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Low-grade Spondylolisthesis Can Be Effectively Treated by Either Coflex® Interlaminar Stabilization or Laminectomy and Posterior Spinal Fusion: Two-year Clinical and Radiographic Results from the US IDE Trial

R.J. Davis[1], J.D. Auerbach[2], H. Bae[3], T.J. Errico[4]

[1]Greater Baltimore Neurosurgical Associates, Baltimore, MD, United States, [2]Bronx-Lebanon Hospital Center, Department of Orthopaedics, Bronx, NY, United States, [3]The Spine Institute, Santa Monica, CA, United States, [4]Department of Orthopaedic Surgery, Hospital for Joint Diseases-NYU, New York, NY, United States

Introduction: The gold standard treatment for low-grade degenerative spondylolisthesis with spinal stenosis remains laminectomy and posterior spinal fusion (PSF) with pedicle screw implants. The potential for substantial perioperative morbidity and adjacent segment degeneration has led to the search for motion-preserving alternatives that still allow for direct neurologic decompression and stabilization. The US IDE trial compares coflex® interlaminar stabilization with laminectomy and PSF for the treatment of the following conditions:

1) low-grade spondylolisthesis, and

2) spinal stenosis with disabling low back pain. In the current study, we report exclusively on the subset of patients at 2 years from this IDE trial with low-grade spondylolisthesis.

Methods: This is a prospective, randomized, multicenter FDA IDE trial comparing coflex® interlaminar stabilization (n=140) with laminectomy and PSF (n=72) to treat 1- and 2-level spinal stenosis with low back pain or up to Grade I degenerative spondylolisthesis. In the spondylolisthesis subset there were 64 coflex® and 34 PSF patients with complete data at 2 years. Study inclusion consisted of moderate to severe spinal stenosis with significant low back pain (VAS Back Pain ≥50/100) and significant disability (ODI ≥40%), with Grade I spondylolisthesis, at spinal segments from L1-L5.

Results: Follow-up for the entire cohort at 24 months was 96.6% and 98.6% for coflex® and PSF groups, respectively. There were no group differences at baseline. Coflex® patients experienced significantly shorter operative times ($p< 0.001$), EBL ($p< 0.001$), and length of stay ($p< 0.001$). ODI scores were lower at all post-operative timepoints with coflex®, with significant improvement at 3months ($p=0.034$) and a trend at 6months ($p=0.093$). Despite equivalence at baseline, 2 year coflex® ODI scores averaged 19.6 compared with 26.0 for PSF ($p=0.141$). The proportion of coflex® patients achieving a 15-point ODI reduction at 24months was 88.0%(44/50) compared with 76.7% with PSF(23/30). ZCQ outcomes were significantly improved with coflex® at 2 years in Symptom Severity ($p=0.041$), Physical Function ($p=0.048$), and Satisfaction ($p=0.015$). SF-12 outcomes revealed no group differences except at 24 months where the coflex® cohort trended towards greater improvement in the Mental Health Component ($p=0.086$). VAS Back and Leg scores revealed equivalent improvement with either coflex® or PSF**.** Based on the stringent FDA composite for overall success including ODI improvement ≥15 points, no device-related complications, no reoperations, and no epidural injections, 67.2%(41/61) of coflex® and 63.6%(21/33) of PSF with spondylolisthesis succeeded, respectively. Finally, PSF exhibited significantly greater angulation (3.77 vs 6.38°, $p=0.0003$) and translation (0.78 vs 1.15mm, $p=0.049$) at the cranial adjacent level (Figure) at 2 years.

coflex™ and Fusion Control
Flexion Extension - Rotation (F to E) (deg)

	coflex™						Fusion Control						
	At Level(s) of Implant (per level)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	75	4.77	4.16	3.80	0.10	18.20	43	4.34	3.62	3.00	0.10	14.80	0.574
Month 24	67	4.76	4.16	3.50	0.00	15.70	41	1.92	2.30	1.30	0.00	12.40	0.000
	Below Level of Implant (per patient)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	57	6.63	4.58	6.20	0.00	18.10	32	6.03	4.44	5.30	0.10	18.10	0.550
Month 24	53	7.62	5.07	6.10	0.20	18.50	29	8.01	4.26	7.20	0.40	18.20	0.727
	Above Level of Implant (per patient)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	62	4.29	3.52	3.75	0.00	16.40	33	3.61	3.13	2.70	0.10	11.30	0.351
Month 24	55	3.77	3.27	2.30	0.10	13.40	32	6.38	5.00	5.50	0.30	19.10	0.003

coflex™ and Fusion Control
Flexion Extension - Translation (mm)

	coflex™						Fusion Control						
	At Level(s) of Implant (per level)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	73	1.07	0.93	0.90	0.00	3.90	39	1.01	0.75	0.90	0.00	2.90	0.691
Month 24	66	1.26	1.14	1.00	0.00	5.70	38	0.43	0.47	0.35	0.00	1.80	0.000
	Below Level of Implant (per patient)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	55	0.58	0.51	0.50	0.00	2.40	28	0.44	0.45	0.35	0.00	2.10	0.210
Month 24	52	0.75	0.68	0.65	0.00	4.10	26	0.80	0.71	0.65	0.00	2.50	0.747
	Above Level of Implant (per patient)												t-test
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	p-value[1]
Pre-0p	60	0.85	0.75	0.60	0.00	2.80	29	0.70	0.72	0.50	0.00	2.50	0.378
Month 24	54	0.78	0.77	0.50	0.00	2.80	29	1.15	0.88	0.80	0.10	3.70	0.049

[Figure: Angulation (Top) and Translation (Bottom)]

Conclusions: Low-grade spondylolisthesis can be effectively treated by decompression and coflex® interlaminar stabilization with equivalent or superior results at 2 years when compared with laminectomy and PSF. The reduced perioperative morbidity, shorter hospital length of stay, equivalent or superior clinical outcomes, and significantly reduced adjacent segment stresses supports the use of coflex® as a viable alternative to PSF in low-grade spondylolisthesis.