Reviewer's report

Title: The Felix-trial Double-blind randomization of interspinous implant or bony decompression for treatment of spinal stenosis related intermittent neurogenic claudication

Version: 1 Date: 10 March 2010

Reviewer: David H Kim

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The proposed prospective randomized trial comparing interspinous process spacers with decompressive surgery is a potentially significant study with important implications regarding relative efficacy. I am a US spinal surgeon, and the specific interspinous process spacer design as well as bilateral laminoforaminotomy are not widely used in the United States, and this will significantly limit applicability for US practice. However, to the extent that bilateral laminoforaminotomy is commonly performed in Europe, this will be a more useful study for European practice.

Major Compulsory Revisions:

1. One year is too short for any conclusions regarding long-term outcome. The highest quality prospective clinical data reported to date was the X-STOP data submitted to the US Food and Drug Administration and suggested significant deterioration in results around one year following surgery. A minimum of two-year follow-up should be strongly considered.

2. Similarly, 8 weeks seems like an arbitrary and clinically minor time point. It is certainly too early to make any meaningful conclusions about outcomes and should be used as the primary endpoint. If a short-term outcome time point is sought, then comparisons can be made at 8 weeks, 6 months, and 1 year; however, the most meaningful time points will be the later ones.

3. Presumably, postoperative radiographs will be required to follow patients who have undergone placement of an implant. How will the double-blind status of the study be protected in terms of obtaining radiographs.

4. The study design lacks the two most important clinical subgroups in its subgroup analysis: spondylolisthesis and osteoporosis.

Minor Compulsory Revisions:

1. Average surgical time will be different for the two procedures, with interspinous process spacer surgery requiring approximately 30 minutes, and bilateral laminotomies requiring twice the time. How will the investigators keep family members from correctly guessing the surgery on the basis of the time of surgery?

2. The investigators can obtain baseline preference scores assessing preoperative patient preferences from "strong preference for IPD" to "strong preference for decompression surgery"; but presumably, nearly all patients with a
strong preference one way or the other will simply decline involvement in the study and elect simply to proceed with the surgery of their choice. How will the investigators be framing the study in order to optimize recruitment? If patients are informed that the two procedures may be equivalent based on available clinical evidence, then any rational patient would decide to proceed with the less risky and less invasive interspinous process spacer and again decline participation in the study. If patients are informed that the interspinous process spacers are less invasive but may be less effective, then this will bias results (if, as is often the case, patients can correctly guess their treatment allocation).

3. A more appropriate design would be a non-inferiority design. Interspinous process spacer placement is considered less invasive and risky than decompressive surgery extending into the spinal canal. Also, the assumption of at least 84% success associated with interspinous process spacers is relatively high considering the one and two-year results reported by Zucherman et al. in the X-STOP trial.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I am a consultant to Pioneer and Medtronic, both companies with an interest in the area of interspinous process spacer technology.