**Author's response to reviews**

**Title:** Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis

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**Version:** 2  
**Date:** 31 March 2014

**Author's response to reviews:** see over
Author’s response to reviews

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Version: 2  Date: 5 March 2014

Author’s response to reviews: see over
Reviewer's report

Title: Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis

Version: 1  Date: 24 December 2013

Reviewer: Franco Postacchini

Reviewer's report:

Major compulsory revisions

This study is interesting even if the goal was not to determine whether an interspinous spacer can provide similar results to surgical treatment, since it is a comparison of a newly introduced spacer with a previously introduced spacer. I have four observations to make:

1) In page 8, subsection “Subjects”, line 4, the authors defined stenosis as moderate when there was “25% to 50% reduction in lateral/central foraminal diameter” It would seem that they refer to the spinal canal and not to the intervertebral foramen because the spinal canal includes central and lateral portions, while the neuroforamen has no central and lateral part. This statement should be changed or clarified.
   We have clarified this sentence as follows: “…defined as 25% to 50% reduction in central canal, lateral recess, or foraminal diameter compared to adjacent levels.

2) Same subsection, line 9. One of the inclusion criteria was that the patient had to be able to walk at least 50 feet. Such a patient, able to walk only 15 meters, usually has an extremely severe stenosis.
   All enrolled patients were diagnosed with “moderate” lumbar spinal stenosis using radiographic criteria. The entry criterion in question, along with others, was included to rule out patients with concomitant severe conditions that might confound study outcomes. Specifically, a patient that cannot walk at least 50 feet likely would not be able to accurately the severity of intermittent claudication symptoms.

3) Same subsection, line 11. One of the exclusion criteria was grade II or greater spondylolisthesis. Grade II means 50% olisthesis, which is an extremely high magnitude of displacement for degenerative spondylolisthesis. In my life, the two most severe degenerative spondylolistheses that I encountered had 34% and 40% displacement, according to the Mayerding classification, and had a very severe stenosis. In the majority of cases, the amount of slipping does not exceed 10-15%, i.e. is well below the limit of the 25% of Grade I.
We agree with the reviewer that the definition of “Grade I” is quite broad with a range of 1% to 25%. We ensured that a patient with spondylolisthesis that caused severe stenosis using radiographic criteria was excluded, based on definition of “moderate” lumbar spinal stenosis.

4) Several studies demonstrated that patients with degenerative spondylolisthesis may have an increase of vertebral slipping when using interspinous spacers, unless the slipping is very mild (less than 10%). The authors should a) extrapolate the patients with spondylolisthesis in the two study group, b) report the mean amount of slipping that they had, c) determine whether the slipping had increased after treatment, independently of the clinical result, d) report the clinical result in patients with spondylolisthesis and e) address the problem of stenosis in patients with spondylolisthesis when treated with spacers in the Discussion.

In Subject Characteristics, we have reported that “Grade I spondylolisthesis was identified in 34% of Experimental patients and 28% of Control patients”. Additionally, we have included a new section in the Results titled “Subgroup analysis: Spondylolisthesis”, which reports main outcomes according to the presence or absence of spondylolisthesis at baseline. Additional data requested by the reviewer including mean amount of slipping and change in slipping over time were unavailable. We have included this as a limitation of the study.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:** I have no competing interests
Reviewer's report

Title: Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis

Version: 1 Date: 5 February 2014

Reviewer: Panagiotis Korovessis

Reviewer's report:

1) This a well made prospective randomized study with appropriate statistics. I would like to see a flow chart as usually is presented in prospective randomized studies with eligible patients, exclusion etc.

Unfortunately, screen failure logs are not available and, therefore, reasons for study exclusion cannot be reported. Of the 250 randomized subjects, safety data are provided for all while patient-reported outcomes are available for 192 subjects. In the 58 subjects without 2-year patient-reported data, they either withdrew from the study or were lost to follow-up. We have included this text in Subject Characteristics.

2) Then, the one-level stenosis very seldom provokes spinal neurogenic claudication. Please comment on this regarding the one-level surgery in this series.

We have included the following sentences in the Devices section: “Interspinous spacers were implanted at 1 (51%) or 2 (49%) levels, with a comparable distribution between groups.”

3) Too many Figures, while in the manuscript there is also a description of these results presented in the Figures. I recommend these authors to reduce either the Figures or the Results section, since there were no significant differences between the groups.

We have deleted Figures 6, 8, and 10 for brevity. We have quantified the relationship between pre-treatment symptom scores and magnitude of improvement over 2 years with correlation coefficients.

4) In Figure 1, I cannot see any degeneration, but an olisthesis grade I! Is this actually an indication for interspinous device implantation? I am afraid no.

The main indication for interspinous implant was radiographically confirmed lumbar spinal stenosis associated with persistent leg, buttock, or groin pain, with or without back pain, that was relieved by lumbar flexion. All patients failed at least 6 months of conservative treatment before enrollment into this trial. Patients were eligible to participate provided spondylolisthesis grade was 0 or 1.
Reviewer’s report

**Title:** Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis

**Version:** 1  **Date:** 13 February 2014

**Reviewer:** Gabriel Tender

**Reviewer’s report:**

1) The authors report good outcomes with X-Stop and Superion in patients with moderate LSS. The data are sound, well presented, and worth publishing. However, there have been reports on high failure and reoperation rates after X-Stop. The authors should describe in much more detail their complications and at least attempt to explain the differences between their work and existing literature (better technique? better patient selection? better implants?).

   In the Complications section, we have described the timing of reoperations during the 2-year follow-up period. Additionally, we have provided Table 1, which lists reoperations by type and treatment group. We state that the clinical outcomes of this study are comparable to those in other studies in Discussion, paragraph 2. We also acknowledge the likely role of strict patient selection in these outcomes in the final paragraph.

2) There might also be some value in analyzing their results in the subset of patients with spondylolisthesis.

   In Subject Characteristics, we have reported that “Grade I spondylolisthesis was identified in 34% of Experimental patients and 28% of Control patients”. Additionally, we have included a new section in the Results titled “Subgroup analysis: Spondylolisthesis”, which reports main outcomes according to the presence or absence of spondylolisthesis at baseline.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:** I declare that I have no competing interests.
Editorial Requirements

1) Name of ethics committee: Please update your ethics statement to include the name of the ethics committee that approved your study.

   We state in the Ethics section that the study was approved “by all researchers and the institutional review board at each respective site”.