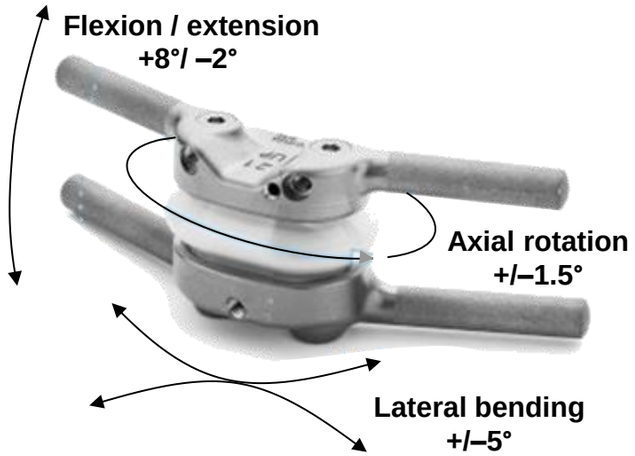
Facet Replacement. A superior solution for Lumbar Spondy and Stenosis

February 2025

What can TOPS do for you?

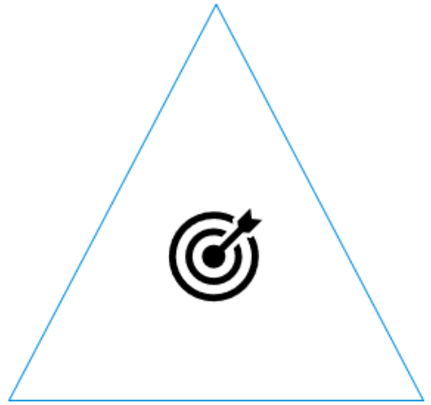
New product to show to your current customers

Opens the door to engage to new surgeons



Who do you target with your elevator pitch?

Believe in data-supported motion preservation solution

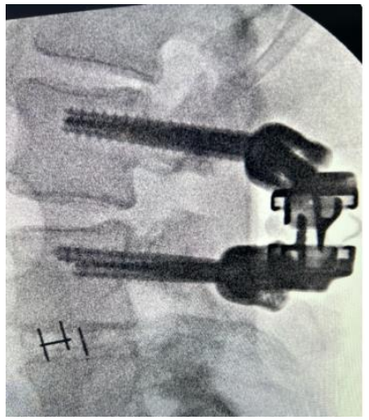


Willing to perform midline incision. See benefit of wide decompression

Willing to fight for a premium priced device in hospital

Premia History

- Bought the original TOPS technology in 2011
- Redesigned TOPS to make it smaller, simplify the surgical technique
- Recommenced clinical cases in 2012
- Focused on selling. No clinical trials
- Naturally attracted private surgeons
- No effort on the academic centers and data collection

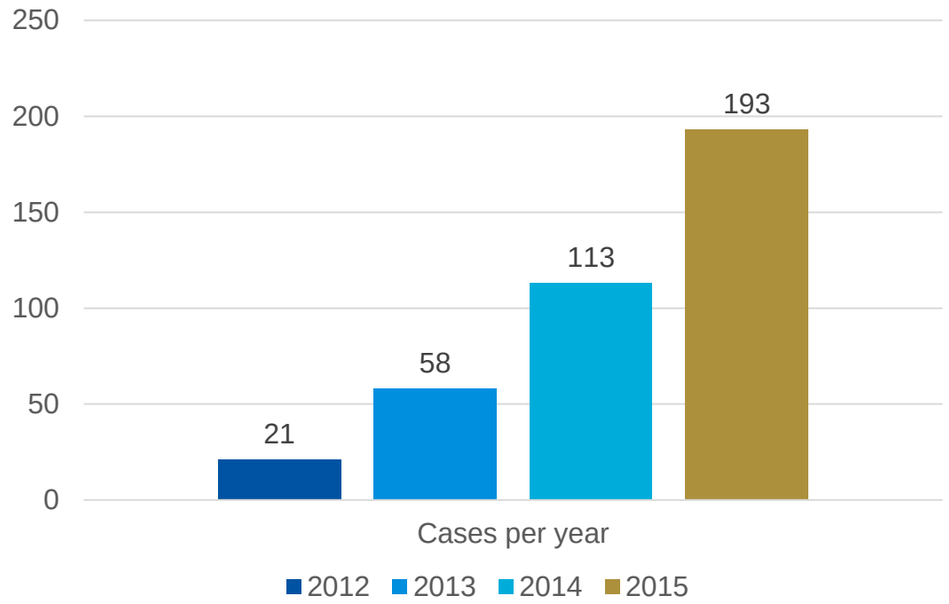


The Early Years (2012 – 2015)

Good initial uptake

Complemented TOPS and Versalink with Nexux and ProMIS Fusion

Aggressive surgeons, who like motion, adopted Premia products

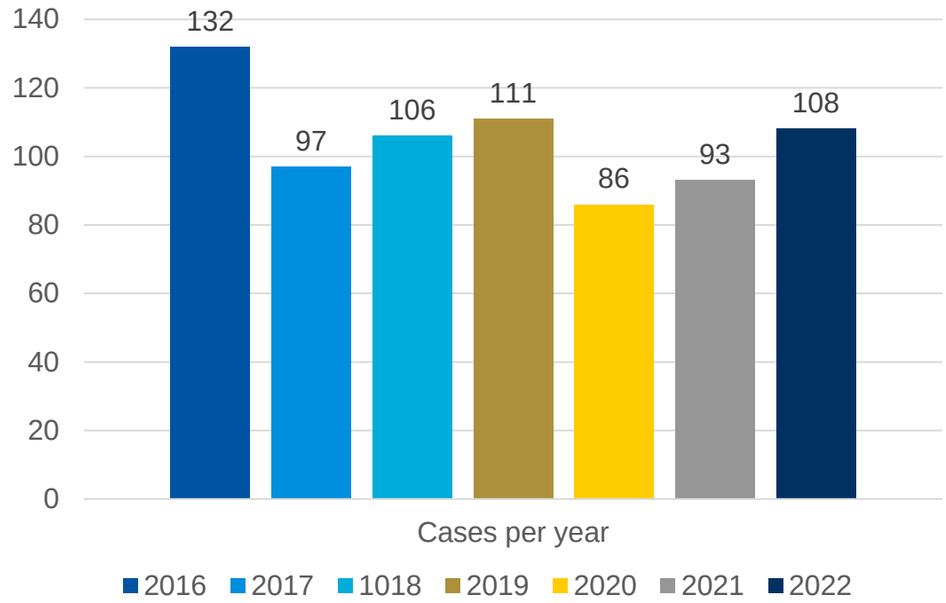


Steady State Years (2016 – 2022)

Inadequate understanding of the right patient, especially Versalink, led to some overuse

Ran into pricing pushback at some centers. Lost some key accounts (e.g., Helios)

Lack of data became more pronounced. Didn’t recruit new growth customers

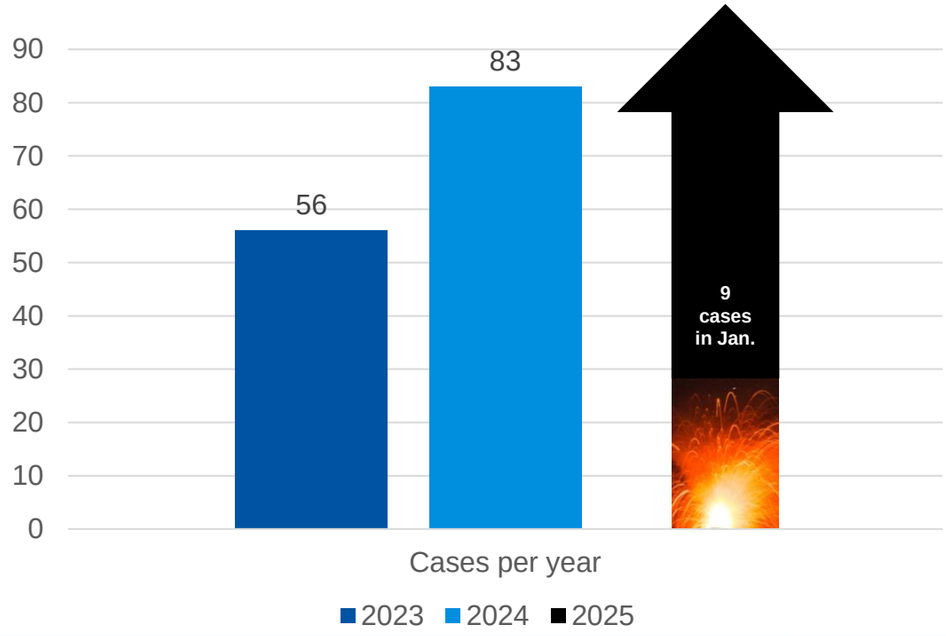


Turnaround Years (2023 – 2025)

Dropped Nexux product line to focus on TOPS

Led with FDA superiority claim in discussions

Returned to Helios Clinic with clinical data



Lumbar Facet Arthroplasty Versus Fusion for Grade-I Degenerative Spondylolisthesis with Stenosis

A Prospective Randomized Controlled Trial

Ahmad Nassr, MD, Domagoj Coric, MD, Zachariah W. Pinter, MD, Arjun S. Sebastian, MD, Brett A. Freedman, MD, Donald Whiting, MD, Ali Chahlavi, MD, Stephen Pirris, MD, Nicolas Phan, MD, Scott A. Meyer, MD, A. David Tahernia, MD, Faheem Sandhu, MD, Harel Deutsch, MD, Eric A. Potts, MD, Joseph Cheng, MD, John H. Chi, MD, MPH, Michael Groff, MD, Yoram Anekstein, MD, Michael P. Steinmetz, MD, and William C. Welch, MD

Background: The comparative effectiveness of decompression plus lumbar facet arthroplasty versus decompression plus instrumented lumbar spinal fusion in patients with lumbar spinal stenosis and grade-I degenerative spondylolisthesis is unknown.

Methods: In this randomized, controlled, Food and Drug Administration Investigational Device Exemption trial, we assigned patients who had single-level lumbar spinal stenosis and grade-I degenerative spondylolisthesis to undergo decompression plus lumbar facet arthroplasty (arthroplasty group) or decompression plus fusion (fusion group). The primary outcome was a predetermined composite clinical success score. Secondary outcomes included the Oswestry Disability Index (ODI), visual analog scale (VAS) back and leg pain, Zurich Claudication Questionnaire (ZCQ), Short Form (SF)-12, radiographic parameters, surgical variables, and complications.

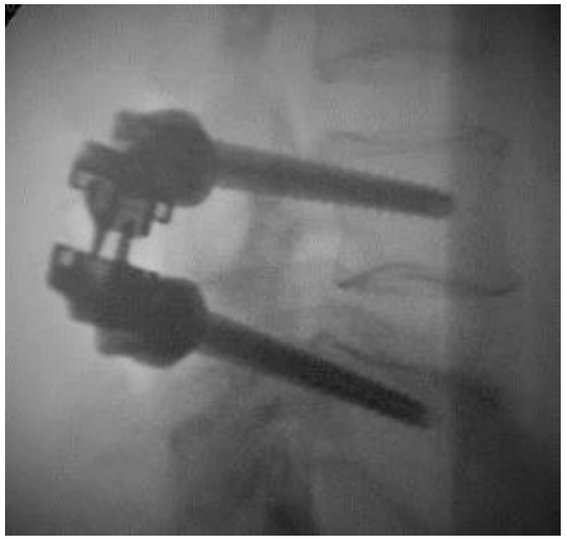
Results: A total of 321 adult patients were randomized in a 2:1 fashion, with 219 patients assigned to undergo facet arthroplasty and 102 patients assigned to undergo fusion. Of these, 113 patients (51.6%) in the arthroplasty group and 47 (46.1%) in the fusion group who had either reached 24 months of postoperative follow-up or were deemed early clinical failures were included in the primary outcome analysis. The arthroplasty group had a higher proportion of patients who achieved composite clinical success than did the fusion group (73.5% versus 25.5%; $p < 0.001$), equating to a between-group difference of 47.9% (95% confidence interval, 33.0% to 62.8%). The arthroplasty group outperformed the fusion group in most patient-reported outcome measures (including the ODI, VAS back pain, and all ZCQ component scores) at 24 months postoperatively. There were no significant differences between groups in surgical variables or complications, except that the fusion group had a higher rate of developing symptomatic adjacent segment degeneration.

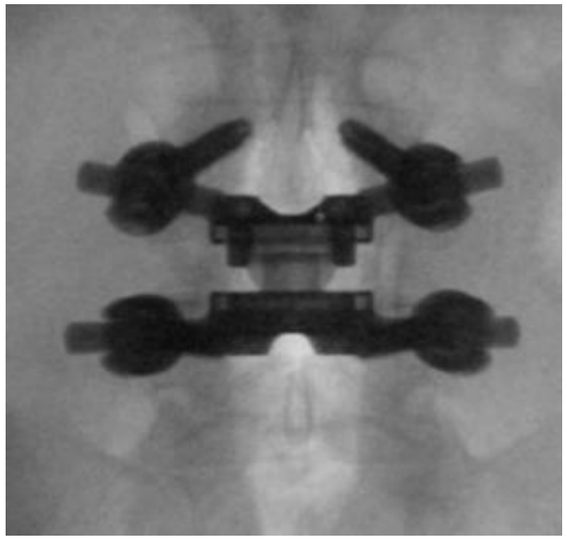
The Future (2025 and beyond)

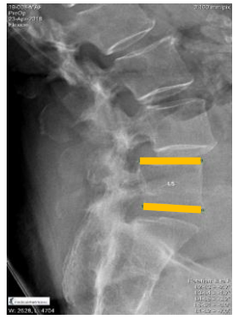
- Focus on distributor partners
- Leverage partner relationships to gain access to surgeons
- Build distributor partners' effectiveness with training and sales support
- Strategy is working very well in the US and France
- Looking for the right distributors in other countries to implement this approach
- We know we've found the right one in Germany in Orthovative!

Summary

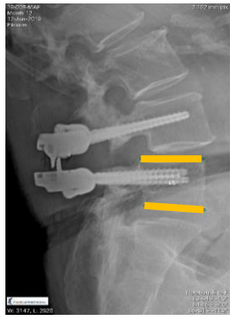
TOPS is a game-changing solution for a large patient population. Let’s introduce it to your surgeons effectively and responsibly



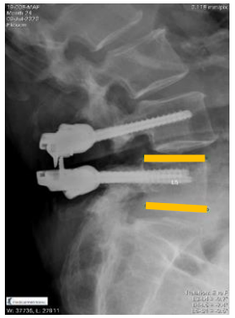




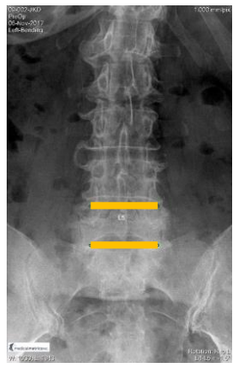
PreOp
FE Angular Motion: 3.2°
FE Translational Motion: 1.7mm



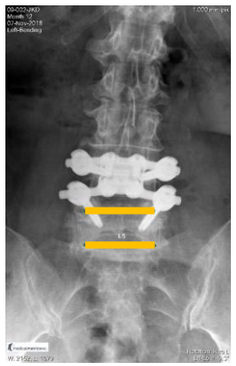
Month 12
FE Angular Motion: 7.6°
FE Translational Motion: 2.6mm



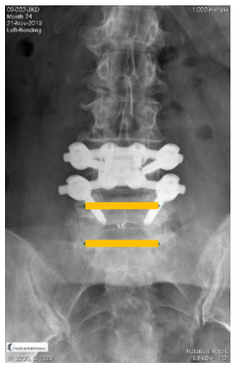
Month 24
FE Angular Motion: 7.4°
FE Translational Motion: 2.1mm



PreOp
Lat. Bend Angular Motion: 1.5°



Month 12
Lat. Bend Angular Motion: 9.3°



Month 24
Lat. Bend Angular Motion: 7.0°

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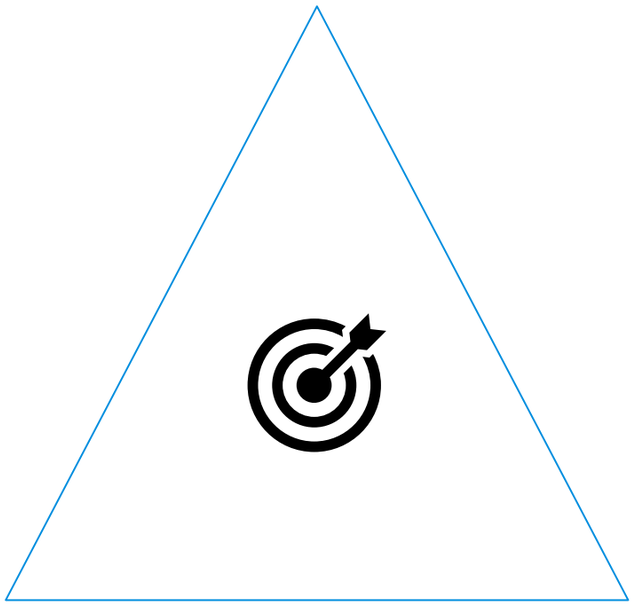


Willing to perform midline incision. See benefit of wide decompression

Willing to fight for a premium priced device in hospital

What is your message?

- ✓ **TOPS differentiates your practice**
- ✓ **Provide superior clinical outcomes**
- ✓ **Easy to master as a procedure**

Set up in-person or Zoom/Team meeting with Premia to take a deep dive

What tools do you have?

- ✓ Premia Spine team: in person or via Team/Zoom
- ✓ Surgeon clinical Powerpoint presentation
- ✓ Spec sheets
- ✓ Published literature
- ✓ Premia website with additional information and patient testimonials

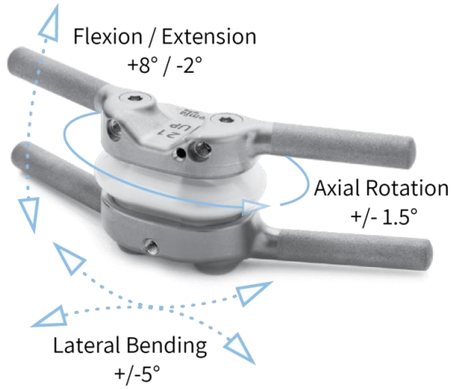
Thanks for your time

avip@premiaspine com
ronsacher@premiaspine.com

Premia Spine's TOPS Posterior Arthroplasty System

A novel non-fusion, motion preservation solution for the treatment of patients with major lumbar diseases—degenerative spondylolisthesis and spinal stenosis

TOPS System Indications For Use



The TOPS System is a motion-preserving spinal implant that is inserted into the lumbar vertebral joint and affixed to the spine via pedicle screws. The TOPS™ System is intended to stabilize the spine following a lumbar decompression without rigid fixation. The TOPS System is indicated for patients between the ages of 35 and 80 years with symptomatic **degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis** and either thickening of the ligamentum flavum or scarring of the facet joint capsule at one level from L3 to L5.

TOPS System Details

Indications

Indications For Use of the TOPS System:

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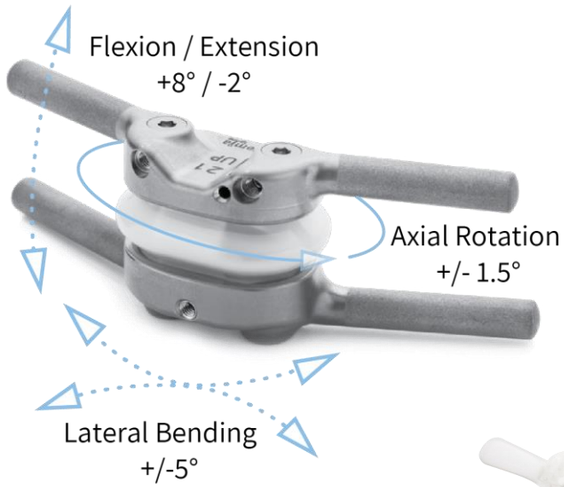
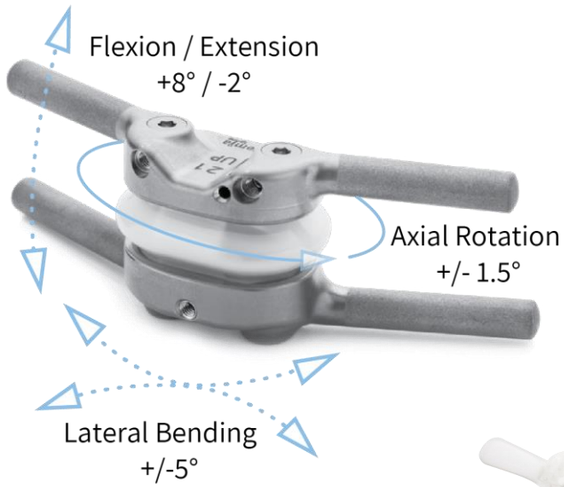


CAUTION: Federal (USA) law restricts this implant to sale by or on the order physician

TOPS System Details

Contraindications

Contraindications: The TOPS System should not be implanted in patients with the following conditions: •Presence of extruded or free fragment disc herniation at the index level •Spondylolisthesis greater than Grade I •Traumatic, dysplastic or lytic spondylolisthesis •Back or non-radicular leg pain of unknown etiology •Stenosis where the etiology is considered to be congenital, iatrogenic, post-traumatic, or metabolic •Known allergy or sensitivity to PEEK, titanium, and/or polyurethane •Scoliosis greater than 10 degrees by major Cobb angle (both angular and rotational) •Morbid obesity defined as a body mass index greater than 40 •Lumbar spine T score less than -2.0 •Active infection - systemic or local •Cauda equina syndrome or neurogenic bowel/bladder dysfunction



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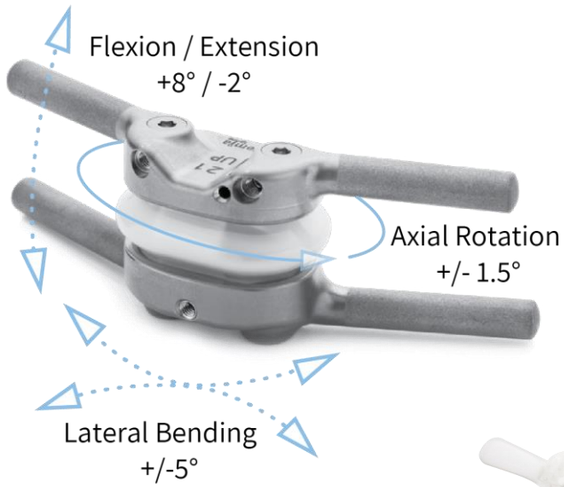
TOPS System Details

Superiority Claim

Clinical Summary:

TOPS demonstrates clinical superiority in overall trial success compared to fusion at 24 months. The difference between the TOPS success rate of 77% and fusion's rate of 24% is statistically superior.



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TOPS System Details

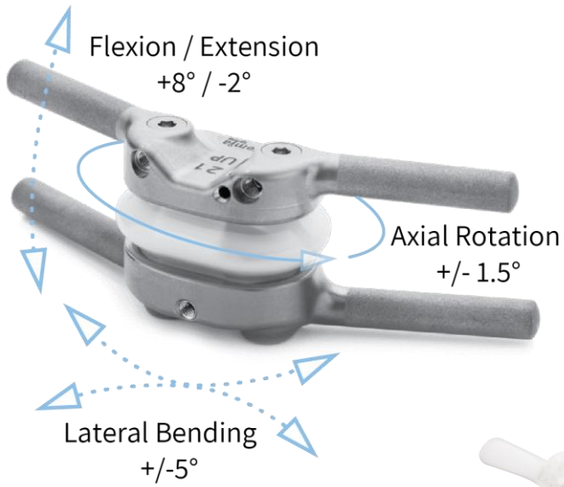
Quotes from the FDA's SSED

Summary of Safety and Effectiveness Data

The TOPS group demonstrated a clinically meaningful and substantial advantage over the Fusion control group with 75.9% (82/108) of subjects randomized to the TOPS group achieving composite clinical success, compared to 23.9% (11/46) of subjects randomized to the Fusion control. Based on these results, the TOPS System was concluded to be superior to the Fusion control with respect to composite clinical success.

The clinical study results demonstrate that the TOPS System is at least as safe as the Fusion control and that the device has a reasonable assurance of safety.

In conclusion, the study data indicate that, at Month 24, the TOPS System is superior to the control treatment (Fusion), for the subject population and indications studied in this investigation, in terms of overall success according to the protocol-specified primary endpoint.



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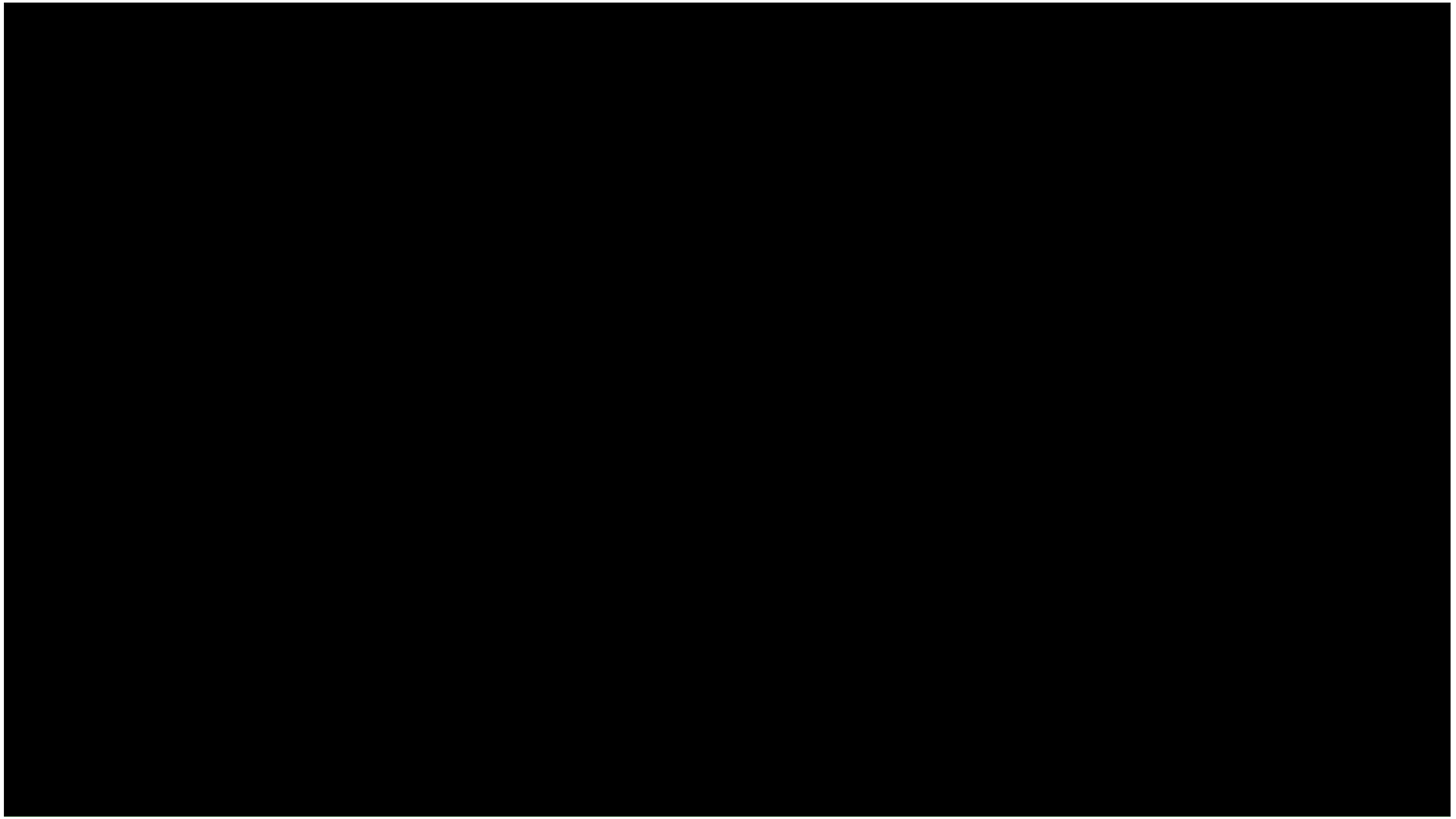
Dr. Steve DeLuca Testimonial

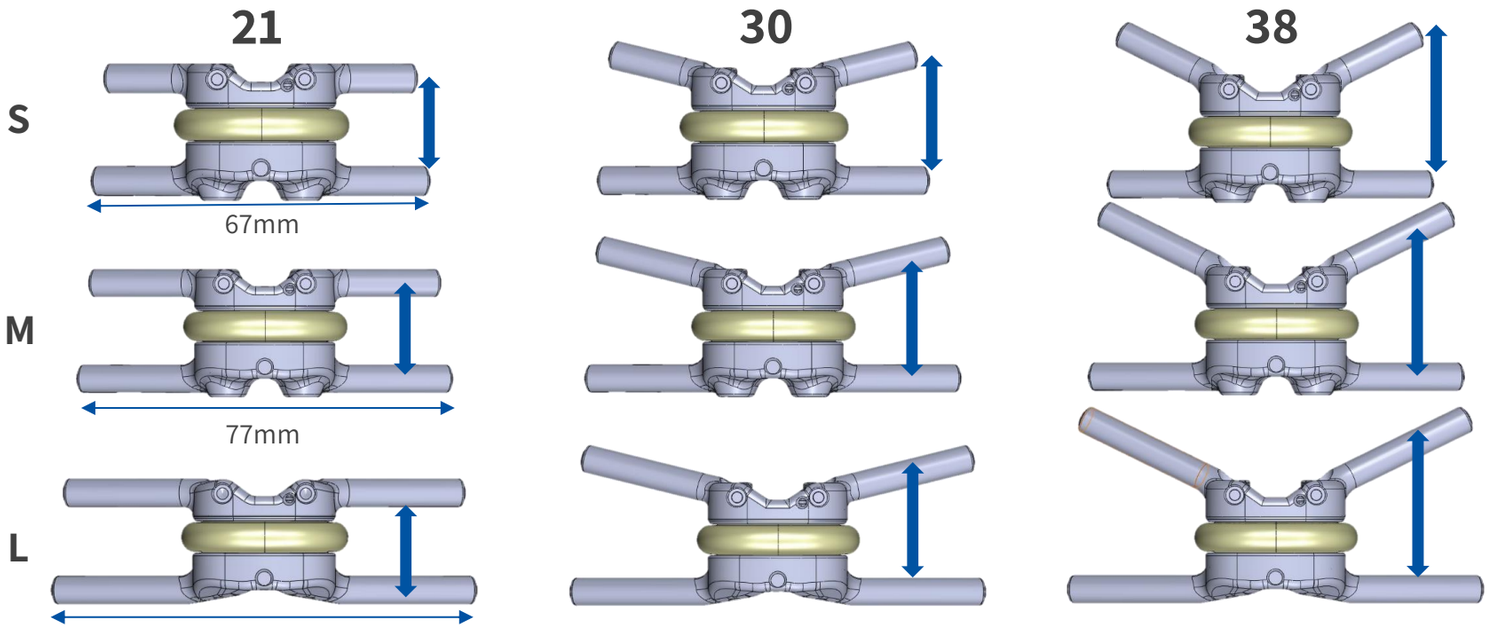


TOPS System Products

Pre-sterile motion device and pedicle screws

- There are 9 sizes of TOPS devices. The loaner kit comes with 7 sizes (30S and 38S are not included). Size 21 is most popular
- TOPS is used with Premia pedicle screws, available in 5.5, 6.5, and 7.5mm diameter and lengths of 40, 45, 50, and 55mm—both cannulated and non-cannulated. Coordinate sizes for each case

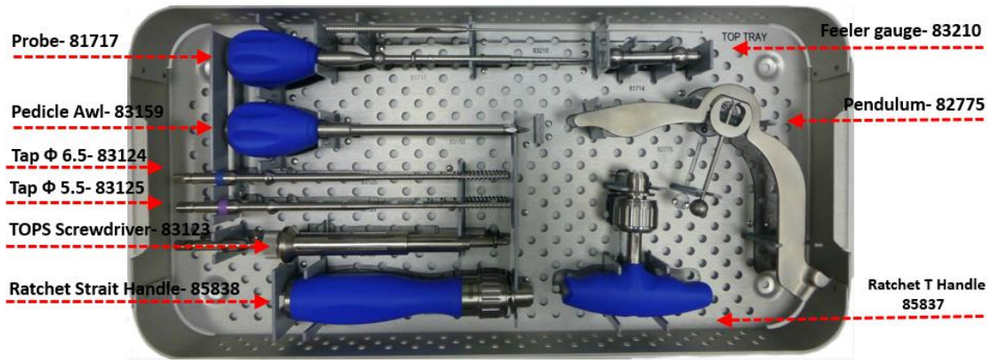
Device	Size / Configuration	Length
TOPS Motion Implant	21 (IPD)	L/M/S
	30 (IPD)	L/M/S
	38 (IPD)	L/M/S



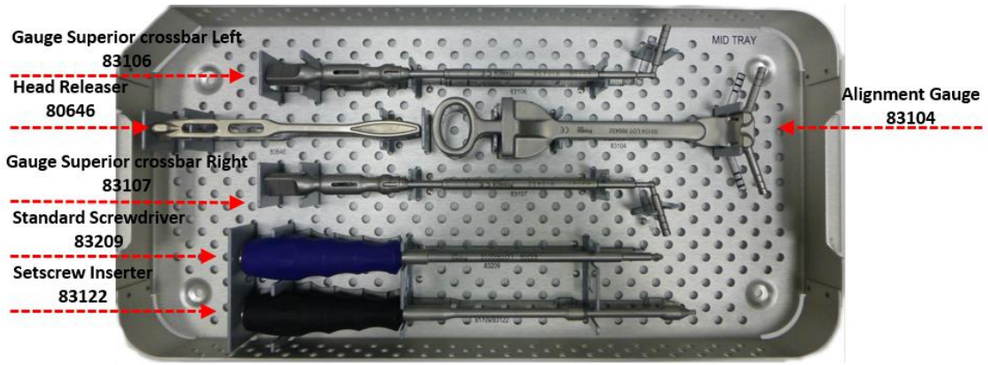
TOPS System Instrumentation

One Container

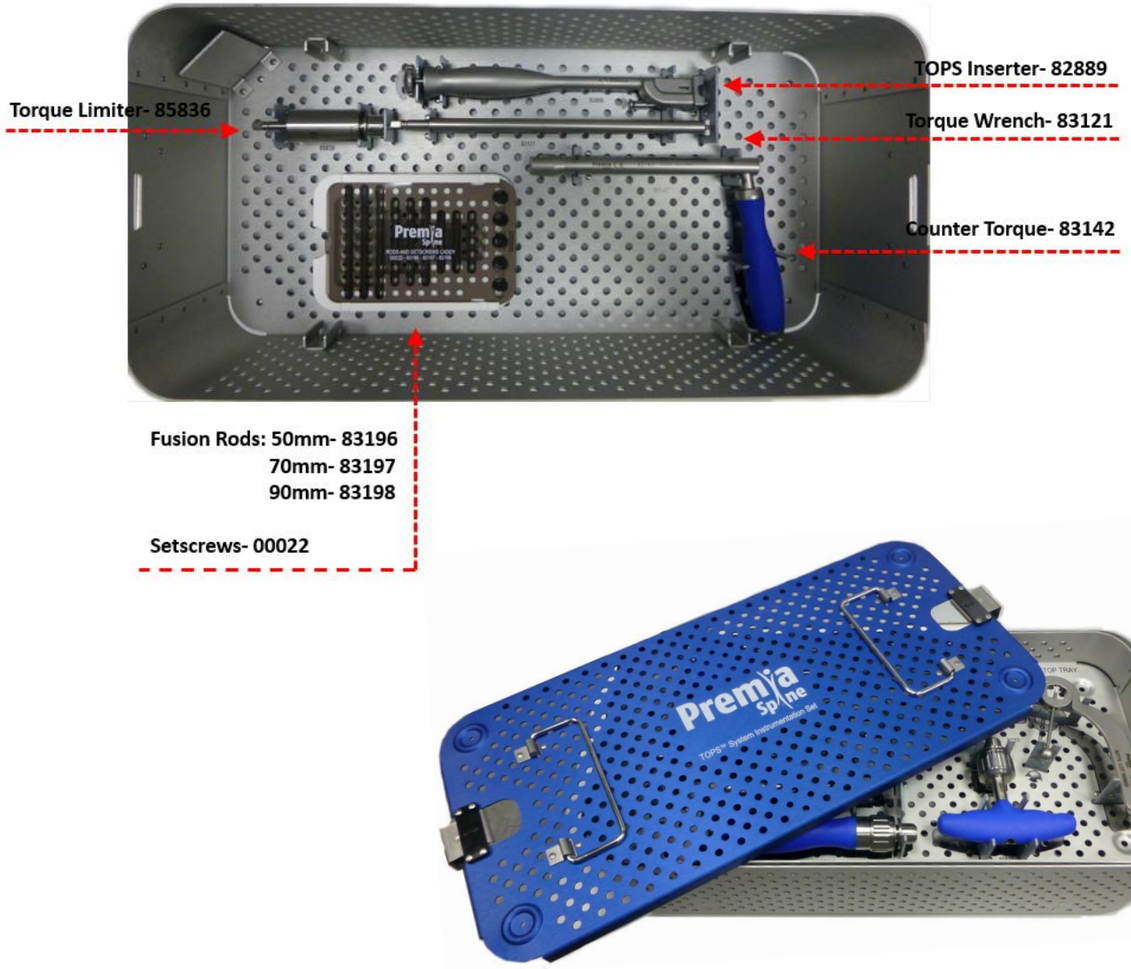
Upper Tray for TOPS™ Instruments Container 83114



Middle Tray for TOPS™ Instruments Container 83115



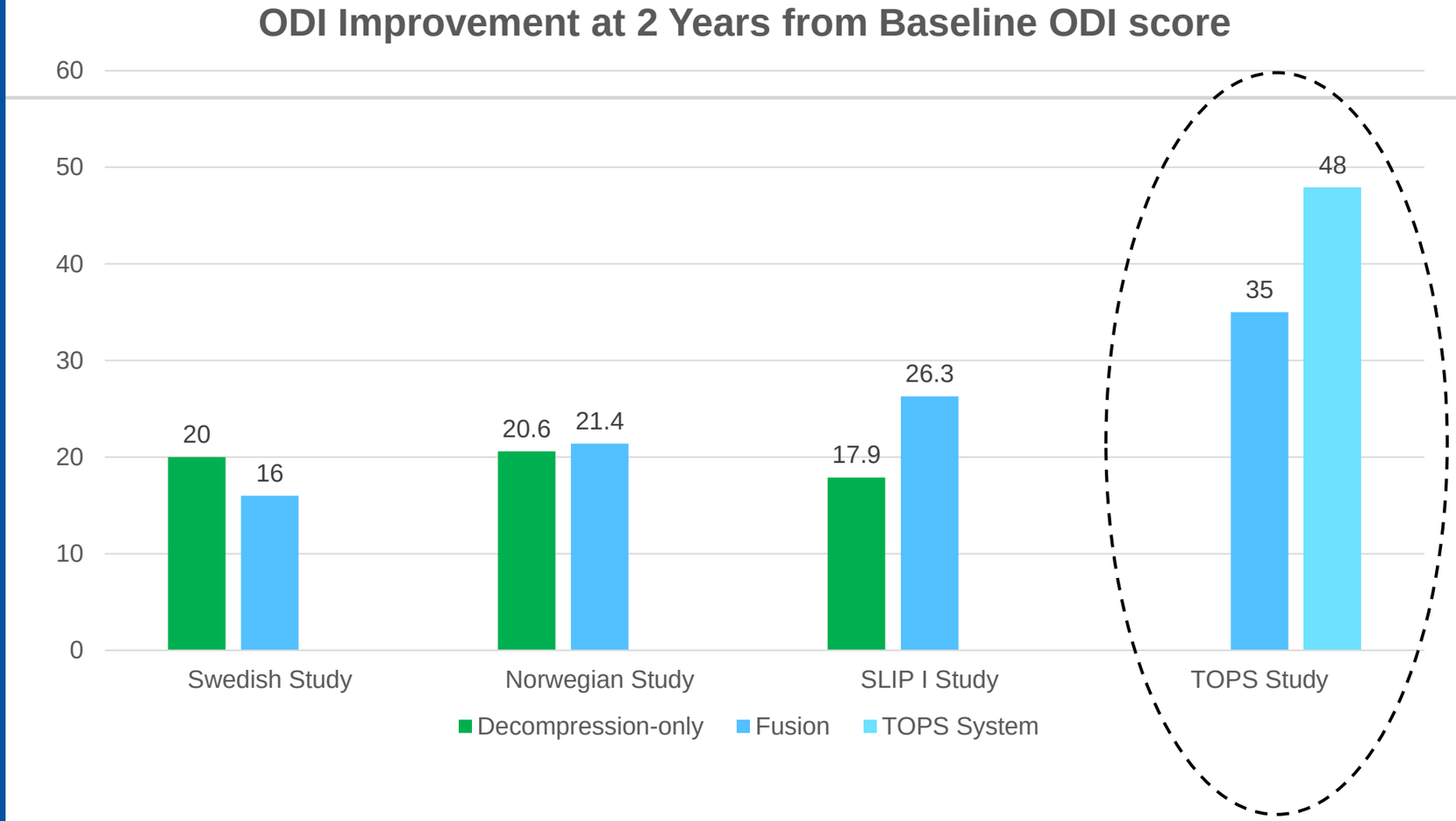
Bottom Tray for TOPS™ Instruments Container 83116



Cadaver Training

Additional Clinical Information

TOPS IDE Study in Context

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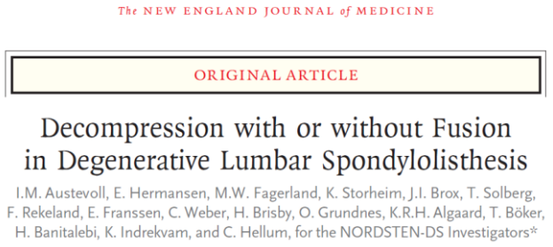
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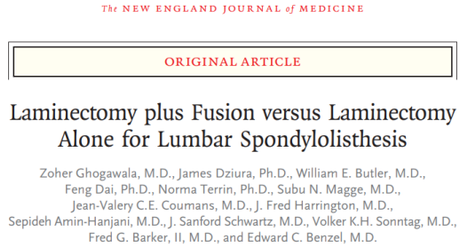
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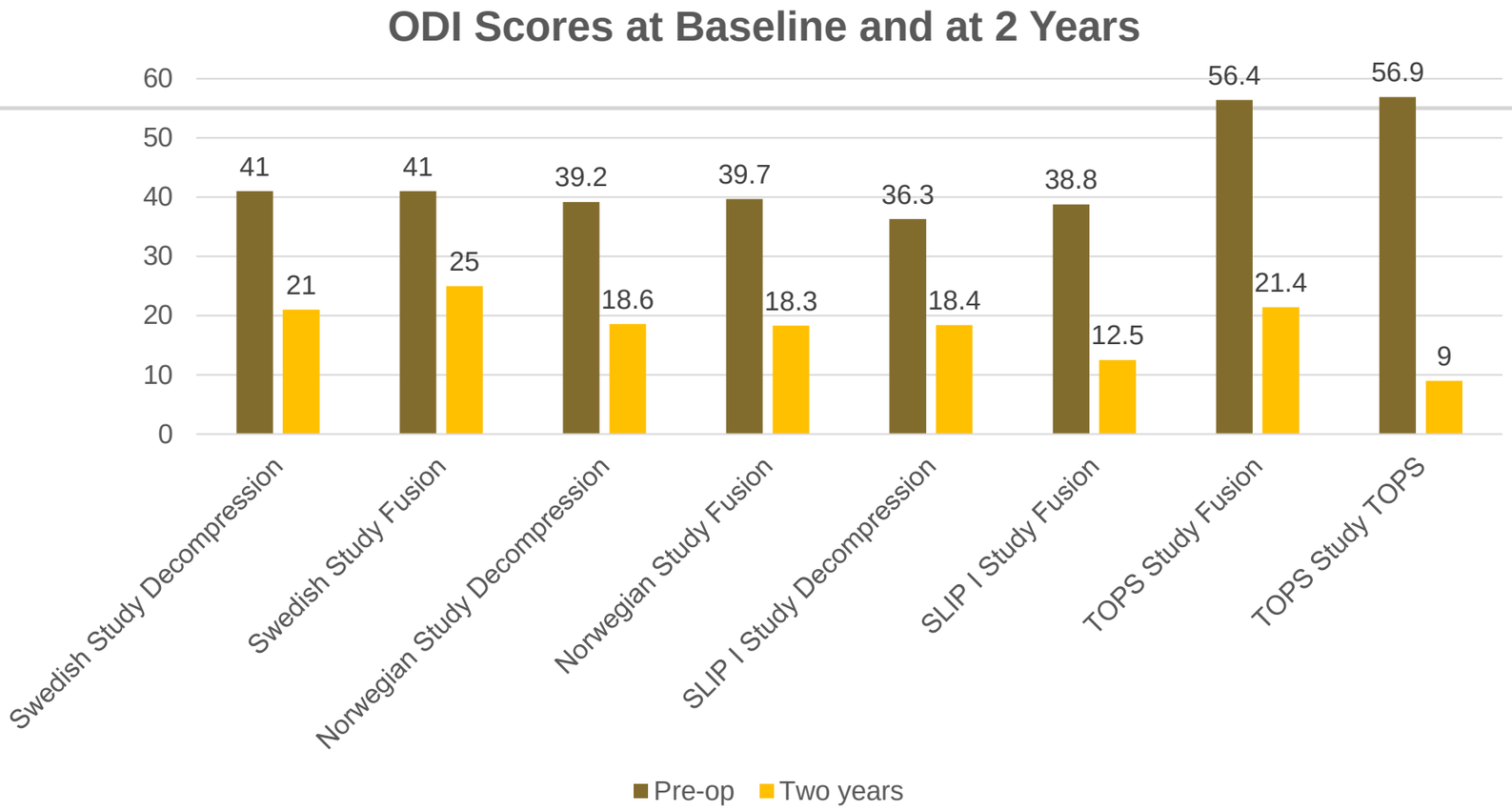


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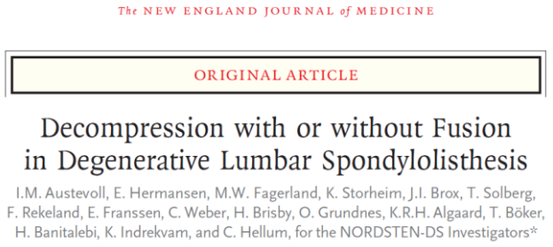
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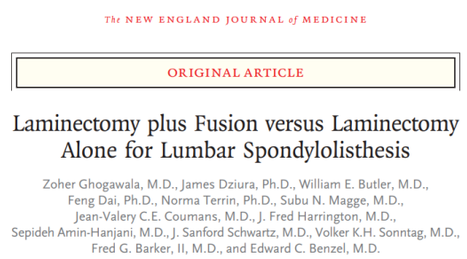
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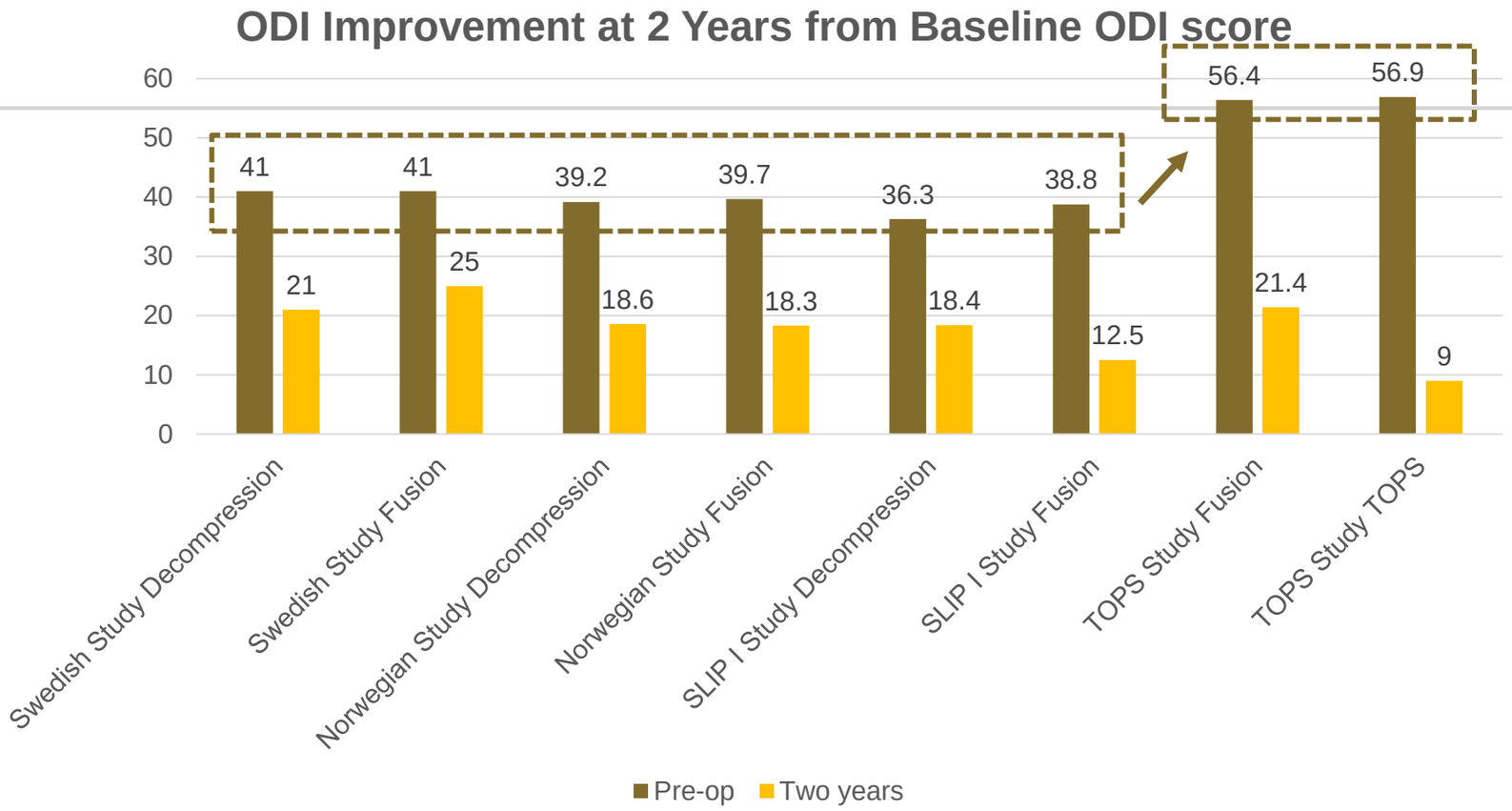


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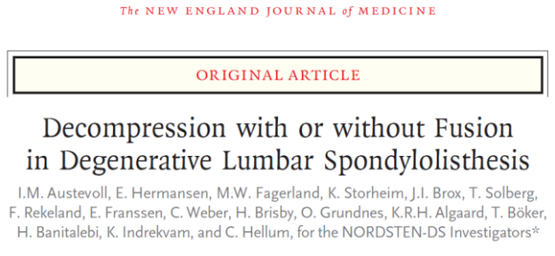
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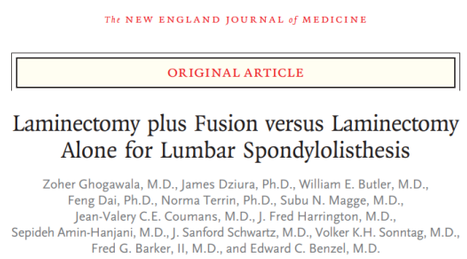
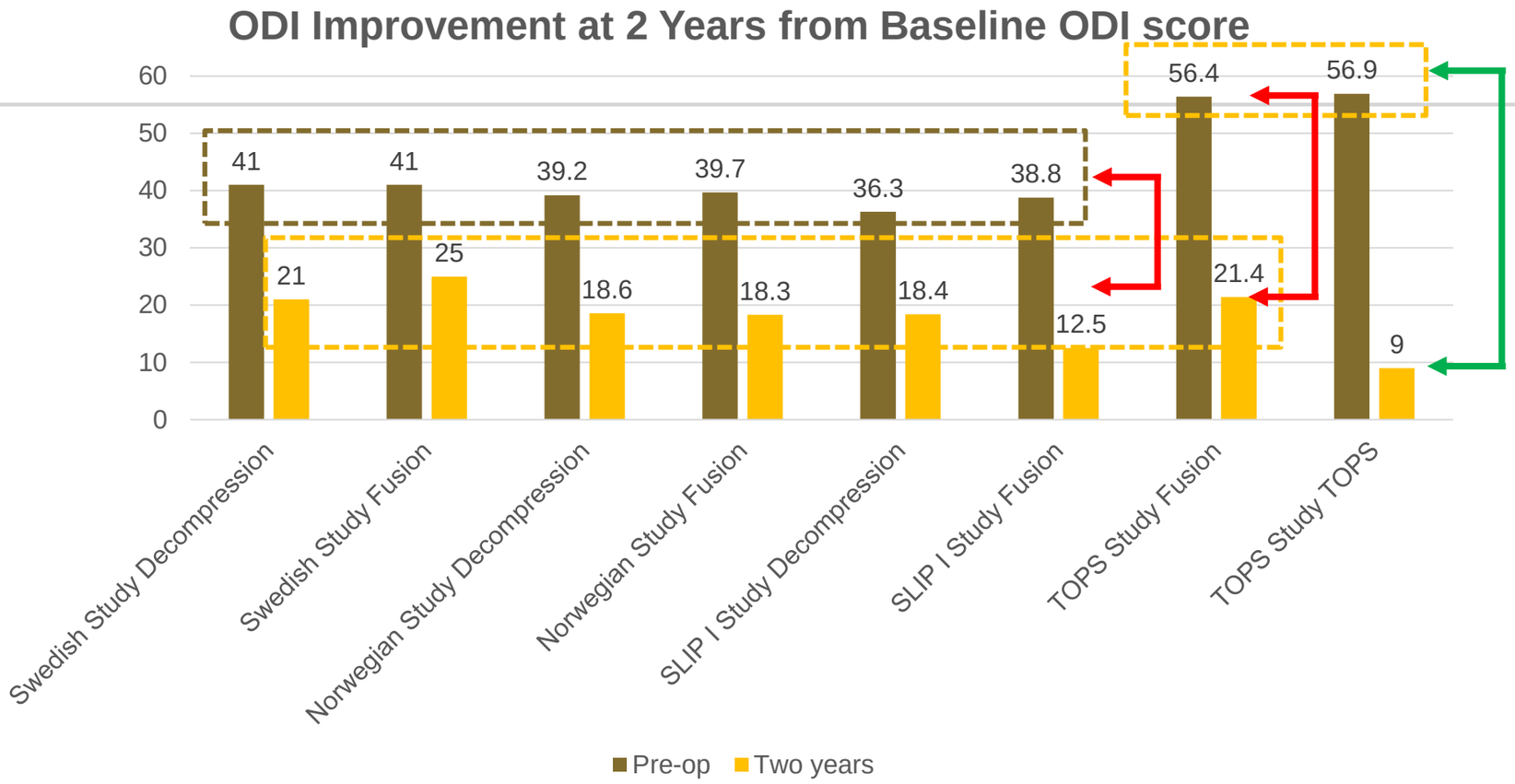

The NEW ENGLAND JOURNAL of MEDICINE

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.

TOPS IDE Study in Context

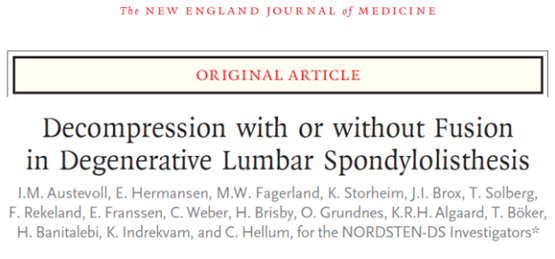



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 14, 2016 VOL. 374 NO. 15

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 Michaelsson, M.D., Ph.D., and Bengt Sandén, M.D., Ph.D.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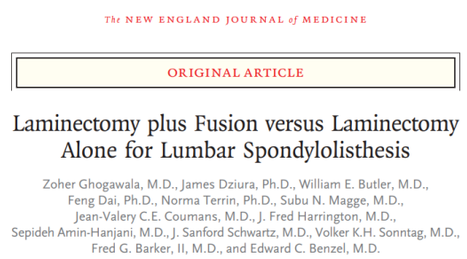
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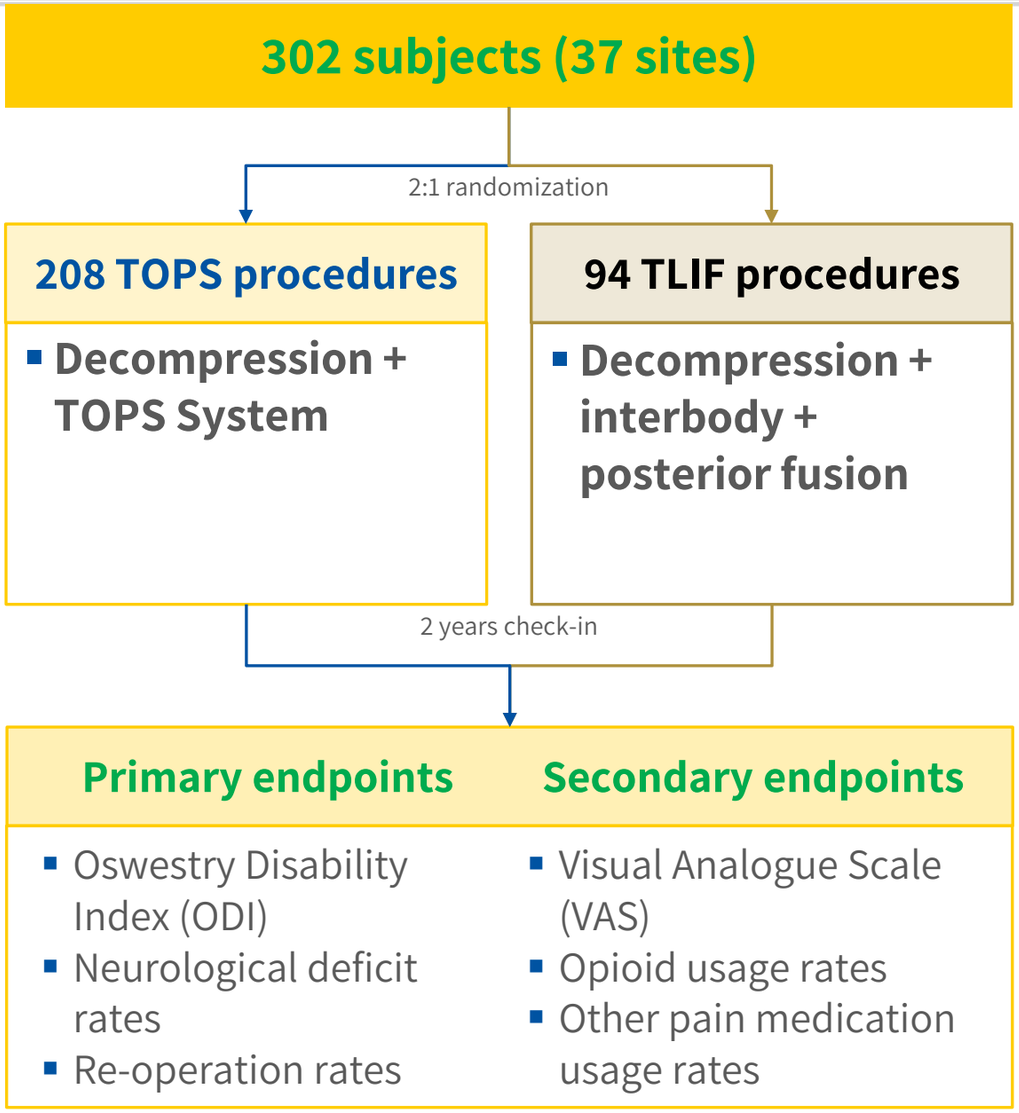
TOPS FDA Pivotal Study Results



Prospective, multi-center randomized study of TOPS System versus TLIF of up to 500 patients with interim looks at 300 and 400 patients

Key inclusion criteria:

- Single level pathology – between L2 – L5
- Moderate spinal stenosis, degenerative spondylolisthesis
- At least 40/100 baseline ODI
- 35-80 years old
- Predominant leg (vs. back) symptoms

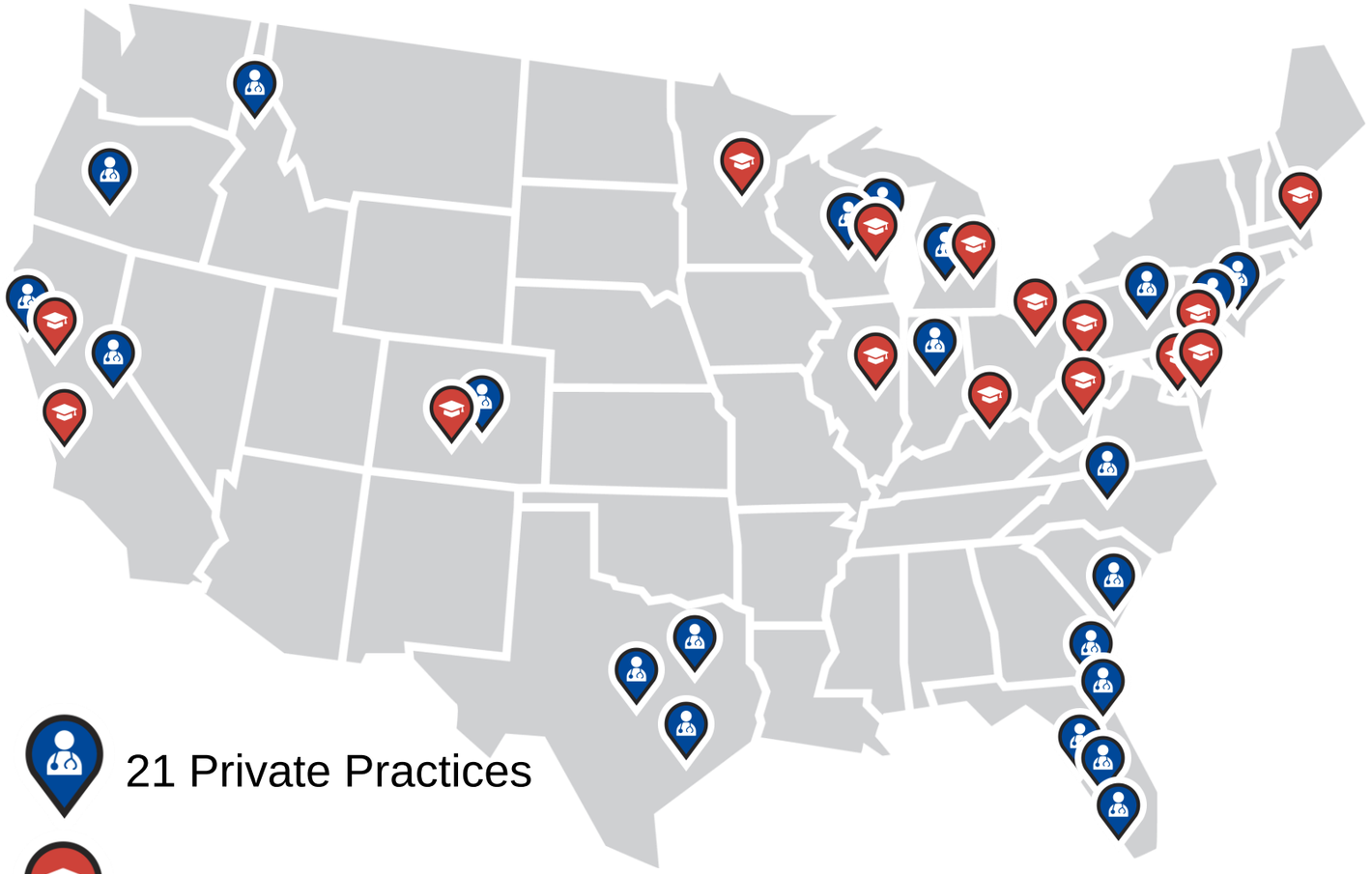
Key exclusion criteria:

- BMI > 40
- More than 1 level involved or <4mm disc height at index level
- Spondylolisthesis > Grade 1 or lytic spondylolisthesis
- Prior surgery at any lumbar level with instrumentation or at adjacent levels without instrumentation

TOPS IDE Clinical Centers / Investigators

37 Heterogeneous Clinical IDE Sites treated Large Homogeneous Patient Population

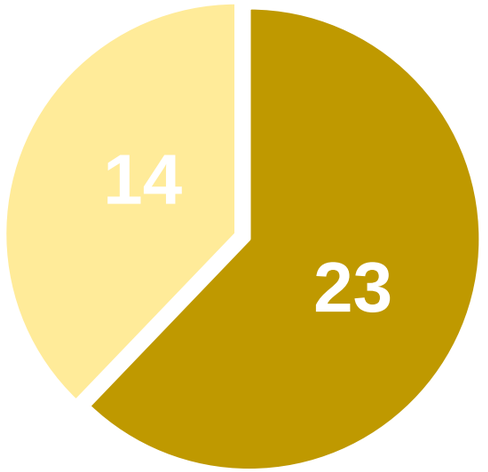
Type of Practice



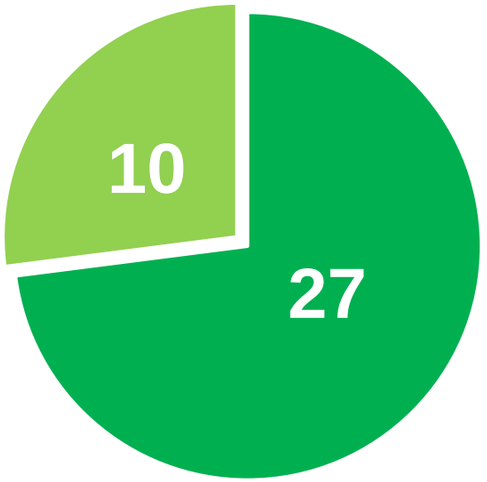
21 Private Practices

16 Academic Practices

Specialty



Practice Size



TOPS IDE Clinical Trial

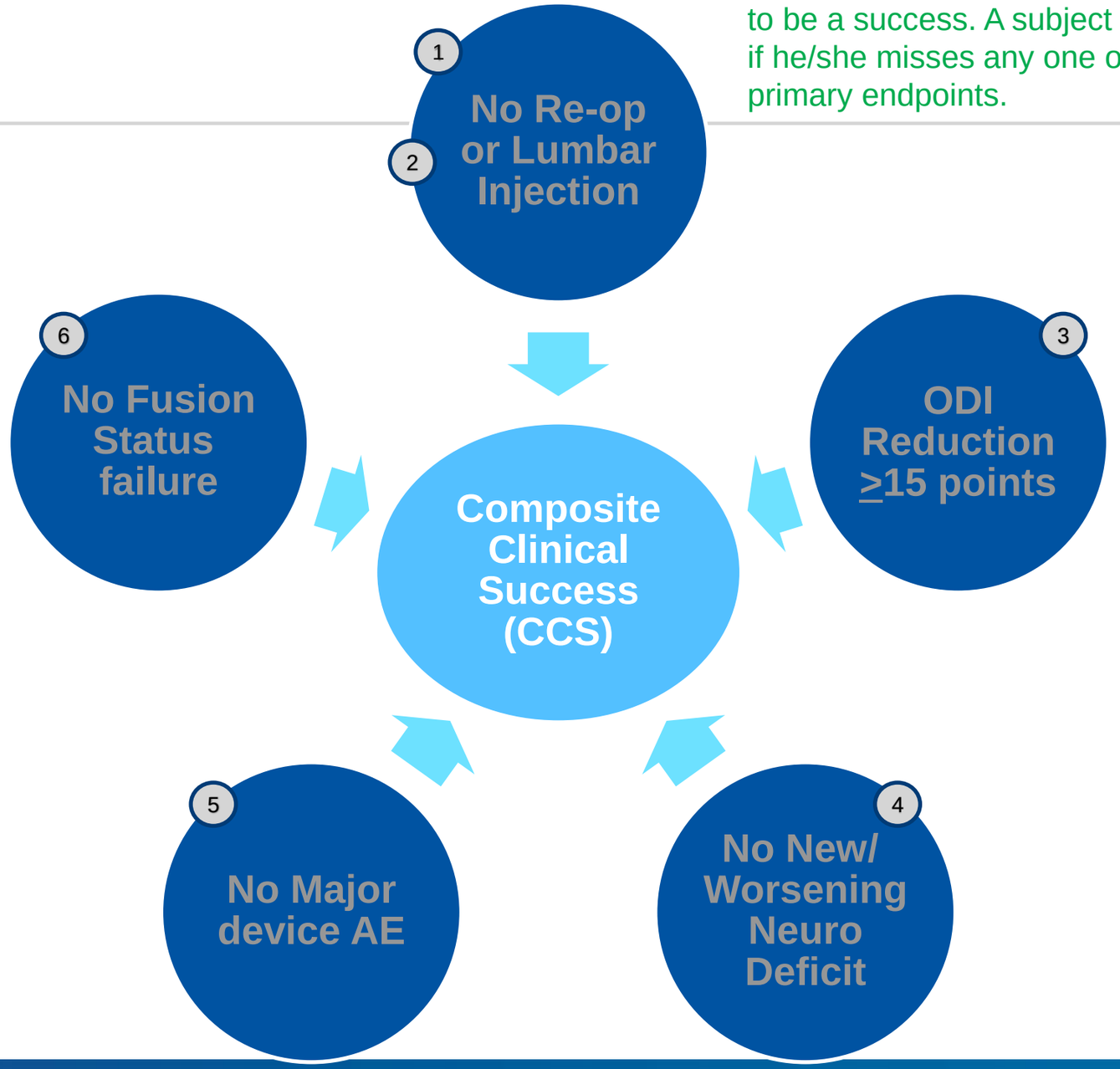
TOPS IDE Study Demographics

Baseline Demographics		
	Fusion	TOPS
Demographics		
Age (years)	64	63
Height (inches)	67	67
Weight (lbs)	190	188
BMI (kg/m^2)	30	29
Sex (Female)	50 (53.7%)	116 (56.3%)
White	86 (92.5%)	191 (92.7%)
Never smoked	59 (63.4%)	127 (61.7%)
Prior lumbar surgery	6 (6.5%)	12 (5.8%)
L4-L5	87 (93.5%)	196 (95.1%)

Operative Characteristics		
	Fusion	TOPS
Time in Surgery (mins)	177	182
Length of Stay (days)	2.9	2.9
EBL (cc)	215	200

Pre-specified Primary Endpoint @ 24 Months

Patients must achieve all 6 endpoints to be a success. A subject is a failure if he/she misses any one of these six primary endpoints.

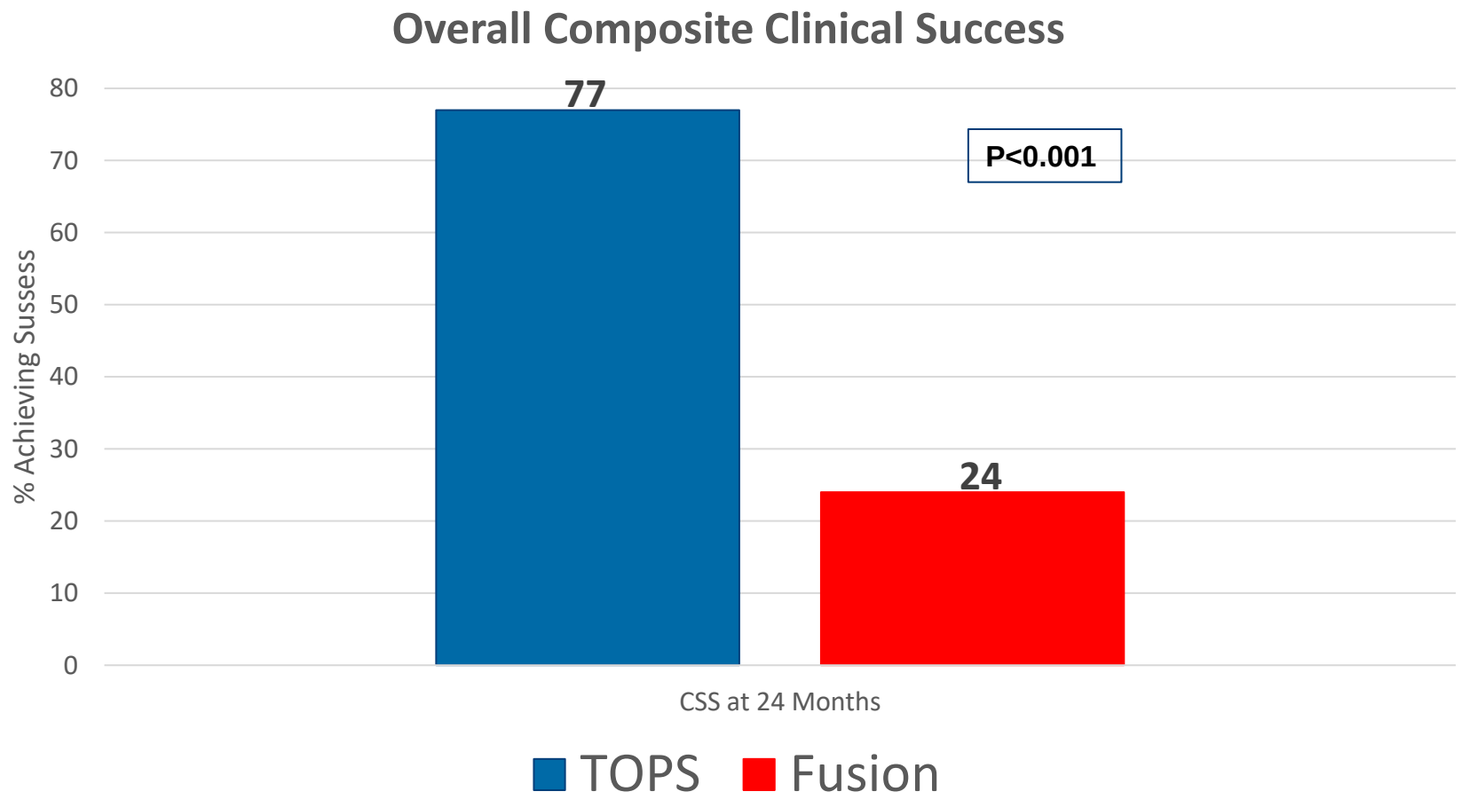


Pre-specified Primary Endpoint @ 24 Months

Conclusions from FDA's SSED:

"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."

Composite Clinical Success @ 24 Months

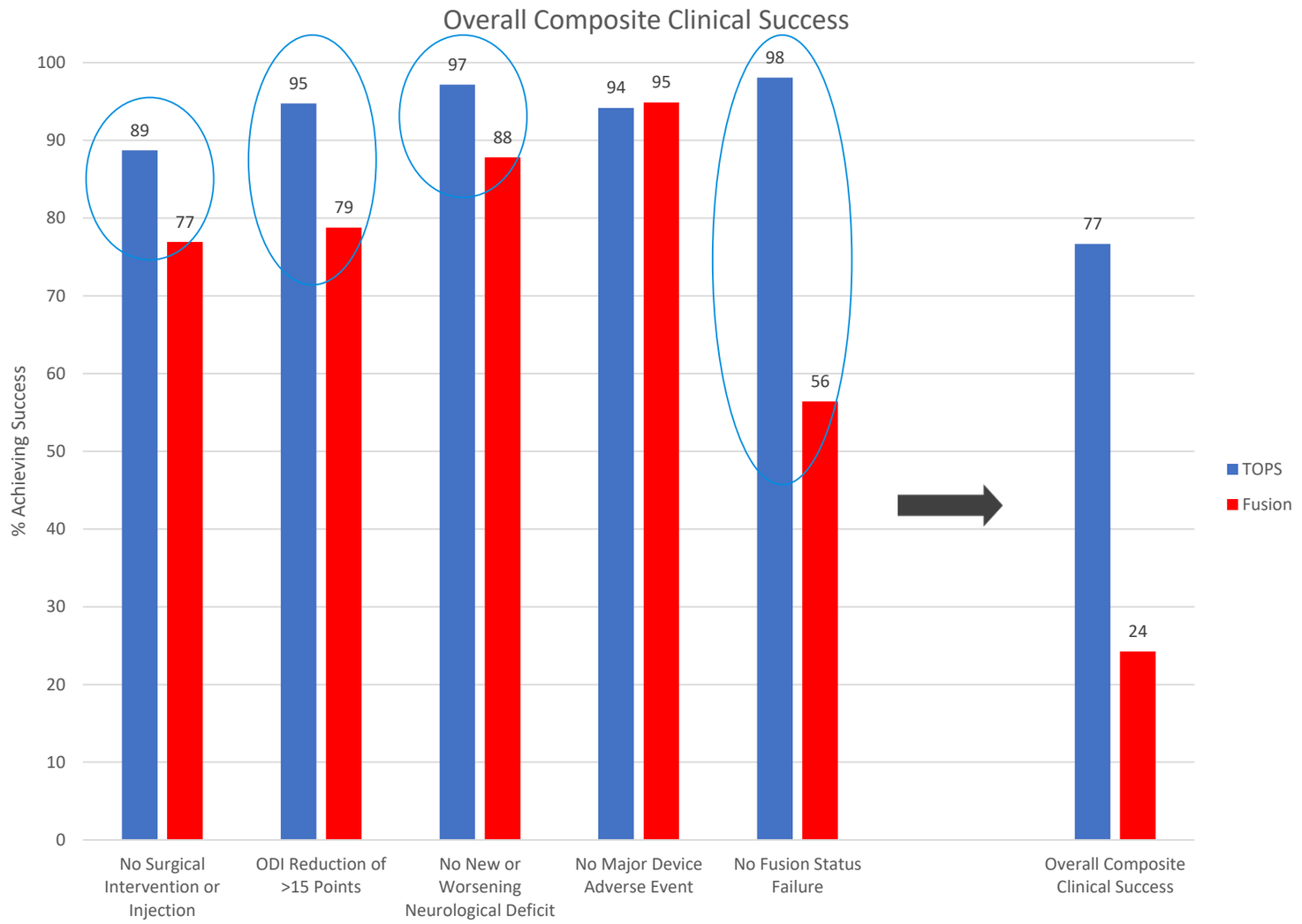


PMA Conclusion: Significant advantage for TOPS over lumbar fusion

Pre-specified Primary Endpoint @ 24 Months

- Absence of bridging trabecular bone across the involved motion segment or
- Angular motion ≥ 3° from flexion to extension or
- Translational motion ≥ 2 mm from flexion to extension.

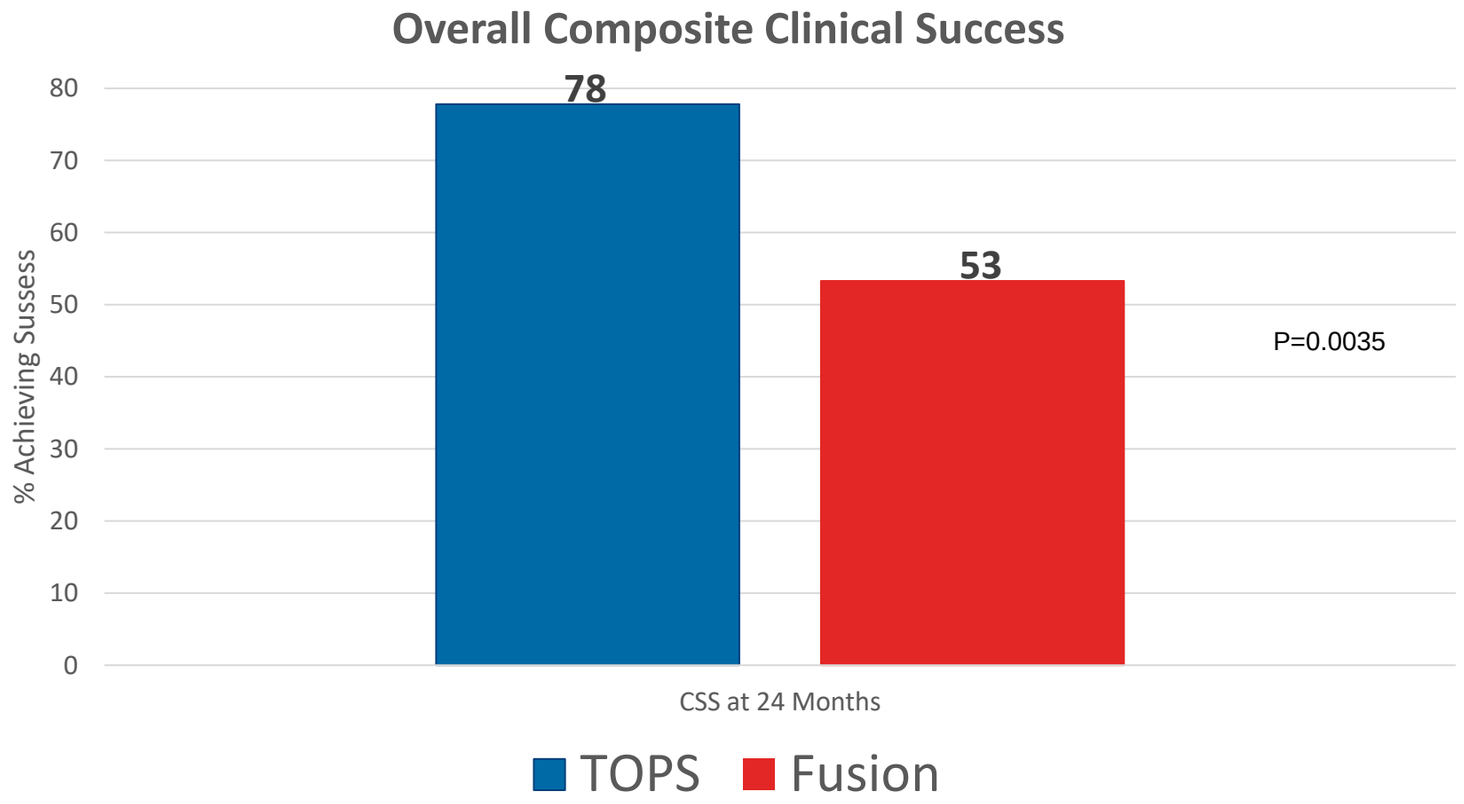
Percent of Patients Achieving Clinical Success



Composite Clinical Success @ 24 Months

Pre-specified Primary Endpoint @ 24 Months

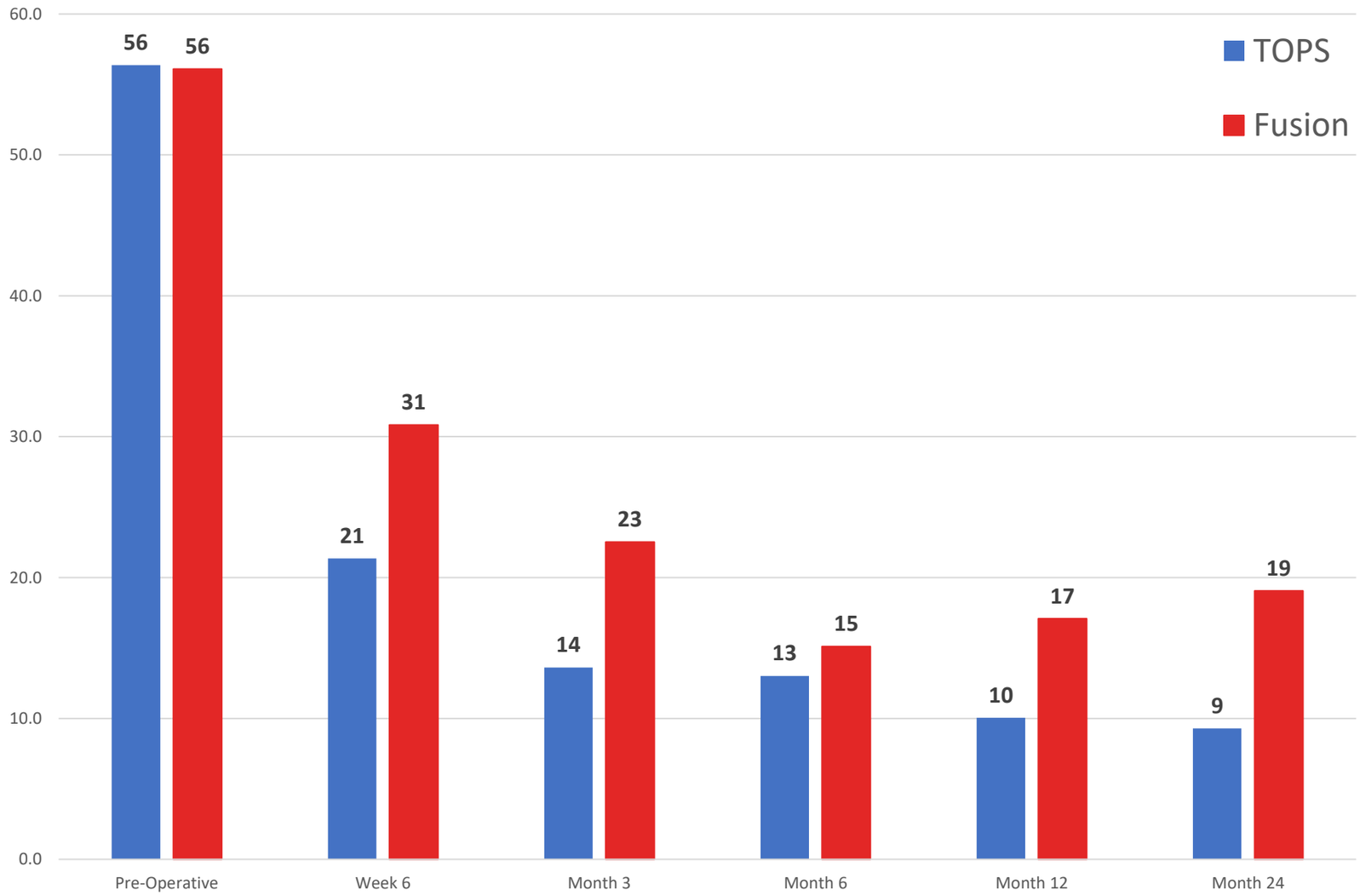
EXCLUDING FUSION COMPONENT



PMA Conclusion: Significant advantage for TOPS over lumbar fusion

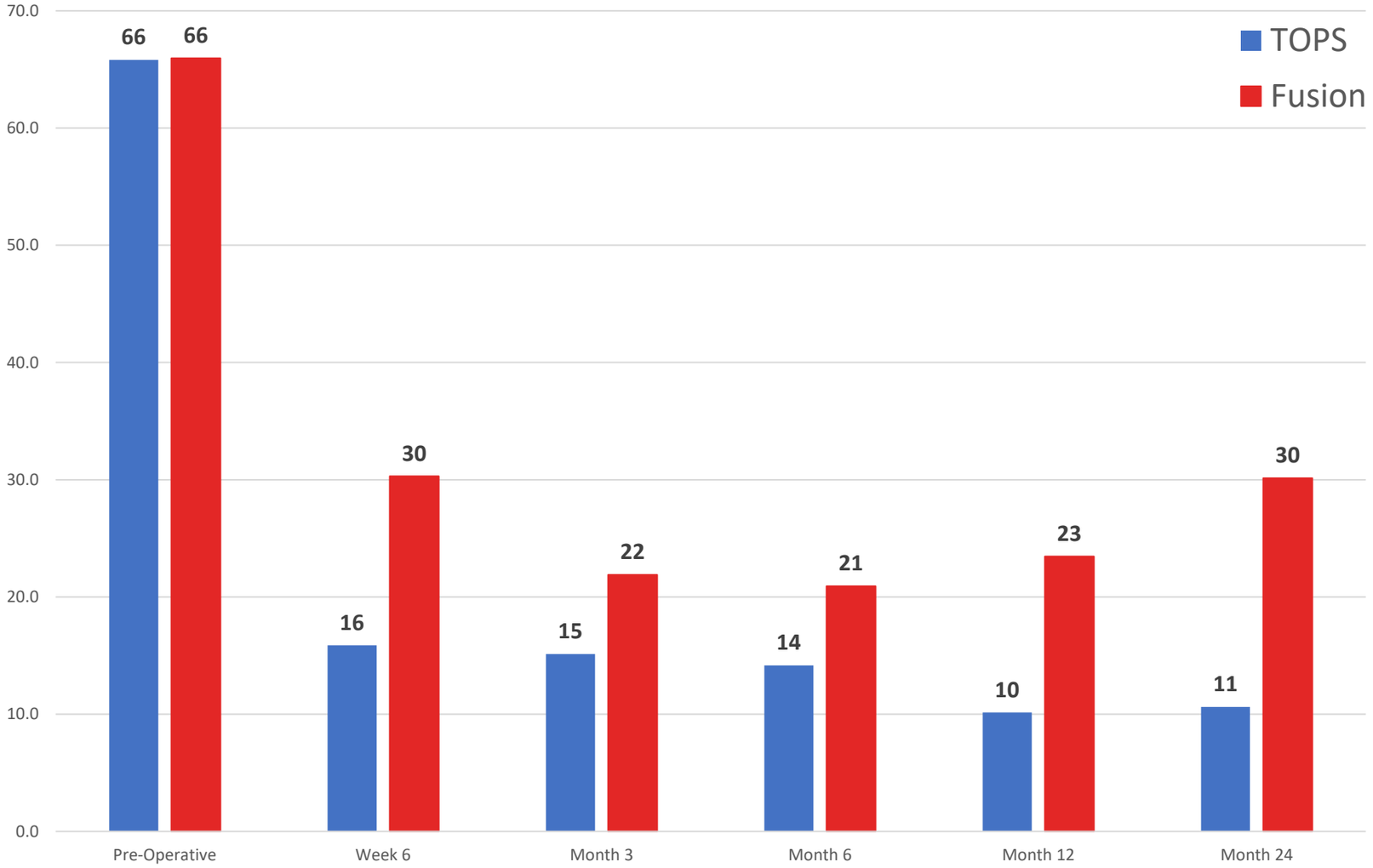
TOPS IDE Clinical Trial

Oswestry Disability Index (ODI)



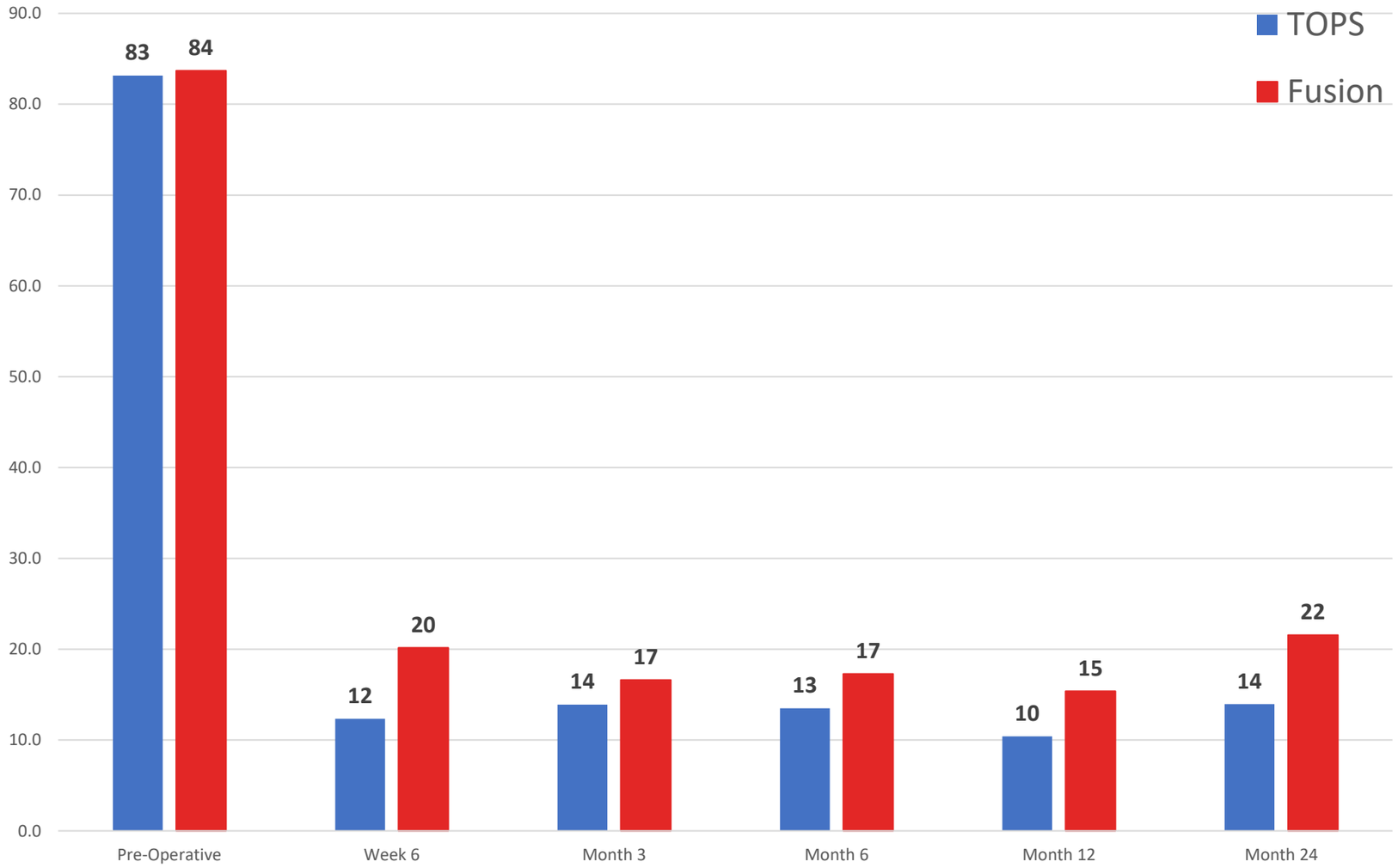
TOPS IDE Clinical Trial

VAS Back Pain



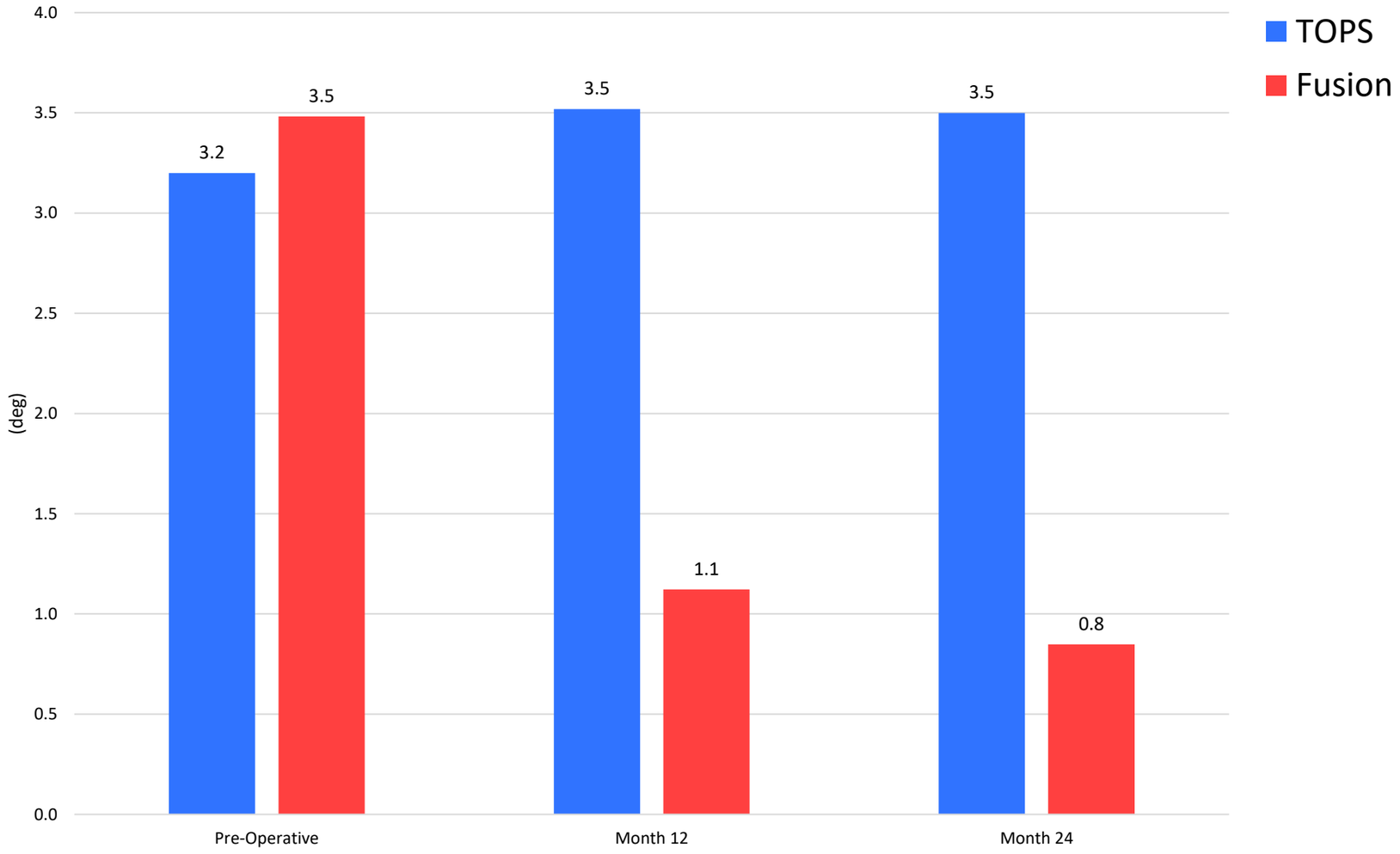
TOPS IDE Clinical Trial

VAS Leg Pain



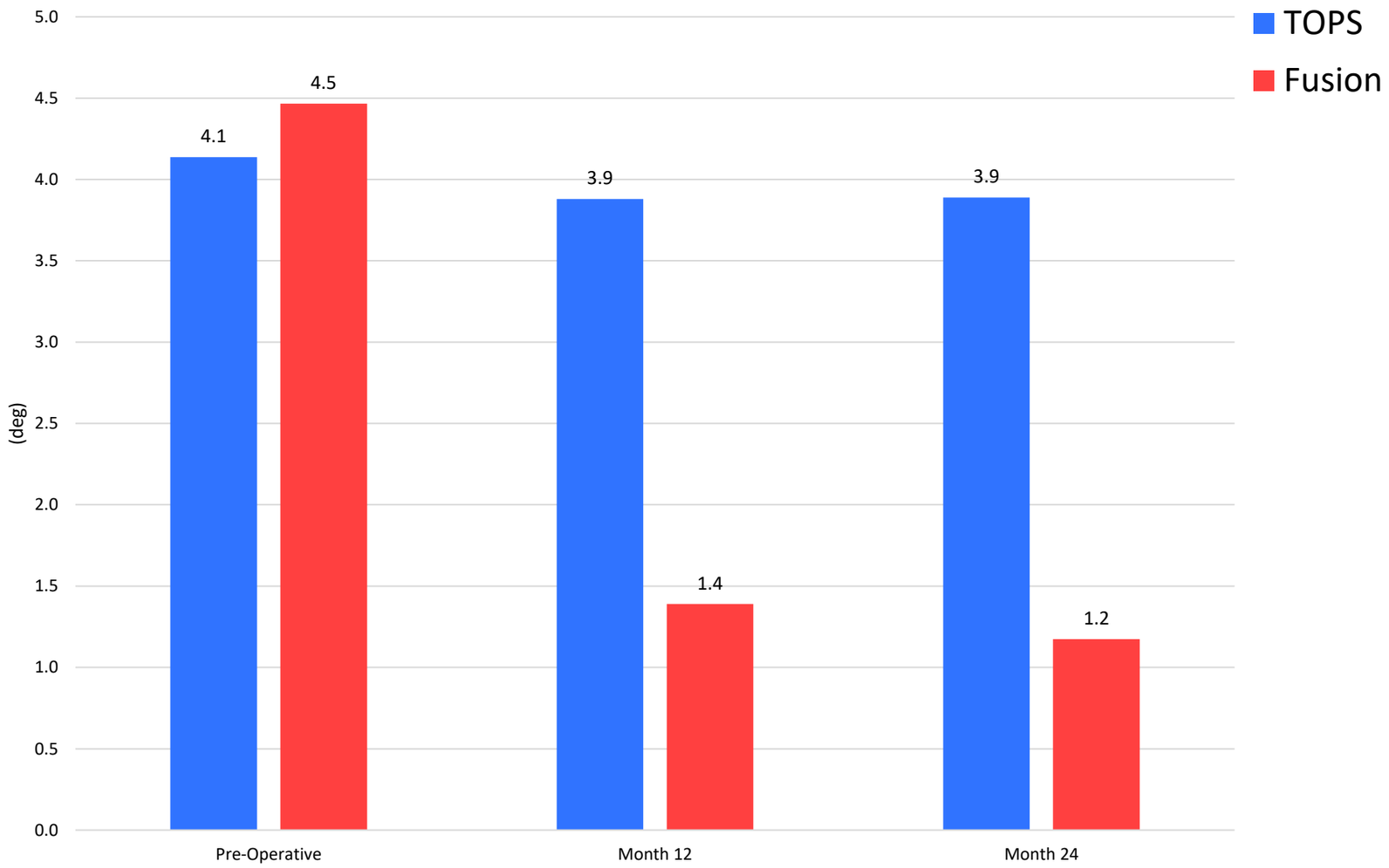
TOPS IDE Clinical Trial

Summary of Left/Right Bend Range of Motion: Angular Motion (deg)



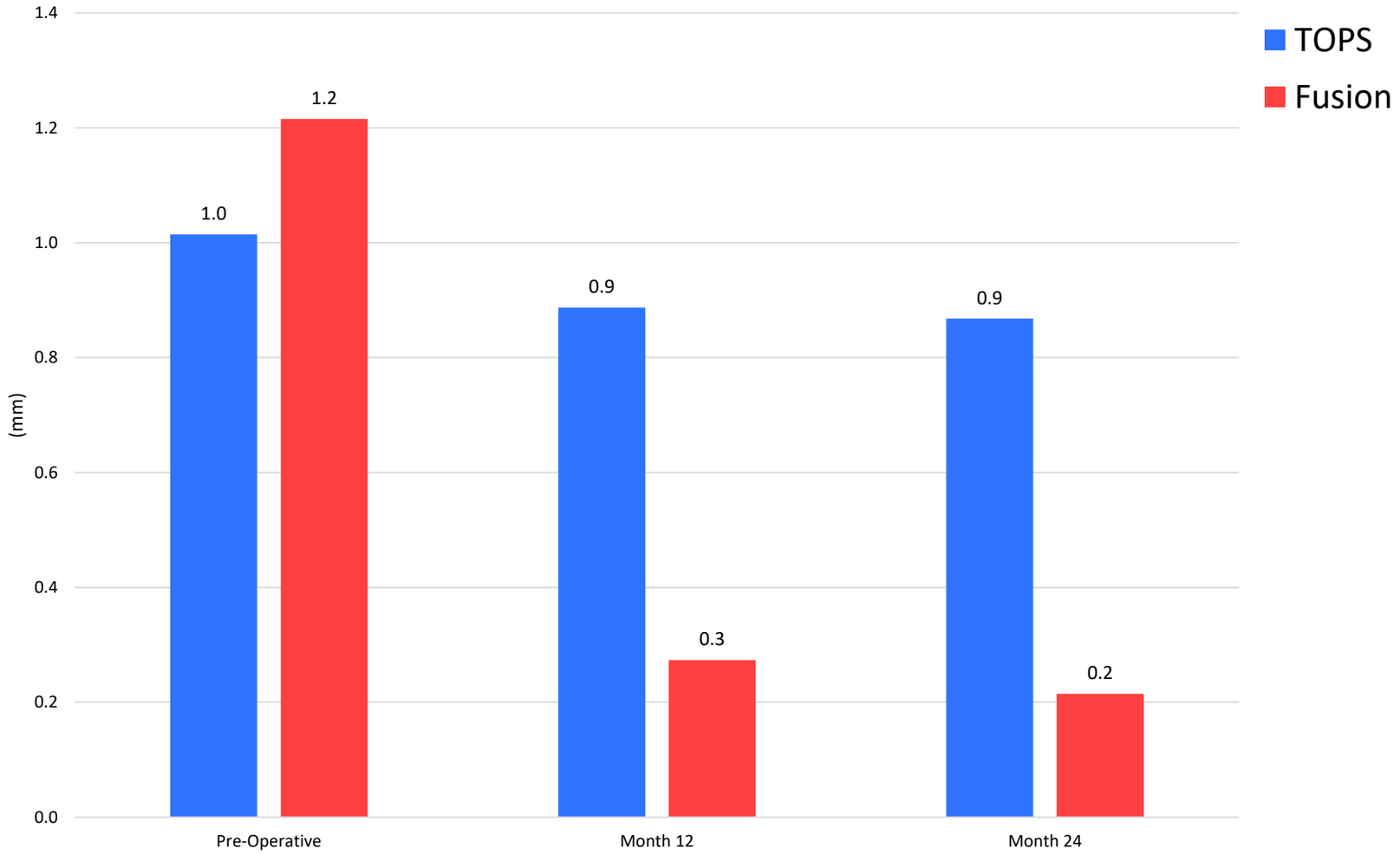
TOPS IDE Clinical Trial

Summary of Flex/Ex Range of Motion: Angular Motion (deg)



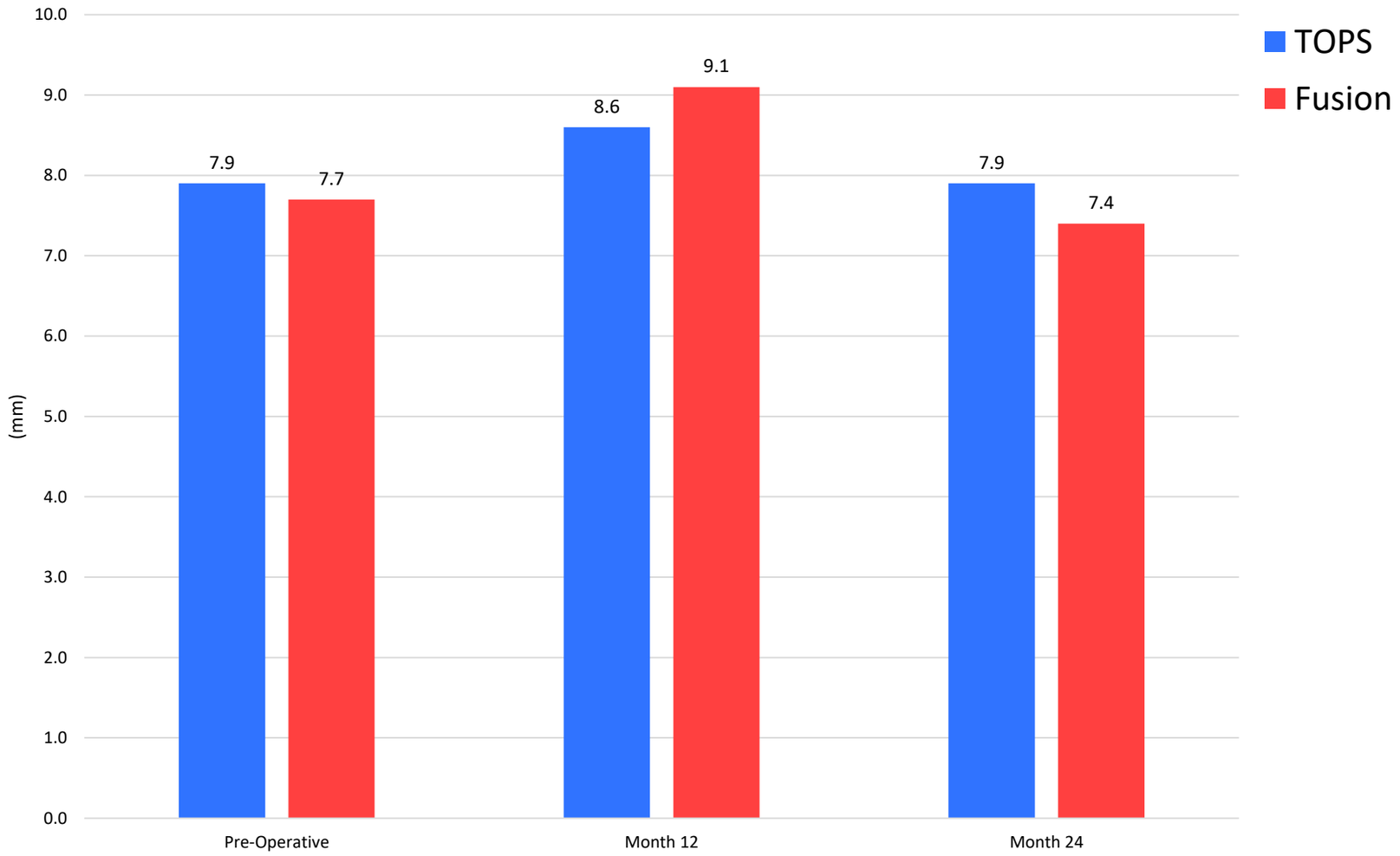
TOPS IDE Clinical Trial

Summary of Flex/Ex Range of Motion: Translation (mm)



TOPS IDE Clinical Trial

Change in Disc Height (mm)



TOPS IDE Clinical Trial

Subsequent Surgical Intervention

	TOPS (N=208)				Fusion (N=94)			
	SSIs	Subs	%	Avg Days	SSIs	Subs	%	Avg Days
Durotomy	4	2	0.96	15	1	1	1.06	11
Wound Complication	3	3	1.44	33	0	0	0.00	0
Retained Surgical Drain	2	2	0.96	27	0	0	0.00	0
Adjacent Segment Disease	0	0	0.00	0	3	3	3.19	380
Pseudoathrosis	0	0	0.00	0	1	1	1.06	771
Pedicle Screw Misplacement	1	1	0.48	5	0	0	0.00	0
Screw Loosening / Implant Migration	2	2	0.96	469	1	1	1.06	32
Unresolved Pain	3	3	1.44	498	4	3	3.19	552
ALL	**15**	**11**	**5.3%**	**131**	**10**	**8**	**8.5%**	**218**

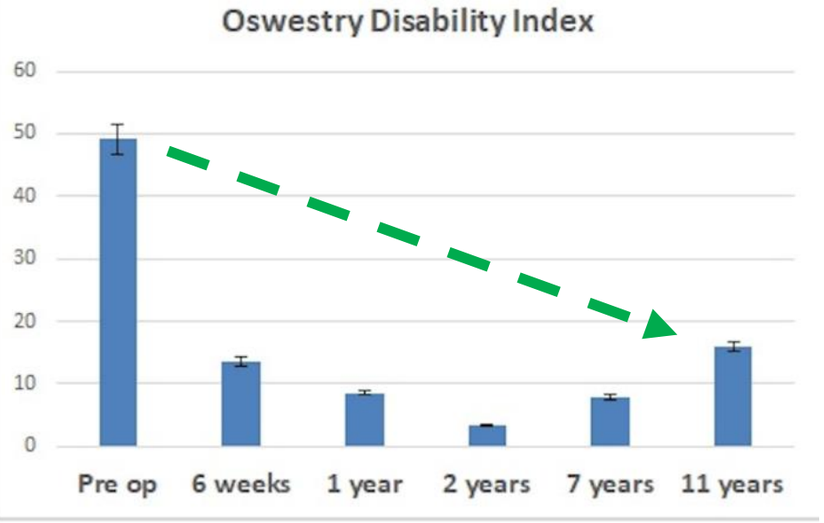
TOPS Publication: Long-term follow-up

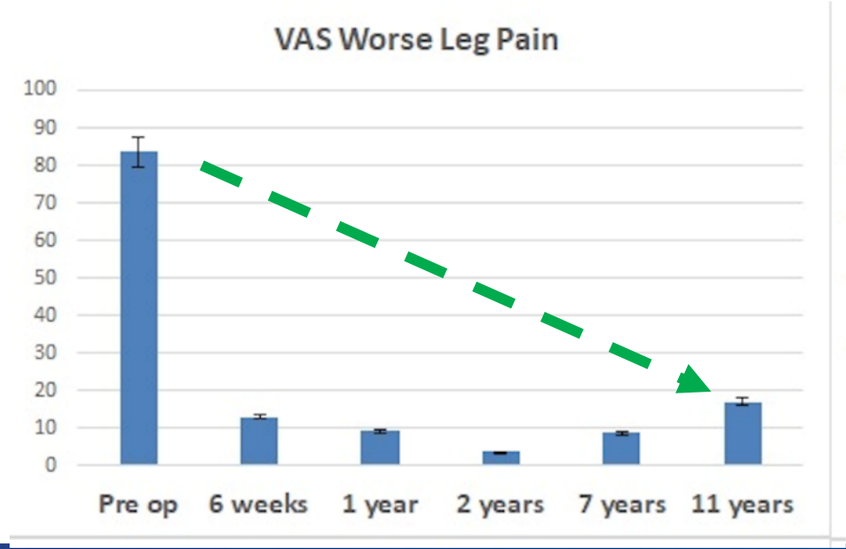
JNS SPINE

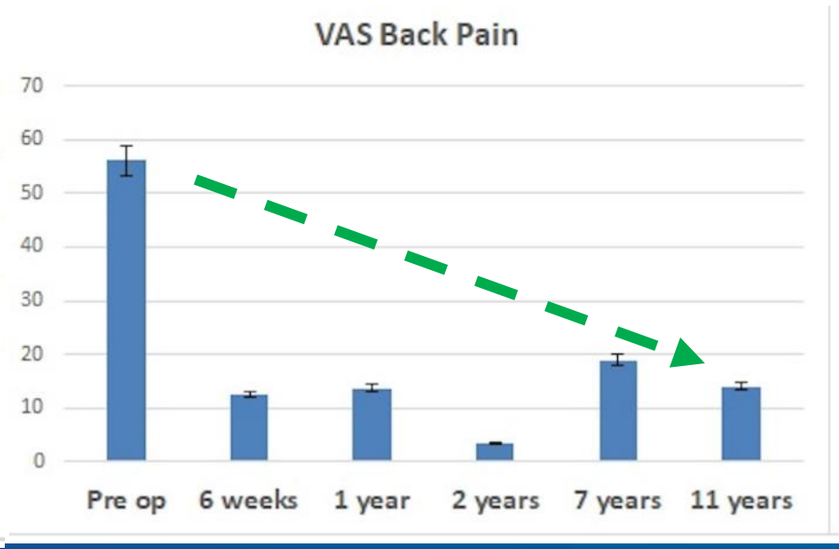
CLINICAL ARTICLE

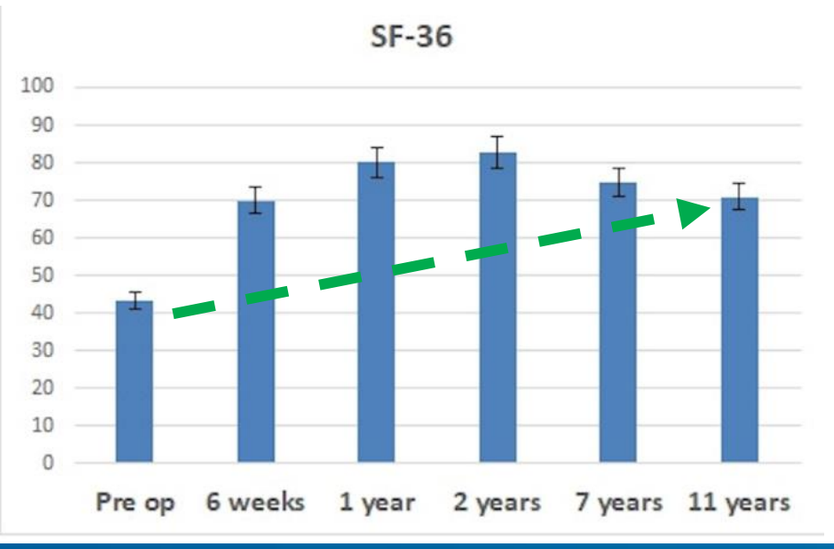
Long-term results for total lumbar facet joint replacement in the management of lumbar degenerative spondylolisthesis

Yossi Smorgick, MD,[2] Yigal Mirovsky, MD,[1] Yizhar Floman, MD,[3] Nahshon Rand, MD,[3] Michael Millgram, MD,[3] and Yoram Anekstein, MD[2]

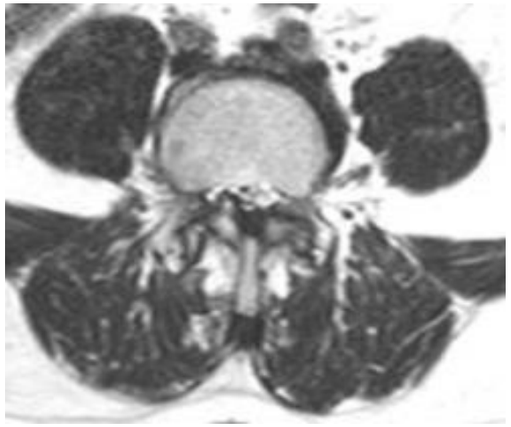


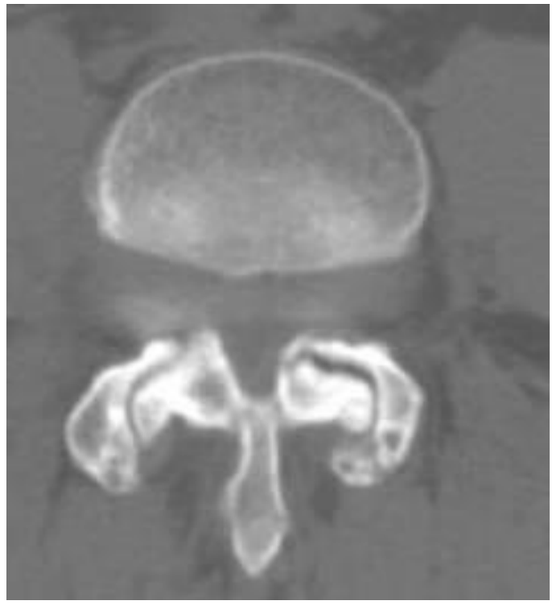


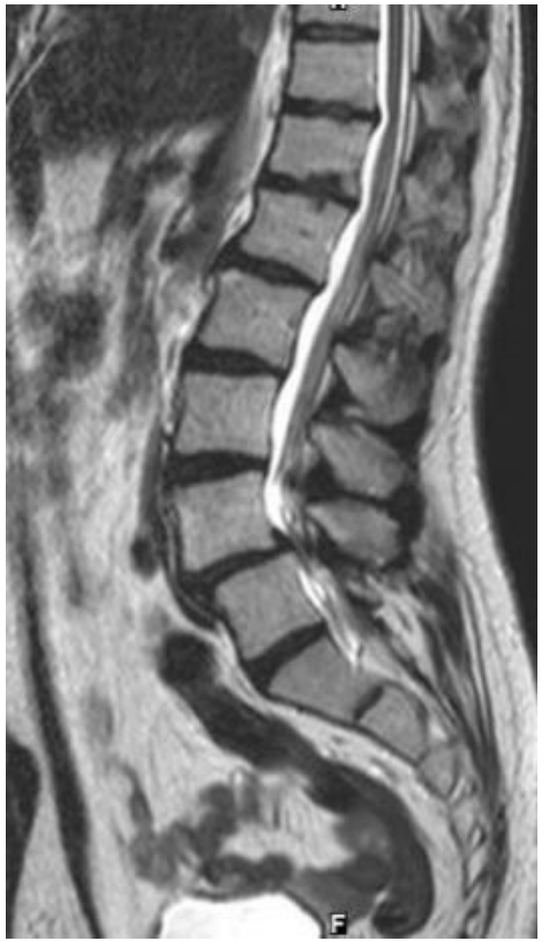


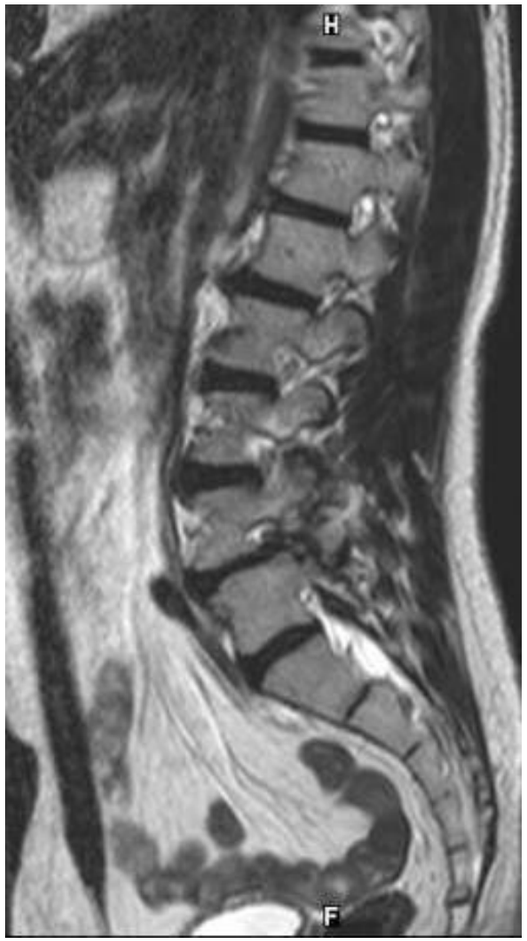


52-yr male, pre-op



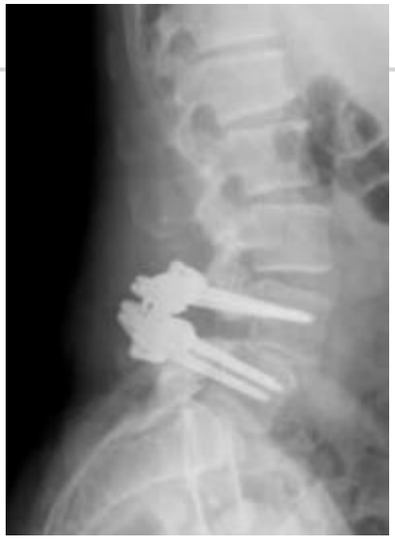


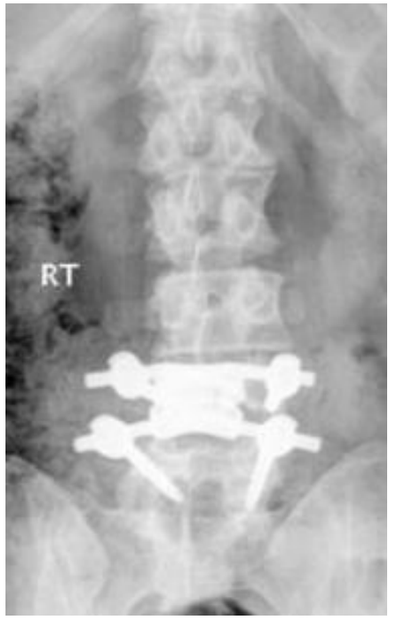




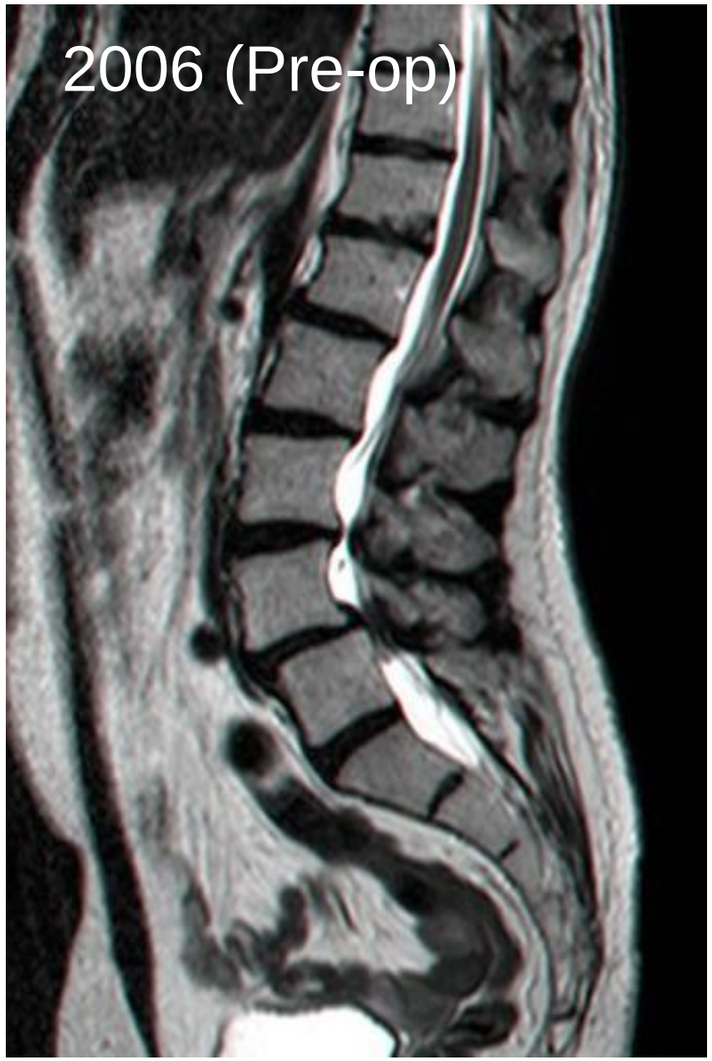
52-yr male, 27-12-2006 surgery

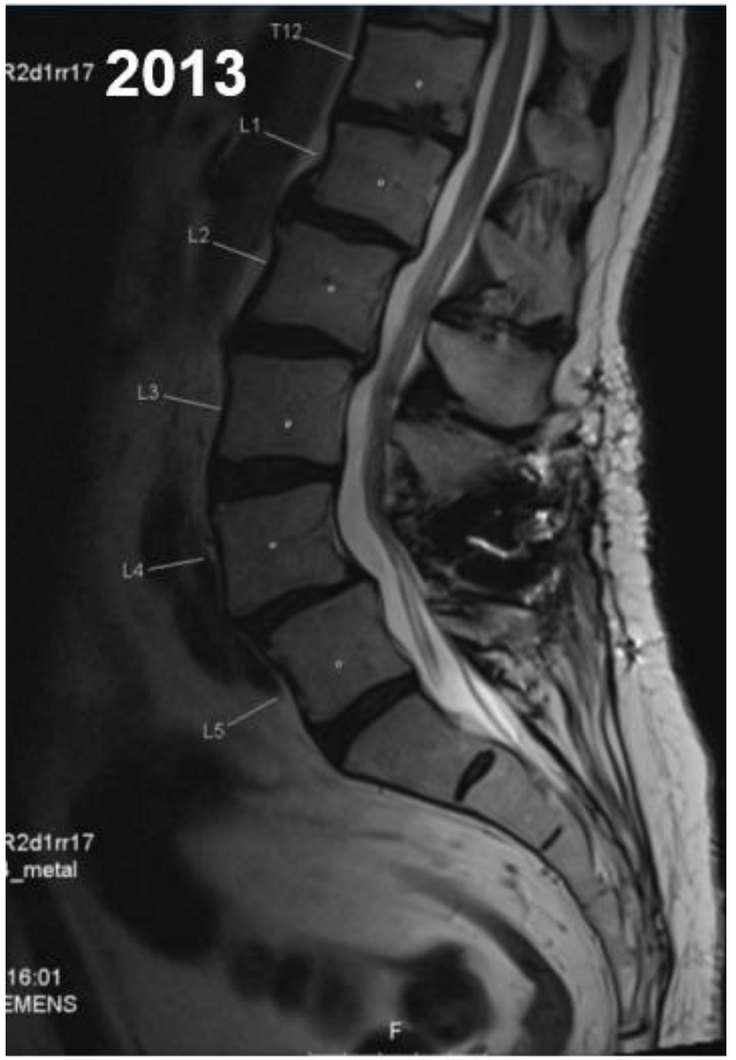
Time Period	ODI	VAS Left	VAS Right	VAS Back
Pre-Op	40	100	40	4
Post-op	30	9	0	0
6 weeks	24	0	0	8
3-months	10	0	0	0
6 months	10	0	0	9
12 months	0	0	0	0
24 months	0	0	0	0





After Seven Years





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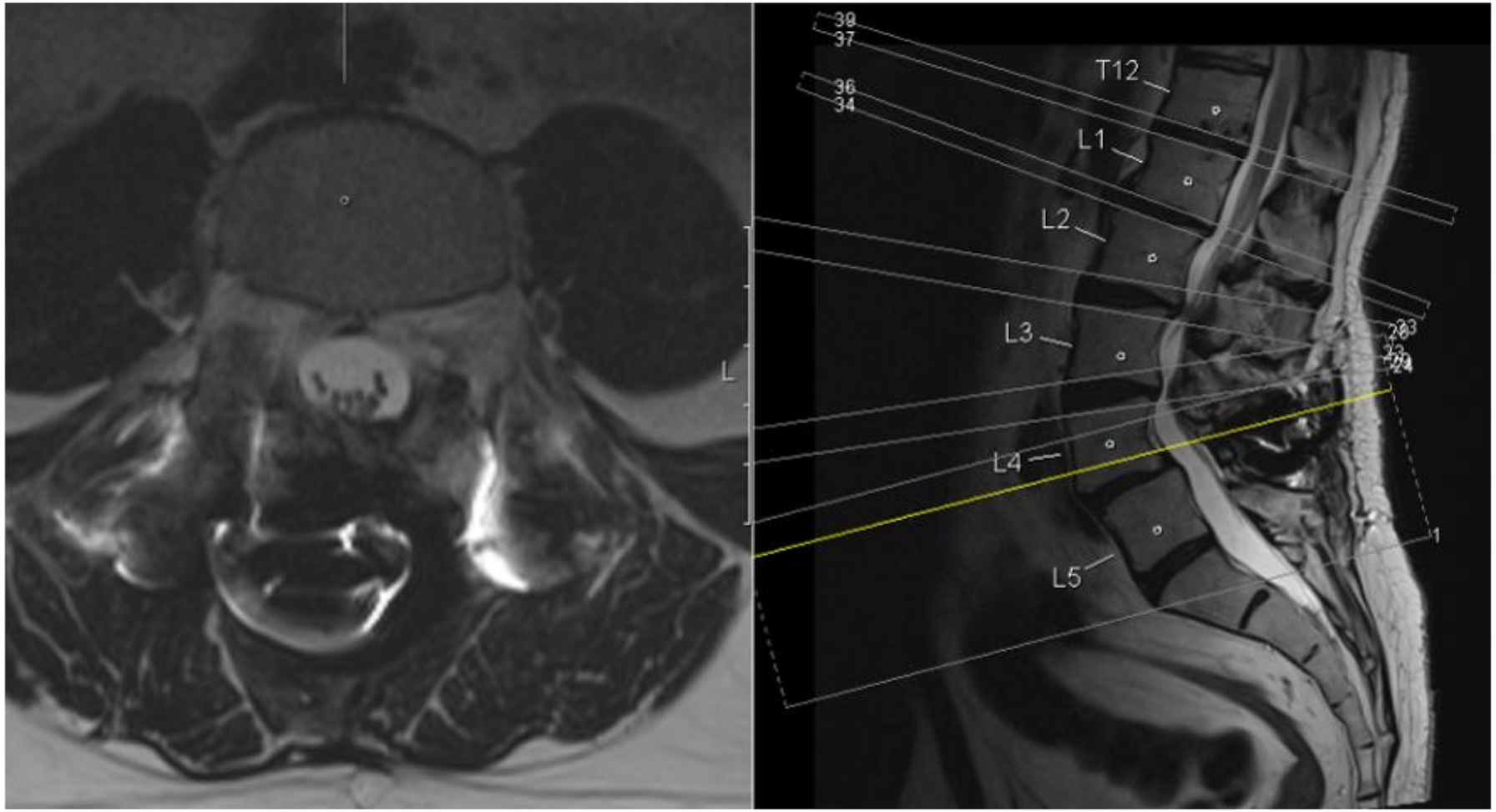
After Seven Years



TOPS Publication: Prospective, randomized controlled IDE study for FDA

Lumbar Facet Arthroplasty Versus Fusion for Grade-I Degenerative Spondylolisthesis with Stenosis

A Prospective Randomized Controlled Trial

Ahmad Nassr, MD, Domagoj Coric, MD, Zachariah W. Pinter, MD, Arjun S. Sebastian, MD, Brett A. Freedman, MD, Donald Whiting, MD, Ali Chahlavi, MD, Stephen Pirris, MD, Nicolas Phan, MD, Scott A. Meyer, MD, A. David Tahernia, MD, Faheem Sandhu, MD, Harel Deutsch, MD, Eric A. Potts, MD, Joseph Cheng, MD, John H. Chi, MD, MPH, Michael Groff, MD, Yoram Anekstein, MD, Michael P. Steinmetz, MD, and William C. Welch, MD

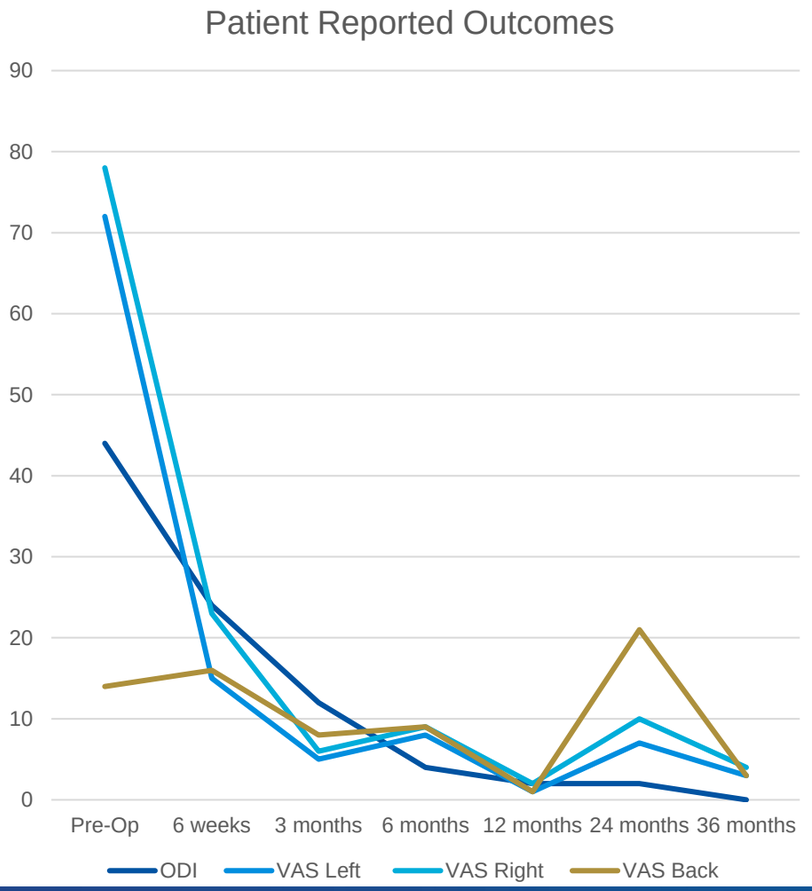
Background: The comparative effectiveness of decompression plus lumbar facet arthroplasty versus decompression plus instrumented lumbar spinal fusion in patients with lumbar spinal stenosis and grade-I degenerative spondylolisthesis is unknown.

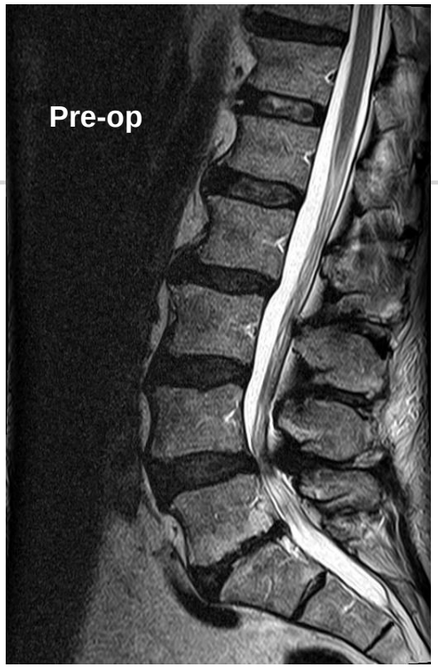
Methods: In this randomized, controlled, Food and Drug Administration Investigational Device Exemption trial, we assigned patients who had single-level lumbar spinal stenosis and grade-I degenerative spondylolisthesis to undergo decompression plus lumbar facet arthroplasty (arthroplasty group) or decompression plus fusion (fusion group). The primary outcome was a predetermined composite clinical success score. Secondary outcomes included the Oswestry Disability Index (ODI), visual analog scale (VAS) back and leg pain, Zurich Claudication Questionnaire (ZCQ), Short Form (SF)-12, radiographic parameters, surgical variables, and complications.

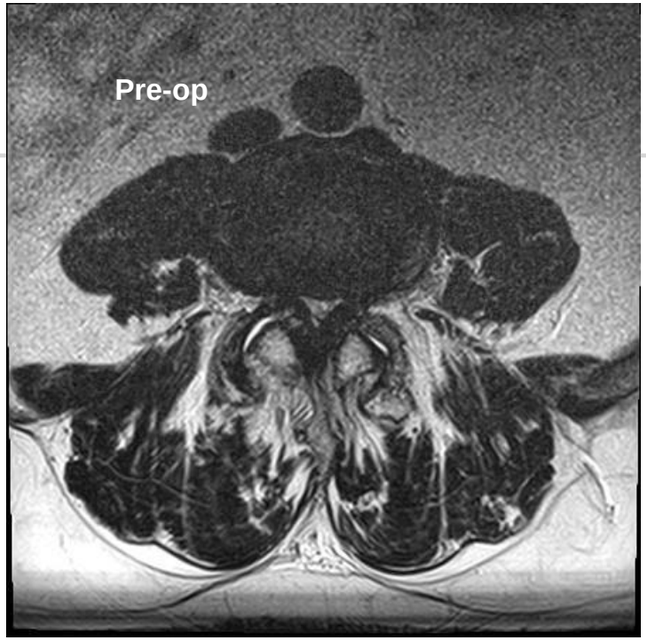
Results: A total of 321 adult patients were randomized in a 2:1 fashion, with 219 patients assigned to undergo facet arthroplasty and 102 patients assigned to undergo fusion. Of these, 113 patients (51.6%) in the arthroplasty group and 47 (46.1%) in the fusion group who had either reached 24 months of postoperative follow-up or were deemed early clinical failures were included in the primary outcome analysis. The arthroplasty group had a higher proportion of patients who achieved composite clinical success than did the fusion group (73.5% versus 25.5%; $p < 0.001$), equating to a between-group difference of 47.9% (95% confidence interval, 33.0% to 62.8%). The arthroplasty group outperformed the fusion group in most patient-reported outcome measures (including the ODI, VAS back pain, and all ZCQ component scores) at 24 months postoperatively. There were no significant differences between groups in surgical variables or complications, except that the fusion group had a higher rate of developing symptomatic adjacent segment degeneration.

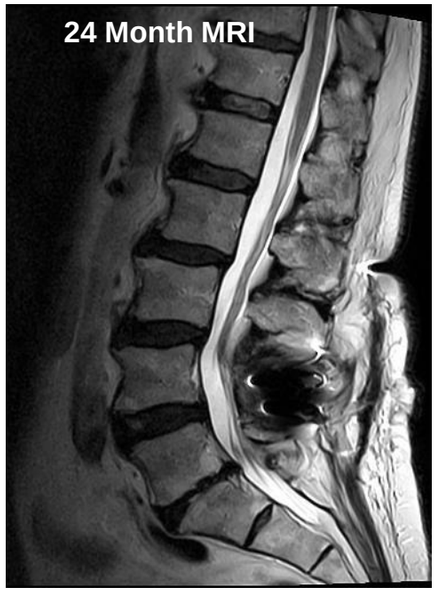
Case Study from IDE

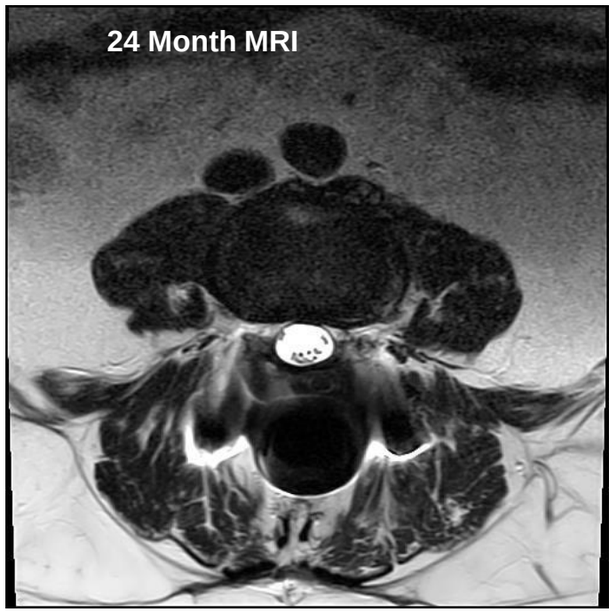
- 74 y/o male (BMI 31.5)
- Single level mod/sev stenosis at L4/5 with Grade I spondylolisthesis
- Complete L4 laminectomy with complete L4/5 bilateral facetectomies





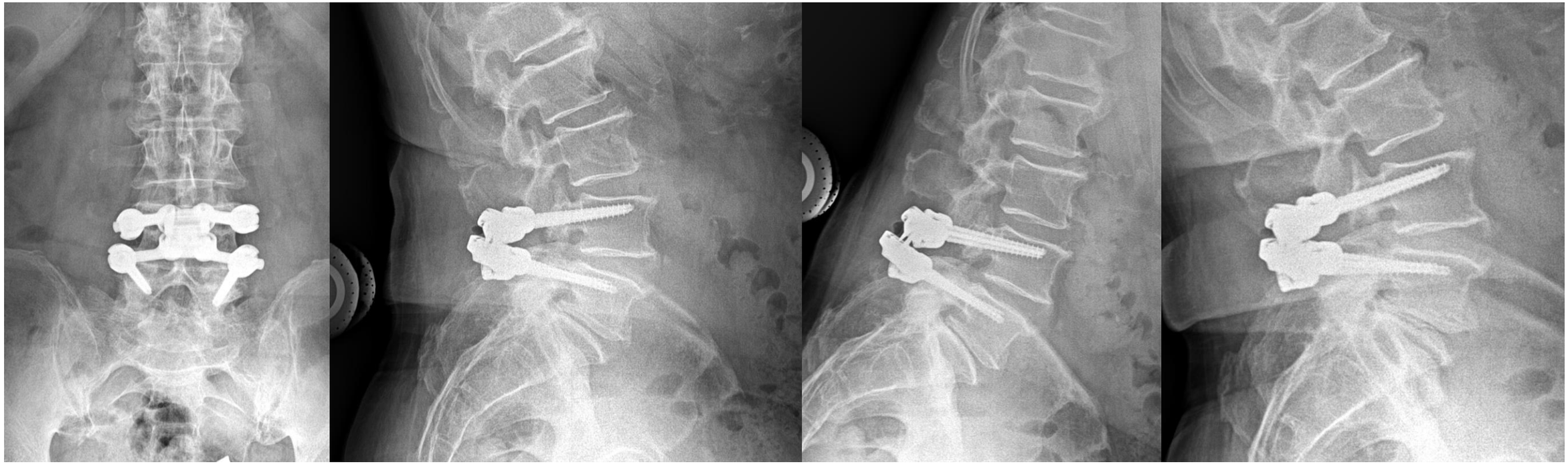






Case Study from IDE

AP | Neutral | Flexion | Extension

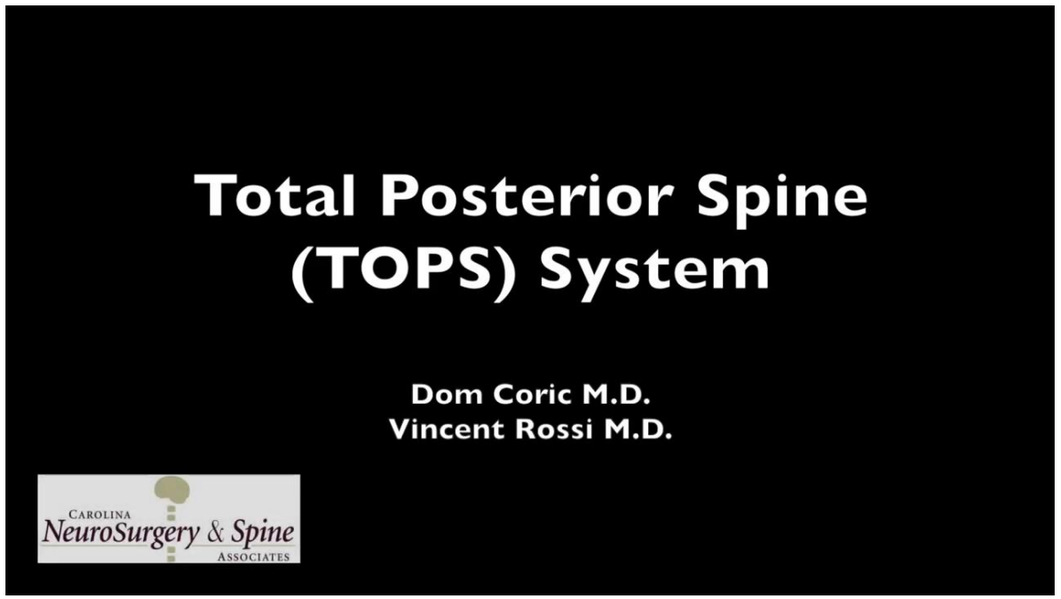


Radiographic Measurements – Treated Level

	Angular Motion (FlexEx)	Translational Motion (FlexEx)	Angular Motion (Lateral Bend)	Average Disc Height
Pre-Op	3.0	0.4	9.5	11.3
12 months	5.1	0.8	7.8	N/A
24 months	5.4	0.8	2.6	12.0

TOPS is a compelling & simple add-on procedure for surgeons

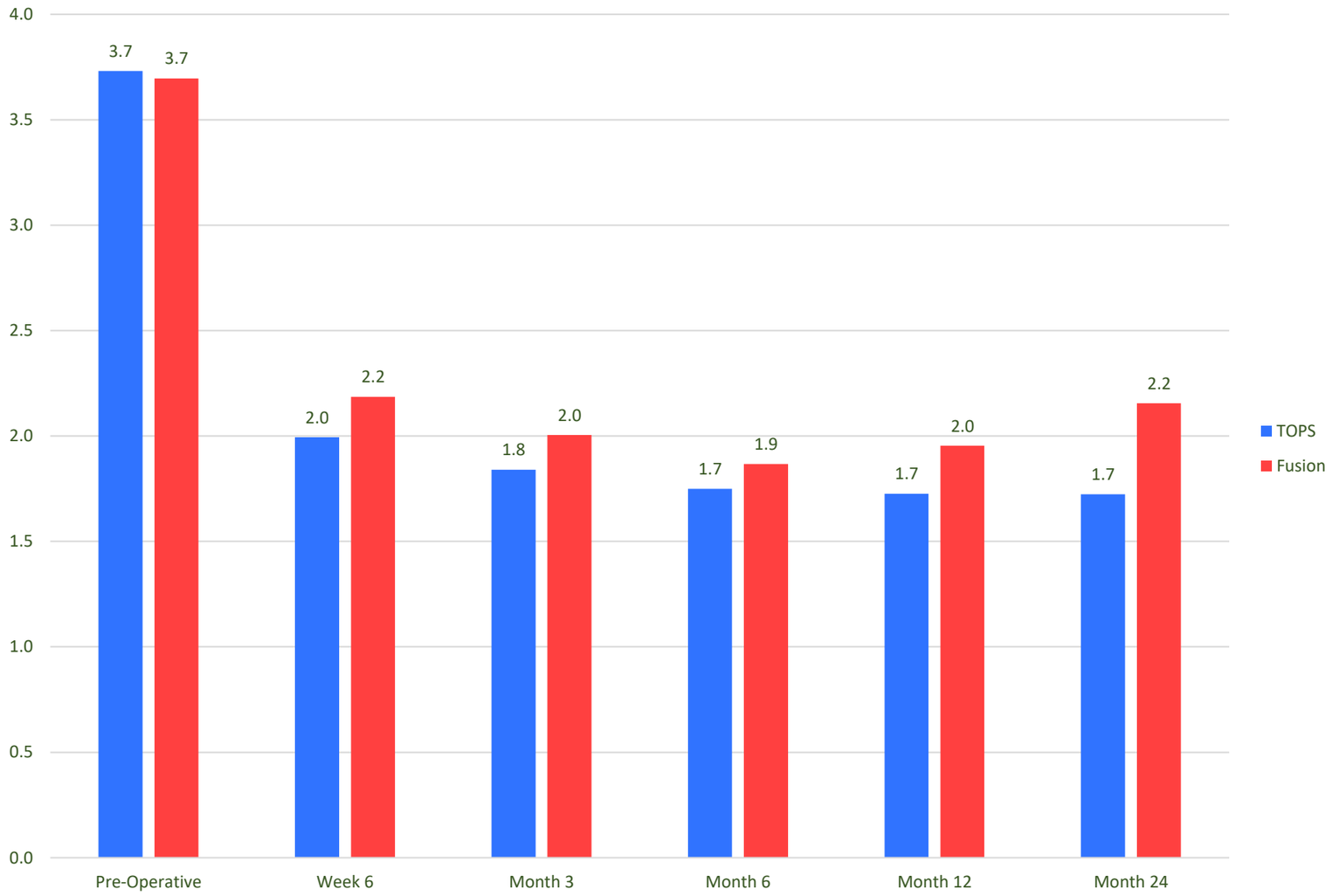
- ✓ Clinically effective, reliable, and innovative procedure
- ✓ **No learning curve – same technique as TLIF but without the cage**
- ✓ **On-label, navigation compatible**
- ✓ Single-pan instrumentation
- ✓ **All sterile implants**
- ✓ Easy to revise



An attractive, differentiated solution for your surgeons

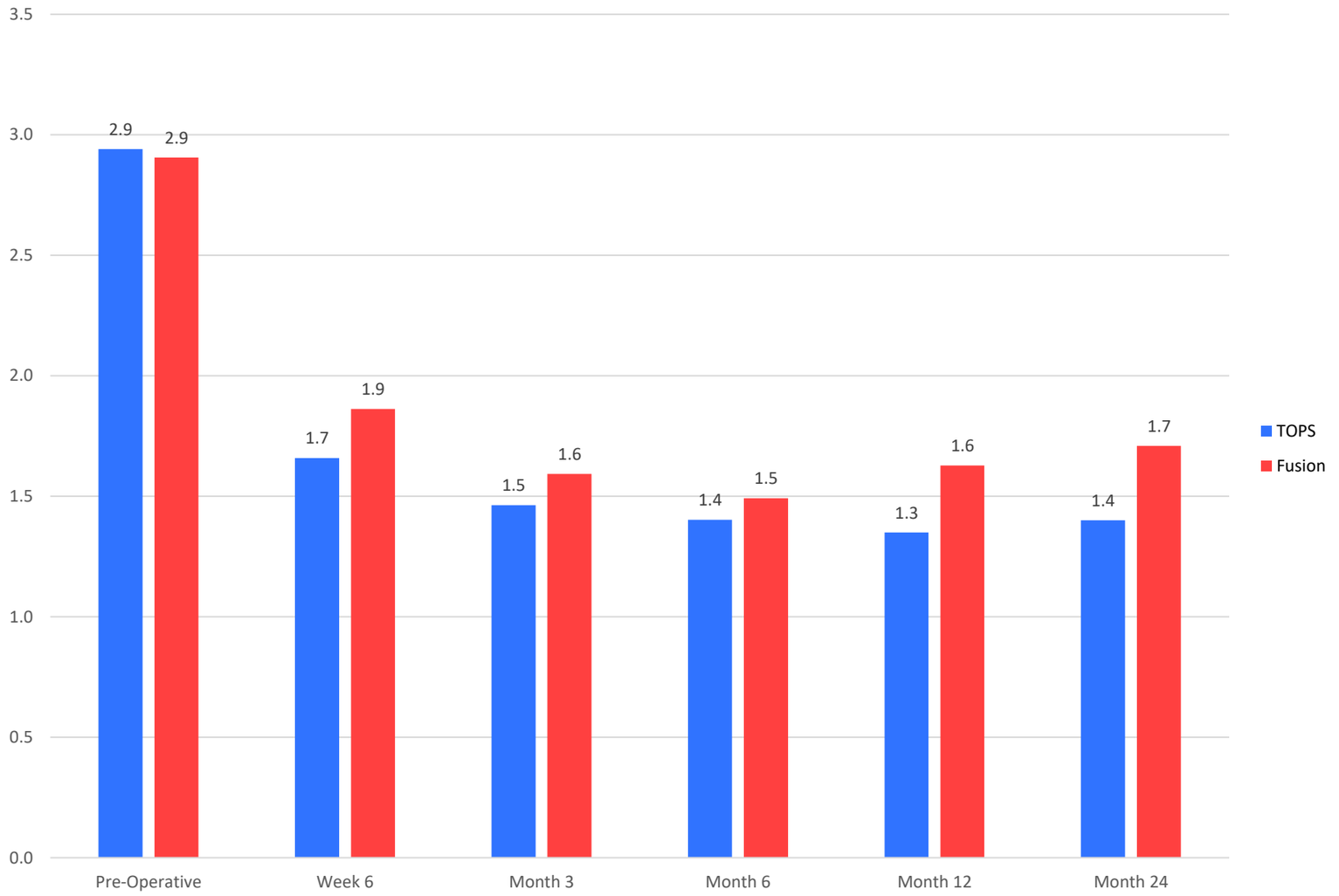
Patient Reported Outcomes

Zurich Claudication Questionnaire – Symptom Severity



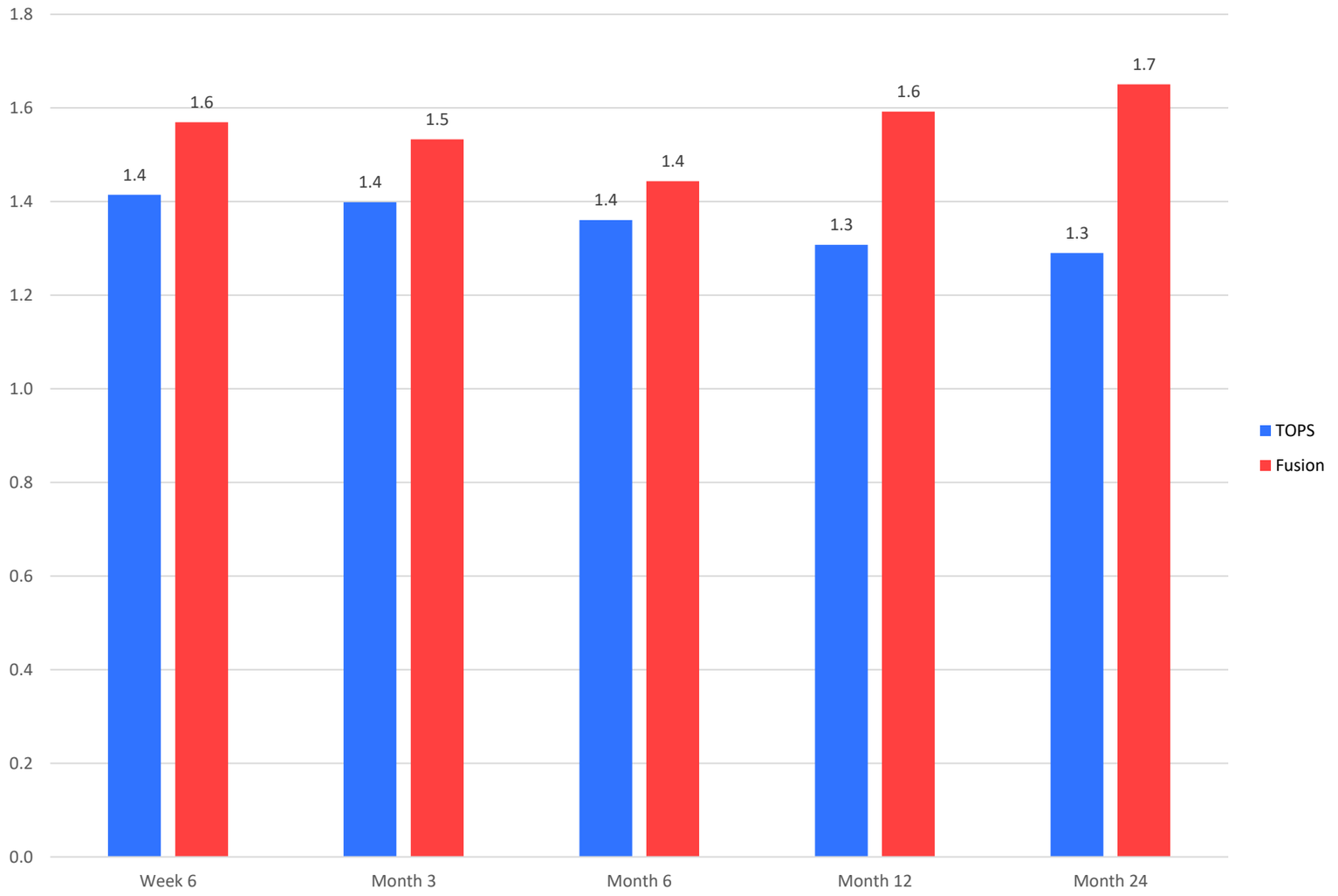
Patient Reported Outcomes

Zurich Claudication Questionnaire – Physical Function



Patient Reported Outcomes

Zurich Claudication Questionnaire – Patient Satisfaction



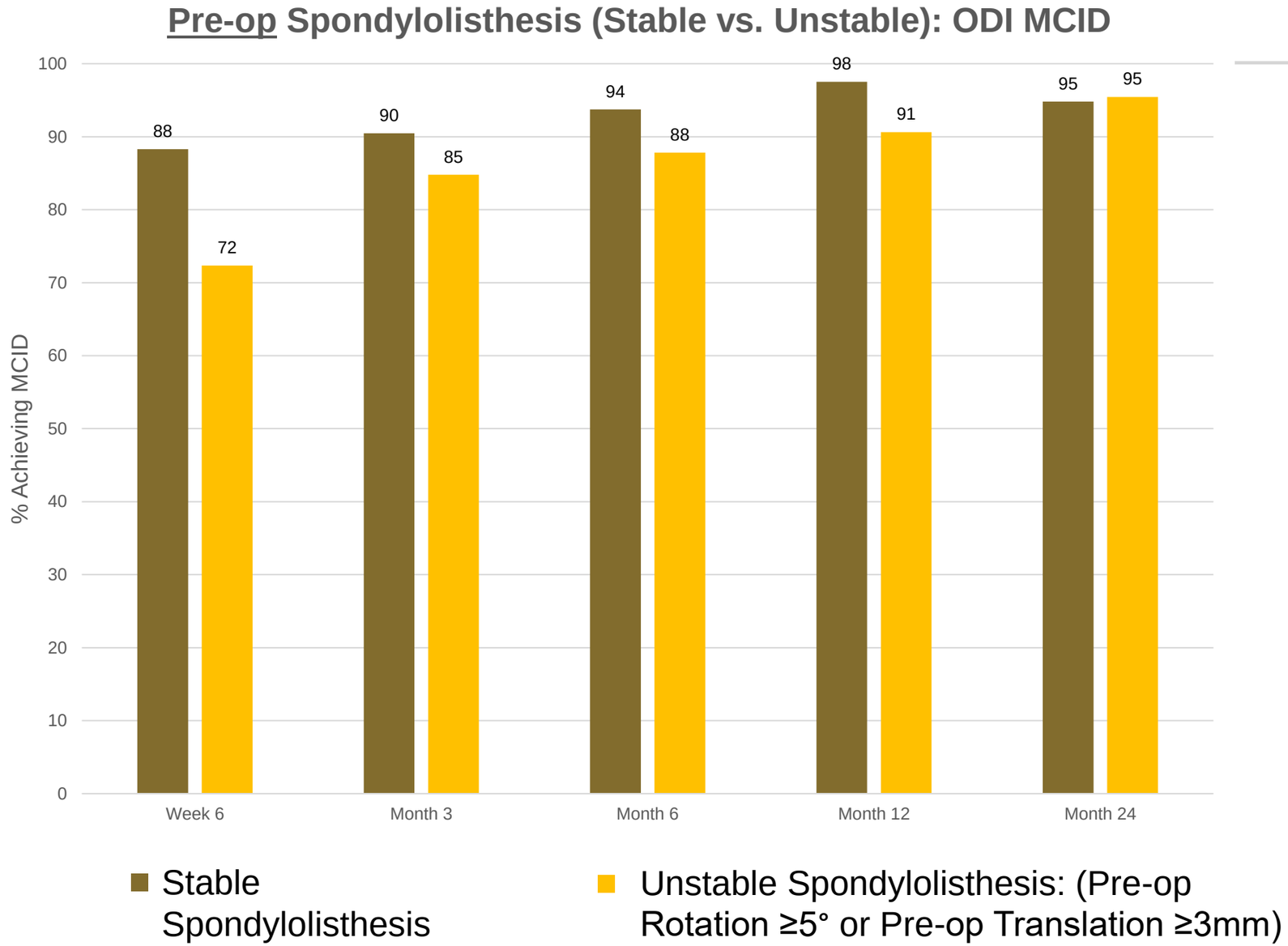
1st TOPS Case vs. All Subsequent TOPS Cases

Learning Curve Analysis

Month 24 Composite Clinical Success Among TOPS Treated Subjects Comparing the 1st TOPS Case (by site) vs Subsequent TOPS cases

Success Variable	1st TOPS Case % Success	2nd+ TOPS Case % Success	Δ	p-value
No SSI or LI	89	93		
No Major Device Adverse Event	94	93		
ODI Reduction of ≥15 Points	96	93		
No New or Worsening Neurological Deficit	94	99		
No Fusion Status Failure	100	99		
Overall Composite Clinical Success	**70**	**75**	**-5**	**1.00**

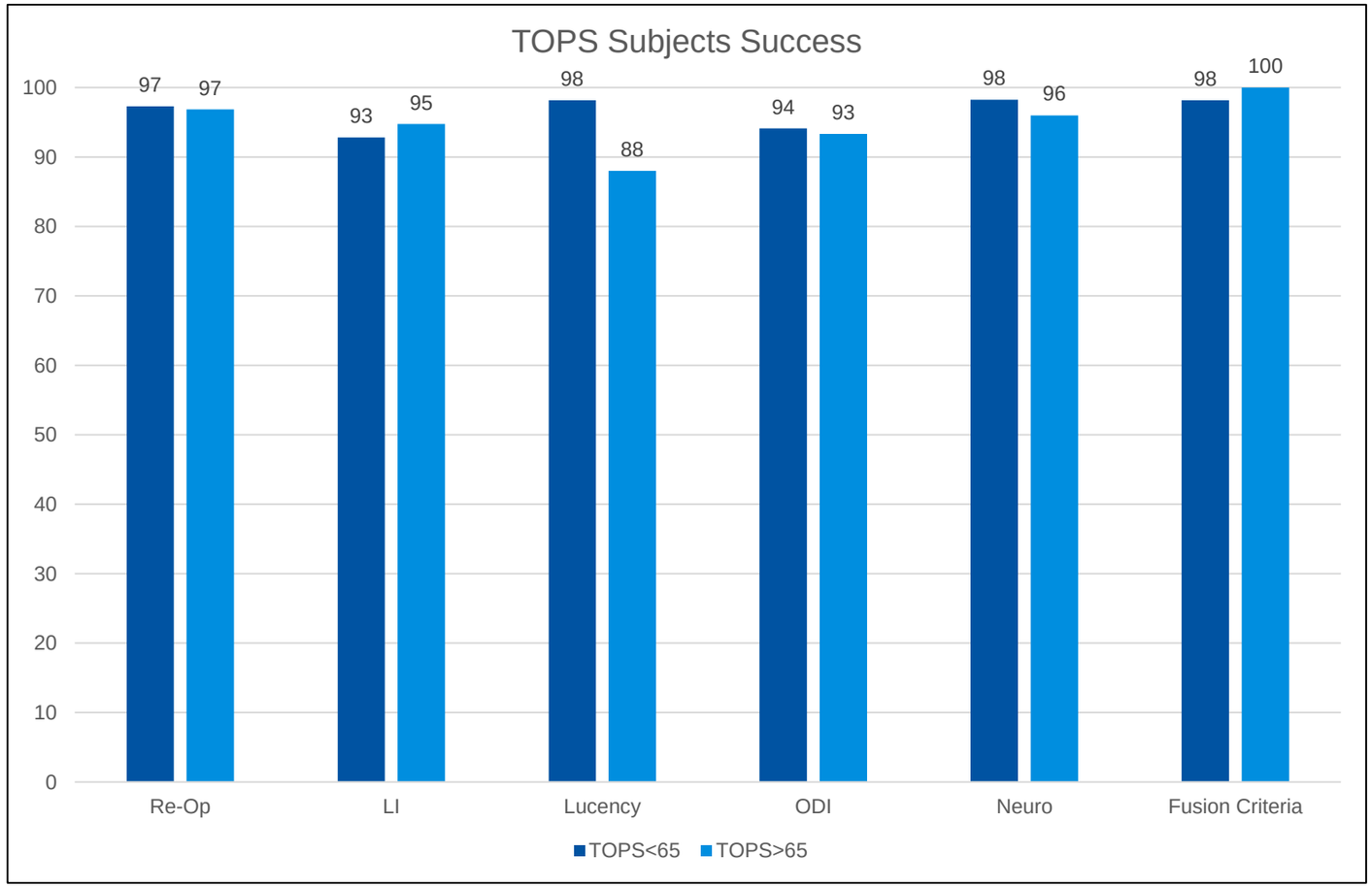
ODI MCID: Stable pre-op spondy vs. unstable pre-op spondy



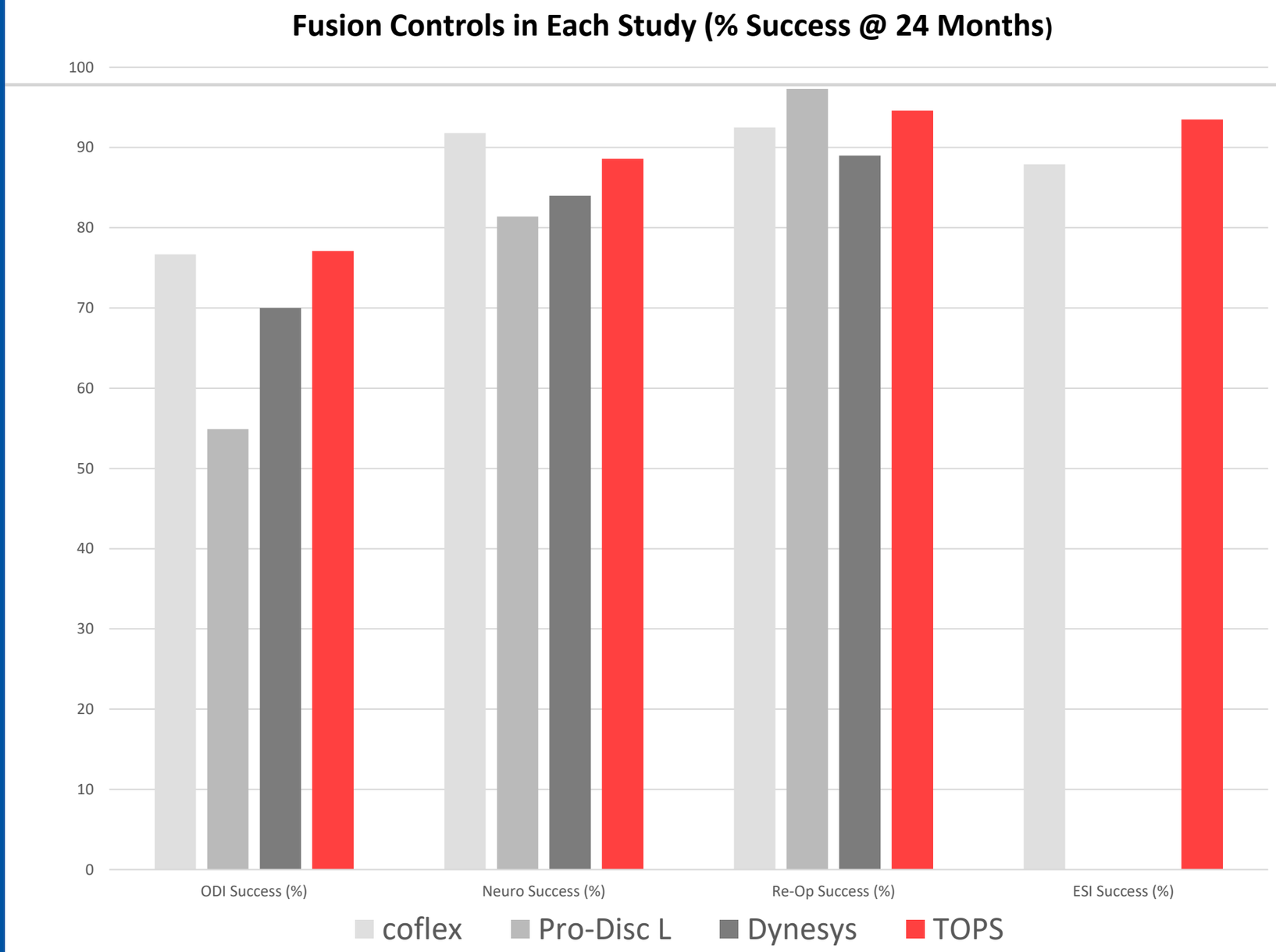
MCID defined as at least a 15-point improvement from baseline

Age-stratified Outcomes

Primary Endpoint Outcomes: Percent Success at Two-Years Post-Op



Fusion Control in TOPS study versus other IDE fusion controls



TOPS save payors $3,700 within 2 years. Gap grows bigger thereafter

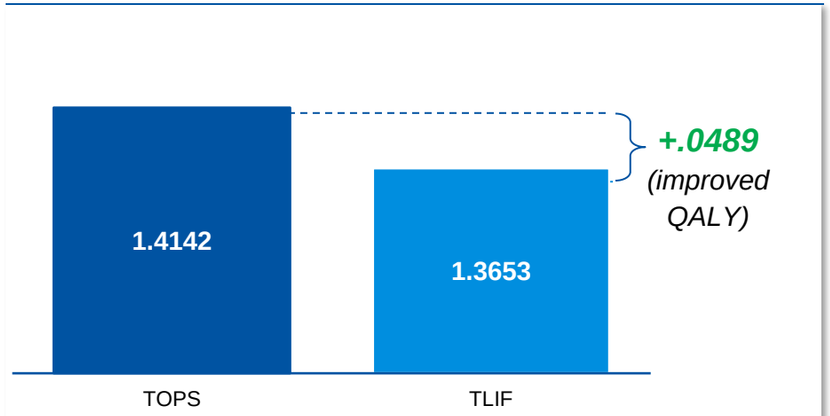
TOPS data shows 2-year economic benefit to health systems and significant value to society vs. fusion

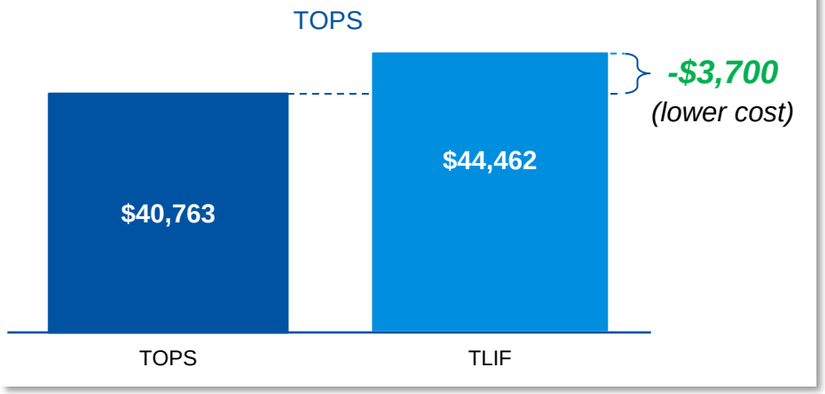
Quality of Life Year (QALY)

Cost

Health Systems economic impact

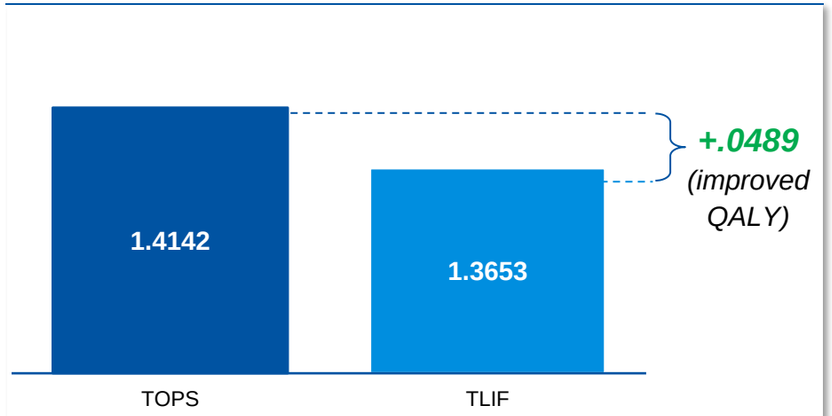
2-year actual TOPS vs. Control (TLIF)

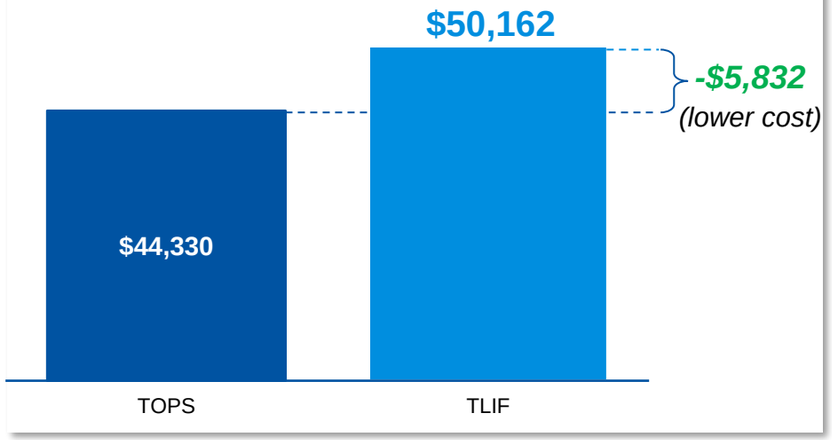




Societal economic impact

2-year actual TOPS vs. Control (TLIF)





✓ ***Dominant outcome for health systems, society and payers with improved quality of life at lower economic cost***

Source: JHEOR. *2022;9(1)*:82-89

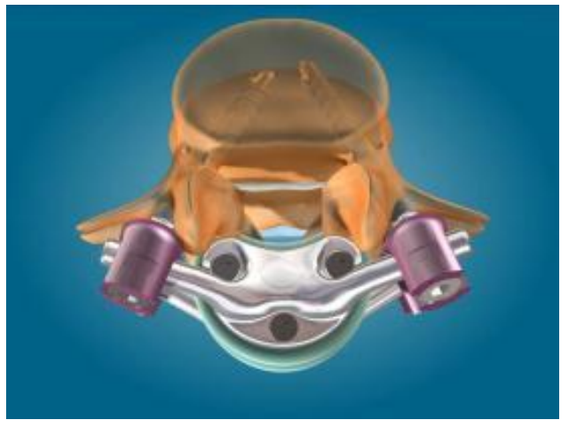
TOPS System

History

- Original device conceived (2003)
- First implantations: Brazil, 2005; Israel, 2006; USA, 2007
- Re-designed the implant after acquisition (2011)
  - 30% smaller than the original device
  - Simplified surgical technique
- Launched the device commercially in Europe (2012)
- Initiated new FDA study (2017)
- FDA approval (2023)

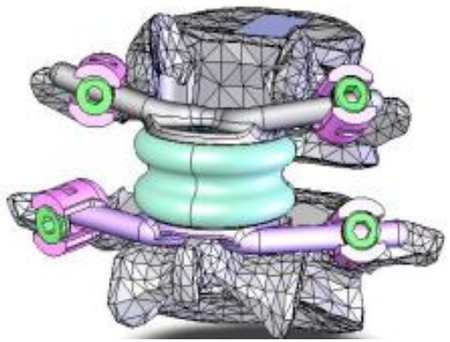
TOPS Screw-to-Bone Interface

- TOPS⁻ worldwide screw loosening rate < 1% with 18 years of clinical usage (n>7,000 screws)
- TOPS⁻ benefits from unique surface treated screw and crossbar design
- Screw threads undergo patented surface treatment which includes blasting with calcium phosphate particles to roughen screw's surface
  - Screw pull out force is 2.32 times greater than standard polished screws
- Device's two crossbars connect two pedicle screws of the same vertebra
  - Prevents screw micro-motions
  - Minimizes risk of screw loosening

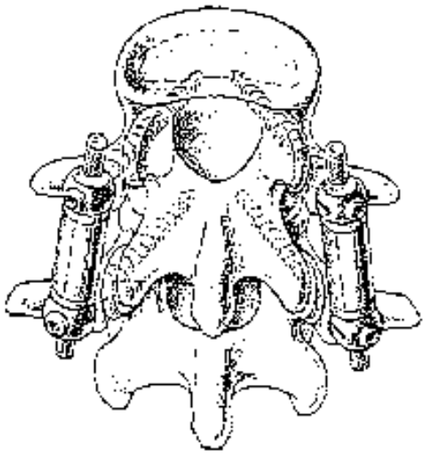


TOPS Screw-to-Bone Interface

TOPS™ connects to pedicle screws of the SAME vertebra



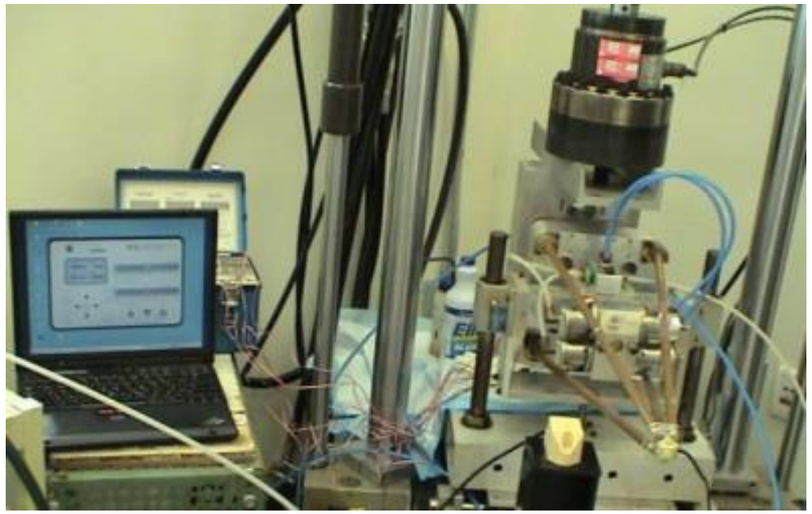
DYNESYS™ connects to pedicle screws of two DIFFERENT vertebra



- Rotational torque load at the screw-bone interface is much less with the TOPS cross- bar concept
- The most problematic load, in terms of screw loosening, is rotation of the screw. This is prevented by TOPS design

TOPS Screw-to-Bone Interface

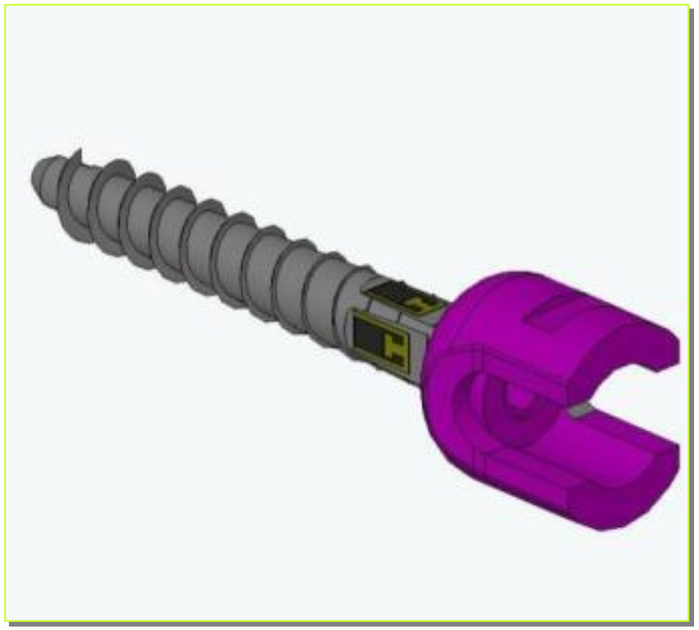
What are the comparative loads on the pedicle screws between the TOPS™ System and the Dynesys™?

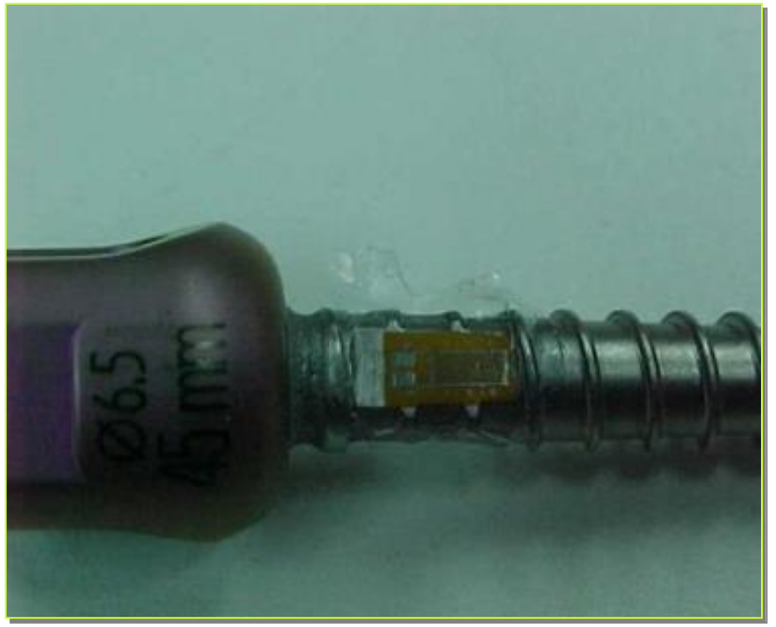


Does the TOPS™ System design lend itself to load sharing among all four screws?

TOPS Screw-to-Bone Interface

Pedicle screw and strain gauge assembly



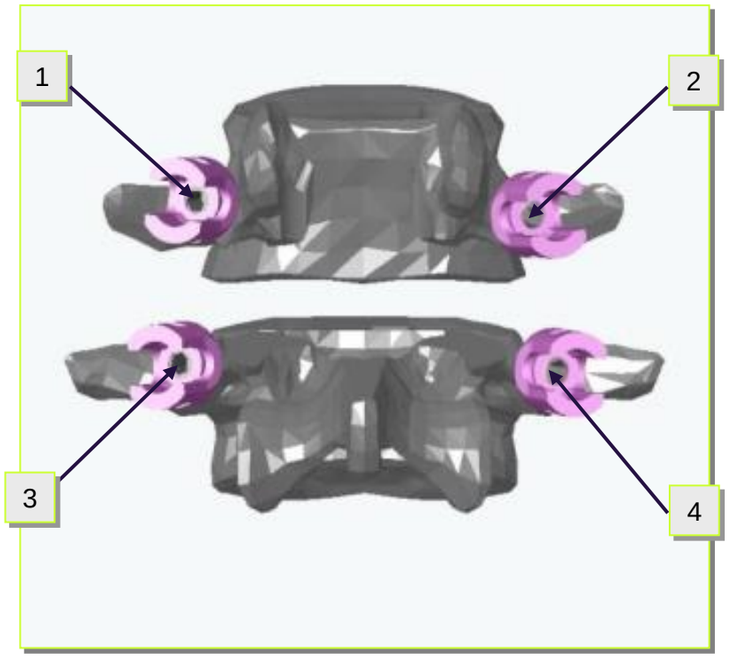


Pedicle screw: Ø6.5x45 mm, with four grinded surfaces for strain gauge bonding.

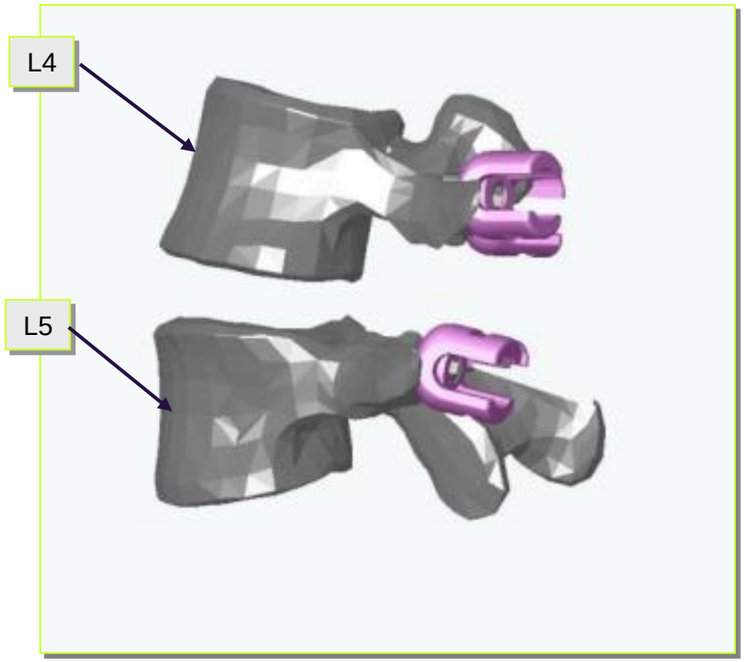
Strain gauge: Vishay 125BZ

TOPS Screw-to-Bone Interface

System Layout



Posterior view



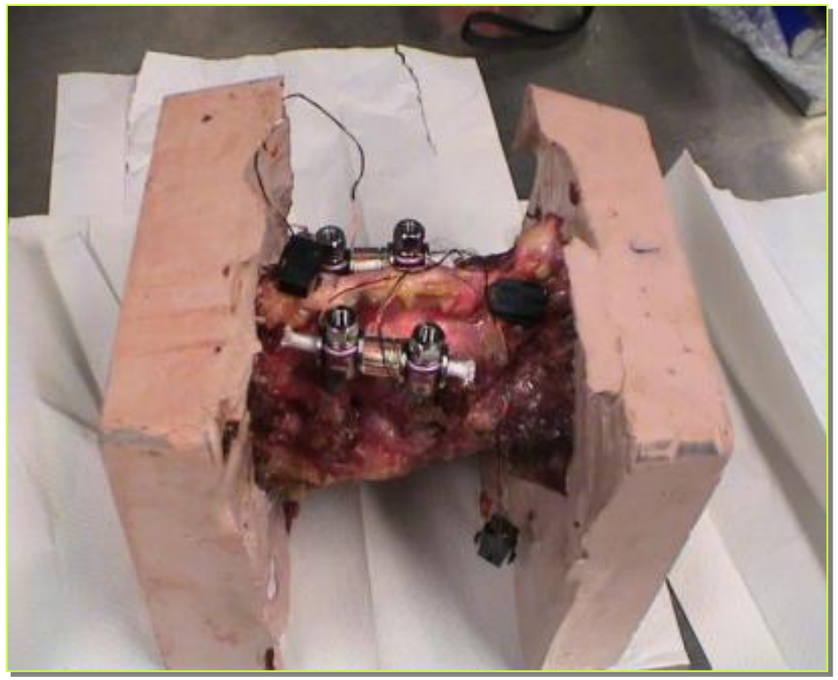
Lateral view

Source: Professor Tim Wright, Hospital for Special Surgery, Biomechanical Laboratory. Pure moments applied (± 10Nm) with preload (630 N) for flexion, extension, and right and left lateral bending. Insertion of pedicle screws. Placement of Dynesys according to its IFU and measurements. Laminectomy and facetectomy and then insertion of TOPS System and measurements.

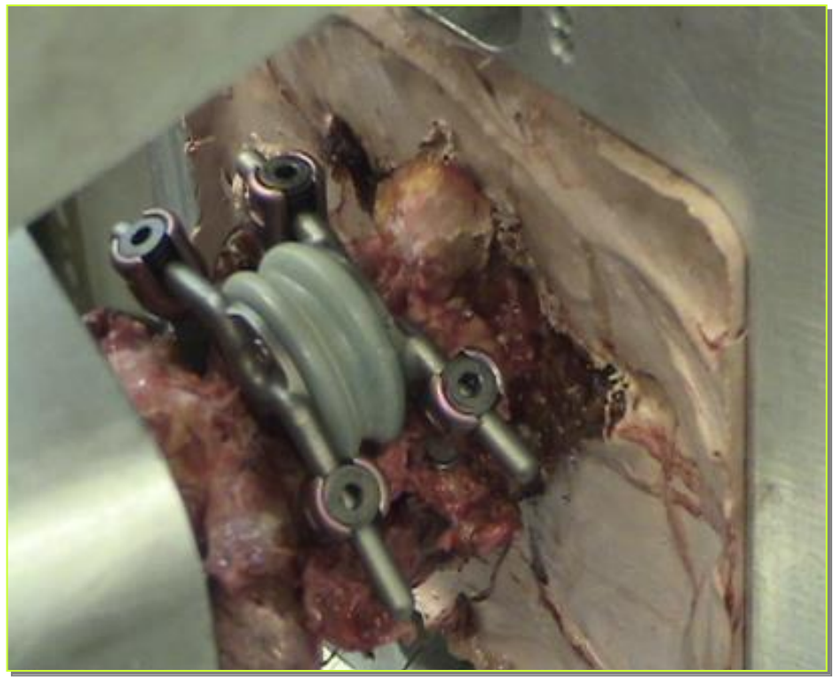
1

TOPS Screw-to-Bone Interface

Cadaver setup



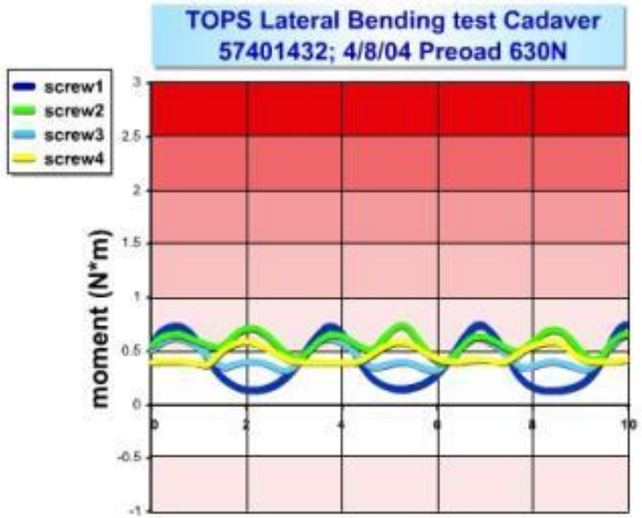
Dynesys ™ System

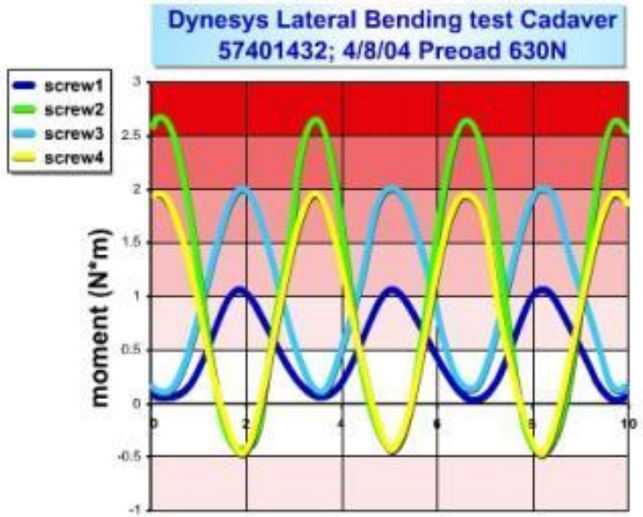


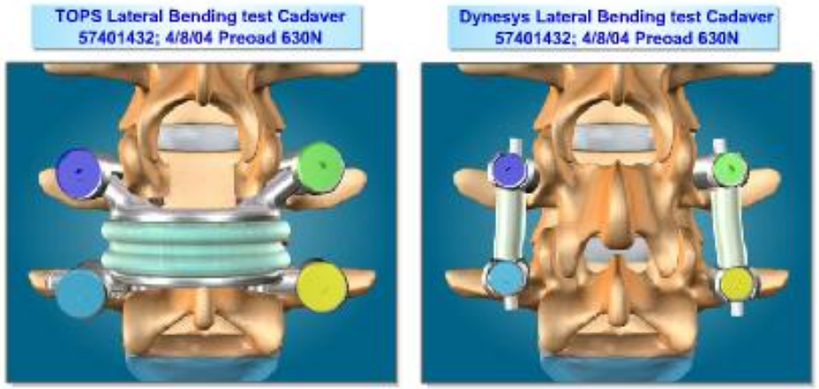
TOPS™ System

1

TOPS Screw-to-Bone Interface







1

HSS Study Conclusions

Moment on the screw heads is significantly lower with the TOPS™ System than with the Dynesys™ System

- **36% lower in flexion-extension**
- **46% lower in lateral bending**

TOPS™ System demonstrates better ROM than the Dynesys™ System

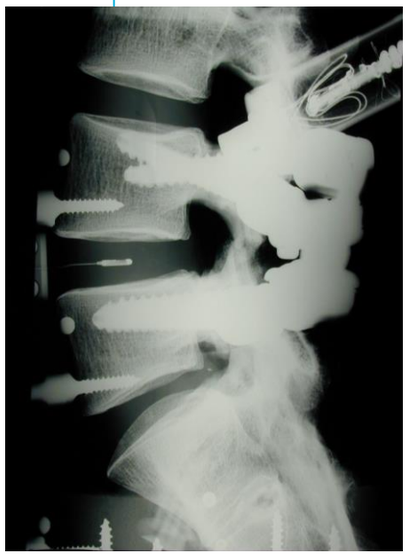
K. Meyers, T. Wright et al Spine Journal 8 pp. 926-932 2008

TOPS—ROM TESTS

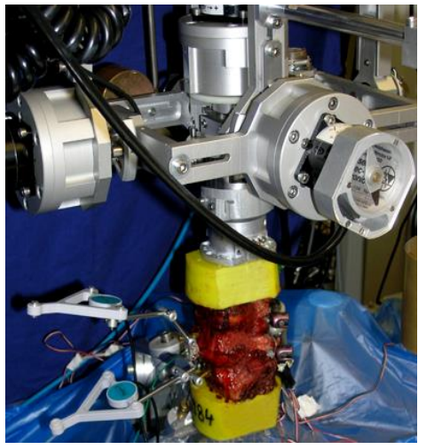
- Pure moments ± 7.5 Nm
- Flexion / extension
- Lateral bending right / left
- Axial rotation left / right

} ROM, NZ from 3rd cycle

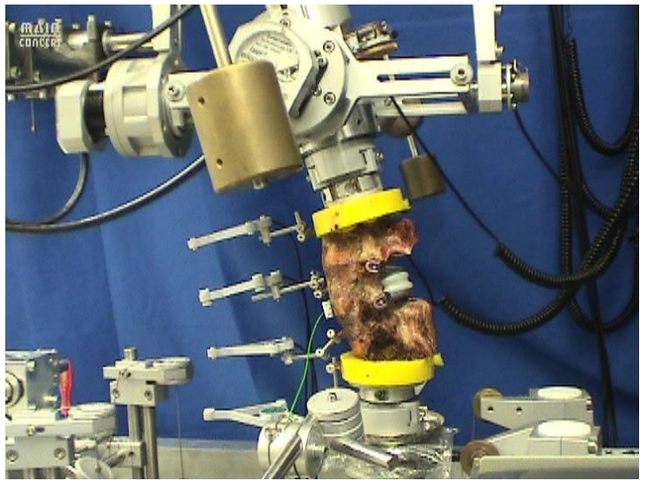
- Without preload
- Measurement of the intradiscal pressure
- ROM in axial rotation as a function in different flexion/extension postures: 2°/ NP / -1°/ -2°/ -3°/ -4°



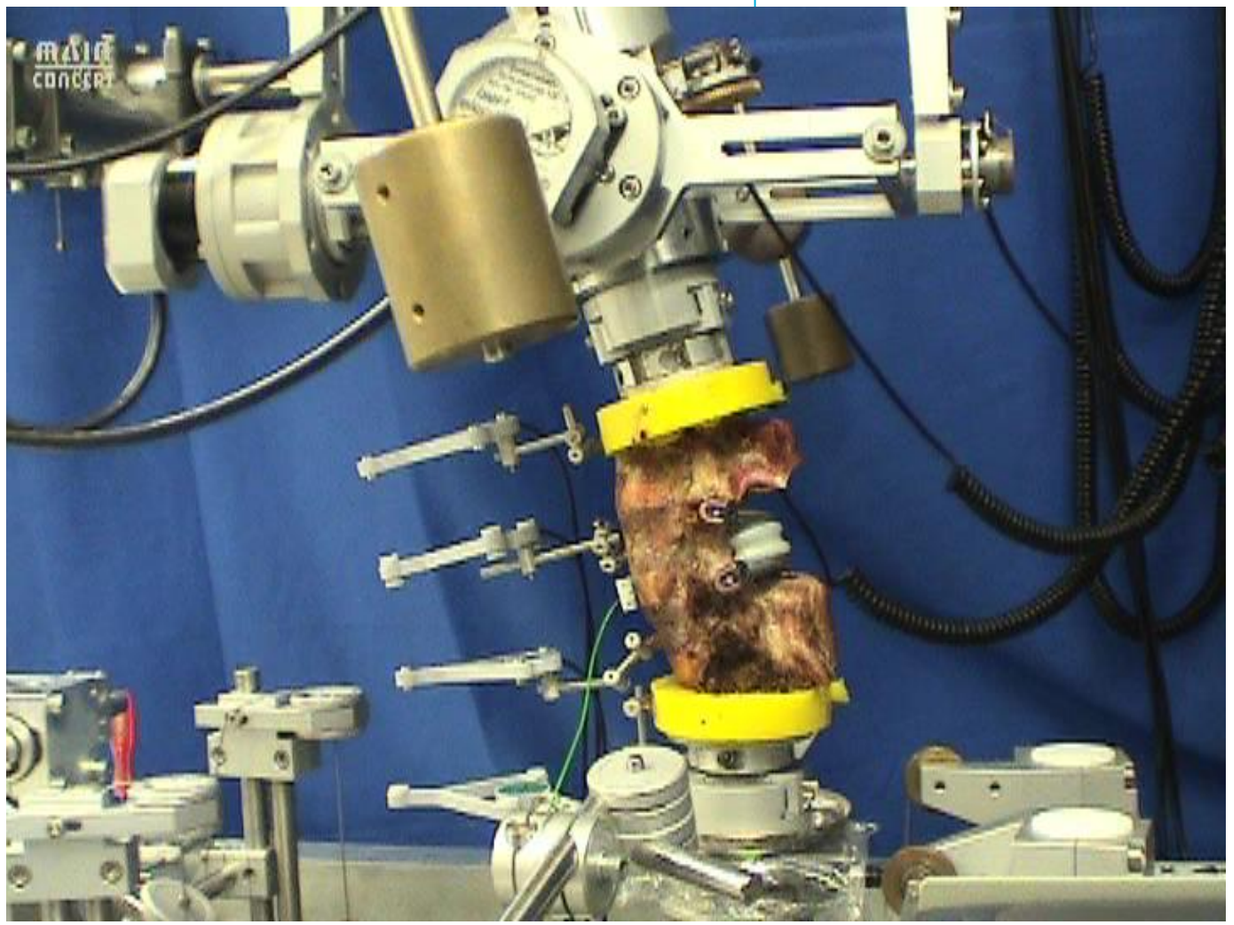
Intradiscal Pressure Sensor



Zebris Motion Analysis System

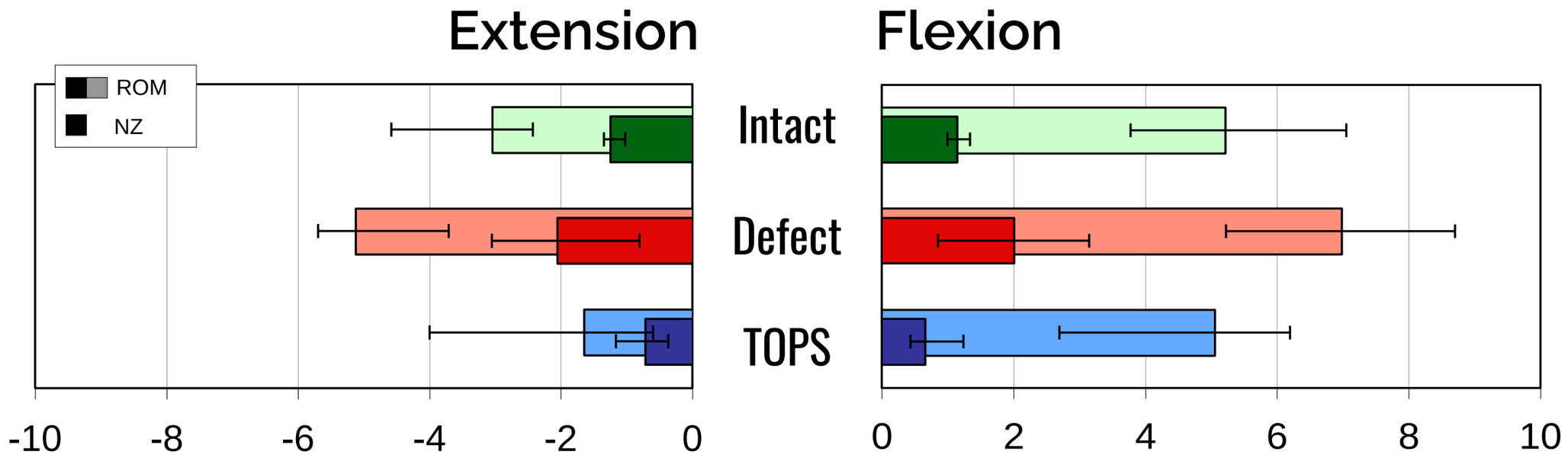


TOPS—ROM TESTS



TOPS—ROM RESULTS

ROM – Primary Stability



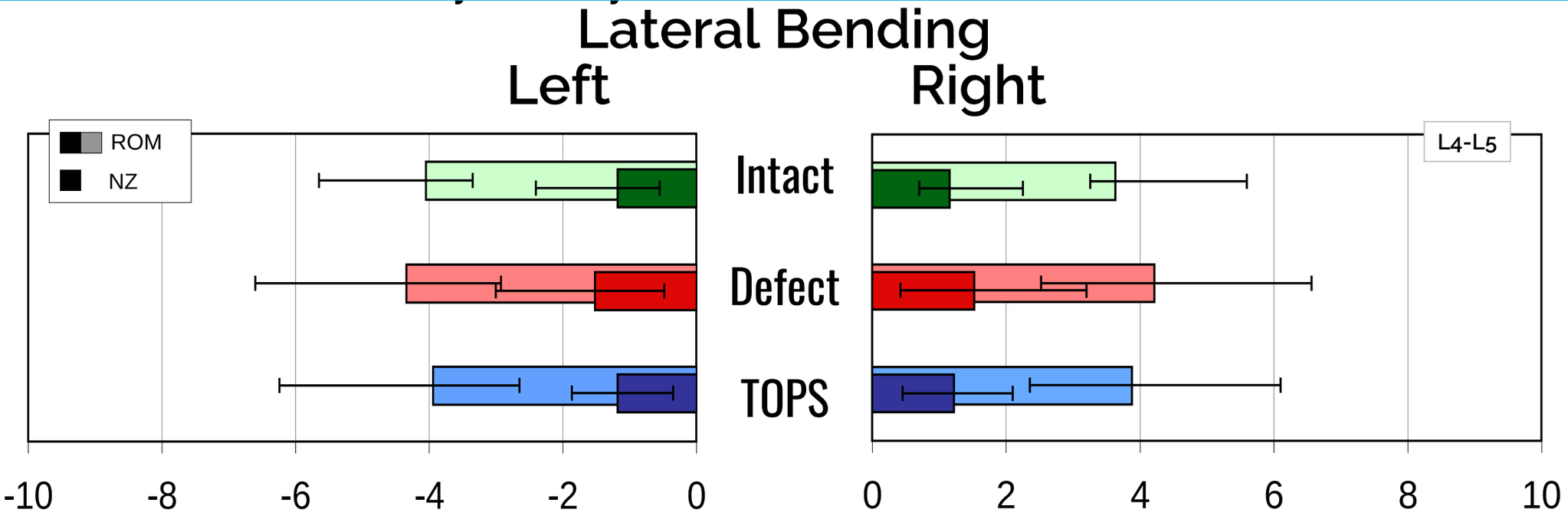
ROM in Degrees at +/- 7.5 Nm

* : p< 0.05, Wilcoxon Signed Rank Test

Source: HJ Wilke, Spine, Nov. 15, 2006

TOPS—ROM RESULTS

ROM – Primary Stability



ROM in Degrees at +/- 7.5 Nm

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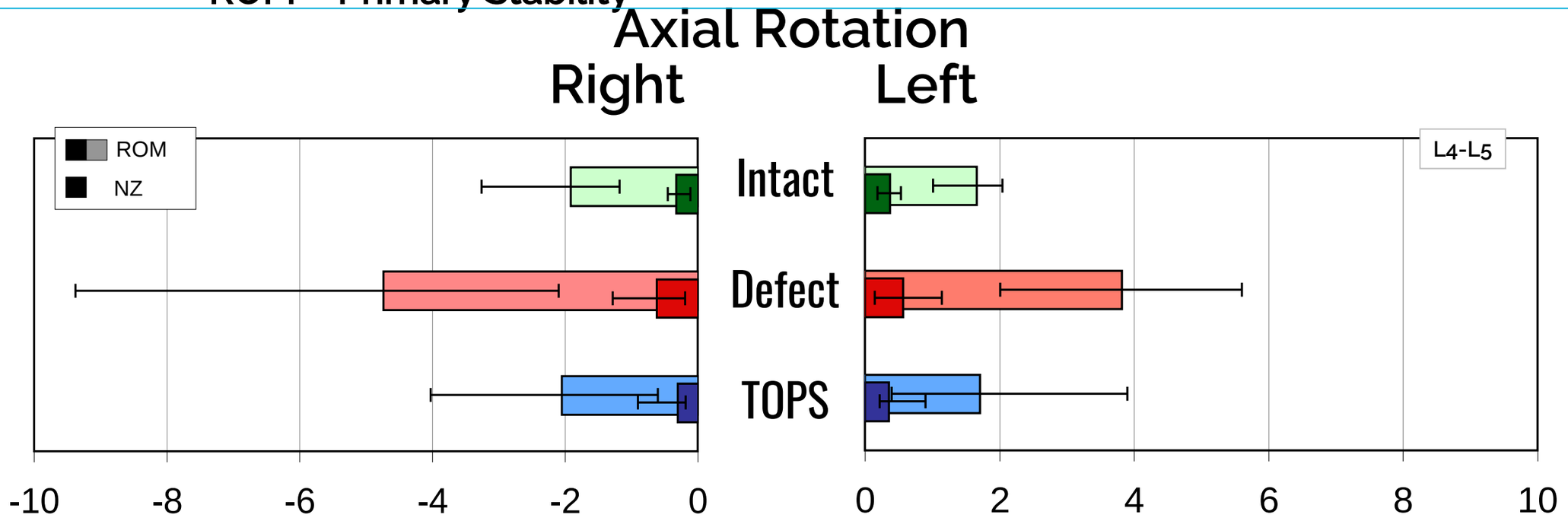
TOPS—ROM RESULTS

ROM – Primary Stability



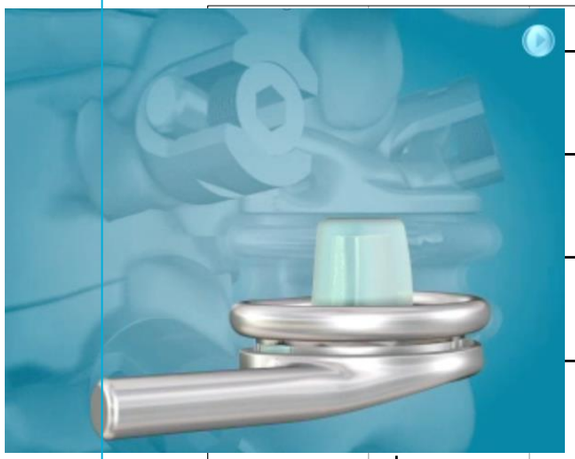
ROM in Degrees at +/- 7.5 Nm

* : p< 0.05, Wilcoxon Signed Rank Test

Source: HJ Wilke, Spine, Nov. 15, 2006

TOPS—ROM RESULTS

ROM – as a function of different flexion/extension postures

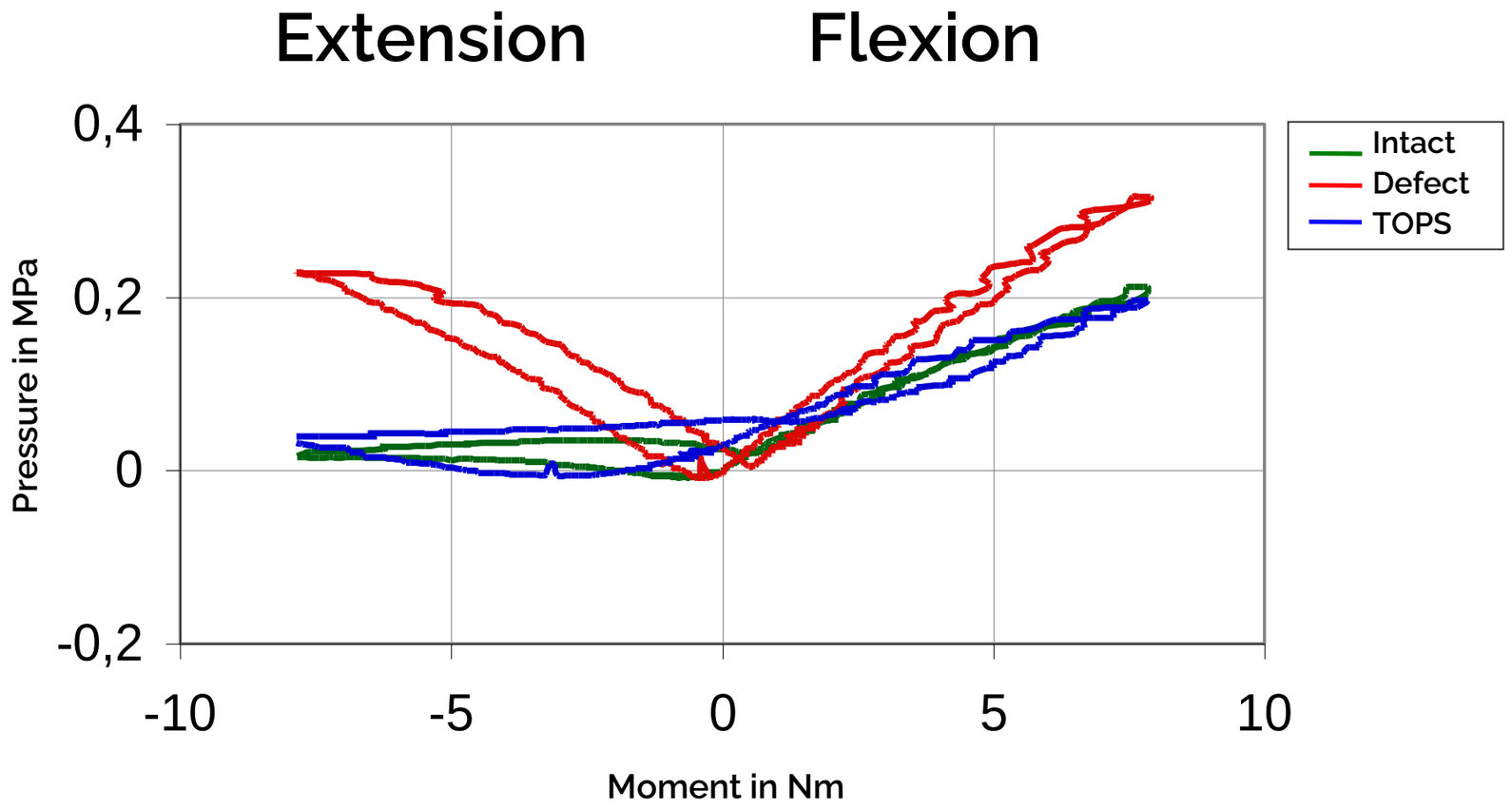


Range of Motion in ° at +/- 7.5 Nm

Source: HJ Wilke, Spine, Nov. 15, 2006

TOPS—ROM RESULTS

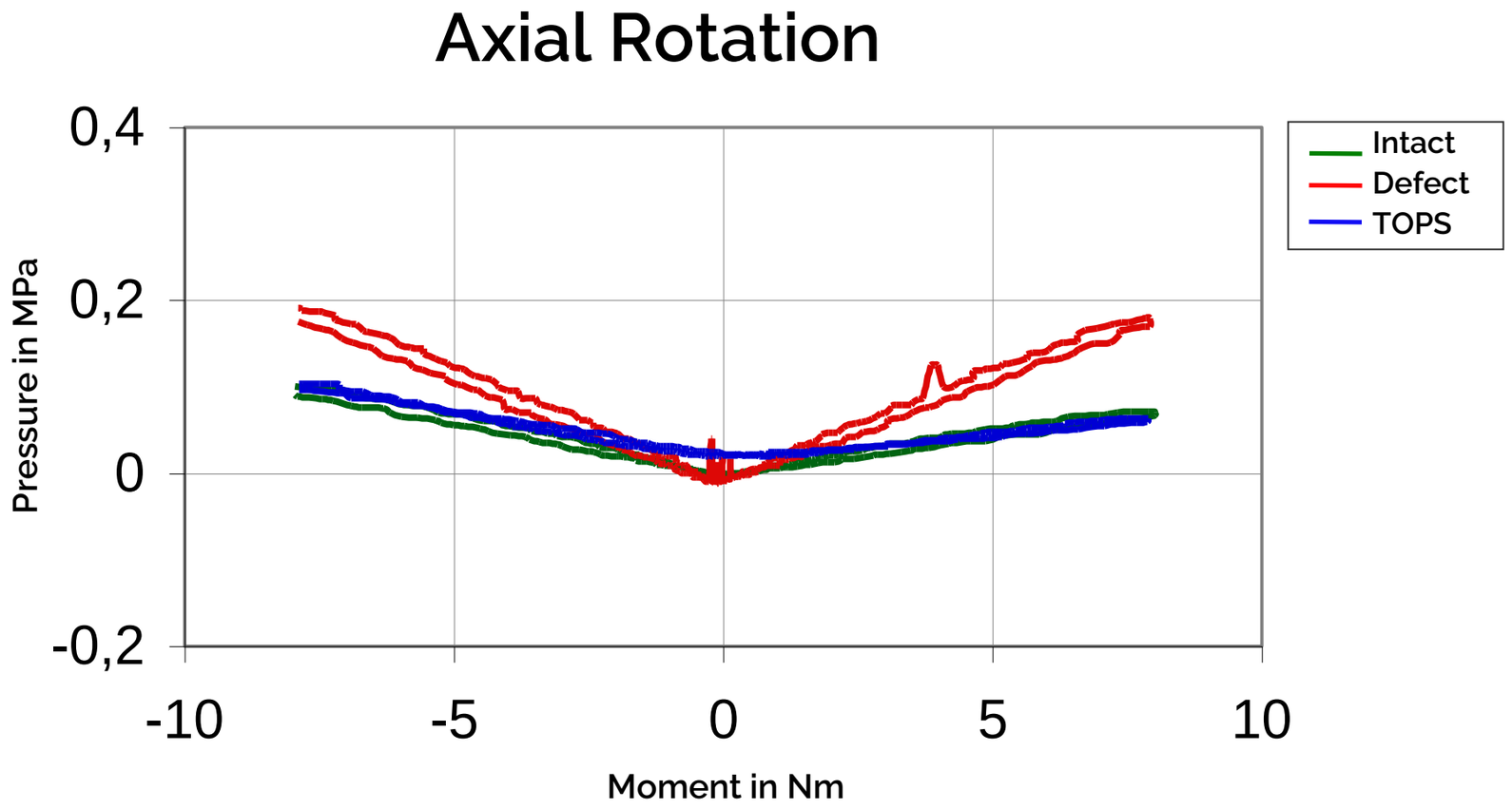
Intradiscal Pressure



Source: HJ Wilke, Clinical Biomechanics, 27 (2012) 218–225

TOPS—ROM RESULTS

Intradiscal Pressure

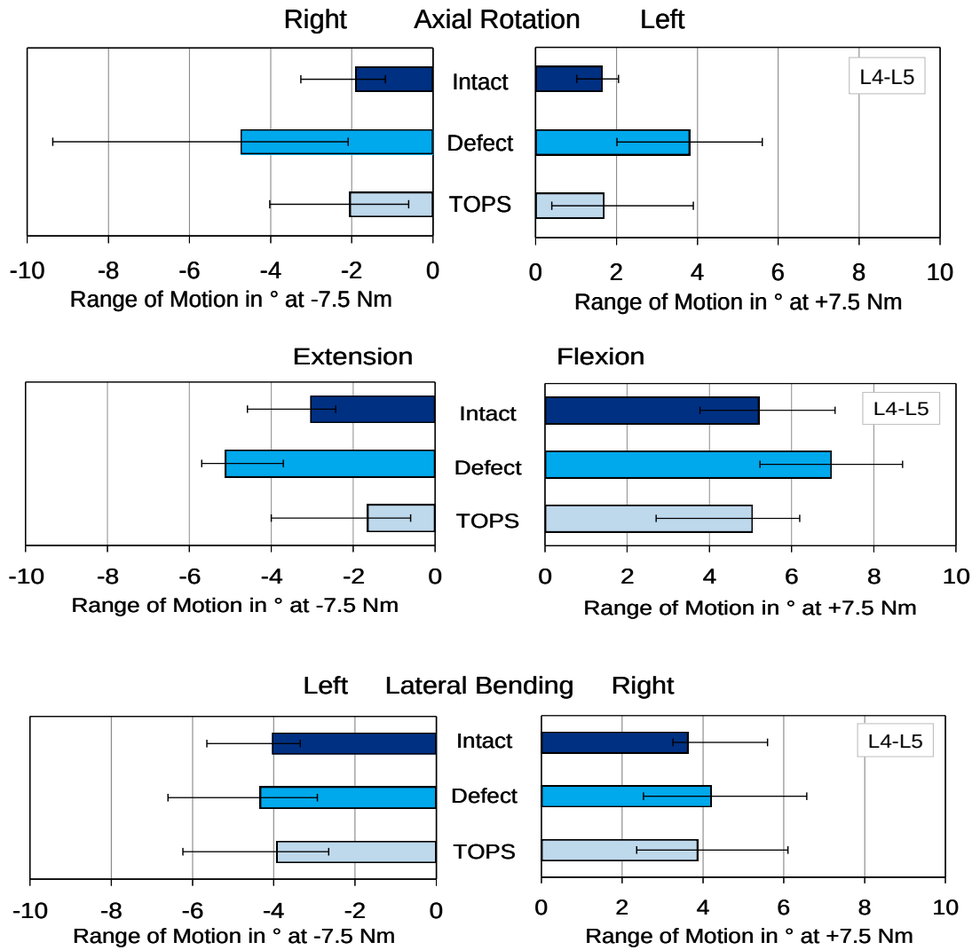


Source: HJ Wilke, Clinical Biomechanics, 27 (2012) 218–225

Range of Motion

TOPS provides normal range of motion after destabilization of the spine segment

- Restabilizes motion in flexion, extension, lateral bending, axial rotation, and sagittal translation
- Preserves the level of motion patients had prior to surgery



Source: HJ Wilke, Spine, Nov. 15, 2006

Quality of Motion

TOPS also recreates physiologic quality of motion after decompression

- The quality motion with TOPS is similar to the native segment in transition across all directions of movement

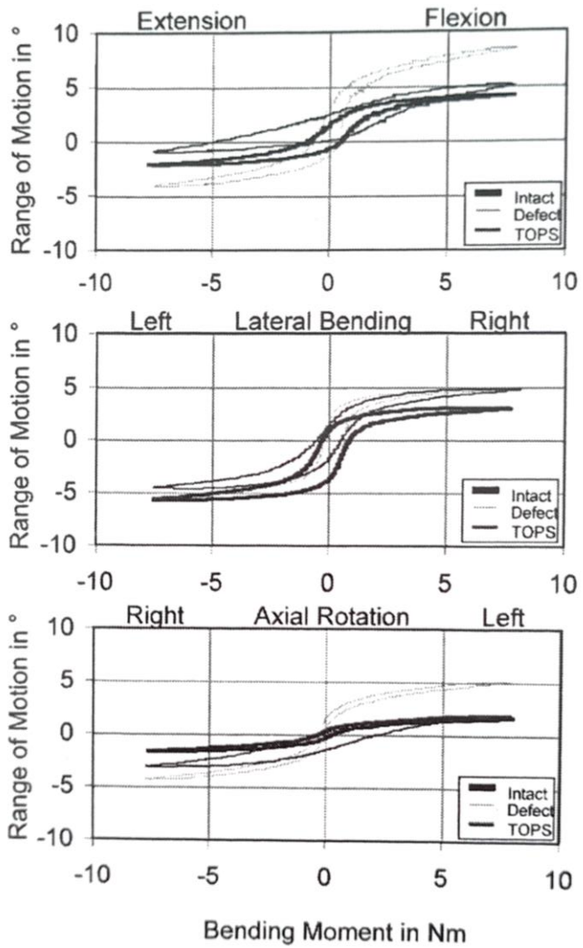


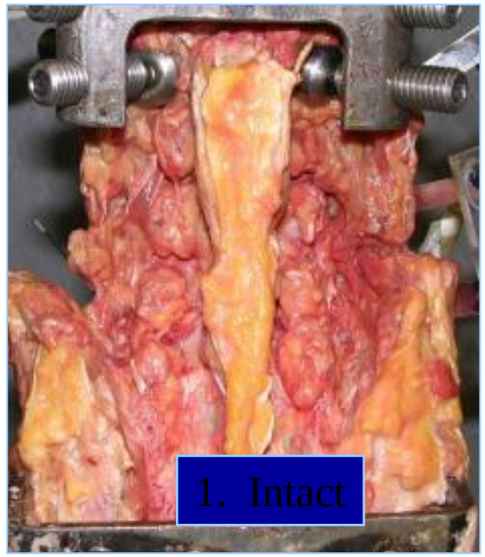
Figure 3. Exemplary load-displacement hysteresis curves in the 3 motion planes. The conditions intact, defect, and with TOPS implant were tested.

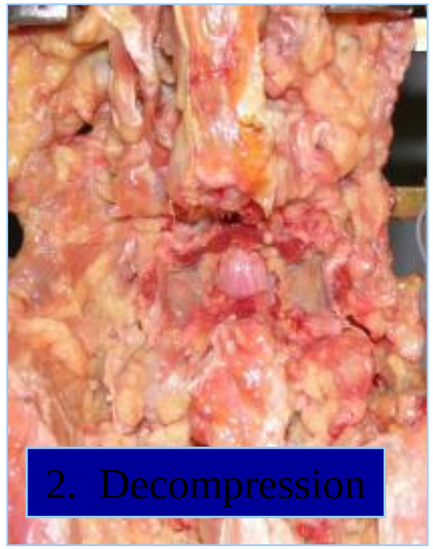
Source: HJ Wilke, Spine, Nov. 15, 2006

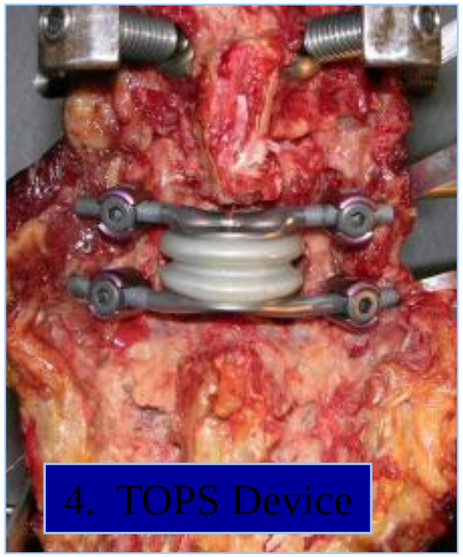
Why is Motion Important

- Measurement of both global and segmental range of motion at baseline, after decompression, after fixation, and after TOPS

- Intact measurements serve as baseline (100%) for other measurements

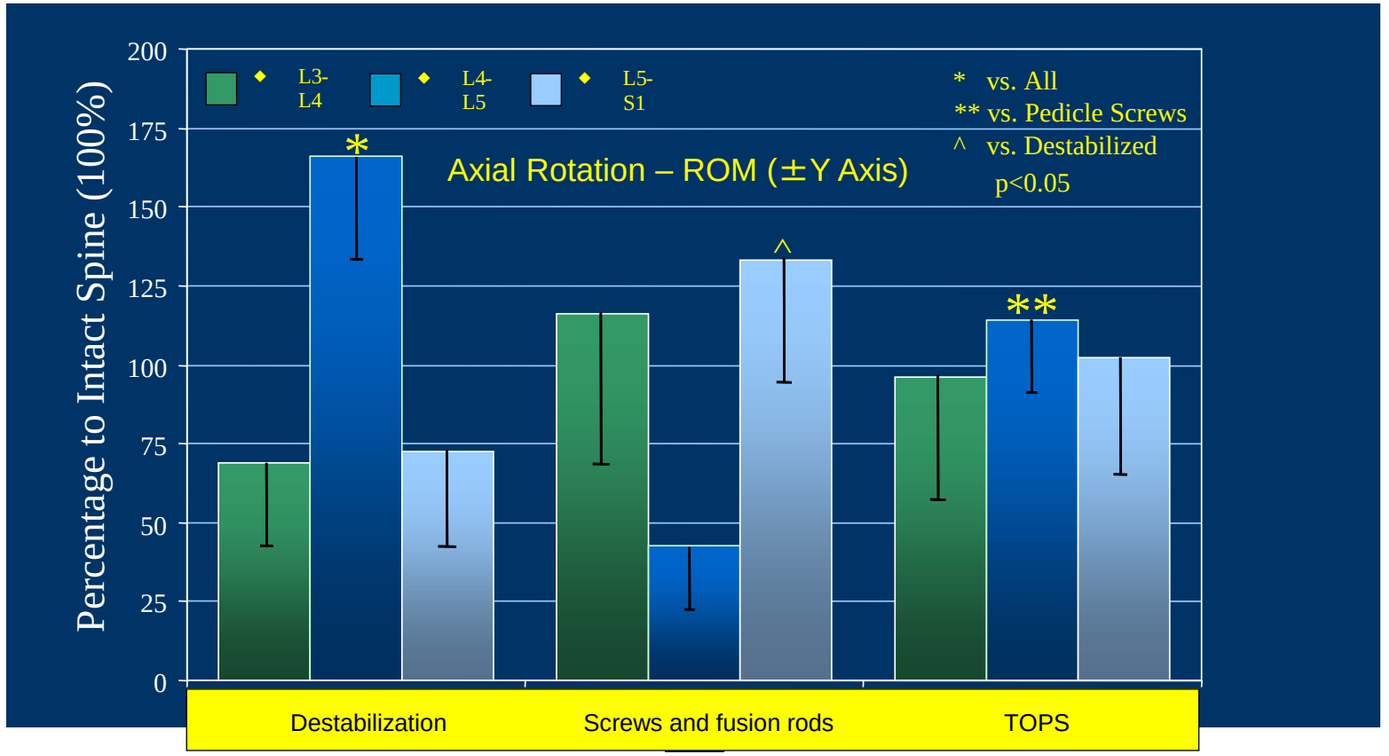






TOPS Protects Adjacent Levels

Normal motion protects the adjacent levels



Source: BW Cunningham, MSc, Orthopaedic Spinal Research Laboratory, Towson, MD

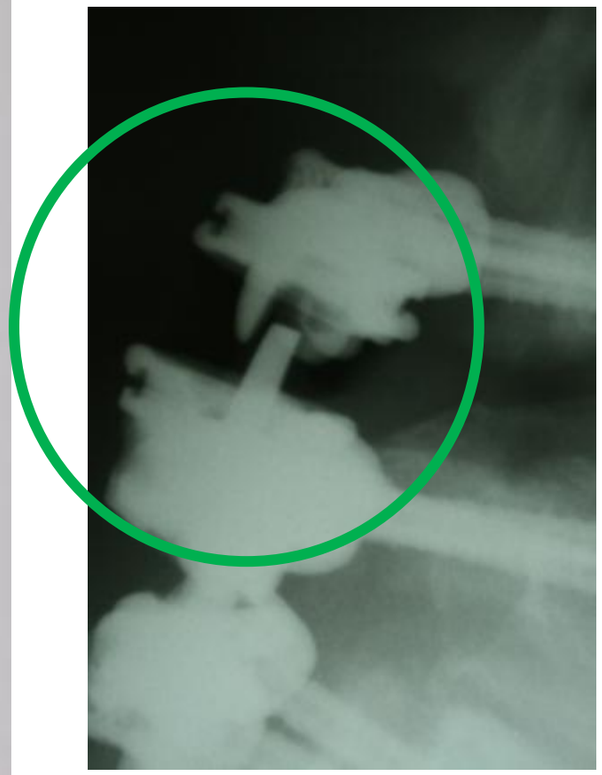
Only Device of Its Kind

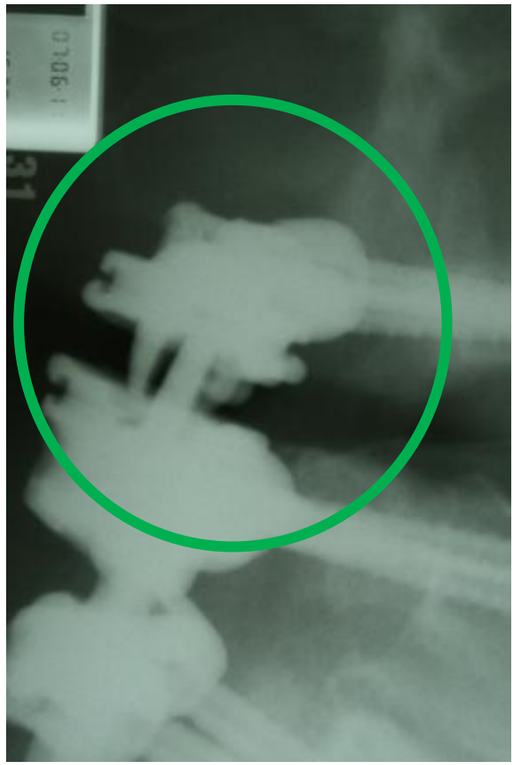
Normal motion protects the adjacent levels

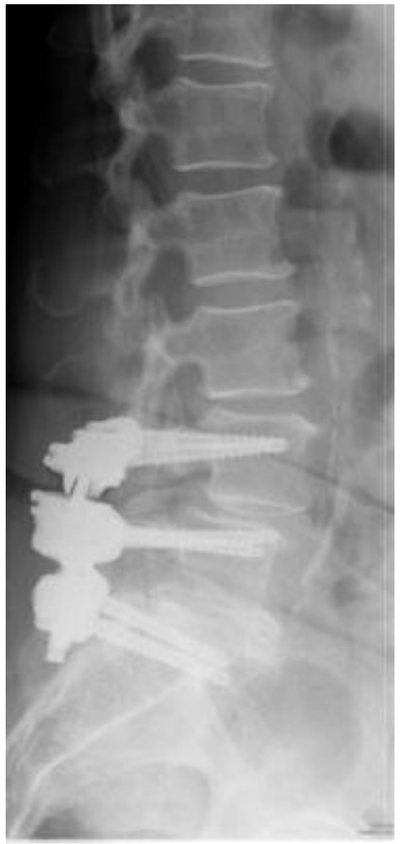
https://www.youtube.com/watch?v=ZyH7VCUY36g&feature=youtu.be

Versalink in Europe

TOPS System with an adjacent level fusion

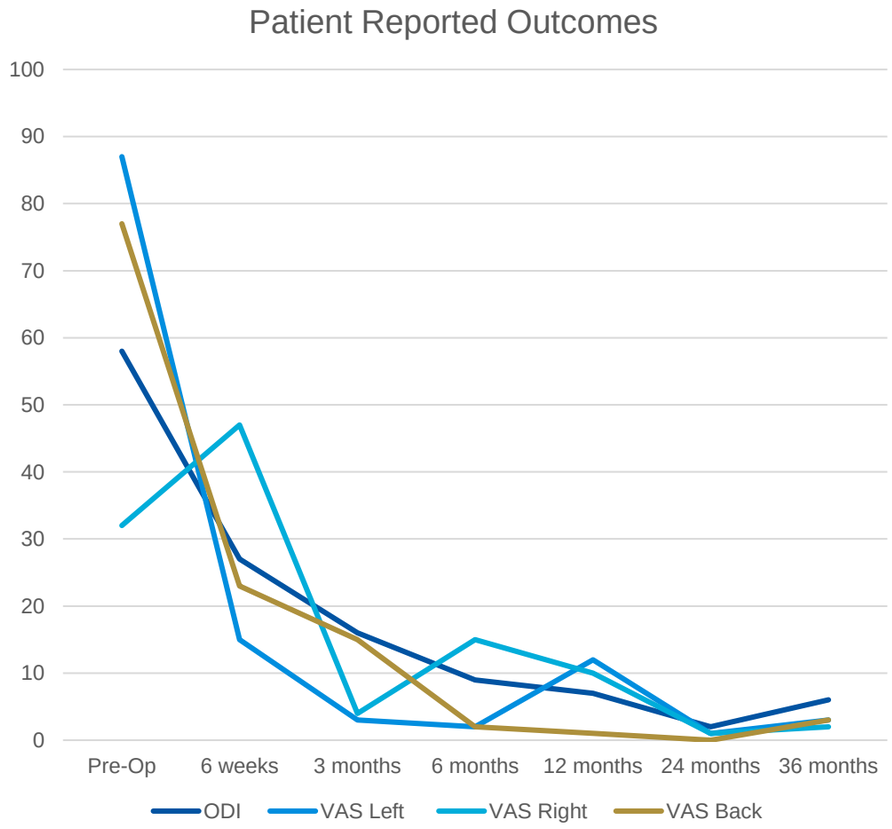


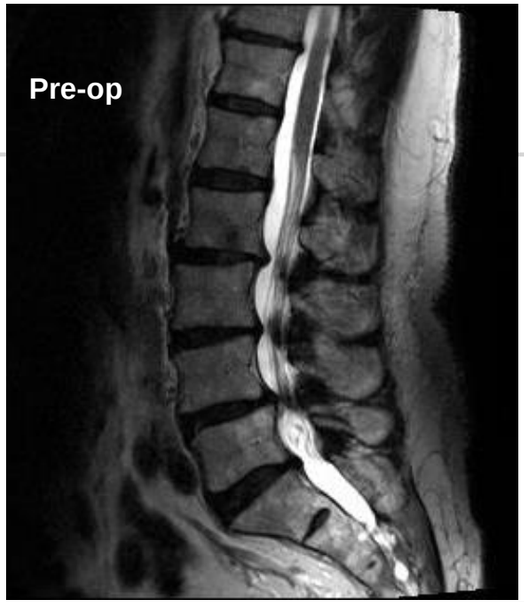


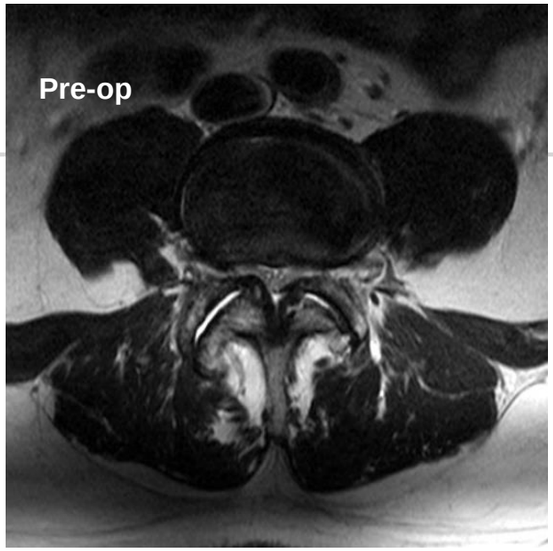


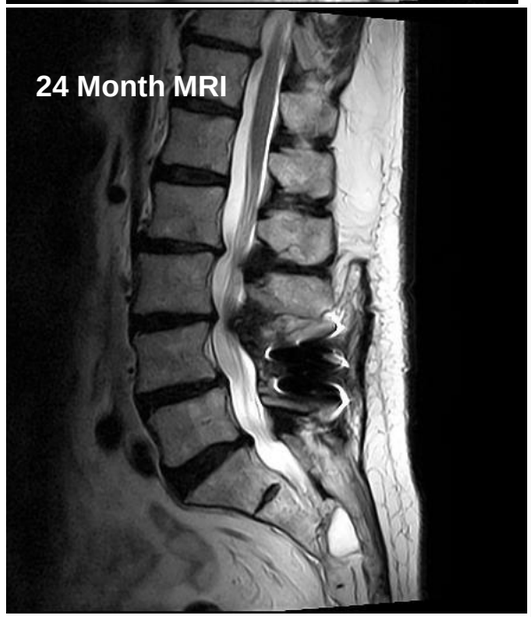
Case Study from IDE

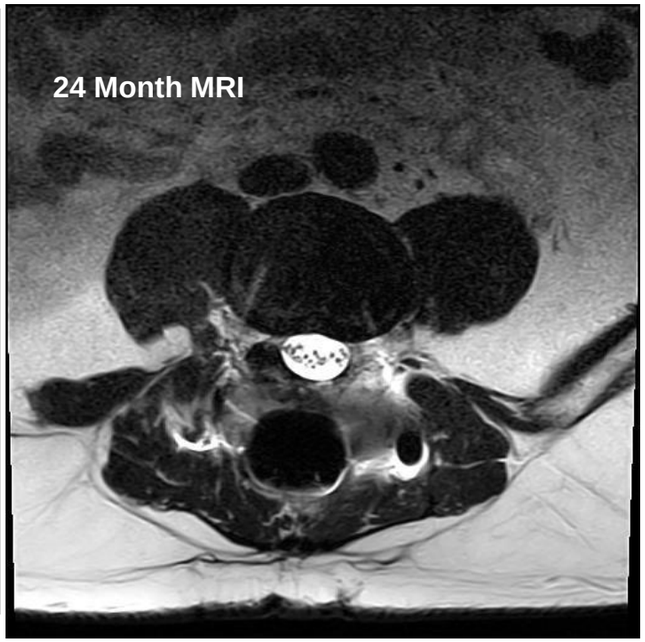
- 71 y/o male (BMI 31.3)
- Single level severe stenosis at L4/5 with Grade I spondylolisthesis, moderate stenosis L3/4
- Complete L4 laminectomy with complete L4/5 bilateral facetectomies





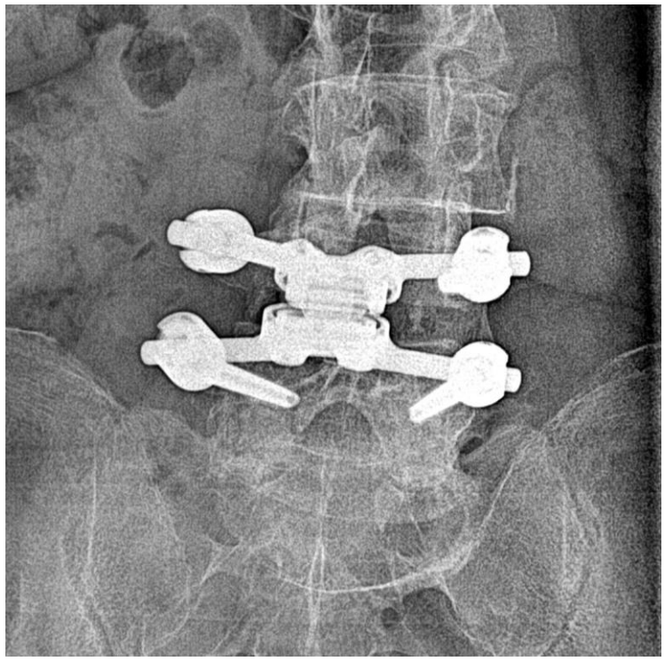




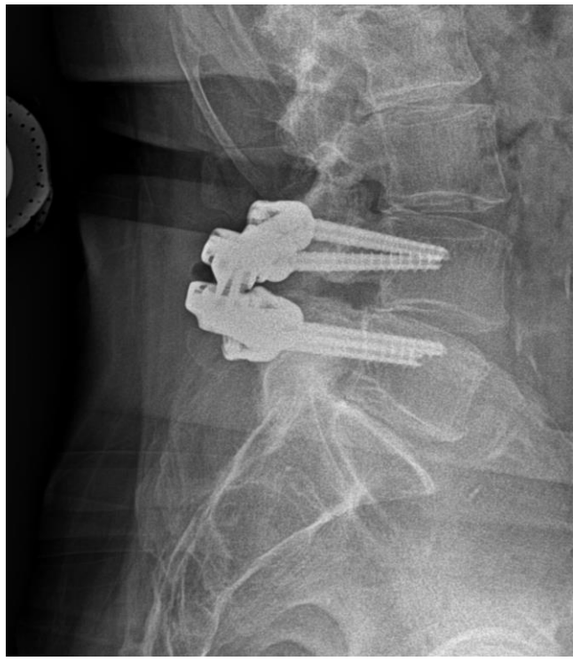


Case Study from IDE – 24 Months

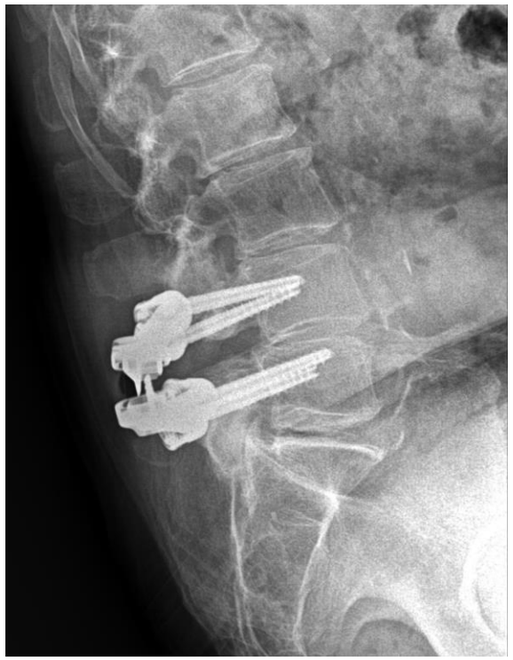
AP



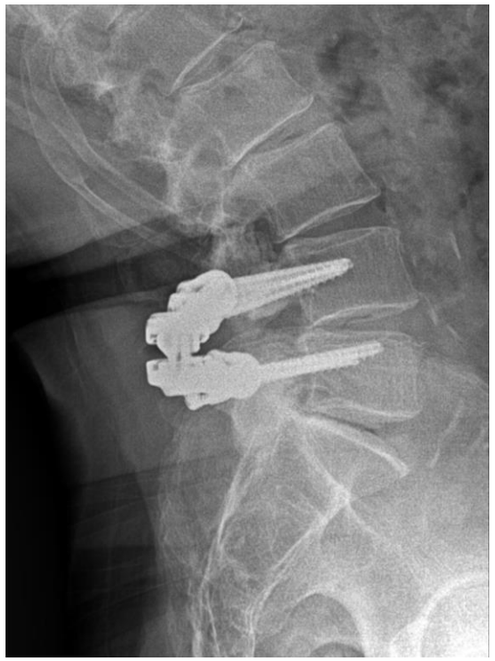
Neutral



Flexion



Extension



Radiographic Measurements – Treated Level

	Angular Motion (FlexEx)	Translational Motion (FlexEx)	Angular Motion (Lateral Bend)	Average Disc Height
Pre-Op	1.6	0.6	0.4	8.1
12 months	8.6	2.1	5.2	N/A
24 months	8.1	2.1	10.7	7.1

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
Alquiza/Rumler	0	0	3	4	3	2	1	0	0	0	0	0	0	13
Bang	0	0	0	0	1	0	6	6	0	0	0	0	0	13
Bierstedt/Illerhaus/Roberg	18	24	38	22	34	33	30	32	26	52	63	6	4	382
Boettcher	0	0	0	0	0	11	24	21	29	14	14	1	1	115
Boluki	0	0	0	0	4	0	0	0	0	0	0	0	0	4
Danne/Meier/PD DrLemcke	0	0	6	5	4	6	6	2	6	7	7	16	3	68
Dienel/Kiriyanthan	0	0	0	7	4	0	0	0	0	0	0	0	0	11
Dorre	0	0	0	0	21	0	0	0	0	0	0	0	0	21
Glocker	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Grimm	0	0	3	7	6	5	2	3	3	1	3	2	1	36
Haritz/(Adelt)	0	0	0	18	0	0	0	0	0	0	0	0	0	18
Igressa/Bulmus/Sadowy/El Khatib/(Weber)	0	0	10	8	2	0	0	0	0	0	0	0	0	20
Laupichler	0	0	12	21	23	18	8	9	9	8	12	6	8	134
Müller-Broich	0	0	0	3	0	0	0	0	0	0	0	0	0	3
Paschalidis	0	0	0	24	0	0	0	0	0	0	0	0	0	24
Pippan/Reith	0	32	33	34	10	3	7	0	5	4	3	6	3	140
Reuland	0	0	0	1	0	0	0	0	0	0	0	0	0	1
Ropers/Adelt	0	0	0	0	0	7	0	0	0	0	0	0	0	7
Salger	3	0	0	0	0	0	0	0	0	0	0	0	0	3
Schneider	0	0	1	0	0	0	0	0	0	0	0	0	0	1
Schul/Krammer/Tomassino/Lumenta	0	0	0	7	0	0	0	0	0	0	0	0	0	7
Stosberg/Meisel/Bone	0	0	0	7	3	0	2	3	1	0	0	0	0	16
Vosberg	0	2	0	0	0	0	0	0	0	0	0	0	0	2
Lay/Woltering	0	0	7	5	0	0	0	0	0	3	5	3	0	23
Wonke/Makki/Assaf/Schuster	0	0	0	0	3	0	0	0	0	0	0	0	0	3
Youssef/Gruber/Soos/Al-	0	0	0	20	14	11	16	25	3	0	0	0	23	112
Prof.Bertagnoli/ Sramek	0	0	0	0	0	0	2	1	0	0	0	0	0	3
Dr.Hejazi	0	0	0	0	0	0	1	0	0	0	0	0	0	1
Prof. Boszczyk /Bengel	0	0	0	0	0	0	1	9	3	0	0	0	0	13
Dr.U.Knappe	0	0	0	0	0	0	0	0	1	2	0	0	0	3
Dr.Amir Zolal	0	0	0	0	0	0	0	0	0	2	0	0	0	2
Tim Rumler von Rüden	0	0	0	0	0	0	0	0	0	0	1	0	0	1
Dr.Schreiber	0	0	0	0	0	0	0	0	0	0	0	6	8	14
Dr.Schnake	0	0	0	0	0	0	0	0	0	0	0	1	0	1
Dr.Eif	0	0	0	0	0	0	0	0	0	0	0	1	6	7
Dr.Bludau	0	0	0	0	0	0	0	0	0	0	0	1	2	3
Dr.Kaminski	0	0	0	0	0	0	0	0	0	0	0	7	21	28
Dr. Tschan	0	0	0	0	0	0	0	0	0	0	0	0	3	3
Total	21	58	113	193	132	97	106	111	86	93	108	56	83	1257