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

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Reviewer: Franco Postacchini

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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.

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.

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.

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.

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