28th Annual Gabor Racz Advanced Interventional Pain Conference and Workshop
Budapest, Hungary August 25-27, 2025

Why are (interspinous) Spacers not so Great?

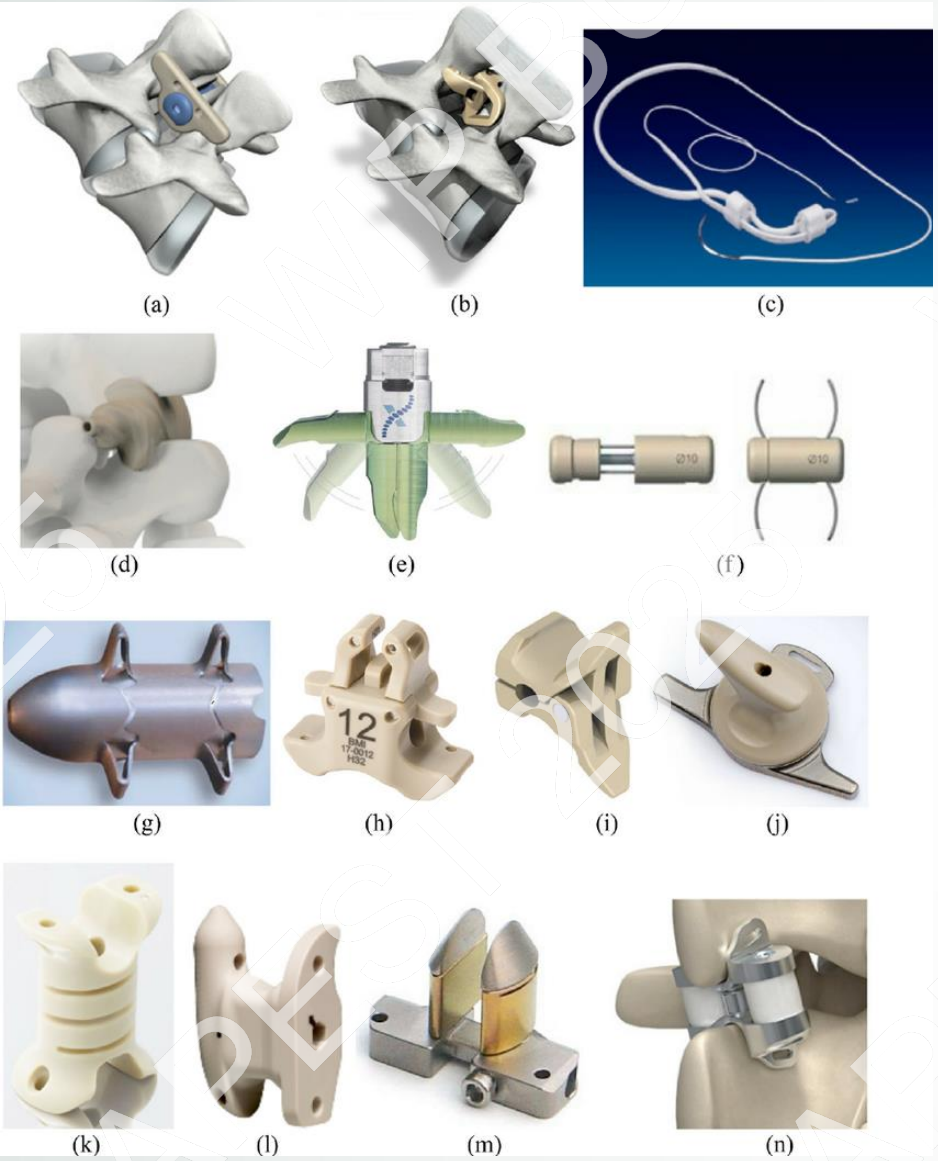
László Entz MD, PhD, FIPP
MIND Clinic Budapest
Semmelweis University Budapest
Hirslanden Clinic Zürich

Conflicts of Interest

- I declare no conflict of interest

Personal Bias....

- I never implanted one, but
- Removed many....



What Are Interspinous Spacers (ISPs)?

- *Designs: static spacers, dynamizing spring-like devices*
- *Materials include:*

titanium, polyetheretherketone (PEEK), and elastomeric compounds

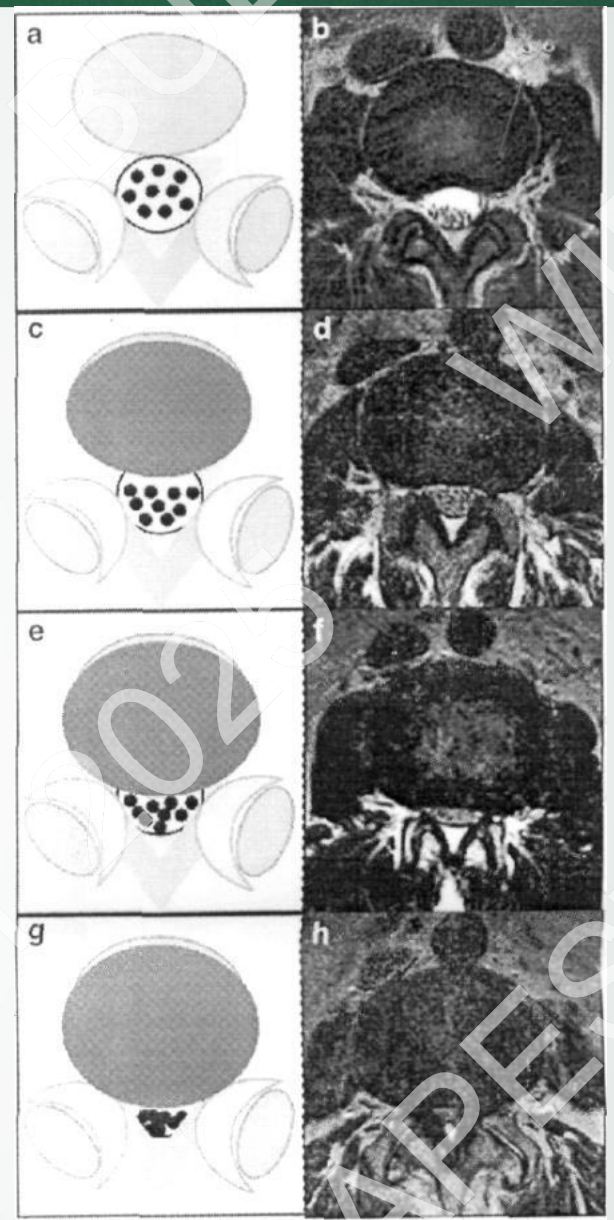
Categories:

- motion preservation devices
- devices that fuse the interspinous space.

C. M. Bono and A. R. Vaccaro, "Interspinous process devices in the lumbar spine," Journal of Spinal Disorders and Techniques, vol. 20, no. 3, pp. 255–261, 2007.

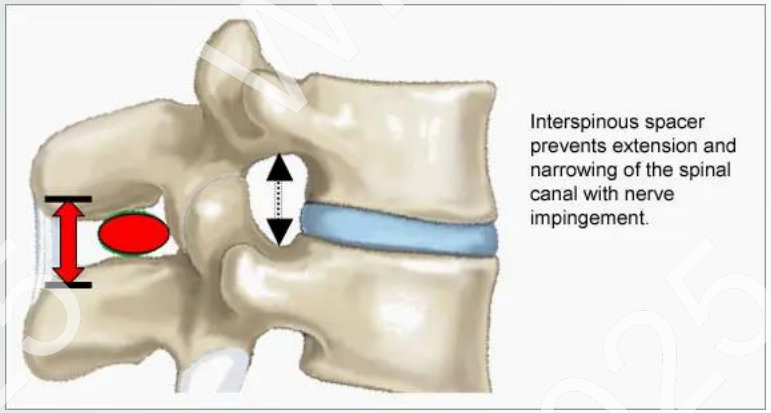
Indications:

1. *Lumbar spinal canal stenosis,*
2. *Grade I degenerative spondylolisthesis,*
3. *Discogenic low back pain,*
4. *Nontraumatic instability,*
5. *Lumbar disc herniation,*
6. *and facet syndrome*



S.M. Kabir, S. R. Gupta, and A. T. Casey, "Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence," Spine, vol. 35, no. 25, pp. E1499–E1506, 2010.
R. Gazzeri, M. Galarza, and A. Alfieri, "Controversies about interspinous process devices in the treatment of degenerative lumbar spine diseases: past, present, and future," BioMed Research International, vol. 2014, Article ID 975052, 15 pages, 2014.

Mechanism of action



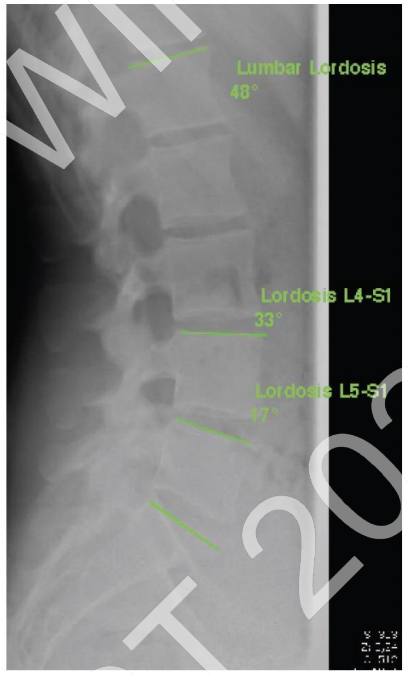
- *Unload the facet joints, to restore foraminal height, and to provide sufficient stability especially in extension but still allow motion in the treated segment.*
- *Motion preserving interspinous implants allow the preservation of a range of motion (ROM)*
- *in the implanted segment, thus avoiding or limiting possible overloading and early degeneration of the adjacent segments as induced by fusion .*

H.Wilke, J. Drumm, K.H¨aussler, C.MacK,W.-I. Steudel, andA. Kettler, "Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure," European Spine Journal, vol. 17, no. 8, pp. 1049–1056, 2008.
J. C. Richards, S.Majumdar, D. P. Lindsey, G. S. Beaupr´e, and S. A. Yerby, "The treatment mechanism of an interspinous process implant for lumbar neurogenic intermittent claudication," Spine, vol. 30, no. 7, pp. 744–749, 2005.

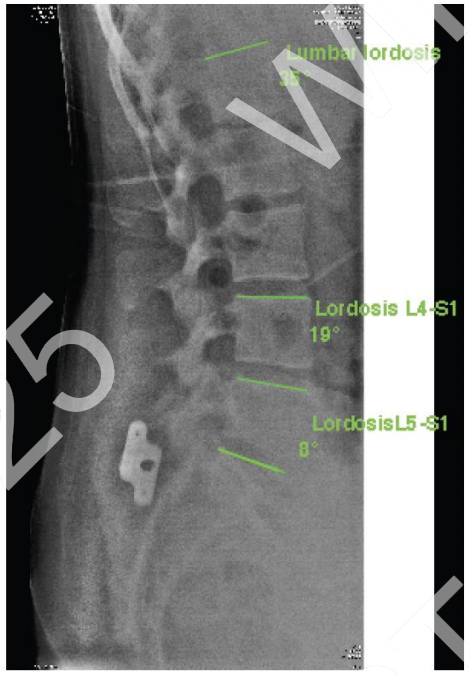
Biomechanical problems

Segmental Lordosis L5-S1
decreased:17º → 8º
Global Lumbal Lordosis L1-S1
Decreased: 48º → 35º

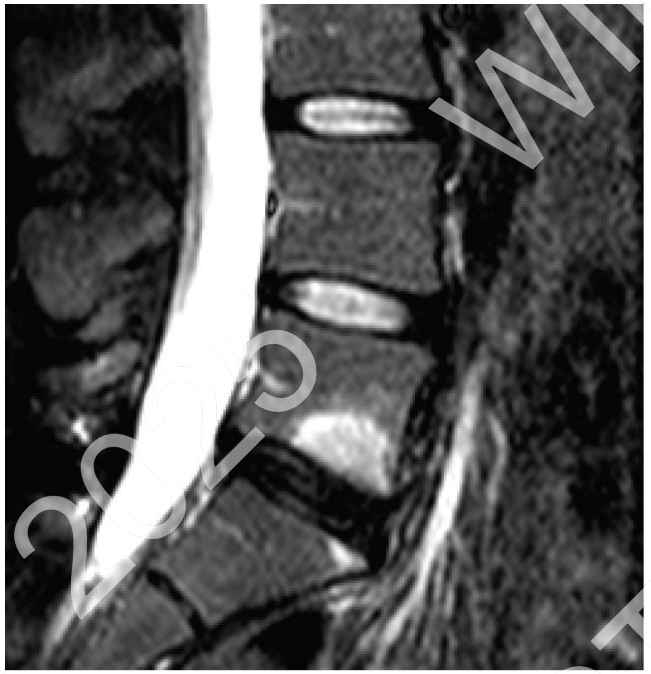
Modic II changes on the ventral endplates at L5-S1 on MRi



Preoperative



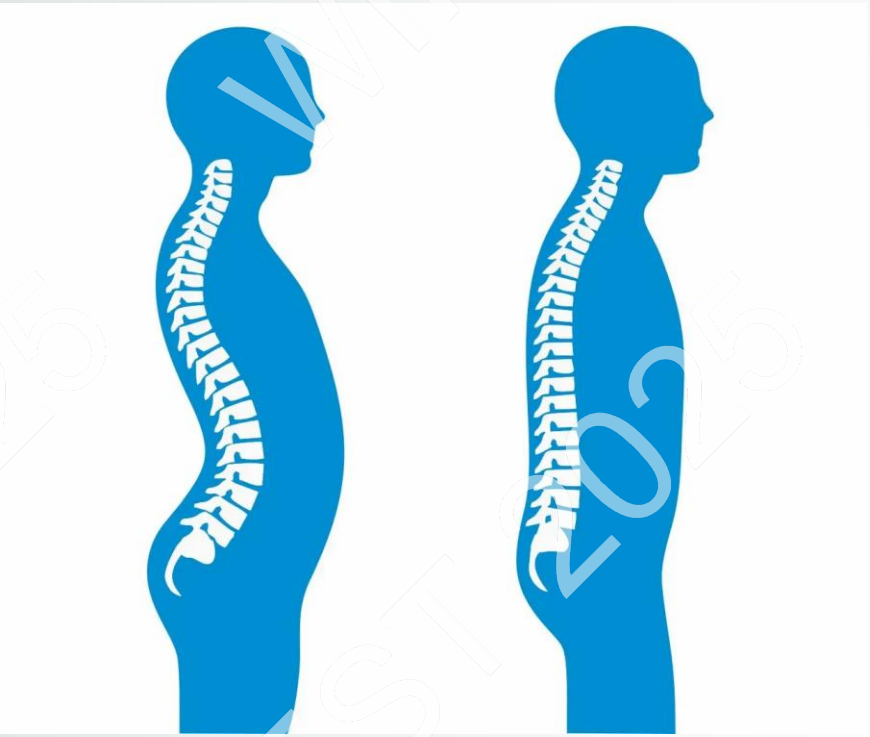
4 y postop.



4 y postop.

Paolo D. Parchi, et al. Hindawi Publishing Corporation
BioMed Research International
Volume 2014, Article ID 839325, 7 pages
http://dx.doi.org/10.1155/2014/839325

Biomechanical problems



„From a biomechanical point of view, it is mandatory to consider that the interspinous device induces a segmentary kyphosis in a tract of the spine which is normally characterized by lordosis and it could cause overload of the anterior disk if used in the standalone configuration."

Paolo D. Parchi et al. Hindawi Publishing Corporation
BioMed Research International
Volume 2014, Article ID 839325, 7 pages
http://dx.doi.org/10.1155/2014/839325

Life is a kyphosing disease

Meta-Analysis > Spine J. 2017 Aug;17(8):1180-1191. doi: 10.1016/j.spinee.2017.04.034. Epub 2017 May 2.

The relationships between low back pain and lumbar lordosis: a systematic review and meta-analysis

Se-Woong Chun [1], Chai-Young Lim [2], Keewon Kim [2], Jinseub Hwang [3], Sun G Chung [4]

Affiliations + expand

PMID: 28476690 DOI: 10.1016/j.spinee.2017.04.034

Conclusions: This meta-analysis demonstrates a strong relationship between LBP and decreased LLC, especially when compared with age-matched healthy controls. Among specific diseases, LBP by disc herniation or degeneration was shown to be substantially associated with the loss of LLC.

Study or Subgroup of Study	Lumbar Lordotic Angle								
	HC group			LBP group					
	mean	SD	N	mean	SD	N	SMD	variance	95% CI
Jackson 1994	60.9	12.00	100	56.3	11.50	100	-0.391	0.020	[-0.671, -0.112]
Wood 1996 (p = 0.190)	58.8		50	55.7		50	-0.264	0.040	[-0.658, 0.130]
Jackson 1998	62.1	10.80	50	59.28	12.88	110	-0.230	0.029	[-0.565, 0.105]
degenerative disc disease				56.5	12.20	50	-0.486	0.041	[-0.884, -0.088]
L5-S1 isthmic spondylolisthesis				66.4	12.10	30	0.381	0.054	[-0.076, 0.837]
scoliosis				56.8	12.01	30	-0.470	0.055	[-0.929, -0.012]
Korovesis 1999	69.0	17.00	120	63.0	18.00	120	-0.520	0.103	[-1.150, 0.110]
age 20 - 29 years	58.0	8.00	20	52.0	11.00	20	-0.175	0.100	[-0.796, 0.446]
age 30 - 39 years	59.0	21.00	20	56.0	12.00	20	-0.997	0.112	[-1.654, -0.339]
age 40 - 49 years	61.0	13.00	20	49.0	11.00	20	-1.325	0.122	[-2.010, -0.641]
age 50 - 59 years	72.0	10.00	20	60.0	8.00	20	-0.894	0.110	[-1.543, -0.244]
age 60 -69 years	67.0	20.00	20	50.0	18.00	20	-0.499	0.103	[-1.128, 0.130]
age 70 - 79 years	57.0	17.00	20	49.0	15.00	20	-0.343	0.017	[-0.598, -0.088]
Tuzun 1999	46.0	13.90	50	44.95	12.33	100	-0.272	0.040	[-0.665, 0.122]
actue LBP				42.7	10.10	50	-0.082	0.030	[-0.421, 0.258]
chronic LBP				47.2	12.70	50	0.090	0.040	[-0.302, 0.482]
Moon 2001	37.5	6.26	10	30.7	8.22	10	-0.931	0.222	[-1.853, -0.008]
Korovessis 2002	52.0	13.00	100	49.0	14.00	100	-0.222	0.020	[-0.500, 0.056]
Barrey 2007	61.0	9.70	160	52.16	13.04	85	-0.806	0.019	[-1.078, -0.533]
degenerative disc disease				48.8	12.50	32	-1.193	0.042	[-1.593, -0.793]
disc herniation				48.8	11.90	25	-1.217	0.051	[-1.658, -0.776]
degenerative spondylolisthesis				59.0	11.90	28	-0.199	0.042	[-0.602, 0.204]
Abbas 2010	45.20	7.00	100	42.8	7.00	67	-0.343	0.025	[-0.654, -0.031]
Endo 2010	49.00	10.00	60	36.7	14.50	61	-0.986	0.037	[-1.363, -0.609]
Liu 2014	42.53	7.86	52	36.01	12.92	61	-0.599	0.037	[-0.977, -0.221]
degenerative spondylolisthesis				44.93	8.63	32	0.294	0.051	[-0.148, 0.737]
spinal stenosis				26.17	9.18	29	-1.959	0.077	[-2.504, -1.414]
Yang 2014	50.17	10.83	115	37.7	13.80	45	-1.063	0.034	[-1.427, -0.699]
no LBP	53.0	9.60	80				-1.356	0.042	[-1.758, -0.954]
no LBP & no disc herniation	43.7	10.70	35				-0.478	0.052	[-0.926, -0.030]
Nguyen 2016	50.2	10.5	10	40.9	13.2	7	-0.798	0.262	[-1.800, 0.205]

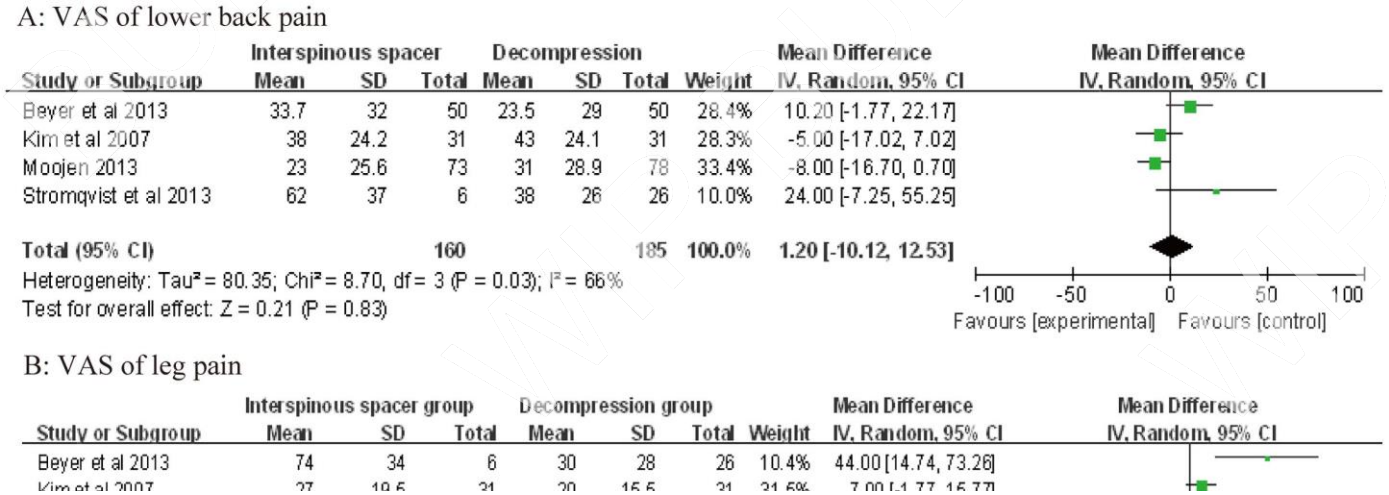
SD standard deviation; N number of subjects; SMD standardized mean difference; CI confidence interval; HC, healthy control; LBP, low back pain

OPEN ACCESS Freely available online

Interspinous Spacer versus Traditional D Surgery for Lumbar Spinal Stenosis: A Sy and Meta-Analysis

Ai-Min Wu[1], Yong Zhou[2], Qing-Long Li[1], Xin-Lei Wu[3], Yong-Long Jin[1], Pe Xiang-Yang Wang[1]*

- No significant difference in LBP or Leg pain between the 2 group
- No significant difference in the ODI scores
- No significant difference in the Roland disability questionaire
- Significantly more revision surgeries in the ISP group



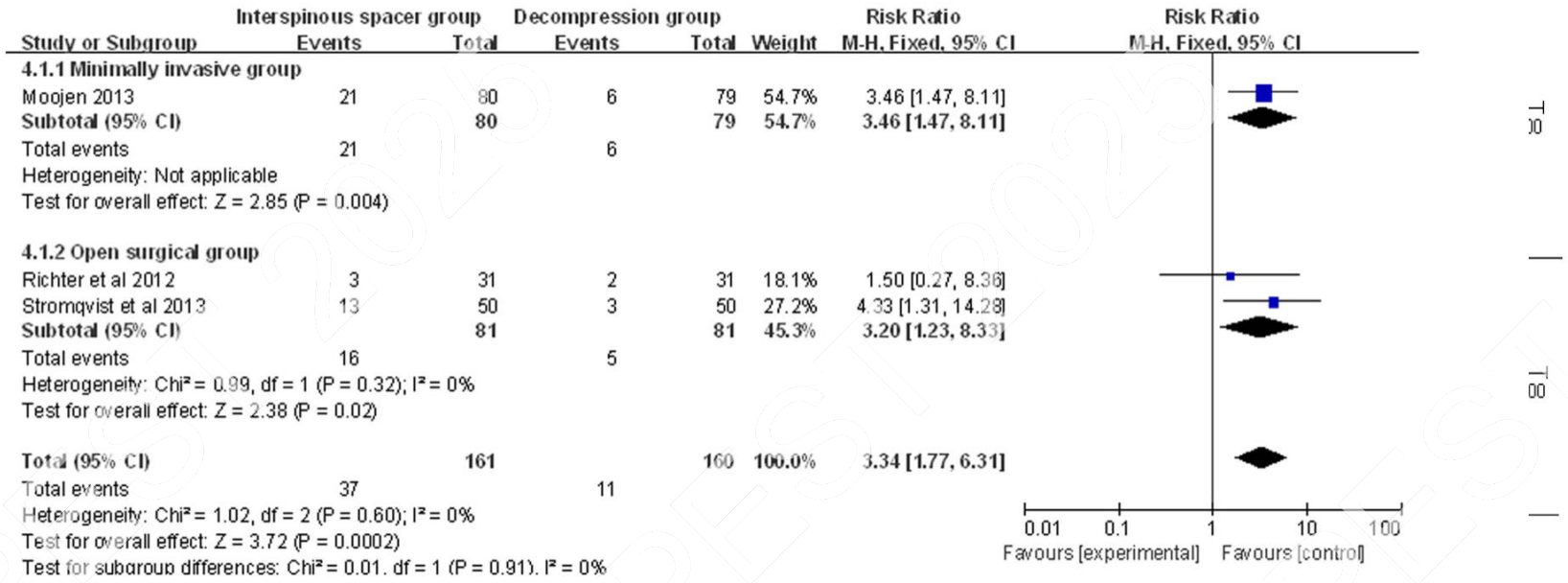


Figure 4. Forest plot showing the meta-analysis for the reoperation rate.
doi:10.1371/journal.pone.0097142.g004

Wu A-M, Zhou Y, Li Q-L, Wu X-L, Jin Y-L, et al. (2014) Interspinous Spacer versus Traditional Decompressive Surgery for Lumbar Spinal Stenosis: A Systematic Review and Meta-Analysis. PLoS ONE 9(5): e97142. doi:10.1371/journal.pone.0097142

ISP Complications

Table 4. Reasons for revision after placement of interspinous process devices.

	Across Implants[a]				Within Implants[b]		
Revision (n = 460)	**Coflex**	**Superion**	**X-Stop**	**Overall, % (n)**	**Coflex**	**Superion**	**X-Stop**
Inadequate efficacy	4.2%	87.4%	8.4%	46.7% (215)	29.0%	49.1%	39.1%
Implant migration	2.0%	91.5%	6.5%	33.3% (153)	9.7%	36.6%	21.7%
Fracture	10.0%	67.5%	22.5%	8.7% (40)	12.9%	7.0%	19.6%
Infection or wound healing	30.4%	52.2%	17.4%	5.0% (23)	22.6%	3.1%	8.7%
Implant malfunction	38.9%	55.6%	5.6%	3.9% (18)	22.6%	2.6%	2.2%
Neurological complication	10.0%	50.0%	40.0%	2.2% (10)	3.2%	1.3%	8.7%
Epidural hematoma	0.0%	100.0%	0.0%	0.2% (1)	0.0%	0.3%	0.0%
IPD-specific complication	6.6%	83.9%	9.5%	45.9% (211)	45.2%	46.2%	43.5%

Infection or wo
Neurological c
Epidural hemat

[a]Across group analy
[b]Within groups analy

Implant migration, fracture, and implant malfunction, 3 complications that are unique to decompression with an IPD as compared with traditional laminectomy, accounted for 45.9% of revisions (211/460), and revision was required in 33.0% of cases where 1 of these complications was reported (211/640).

Case report

- 78 y/o female
- 11 years earlier implantation of ISP at L4/5 due to spinal claudication
- 7-8 years good outcome
- Claudication returned with severe leg pain (70%), some low back pain (30%) and progressive decrease of QoL
- Minimal-invasive pain procedures including epidurolysis, epidural steroids resulted in temporary relief

Preoperative CT

- Massive hyperostosis around the implant
- Polysegmental degenerative changes
- Severe facet arthropathy
- L5-S1 degenerative spondylolisthesis
- Maasiv central and lateral spinal canal stenosis
- Severe polysegmental discopathy

Treatment options:

- Conservative therapy failed
- Minimal-invasive pain procedures over 2 years failed
- ISP already implanted
- Surgical options:
  - Removel of the ISP and minimal-invasive micro-decompression L2-S1
  - Removel of the ISP, decompression and fusion

Outcome:

- Immediate relief of the leg pain
- Claudication diminished, walking distance increased remarkebly
- Some residual low back pain
- Significant increase in QoL

Postoperative MRI 2y later

Comparable to decompressi
reoperation rates – Systemati
show that ISPs provide similar
disability compared to decom
report worse outcomes for bac
reoperations, even though the
and shorter hospital stays (Wu

Eur Spine J (2008) 17:188–192
DOI 10.1007/s00586-007-0492-x

EXPERT REVIEWS

Stand-alone interspinous spacer versus decompressive laminectomy for treatment of lumbar spinal stenosis

Expert Rev. Med. Devices 12(6), 763–769 (2015)

Carl Lauryssen[1], Robert J Jackson[2], Jeffrey M Baron[3], Richard A Tallarico[4], William F Lavelle[4], Harel Deutsch[5], Jon E Block[*6] and Fred H Geisler[7]

[1]*Neurosurgical Spine Institute, Lakeway, TX 78738, USA*
[2]*Orange County Neurosurgical*

Objective: To compare the two-year clinical outcomes of a prospective, randomized controlled trial of an FDA-approved interspinous spacer with the compilation of published findings from 19 studies of decompressive laminectomy for the treatment of lumbar spinal stenosis. Methods: Back and leg pain, Oswestry disability index (ODI), and Zurich Claudication Questionnaire (ZCQ) values were compared between spacer- and laminectomy-treated patients preoperatively and at 12 and 24 months. Results: Percentage improvements between baseline and 24 months uniformly favored patients treated with the spacer for back pain (65% vs. 52%), leg pain (70% vs. 62%), ODI (51% vs. 47%) and ZCQ symptom severity (37% vs. 29%) and physical function (36% vs. 32%). Conclusion: Both treatments provide effective and durable symptom relief of claudicant symptoms. This stand-alone interspinous spacer offers the patient a minimally invasive option with less surgical risk.

The X-Stop story:

Randomized Controlled Trial > Spine (Phila Pa 1976). 2013 Aug 1;38(17):1436-42.
doi: 10.1097/BRS.0b013e31828ba413.

X-stop versus decompressive surgery for neurogenic intermittent claudication controlled trial with 2-year follo

Björn H Strömqvist [1], Svante Berg, Paul Gerdhem, [illegible]
Tage Sahlstrand, Ahmed Soliman, Tycho Tullb[illegible]

Conclusion: For spinal stenosi[illegible] claudication, decompressive su[illegible] appropriate procedures. Similar [illegible] both groups, however, with a highe[illegible] reoperations in the X-Stop group. Pa[illegible]ng X-Stop removal and decompression experien[illegible]esults similar those randomized to primary decompression.

> Neurosurg Focus. 2010 Jun;28(6):E8. doi: 10.3171/2010.3.FOCUS1047.

Dynamic interspinous process stabilization: review of complications associated with the X-Stop device

Christian Bowers [1], Amin Amini, Andrew T Dailey, Meic H Schmidt

. Med (Seoul). 2021 Apr 19;16(2):177–183. doi: 10.17085/apm.20093

Real world adverse events of interspinous spacers using Manufacturer and User Facility Device Experience data

Nitish Aggarwal [1,✉], Robert Chow [1]

Author information Article notes Copyright and License information
PMCID: PMC8107255 PMID: 33866770

MILD vs. IPS

Pain Pract. 2023 Sep;23(7):776-784. doi: 10.1111/par

Percutaneous image-g
and interspinou
spinal ste
Ben

Peter
Natalie H Strand [4], Lawrence Poree [5]

Conclusions: This comprehensive study of real-world Medicare claims data demonstrated a significantly lower rate of harms for the mild procedure compared to interspinous spacers for patients diagnosed with LSS with NC, and a similar rate of subsequent interventions during 2-year follow-up.

Conclusions

- ISP's do work in most of the indications in the short to mid term, but
- On the cost of higher reoperation rates and complication rates
- It causes segmental and global kyphosis in the lumbar spine -- provoke LBP
- There are better alternatives with better long term/side effect profile, such as: microdecompression

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Thank you for your attention!

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