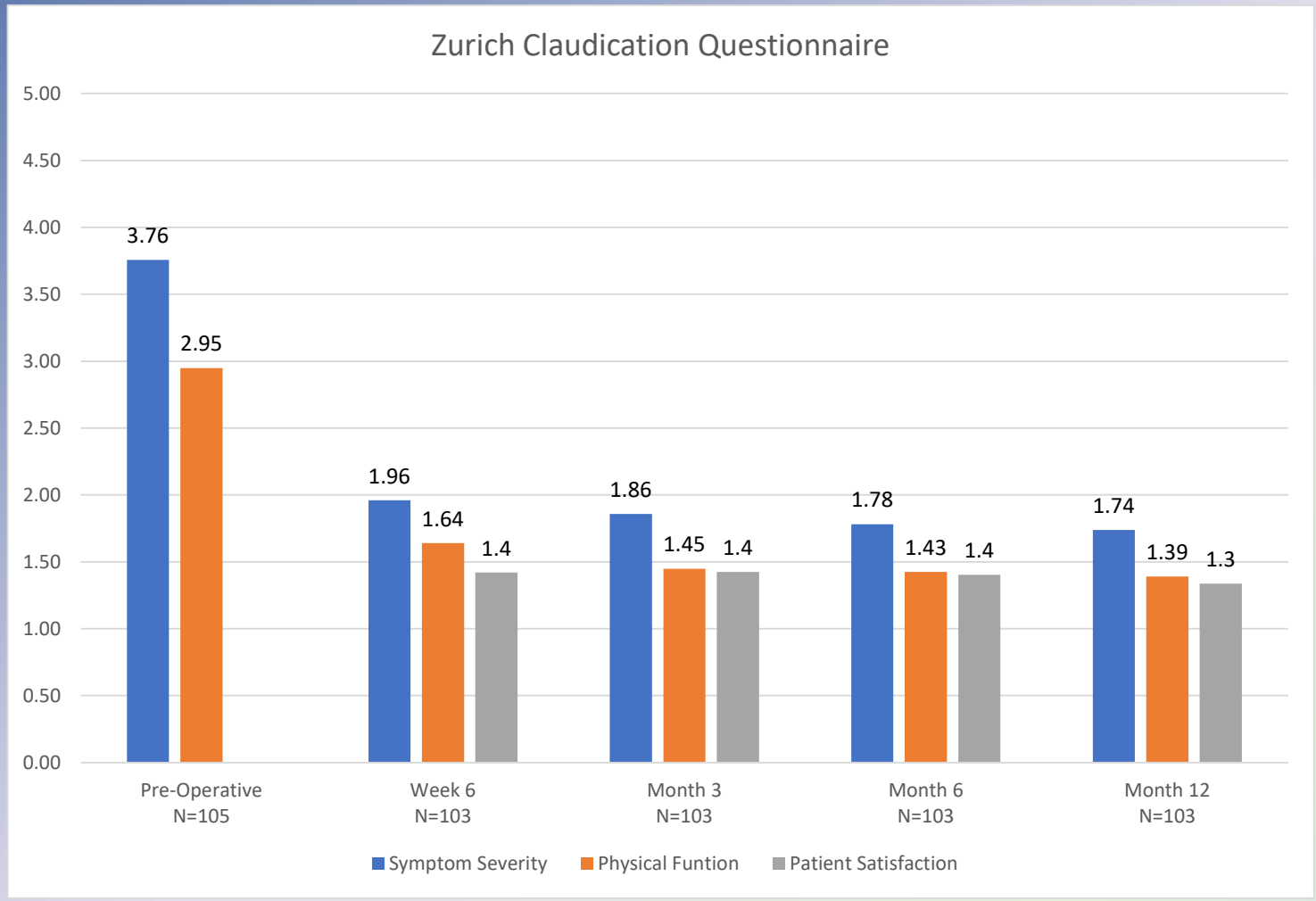
TOPS (N)	163	155	144	122	84
Fusion (N)	75	73	68	53	34

Back VAS MCID at 24 Months



TOPS (N)	163	155	144	122	84
Fusion (N)	75	73	68	53	34

Zurich Claudication Questionnaire



TOPS and TLIF Safety Outcomes

Repeat Surgical Intervention Summary

	TOPS (N=172)				Fusion (N=80)			
	SSIs	**Subjs**	**%**	**Avg Days**	**SSIs**	**Subjs**	**%**	**Avg Days**
Durotomy*	4	2	1.2%	23	1	1	1.3%	11
Wound Complication	3	3	1.7%	33	0	0	0.0%	0
Retained Surgical Drain	2	2	1.2%	27	0	0	0.0%	0
Adjacent Segment Disease	0	0	0.0%	0	3	3	3.8%	380
Pseudoarthrosis	0	0	0.0%	0	1	1	1.3%	771
Pedicle Screw Misplacement**	1	1	0.6%	5	0	0	0.0%	0
Screw Loosening/Implant Migration	1	1	0.6%	517	1	1	1.3%	32
Unresolved Pain	3	3	1.7%	483	3	2	2.5%	323
ALL* **	**14**	**10**	**5.8%**	**180**	**9**	**7**	**8.8%**	**261**

* A TOPS subject underwent 3 reinterventions for durotomy ultimately converting to fusion

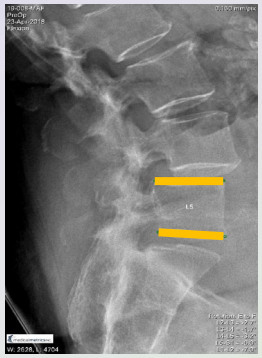
**Pedicle screw misplacement corrected 5 days after TOPS implant. TOPS implant remained in place

***Same fusion subject underwent reintervention for both pseudoarthrosis and unresolved pain

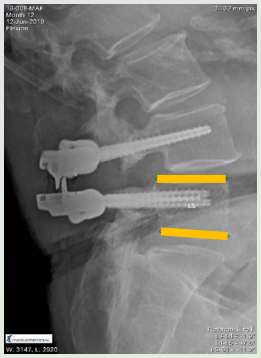
- TOPS treated subjects reported a lower incidence of clinically meaningful repeat surgical intervention

Summary

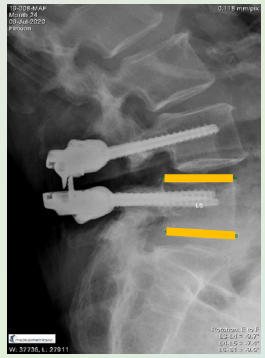
- Preliminary RCT results demonstrate good clinical outcomes at the immediate post-op time point with continued improve through 2 years.
- TOPS demonstrates significant and sustained improvement in ODI, VAS back and VAS leg with equal to or significantly better outcomes than TLIF at every time point out to 2 years
- Re-operation rates are below those in the TLIF control arm
- TOPS Facet arthroplasty may offer a motion preserving surgical alternative for stenosis/spondy patients



PreOp
FE Angular Motion: 3.2°
FE Translational Motion: 1.7mm



Month 12
FE Angular Motion: 7.6°
FE Translational Motion: 2.6mm



Month 24
FE Angular Motion: 7.4°
FE Translational Motion: 2.1mm

Conclusions

- TOPS is a good solution for degenerative Grade I spondylolisthesis and spinal stenosis
- The keys to success are a wide decompression and sticking to the right indications
- TOPS and TLIF results will be available in January 2022 when a direct comparison will be made