HOSPITAL FOR SPECIAL SURGERY

Comparison of Decompression with Interlaminar Stabilization vs. Decompression with in Patients Requiring 2 Levels of Surgical Treatment for Spinal Stenosis

Rachel Simon, **Christina Dowe**, Samuel Grinberg,
Frank P. Cammisa, Jr., M.D., Celeste Abjornson, Ph.D.
Integrated Spine Research Program
Hospital for Special Surgery
New York, NY, USA

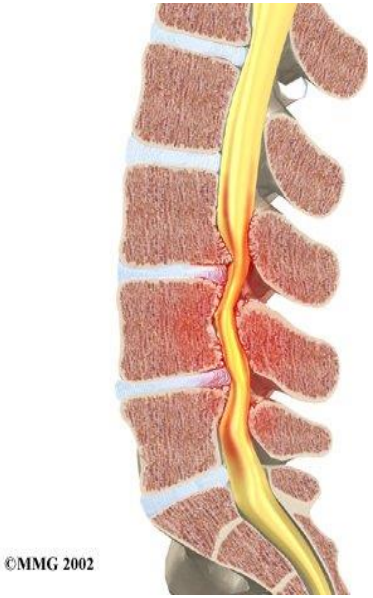
Background

Current Accepted Treatment Options for Lumbar Spinal Stenosis

Non-Surgical Conservative Care
- Epidural Steroid Injections
- Pain medications
- Physical Therapy

Symptoms persist >12 weeks[1]

Surgical Treatment Options



Decompression Alone

Decompression with Fusion

Studies have looked at surgical treatment options in general cohorts of stenosis patients, but have not specifically examined the longevity of multi-level surgical treatments

[1]Weinstein, *NEJM*, 2008

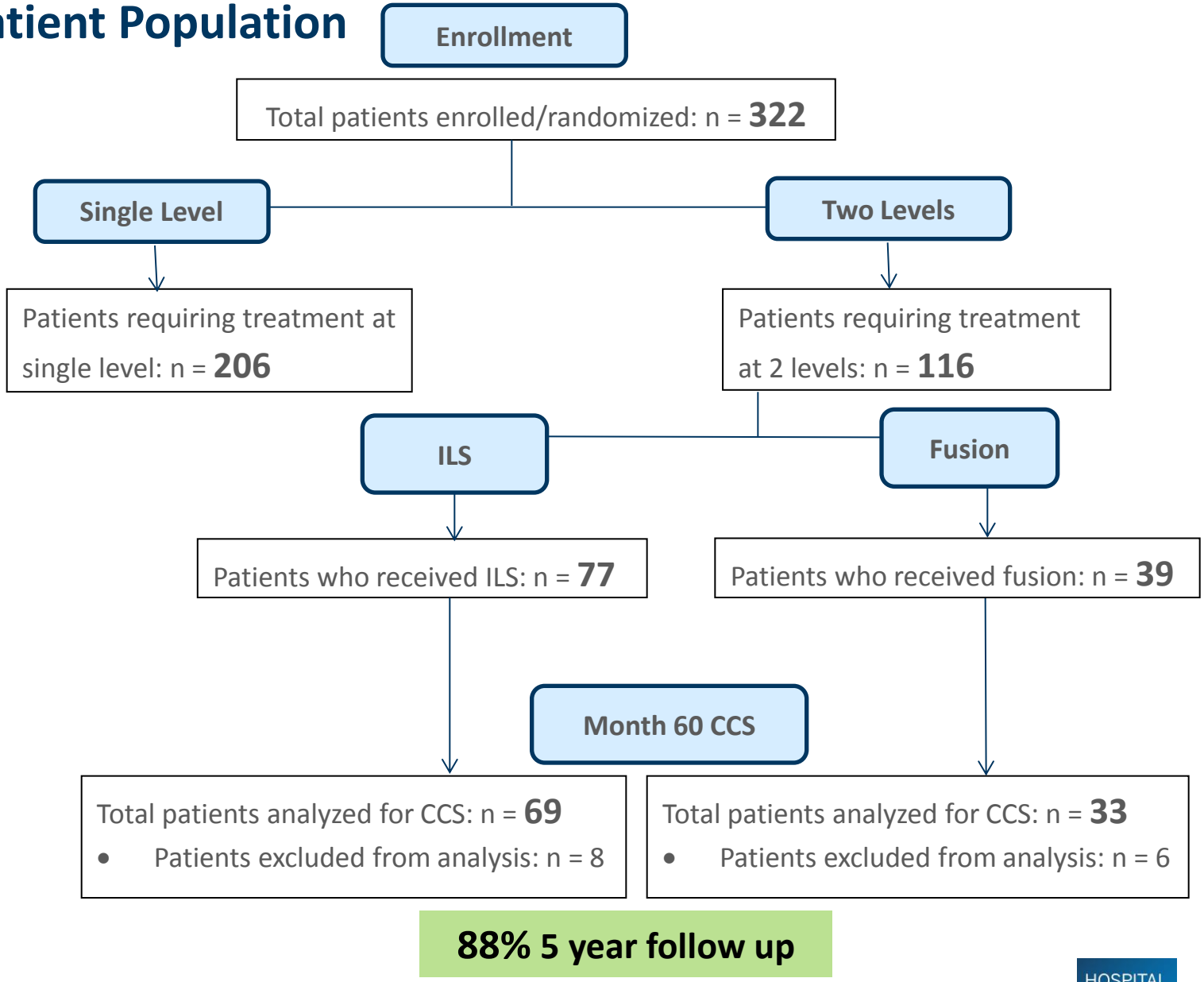
Interlaminar stabilization (ILS)

- **Hypothesis: ILS is a viable alternative to decompression with fusion for treating two levels of spinal stenosis**
  - Example: coflex® (Paradigm Spine, NY, NY) ILS device achieved FDA PMA approval, for up to a Grade I spondylolisthesis, in 2012
  - U-shaped device, fixed **between lamina** after decompression
  - Goals:
    - **Unload** facet joints
    - **Stabilize** the motion segment
    - **Maintain** the neurological decompression & foraminal height
    - **Preserve** some motion

Until now, the two-level experience of ILS compared to instrumented fusion has not yet been formally analyzed or described

HOSPITAL FOR SPECIAL SURGERY

Methods: Patient Population



88% 5 year follow up

Results: Composite Clinical Success

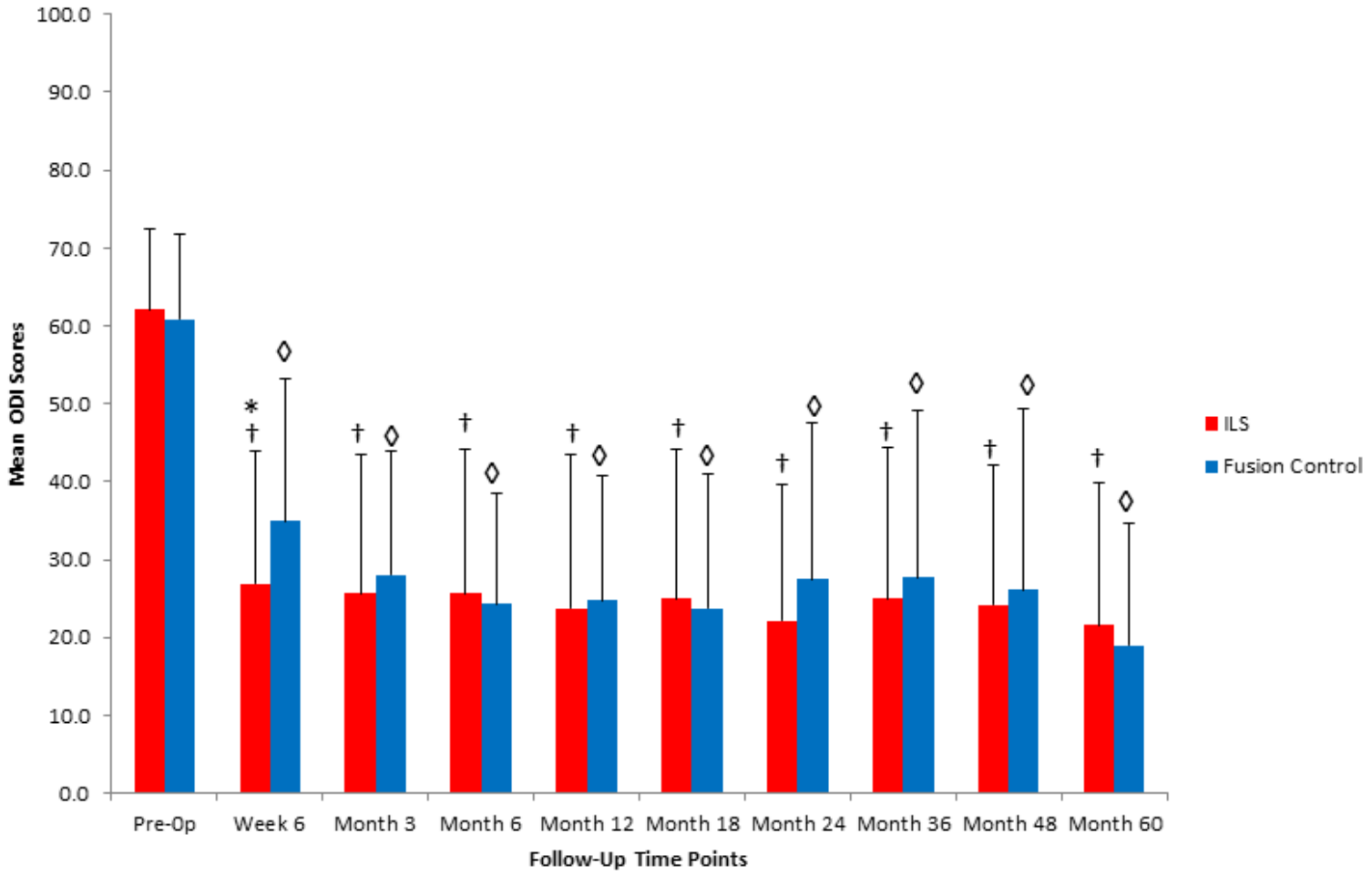
Month 60 Overall Efficacy: Two Level Procedures			
	Decompression +ILS	Decompression + fusion	
Status pre-op compared with Month 60	Percentage meeting Criteria (%)	Percentage meeting Criteria (%)	p-value[1]
Improvement of ≥15 points in ODI at Month 60 compared to baseline	86.7	92.9	0.532
No reoperation or epidural steroid injection (Up to Day 1825)	68.8	51.3	0.065
No reoperations, revisions, removals, or supplemental fixation	87.0	74.4	0.088
No epidural injection at any lumbar level up to and including the Month 60 visit	80.5	69.2	0.174
No persistent new or increasing sensory or motor deficit at 60 months	96.5	96.2	0.939
No persistent new or increasing sensory deficit	98.3	100.0	0.493
No persistent new or increasing motor deficit	98.2	96.2	0.564
No major device-related complications	97.4	94.9	0.480
Composite Clinical Success (Month 60 CCS-FDA)	**55.1**	**36.4**	**0.077**

[1]Chi-Square test

Reoperation Categories

Reoperation Category	D+ILS (N=77) n (%)	D+Fusion (N=39) n (%)
Wound/surgery related	3 (3.9%)	1 (2.6%)
Under treatment	2 (2.6%)	2 (5.1%)
Device related issue	2 (2.6%)	2 (5.1%)
Device ineffective		
A. Early (≤2 years post-op)	2 (2.6%)	1 (2.6%)
B. Late (>2 years post-op)	1 (1.3%)	4 (10.3%)
Trauma	0	0
Total	10 (13.0%)	10 (25.7%)

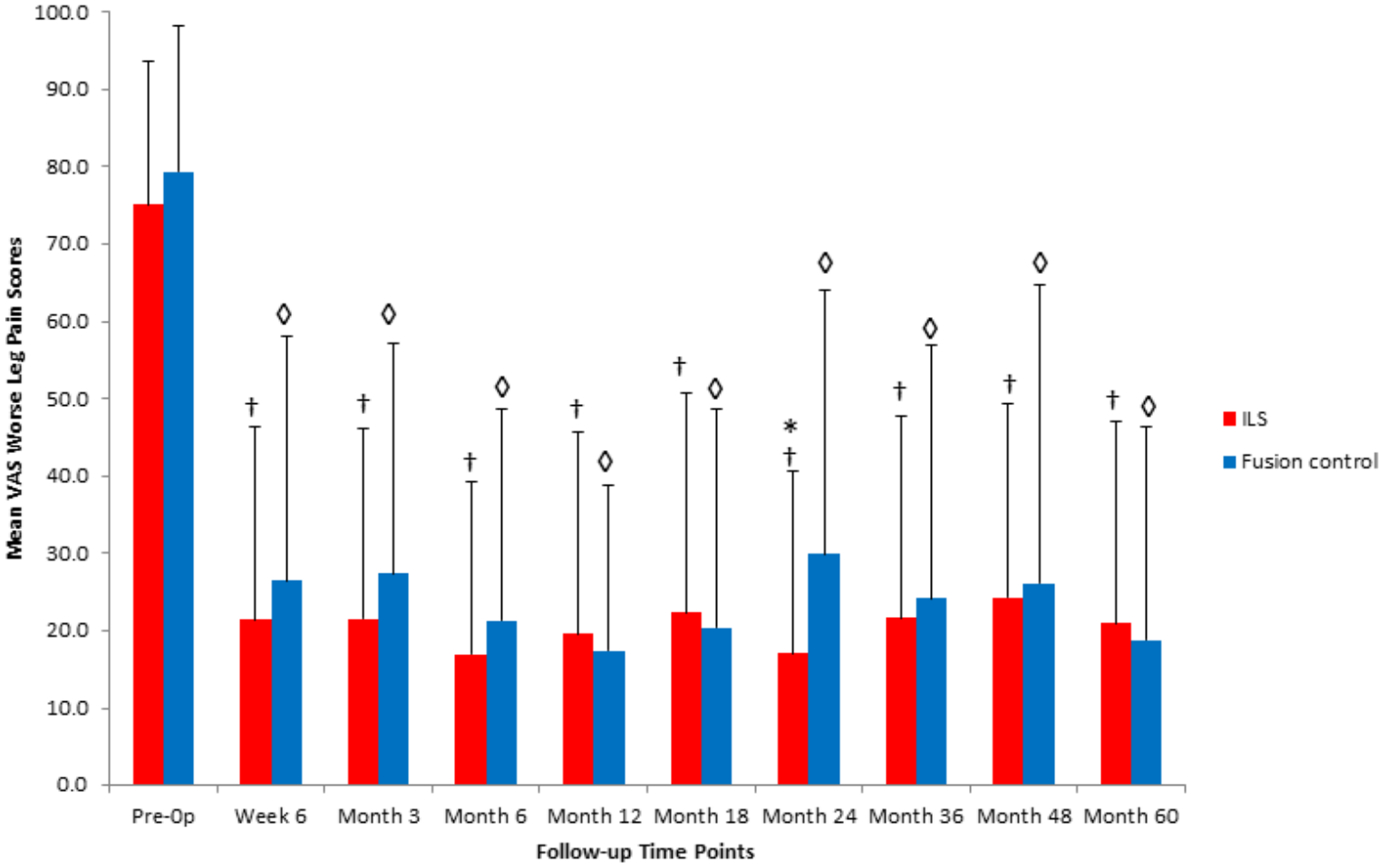
Results: ODI



*Significant difference between ILS and fusion groups: two sample pooled t-test p-value = 0.023
† Significant difference between ILS baseline and follow-up: within-group paired t-test
◊ Significant difference between fusion baseline and follow-up: within-group paired t-test

HOSPITAL FOR SPECIAL SURGERY

Results: Mean VAS Leg Pain for Most Symptomatic Leg



*Significant difference between ILS and fusion groups: two sample pooled t-test p-value = 0.035
† Significant difference between ILS baseline and follow-up: within-group paired t-test
◊ Significant difference between fusion baseline and follow-up: within-group paired t-test

HOSPITAL FOR SPECIAL SURGERY

Conclusions

- This is the first analysis that specifically focuses on the sustainability of two-level fusion vs. ILS treatments
- At 5 years post-op, patients who received ILS at two levels performed **as well, if not better**, than patients who received fusion at two levels
  - As demonstrated by Composite Clinical Success and secondary outcome measures
- The reoperation rate for fusion patients was **twice** the rate for ILS patients:

25.7% fusion vs. 13.0% ILS

  - With regard to late-term (>2 years post-op) device sustainability:

10.3% fusion late device ineffective vs.1.3% of ILS late device ineffective

- ILS has been found to be a **durable** and **sustainable** option for treating two levels of spinal stenosis

Thank you!

HOSPITAL FOR SPECIAL SURGERY

References

- Abjornson C, Yoon BJ, Callanan T, Shein D, Grinberg S, Cammisa FP. Spinal Stenosis in the Absence of Spondylolisthesis: Can Interlaminar Stabilization at Single and Multi-levels Provide Sustainable Relief?. Int J Spine Surg. Accepted
- Davis RJ, Errico TJ, Bae H, Auerbach JD. Decompression and coflex interlaminar stabilization compared with decompression and instrumented spinal fusion for spinal stenosis and low-grade degenerative spondylolisthesis: Two-year results from the prospective, randomized, multicenter, food and drug administration investigational device exemption trial. *Spine (Phila Pa 1976)*. 2013;38(18):1529-1539.
- Davis R, Auerbach JD, Bae H, Errico TJ. Can low-grade spondylolisthesis be effectively treated by either coflex interlaminar stabilization or laminectomy and posterior spinal fusion? two-year clinical and radiographic results from the randomized, prospective, multicenter US investigational device exemption trial: Clinical article. *J Neurosurg Spine*. 2013;19(2):174-184.
- Forsth P, Olafsson G, Carlsson T, et al. A randomized, controlled trial of fusion surgery for lumbar spinal stenosis. *N Engl J Med*. 2016;374(15):1413-1423.
- Ghogawala Z, Dziura J, Butler WE, et al. Laminectomy plus fusion versus laminectomy alone for lumbar spondylolisthesis. *N Engl J Med*. 2016;374(15):1424-1434.
- Guyer R, Musacchio M, Cammisa F, Lorio M. ISASS Recommendations/Coverage criteria for decompression with interlaminar stabilization - coverage indications, limitations, and/or medical necessity. *International journal of spine surgery*. 2016;10.
- Kumar N, Shah SM, Ng YH, Pannierselvam VK, Dasde S, Shen L. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. *Asian Spine J*. 2014;8(2):161-169.
- Modhia U, Takemoto S, Braid-Forbes MJ, Weber M, Berven SH. Readmission rates after decompression surgery in patients with lumbar spinal stenosis among medicare beneficiaries. *Spine (Phila Pa 1976)*. 2013;38(7):591-596.
- Musacchio MJ, Lauryssen C, Davis RJ, et al. Evaluation of decompression and interlaminar stabilization compared with decompression and fusion for the treatment of lumbar spinal stenosis: 5-year follow-up of a prospective, randomized, controlled trial. *Int J Spine Surg*. 2016;10:6.
- Roder C, Baumgartner B, Berlemann U, Aghayev E. Superior outcomes of decompression with an interlaminar dynamic device versus decompression alone in patients with lumbar spinal stenosis and back pain: A cross registry study. *Eur Spine J*. 2015;24(10):2228-2235.
- Son S, Kim WK, Lee SG, Park CW, Lee K. A comparison of the clinical outcomes of decompression alone and fusion in elderly patients with two-level or more lumbar spinal stenosis. *J Korean Neurosurg Soc*. 2013;53(1):19-25.
- Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. 2008;358(8):794-810.
- Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the spine patient outcomes research trial. *Spine (Phila Pa 1976)*. 2010;35(14):1329-1338.

Disclosures

Research support was provided by Paradigm Spine, LLC (NY, NY, USA)

HOSPITAL FOR SPECIAL SURGERY