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### Indications of IDD

- Lumbar stenosis
- Degenerative disc disease
- Mechanism
  - Foraminal and posterior disc height distraction
  - Canal expansion
  - Stress-shielding phenomenon of soft, or osseous, tissues adapting to tensile loads via Davis' or Wolff's Laws, respectively
- Motion preservation?
- Fusion?



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### My Complication



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### High failure rate of the interspinous distraction device (X-Stop) for the treatment of lumbar spinal stenosis caused by degenerative spondylolisthesis

Olaf J. Verhoof · Johannes L. Bron ·  
Frits H. Wagstra · Barand J. van Royen

- Retrospective, 12 patients
- 8/12 with complete pain relief
  - 7/12 (58%) required lami/PSF in 24 months
  - 7/8 = 87.5% of responders\*\*\*
- Not recommended
- Contraindicated in spody with sagittally oriented facet joints due to progressive forward slip



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### Biomechanical effect of different interspinous devices on lumbar spinal range of motion under preload conditions

Frank Hartmann · Sven-Oliver Dietz ·  
Hans Hüb · Paul Maria Rimmens · Errol Gereck

- Aperius, In-Space, X-Stop, and Coflex
- Sig ROM ↓ E, F \*  
(\*after the follower load)
- ↑ lateral bend and AR ROM



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### Influence of Bone Mineral Density on the Fixation of Thoracolumbar Implants A Comparative Study of Transpedicular Screws, Laminar Hooks, and Spinous Process Wires

JEFFREY D. COE, MD,\* KAREN E. WARDEN, M BIOMED ENGR, MICHAEL A. HERZIG, MD,  
and PAUL C. MCAFEE, MD

Table 3. Results of Biomechanical Tests and Correlations with BMD

Implant	Mean density (g/cm <sup>3</sup> )	Standard deviation	Standard error	Correlation coefficient with BMD	Statistical significance
Spinous process wire	361.7	219.3	22.7	0.47	P < 0.001
Laminar hook	645.9*	229.4	26.1	0.098	Not Significant
Coned Outermost pedicle screw	344.9	182.5	21.8	0.37	P < 0.001
Shelfie pedicle screw	430.2	235.6	27.3	0.46	P < 0.001

\*Significant at the P < 0.05 level. BMD, Bone Mineral Density.

- Loads of failure did not vary with vertebral levels
  - Laminar hooks: L2 > T4-8, L3 > T3-9, L4- T3-9 and 11

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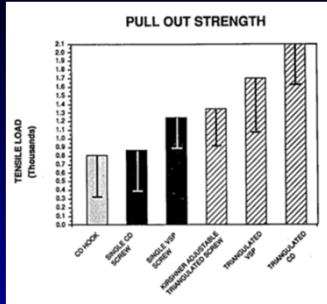
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### Triangulation of Pedicular Instrumentation A Biomechanical Analysis

CHARLES M. RULAND, MD, PAUL C. McAFEE, MD, KAREN E. WARDEN, M Biomech Eng, and  
BRYAN W. CUNNINGHAM, BS




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### PULLOUT STRENGTH OF PEDICLE SCREWS VERSUS PEDICLE AND LAMINAR HOOKS IN THE THORACIC SPINE

U. LILJENQVIST, L. HACKENBERG, T. LISK, H. HALM

Table II. — Average pullout strength of pedicle screws and pedicle and laminar hooks

	upper thoracic spine (T4-T8)			lower thoracic spine (T9-T12)		
	pedicle screw	pedicle hook	p-value	pedicle screw	laminar hook	p-value
pullout strength	551.7 ± 213.8 N (224-1072 N)	321.4 ± 111.6 N (117-579 N)	< 0.0001	807.9 ± 207 N (458-1221 N)	600.1 ± 167.2 N (299-891 N)	0.02

Table III. — Failure modes of pedicle screws and pedicle and laminar hooks

	Failure mode
Pedicle screws	23 x class pullout 17 x unilateral pedicle fracture 5 x bilateral pedicle fracture
Pedicle hooks	20 x unilateral pedicle fracture 4 x bilateral pedicle fracture 3 x fracture of articular process
Laminar hooks	12 x laminar fracture 3 x unilateral pedicle fracture 3 x bilateral pedicle fracture

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### Clinical outcome following DIAM implantation for symptomatic lumbar internal disk disruption: a 3-year retrospective analysis

- Internal disk disruption (IDD) based on MRI with HIZ, discography, Intradiskal pressure measurement
- DIAM
  - ↓ IDP\*, ↓ pain in all (34)
  - 91% symptom-free at 3 years
  - 9% with recurrent pain
    - (unrelated to IDD or surgery)
  - F-E maintained in 90% c/t preop
  - No adjacent segment degeneration




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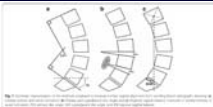

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International journal of orthopaedics and spine disorders 2013; 16(1): 1-6  
 Scoliosis and Spinal Disorders

**RESEARCH** Open Access

**Change of sagittal spinal alignment and its association with pain and function after lumbar surgery augmented with an interspinous implant**

**Table 2** Mean (standard deviation) values for lumbosacral sagittal alignment, and back pain, leg pain and function

	B	6w	12 m	24 m
LL (°)	53.3 (12.3)	53.3 (10.6)	55.3 (9.2)	
SI (°)	36.4 (7.3)	35.9 (7.0)	36.7 (6.6)	
PDA (°)	9.2 (5.7)	7.0 (4.5)	7.7 (4.8)	
SDA (°)	9.9 (4.9)	9.8 (4.1)	10.5 (4.4)	
RSB (mm)	5.6 (38.0)	11.1 (33.7)	9.5 (38.7)	
Back Pain (VAS)	49.2 (27.4)	17.1 (18.3)	20.3 (21.3)	23.9 (28.0)
Leg Pain (VAS)	40.1 (33.5)	12.7 (19.4)	16.4 (23.4)	21.0 (30.1)
Function (ODI)	36.9 (14.7)	21.9 (18.0)	19.8 (16.4)	21.5 (19.6)

B preoperative baseline, 6w 6 weeks, 12 m/24 m 12/24 months postoperative.  
 LL lumbar lordosis, SI sacral inclination, PDA primary disc angle, SDA suprafacient disc angle, RSB regional sagittal balance, VAS visual analogue scale, ODI Oswestry Disability Index

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**Lavelle et al. X-Ray Reliability to Detect Spinous Process Fractures after Placement of Interspinous Process Spacer. LSRS, 2016**

- 42 patients, X-stop and Superior
- X-rays assessment for SP fracture with CT confirmation
  - Superior: 11 with and 9 without fractures
    - 12.3 % at 2 years
  - X-STOP: 13 with and 9 without fractures
    - 28.9% vs IDE at 1% at 2 years
- 70% accuracy with x-rays
- Underreported fractures clinically

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**Interspinous Process Decompression: Expanding Treatment Options for Lumbar Spinal Stenosis**

Pierce D. Nunley,<sup>1</sup> A. Nick Shamiq,<sup>2</sup> Scott L. Blumenthal,<sup>3</sup> Douglas Orndorff,<sup>4</sup> Jon E. Block,<sup>5</sup> and Fred H. Geisler<sup>6</sup>



**Mod LSS +/- spondy (Gr I)**

- FDA approved stand-alone (no decompression) in US (5/20/15)
  - As of January 2017, replaced cat 3 (1<sup>st</sup> gen) to cat 1
  - ASC usage approved as of Jan 2016
- IDE trial c/t 2 laminectomy studies (Cohen formula)
  - ODI: >1 for Superior and lami
  - ZCQ at 2 years: Severity and physical function
    - Superior: 1.26 and 1.29 (vs. 1.07 and 0.80)

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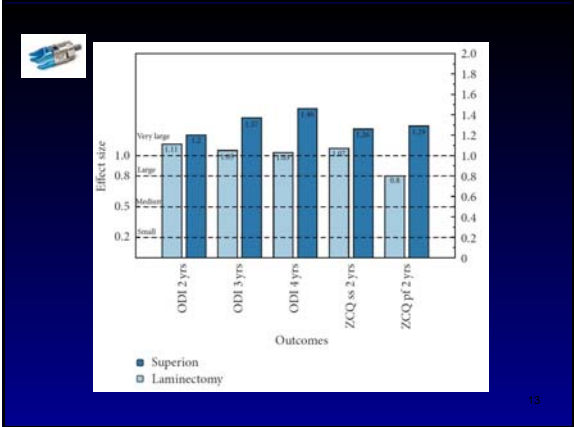
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Interspinous implants to treat spinal stenosis  
 Raj A. Gaba<sup>1,2</sup>, Glenn S. Russo<sup>1</sup>, Peter G. Wang<sup>3</sup>

**Superior**  
 = Decomp and fusion in Mod LSS  
 Dynamic stability without the rigidity  
 Improved 3 year outcome c/t decomp/PSF

**Percutaneous**  
 improved outcome in 3 years vs. X-STOP

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Interspinous implants: are the new implants better than the last generation? A review  
 Michael Pimenta<sup>1</sup>, Alexander Daffy<sup>2</sup>, Farouk Vahedi<sup>3</sup>, George Rimmerink<sup>4</sup>, Joshua Miller<sup>5</sup>

- 37 studies (18 retro, 12 pro, 7 RCT) from 2011 to 2016
  - 6 weeks-6 months of symptoms
  - Gen II: Lower reoperation rate at 2 years, 3.7 vs 11.1%\*\* (requires meta-analysis verification)
    - Failure due to spinous process fracture
    - Osteoporosis, over-distraction, inappropriate size, poor technique
    - No difference in ODI (1 RCT) and ZCQ (2 RCT) between Superior and X-STOP
- Questionable long term functionality
  - Caution in osteoporotic patients
  - Radiologic changes and recurrent symptoms in 2 years
  - Less recurrence in 2<sup>nd</sup> generation (PEEK vs. Titanium)

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## Coflex vs. PLIF

- Decreased OR time, EBL and length of stay
  - Cost effective
- Decompression + Coflex = PLIF alternative\*
  - Rigid fusion not always necessary
- Avoidance of ASD
  - Not statistically significant
- No instrumentation necessary without back pain

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## 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



Michael J. Bosworth, MD,\* Carl Lavender, MD,† Raymond J. Davis, MD,† Miles W. Bos, MD,† John H. Pinner, MD,† Richard D. Gayer, MD,† Jack P. D'Agostino, MD,† Dennis D. Okonko, Dr.Med.,† Scott Lewis, MD,†  
 \*Department of Neurosurgery, Northshore University HealthSystem, Rossmore, IL; †North Shore, Aurora, IL; ‡Laser Spine Institute, Philadelphia, PA; §The Spine Institute, Irvine, Orange, CA; ¶Texas Back Institute, Plano, TX; ††Texas Back Institute, Plano, TX; †††Texas Back Institute, Round Rock, Texas; ††††Texas Back Institute, San Diego, CA

- Prospective, randomized, controlled trial in 21 centers
- 215 D + ILS, 107 D + PS (pedicle screws)
- 80.6% vs 73.2% > 15 point improvement\*
- Improved VAS, SF-12 and ZCQ scores\*
- Higher SF-12 and ZCQ in ILS in early follow up.
- ILS maintained FH, DSH and ROM Index level
- ILS as a viable alternative

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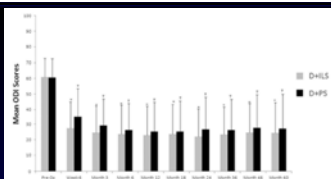
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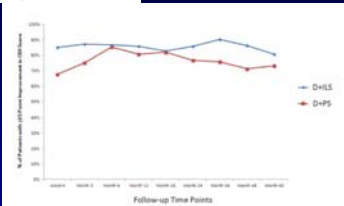
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\*Statistically significantly improved from pre-op values in the D+ILS group  
 †Statistically significantly improved from pre-op values in the D+PS group




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**DYNAMIC STABILIZATION** **SASJournal**

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**Survivorship of coflex Interlaminar-Interspinous Implant**

*Thomas J. Errico, MD,\* Jonathan R. Kamerling, MD,\* Meritt Quirin, MD,\* Jacques Sameni, MD,\*  
and Robert J. Chomiak, MS*

- 163 patients by one surgeon, 6.3 year follow up
- VAS and pain severity score, satisfaction
- LSS +/- HNP = 55.1%
- ↓ back pain at 2 and 5 years from mod to mild (33%)\*
- ↓ leg pain at 2 and 5 years from sev to mild (66%)\*
- 46% v satisfied, 46% satisfied
- 8% device related issues

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**ClinicoEconomics and Outcomes Research** **Dovepress**

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**ORIGINAL RESEARCH**

**Comparative cost effectiveness of Coflex® interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis**

- \$15,182 for Coflex vs. \$26,863 for the fusion control (2013)
- Mean quality-adjusted life years were higher for Coflex (3.02 vs 2.97).
- more utility, on average, than those treated with fusion, but at substantially lower costs
- cost advantage for Coflex relative to fusion was even larger for two-level procedures compared to one-level procedures

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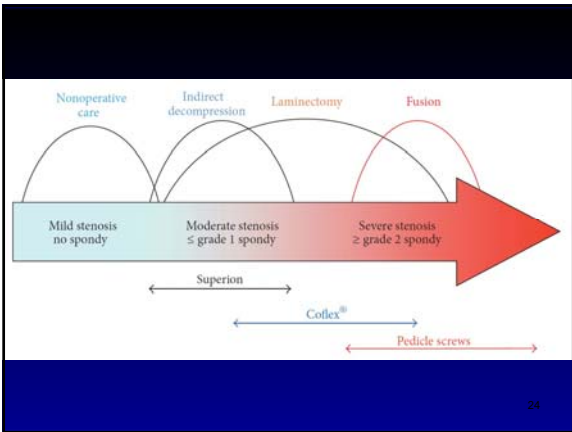
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The golden rule.  
He who has the gold, makes the rules.

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- Sobering reality
- Bundling in spine. Will it occur?
  - i.e. 63075 (19.6 rvu) + 22554 (17.69 rvu) ≠ 22551 (25)
- Clinical equivalence
  - If lami + Coflex = PLIF, then would the reimbursement be the same?

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### Surgeon Reimbursement

CPT	IDD	PSF	PLIF
63047	15.37	15.37	15.37
22867	13.5		
22612		23.53	
22840		12.52	12.52
20936		0	
22853		0	4.25
22630			22.09
Total	28.87	51.42	54.23
Adjusted	22.12	43.73	38.86

RVU Conversion	IDD	PSF	PLIF
Ohio, \$ 21.77	\$481.55	\$952.00	\$845.98
Florida, \$22.36	\$494.60	\$977.80	\$868.91
Florida, \$	\$483.20	\$974.31	

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