Abstracts of the 2013 Annual Meeting of the Lumbar Spine Research Society

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Oral Presentation Abstracts

Paper 1. Interspinous Fusion Device (IFD) Versus Laminectomy For Lumbar Spinal Stenosis: A Comparative Effectiveness Study

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Introduction: The aim of this study is two-fold: (1) to evaluate reoperation, complications, healthcare utilization, and costs for patients undergoing interspinous fusion device (IFD) placement, and (2) to assess potential outcome differences between IFD- and laminectomy-treated patients.

Methods: We reviewed the MarketScan database for adult patients with lumbar spinal stenosis (LSS) who underwent IFD placement as a primary inpatient procedure between 2007 and 2009. Reoperation, complications, healthcare utilization, and costs up to 18 months post-operation were analyzed. Each IFD patient was matched with a laminectomy patient on the basis of age, gender, comorbidities, and insurance status using propensity score matching. Wilcoxon rank-sum and Chi-square tests were used to assess outcome differences between IFD and laminectomy patients.

Table 4. Post-operative outcomes of matched patients with at least 18 months post-operative follow-up in an inpatient setting

Outcome	Laminectomy (n=174)	IFD (n=174)	p-value
12 month Reoperation [n (%)]			
All-type	10 (5.75)	22 (12.64)	0.0260*
Laminectomy	4 (2.30)	19 (10.92)	0.0012*
New interbody spinal fusion	6 (3.45)	4 (2.30)	0.521
Revision interbody spinal refusion	4 (2.30)	8 (4.60)	0.2399
IFD	0 (0.00)	1 (0.57)	1
18 month Reoperation [n (%)]			
All-type	17 (9.77)	26 (14.94)	0.1426
Laminectomy	7 (4.02)	23 (13.22)	0.0022
New interbody spinal fusion	10 (5.75)	4 (2.30)	0.1017
Revision interbody spinal refusion	6 (3.45)	12 (6.90)	0.1464
IFD	0 (0.00)	1 (0.57)	1
Complications [n (%)]			
Index hospitalization	13 (7.47)	6 (3.45)	0.0986
30-day complications	16 (9.20)	6 (3.45)	0.0276*
90-day complications	16 (9.20)	6 (3.45)	0.0276*
Index hospitalization			
Length of stay (LOS) in days	2.49 (2.77)	1.58 (1.41)	<.0001*
Cost in 2009 US$	$12,670 ($9,883)	$17,674 ($19,959)	0.0001*
18 month hospital use, mean (SD)			
Cumulative LOS in days (excluding index hospitalization)	3.28 (11.20)	2.69 (6.84)	0.473
Cost in 2009 US$ (cumulative, excluding index hospitalization)	$12,331 ($23,944)	$13,559 ($41,803)	0.499
18 month outpatient ED services			
Cumulative services (excluding index hospitalization)	2.14 (7.36)	1.84 (3.52)	0.0757
Cost in 2009 US$ (cumulative, excluding index hospitalization)	$272 ($851)	$322 ($688)	0.0593
Overall costs in 2009 US$			
12 month (including index hospitalization)	$34,324 ($33,209)	$39,173 ($45,608)	0.289
18 month (including index hospitalization)	$44,834 ($39,670)	$51,255 ($62,959)	0.6846

Results: Among 498 inpatients that underwent IFD placement between 2007 and 2009, a subset of 182 patients was identified as having at least 18 months post-operative follow up; the average age was 73 years with 53.9% females. Most patients had no comorbidities (Charlson index 0; 75.8%) and had Medicare insurance (78.0%). The cumulative reoperation rates after IFD at 12 and 18 months were 21% and 23%, respectively. The average inpatient hospitalization lasted 1.6 days with an associated cost of $17,432.

Two propensity-matched cohorts of 174 patients had undergone IFD vs. laminectomy with 18 months post-operative follow-up were analyzed. Longer length of stay was observed in the laminectomy cohort (2.5 days vs. 1.6 days, p<.0001), while IFD patients accrued higher costs at index hospitalization ($17,674 vs. $12,670, p=.0001). Index hospitalization (7.5% vs. 3.5%, p=.09), 30-day (9.2% vs. 3.5%, p=.03) and 90-day (9.2% vs. 3.5%, p=.03) complications were higher in the laminectomy cohort compared to the IFD cohort. IFD patients had significantly higher reoperation rates than laminectomy patients at 12 months follow-up (12.6% vs. 5.8%, p=.03). IFD patients incurred higher cumulative costs than laminectomy patients at 12 months follow-up ($39,173 vs. $32,324, p=0.3).

Conclusions: Patients that underwent laminectomy had longer in-hospital stays and were more likely to experience postoperative complications. However, 12 month reoperation rates and index hospitalization costs were significantly higher among patients who underwent IFD compared to laminectomy for LSS.

Paper 2. The Safety and Efficacy of a Novel Minimally Invasive Interspinous Spacer for the Treatment of Moderate Lumbar Stenosis: 18 Month Outcomes of a Prospective, Randomized, Controlled FDA IDE Clinical Trial

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Introduction: This study reports 18-month clinical outcomes in patients with moderate LSS treated with an investigational interspinous spacer (Superion®) compared to X-STOP®.

Methods: This prospective, randomized, controlled IDE trial (NCT00692276) enrolled 145 patients with radiographically confirmed moderate LSS unresponsive to at least 6 months conservative care. Patients were treated randomly with the Superion (n=75) or X-STOP (n=70) interspinous spacer and all were followed through 18 months post-treatment.

Results: ZCQ symptom severity and physical function scores improved 30% to 32% in both groups (all p<0.001). ZCQ patient satisfaction scores at 18 months were 1.7±0.8 with Superion and 1.6±0.7 with X-STOP. Axial pain decreased from 59±25 mm at pre-treatment to 24±27 mm at 18 months in the Superion group (p<0.001) and from 54±24 mm to 26±26 mm with X-STOP (p<0.001) (p=0.28 between groups). Extremity pain decreased from 66±23 mm at pre-treatment to 20±27 mm with Superion (p<0.001) and from 65±23 mm to 25±26 mm with X-STOP (p<0.001) (p=0.71 between groups). Back function similarly improved with Superion (37±11% to 21±15%; p<0.001) vs. X-STOP (41±11% to 21±14%; p<0.001) (p=0.46 between groups).

Discussion: The mid-term results of the Superion Interspinous

Spacer suggest that clinical improvements in axial and extremity pain and function remain durable 18 months after treatment.

Conclusions: The Superion Interspinous Spacer provides similar benefits as X-STOP in reducing pain and improving back function in appropriately selected patients with moderate LSS.

Paper 3. Characterization of Lumbar Spinous Processes for Applications in Minimally Invasive Spine Surgery

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Introduction: Detailed quantitative anatomy of lumbar spinous processes is essential for treatment of spinal stenosis using interspinous process distraction devices. The goal of the present study was to provide normative anatomic data pertinent to surgical patient selection, implant design and minimally invasive spine surgery.

Methods: This study utilized 2,955 cadaveric lumbar vertebrae from 591 human spines at the Hamann-Todd Human Osteological Collection, Cleveland, Ohio. Samples were evenly distributed between ages 20 to 79. Each vertebra was photographed and measured digitally. Direct measurements were made of the height, length, width, slope and curvature of the lumbar spinous process for each vertebra. Height, sex, race and age were recorded and analyzed.

Results: Of 591 subjects measured, 244 were female and 347 male. Females averaged 46.5 ± 15.34 years of age, while males averaged 50 ± 17.39. Spinous processes (SPs) varied in length by level, ranging from 24.76 ± 4.58 at L5 to 33.93 ± 3.90 mm at L3. Relative to other levels, L5 had smaller SP height at 18.2 ± 2.66 mm. The cranial aspect of the L5 SP was wider than others at 3.76 ± 1.38 mm, however, the caudal aspect of the L4 SP was widest at 11.09 ± 2.85 mm. L5 had a slope of 23.68 ± 10.51 degrees relative to the mechanical axis, which was steeper than other levels. At L2-L5, more SPs have convex morphology. Conversely, L1 exhibits convex morphology only 38.7% of the time (Table 1).

Table 1: Spinous Process Morphology

Dimensions	Female Mean ± STD (mm)	Male Mean ± STD (mm)	All Mean ± STD (mm)
L1 Spinous Process Length	26.95 ± 2.77	29.73 ± 3.07	28.58 ± 3.25
L2 Spinous Process Length	30.19 ± 3.08	33.88 ± 3.23	32.36 ± 3.66
L3 Spinous Process Length	31.68 ± 3.30	35.51 ± 3.50	33.93 ± 3.90
L4 Spinous Process Length	29.79 ± 3.89	32.86 ± 4.23	31.59 ± 4.36
L5 Spinous Process Length	23.73 ± 4.36	25.48 ± 4.60	24.76 ± 4.58
L1 Spinous Process Effective Length	18.46 ± 2.21	20.18 ± 2.57	19.47 ± 2.57
L2 Spinous Process Effective Length	20.86 ± 2.47	23.35 ± 2.71	22.32 ± 2.89
L3 Spinous Process Effective Length	22.85 ± 2.64	25.7 ± 2.88	24.52 ± 3.12
L4 Spinous Process Effective Length	23.32 ± 2.96	25.49 ± 3.24	24.59 ± 3.30
L5 Spinous Process Effective Length	21.65 ± 3.06	23.47 ± 3.34	22.72 ± 3.33
L1 Spinous Process Height	19.88 ± 2.32	20.57 ± 2.24	20.29 ± 2.30
L2 Spinous Process Height	19.87 ± 2.27	20.67 ± 2.34	20.34 ± 2.34
L3 Spinous Process Height	20.51 ± 2.61	21.07 ± 2.52	20.83 ± 2.57
L4 Spinous Process Height	20.39 ± 2.72	20.81 ± 2.73	20.52 ± 2.73
L5 Spinous Process Height	17.8 ± 2.61	18.48 ± 2.66	18.2 ± 2.66
L1 Spinous Process Width (Cranial)	2.88 ± 0.86	2.86 ± 0.87	2.87 ± 0.86
L2 Spinous Process Width (Cranial)	2.72 ± 0.77	2.76 ± 0.83	2.74 ± 0.80
L3 Spinous Process Width (Cranial)	3.01 ± 0.97	3.13 ± 1.01	3.08 ± 1.00
L4 Spinous Process Width (Cranial)	3.27 ± 1.16	3.44 ± 1.23	3.37 ± 1.20
L5 Spinous Process Width (Cranial)	3.52 ± 1.29	3.9 ± 1.43	3.76 ± 1.38
L1 Spinous Process Width (Caudal)	9.03 ± 1.73	9.19 ± 1.72	9.12 ± 1.73
L2 Spinous Process Width (Caudal)	9.18 ± 1.92	9.61 ± 1.85	9.43 ± 1.89
L3 Spinous Process Width (Caudal)	10.45 ± 2.19	10.81 ± 2.17	10.66 ± 2.19
L4 Spinous Process Width (Caudal)	10.97 ± 2.85	11.18 ± 2.84	11.09 ± 2.85
L5 Spinous Process Width (Caudal)	9.41 ± 2.67	9.88 ± 2.73	9.69 ± 2.71
L1 Spinous Process Radius	22.45 ± 19.89	21.09 ± 19.35	21.65 ± 19.57
L2 Spinous Process Radius	23.98 ± 26.55	23.17 ± 20.72	23.51 ± 23.29
L3 Spinous Process Radius	27.51 ± 27.48	30.52 ± 29.88	29.28 ± 28.93
L4 Spinous Process Radius	24.21 ± 21.9	25.05 ± 23.03	24.70 ± 22.55
L5 Spinous Process Radius	24.99 ±25.59	26.44 ± 21.94	25.84 ± 23.51
Slope	Female Mean ± STD (°)	Male Mean ± STD (°)	All Mean ± STD (°)
L1 Spinous Process Slope	15.53 ± 18.64	13.36 ± 13.68	14.25 ± 15.94
L2 Spinous Process Slope	14.95 ± 7.8	13.26 ± 7.63	13.95 ± 7.74
L3 Spinous Process Slope	16.11 ± 7.61	15.00 ± 7.57	15.46 ± 7.60
L4 Spinous Process Slope	18.18 ± 9.45	17.66 ± 8.78	17.88 ± 9.06
L5 Spinous Process Slope	24.11 ± 10.13	23.37 ± 10.78	23.68 ± 10.51
Morphology	Female	Male	All
L1 Concave	67.6%	56.8%	61.3%
L1 Convex	32.4%	43.2%	38.7%
L2 Concave	38.1%	35.4%	36.5%
L2 Convex	61.9%	64.6%	63.5%
L3 Concave	25.8%	25.6%	25.7%
L3 Convex	74.2%	74.4%	74.3%
L4 Concave	20.5%	18.4%	19.3%
L4 Convex	79.5%	81.6%	80.7%
L5 Concave	32.4%	32.6%	32.5%
L5 Convex	67.6%	67.4%	67.5%

Discussion: Past studies have examined the quantitative anatomy of the lumbar spine as it pertains to pedicle fixation for posterior spinal fusions. Little work, however, has been done to examine lumbar spinous processes and their variable morphology. Spinous process length, width, height and slope were consistently different at L5, relative to L1-L4.

Conclusion: This large cadaveric study provides valuable normative data. The detailed quantitative anatomy of lumbar spinous processes has broad implications for enhanced pre-operative planning, as well as improved implant design and performance.

Paper 4. Obese Class III Patients At Significantly Greater Risk Of Multiple Complications After Lumbar Surgery: An Analysis Of 10,484 Patients In The ACS-NSQIP Database

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Introduction: Prior studies on the impact of body mass index (BMI) on lumbar surgery outcomes have mostly come from single institutions with the exception of two large database studies which focused only on lumbar arthrodesis. National spine data from multiple institutions is amassing, allowing for large database comparisons. The purpose of our study is to characterize and compare with the literature the 30-day outcomes—while accounting for comorbidities—of patients with graded BMI from the American College of Surgeons National Surgical Quality Improvement Program database (ACS-NSQIP).

Methods: Patients undergoing lumbar anterior arthrodesis, posterior arthrodesis, TLIF/PLIF, discectomy, or decompression in the ACS-NSQIP, 2005-10 were categorized into 4 groups based on BMI: normal/overweight (18.5-29.9 kg/m2), obese I (30-34.9 kg/m2), obese II (35-39.9 kg/m2), obese III (> 40 kg/m2). Obese I-III patients were compared to patients in the normal/overweight category using $\chi 2$ and ANOVA. Multivariate linear/logistic regression models were used to adjust for preoperative comorbidities. Significance was defined as $P<0.05$.

Results: Data was available for 10,484 patients undergoing lumbar surgery. Of these, 4.6% underwent anterior arthrodesis, 17.9% posterior arthrodesis, 6.3% TLIF/PLIF, 40.5% discectomy, 30.5% decompression. Among all patients, 25.6% were obese I, 11.5% obese II, and 6.9% obese III. On multivariate analysis, obese I, III had a significantly increased risk of urinary complications and obese II, III patients had a significantly increased risk of wound complications and of longer operation times. Only obese III patients, however, had a statistically increased risk of having an extended length of stay, septic complications and of having > 1 complication.

Conclusions: Patients with high BMI appear to have higher complication rates after lumbar surgery than patients who are of a normal/overweight BMI. However, the complication rates seem to increase substantially for obese III patients. These patients have longer operation times, extended hospitals stays and an increased risk for wound, urinary, and septic complications. Our results confirm the previous findings of large database research on lumbar surgery outcomes for obese patients. Surgeons should be aware of the increased risk of multiple complications for patients with BMI > 40 kg/m2.