



Editorial on: “Superion[®] InterSpinous Spacer Treatment of Moderate Spinal Stenosis: 4-year Results”

Federico Caporlingua

Centro Chirurgico Toscano, Arezzo, Italy

Correspondence to: Federico Caporlingua. Via Gennaro Cassiani 10, 00155 Rome, Italy. Email: capor51@gmail.com.

Provenance: This is an invited Editorial commissioned by the Section Editor Guoxin Fan, MD (Department of Orthopedic Surgery, Shanghai Tenth People's Hospital, Tongji University School of Medicine, Shanghai, China).

Comment on: Nunley PD, Patel VV, Orndorff DG, et al. Superion Interspinous Spacer Treatment of Moderate Spinal Stenosis: 4-Year Results. *World Neurosurg* 2017;104:279-83.

Submitted Mar 26, 2018. Accepted for publication Aug 13, 2018.

doi: 10.21037/jss.2018.08.01

View this article at: <http://dx.doi.org/10.21037/jss.2018.08.01>

Nunley *et al.* must be commended for the effort they are currently putting in following-up, since 5 years by now, a cohort of patients treated with Superion implant (1). Originally, the study compared the results of this device with those of the X-Stop. Due to the recall of the X-Stop from the market and the unavailability of patients treated with this device, the authors were obliged to present the data about the Superion without any control.

The included patients were >45 years with diagnosis of one-level or two-level moderate lumbar spinal stenosis (LSS) causing an intermittent neurogenic claudication resistant to 6 months of conservative treatment.

The device is presented as a valid alternative to laminectomy not only because the epidural space is not opened preventing epidural scarring and unintentional durotomy, but it is a regional/spinal anesthesia procedure also. Nevertheless, the cited bibliography in favor to regional/spinal anesthesia use is inconsistent. Cited works talk about general anesthesia unrelated deaths or complications occurred during the treatment of non-spinal pathologies. It does not exist, at the present time, any prospective randomized trial comparing general to regional/spinal anesthesia for the treatment of LSS. It would be interesting to know if general anesthesia is more dangerous when treating LSS, but at the present time, we should not spread wrong or evidence-unbased messages. Moreover, 82.1% of patients who received the Superion implant were operated on with general anesthesia (2).

Epidural scar formation occurs every time the epidural space is opened. The scar thickness is somewhat

proportional to the surgical field width (3). Epidural scar together with many other postoperative issues (restenosis, hernia extrusion, vertebral instability, symptomatic facet syndrome) are the cause of failed-back surgery syndrome (FBSS). While the role of epidural scar in producing symptoms is defined, its clinical weight into this galaxy of FBSS possible causes is still unproven.

Evidence of the superiority of the Superion implant is also built comparing its results with those cited in in the current literature for the treatment of LSS with laminectomy with or without fusion. “*Diagnosis of lumbar spinal stenosis which requires any direct neural decompression or surgical intervention other than those required to implant the control or experimental device*” was an exclusion criterion. This criterion may be responsible of a selection bias. Current evidence shows that surgery is indicated after 6 months of failed conservative treatment (4,5). Finding a patient unresponsive to conservative treatment with slight foraminal or central root compression which does not require direct neural decompression is somewhat difficult. It is likely that patients were treated anyway if they presented “lower” disability (if they were able to sit for 50 minutes without pain and walk more than 50 feet), as stated in the inclusion criteria.

Inclusion of patients with radiological diagnosis of neural compression may be the cause itself of the biggest issue related to the stand-alone interspinous implantation: reoperation. One of the strongest point in favor to this technique is the safety of reoperation given that the epidural space is left intact during the

first surgery. The rate of reoperation is compared to that published by Forsth *et al.* (6) who followed up their patients for 6.5 years and during which they reoperated on 21% of the decompression-alone group at 21 months (mean, no spondylolisthesis) and 26 months (mean, with spondylolisthesis). This is one of the highest rate ever published; a recent meta-analysis reported that interspinous spacers have a significantly higher reoperation rate (28% vs. 7%) compared to decompression with or without fusion (7). Nunley *et al.* actually reoperated on 23.2% of the Superior arm at 24 months. Consequently, it can be inferred that most of reoperation occurs within the first 24 months and that patients who do not develop restenosis or instability are actually stable during the 3rd and 4th years postoperative. The results are stable at 5 years postoperative also (8).

It may be far more interesting to know which kind of patient required a revision surgery given that almost one out of 3 was reoperated on. Probably, better results were obtained in dynamic foraminal stenosis rather than in central fixed bony stenosis. This data should be shared in order to better define and perfectionate the indication to the Superior implantation. Indeed, especially in times when the incidence of fusion surgeries is in constant increase (9), to decrease reinterventions is a cost-limiting strategy. Parker *et al.* (10) reported that decompressive surgery and interspinous spacer implantation are cheaper than protracted conservative treatment. In times when reimbursement for laminectomy has decreased by 33% and fusion by 20% (11), spine surgery needs to be regulated and unnecessary interventions limited. Every surgery must be performed keeping in mind what is best for the patient (12).

In conclusion, the Superior spacer may be a valid alternative to open surgery in a well restricted population of patients affected by LSS providing long term results. Patients should be informed of the high rate of possible reintervention. Nevertheless, if correctly indicated, this simple, cost-effective and minimally invasive procedure might have long term results on pain and disability.

Acknowledgements

None.

Footnote

Conflicts of Interest: The author has no conflicts of interest to declare.

References

1. Nunley PD, Patel VV, Orndorff DG, et al. Superior Interspinous Spacer Treatment of Moderate Spinal Stenosis: 4-Year Results. *World Neurosurg* 2017;104:279-83.
2. Patel VV, Whang PG, Haley TR, et al. Superior interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial. *Spine (Phila Pa 1976)* 2015;40:275-82.
3. Fritsch EW, Heisel J, Rupp S. The failed back surgery syndrome: reasons, intraoperative findings, and long-term results: a report of 182 operative treatments. *Spine (Phila Pa 1976)* 1996;21:626-33.
4. Kovacs FM, Urrútia G, Alarcón JD. Surgery versus conservative treatment for symptomatic lumbar spinal stenosis: a systematic review of randomized controlled trials. *Spine (Phila Pa 1976)* 2011;36:E1335-51.
5. May S, Comer C. Is surgery more effective than non-surgical treatment for spinal stenosis, and which non-surgical treatment is more effective? A systematic review. *Physiotherapy* 2013;99:12-20.
6. Epstein NE. Commentary on: A randomized controlled trial of fusion surgery for lumbar spinal stenosis (Forsth P, Ólafsson G, Carlsson T, Frost A, Borgström F, Fritzell P, et al. *N Eng J Med* 2016;374:1414-23). *Surg Neurol Int* 2016;7:S641-3.
7. Machado GC, Ferreira PH, Harris IA, et al. Effectiveness of surgery for lumbar spinal stenosis: a systematic review and meta-analysis. *PLoS One* 2015;10:e0122800.
8. Nunley PD, Patel VV, Orndorff DG, et al. Five-year durability of stand-alone interspinous process decompression for lumbar spinal stenosis. *Clin Interv Aging* 2017;12:1409-17.
9. Ausman JI. The death of spine surgery as we know it today. *Surg Neurol* 2003;60:469.
10. Parker SL, Anderson LH, Nelson T, et al. Cost-effectiveness of three treatment strategies for lumbar spinal stenosis: Conservative care, laminectomy, and the Superior interspinous spacer. *Int J Spine Surg* 2015;9:28.
11. Watts C. Neurosurgery: A profession or a technical trade? *Surg Neurol Int* 2014;5:168.
12. Epstein NE. Lumbar stenosis surgery: Spine surgeons not insurance companies should decide when enough is better than too much. *Surg Neurol Int* 2017;8:247.

Cite this article as: Caporlingua F. Editorial on: "Superior® InterSpinous Spacer Treatment of Moderate Spinal Stenosis: 4-year Results". *J Spine Surg* 2018;4(3):666-667. doi: 10.21037/jss.2018.08.01