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: 2  Date: 20 April 2010

Reviewer: Alexander Richter

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Minor Compulsory Revisions:
As I pointed out in my former review I’m still missing the discussion on the indication for the coflex device for indirect decompression.

The Indication for the Coflex IPD is to unload the facet joints, restore foraminal height and provide stability after decompressive surgery in order to improve the clinical outcome. To my knowledge the implant is still not recommended by the Company for an indirect decompression procedure (see indications www.paradigm-spine.com). Wilke et al. (Eur Spine J 2008) could show in their biomechanical analysis, that four different types of interspinous implants (Diam, Coflex, X-Stop, Wallis) are able to stabilize and reduce the intradiscal pressure in extension, but had almost no effect in flexion, lateral bending and rotation. In Extension all implants allowed about 50% of the range of motion of the intact state. They did not investigate if the implant has an effect of indirect decompression to the neurological structures or not. Up to my knowledge there is no study on the market, which deals with the indirect decompression of the spinal canal by implanting a Coflex device (in comparison to the X-Stop device, which is very well biomechanical and radiological investigated). It might work as a indirect decompression device, but the use for this specific indication is in my opinion still experimental.

I still think, that using this Coflex implant for indirect decompression is a new indication for this specific implant and should be explained more detailed and pointed out by the authors.

The study protocol is well designed und fulfils high evidence level.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:
I declare that I have no competing interests