Author's response to reviews

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

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Author's response to reviews: see over
Dear Editor and reviewers,

Firstly, we want to thank the reviewers for their work and precise reading of our manuscript. In this letter we would like to comment on the reviewers’ points of concern.

The design of the Felix Trial is presented in this protocol. Inclusions have started in January 2009. Therefore, not all supposed revisions could be made due to some ethical and, especially, epidemiological reasons. Our research group includes two epidemiologists, neurosurgeons, neurosurgery residents, PhD students and research nurses (www.lumc.nl/con/5038 or www.lumc.nl/sips). In the following we would like to emphasize our comment on your proposed revisions.

Kook Jin Chung discusses the paper of Kirkaldy-Willis. Kirkaldy-Willis et al reported in 1978, based on an autopsy study a spectrum of degenerative changes that leads from minor to marked stenosis. Others like Arnoldi et al stated a few types lumbar spinal stenosis in 1976. He reported the “general opinion” of a spine “symposium” concerning lumbar spinal stenosis. Different types have often been suggested. Most studies distinguish between congenital and degenerative stenosis. Most recent prospective trials, like Malmivaara et al in Spine 2008 and Weinstein et al in New England Journal of Medicine in 2008, do not distinguish between different types of “degenerative lumbar spinal stenosis”. Quote Weinstein et al 2008: “All patients had a history of neurogenic claudication or radicular leg symptoms for at least 12 weeks and confirmatory cross-sectional imaging showing lumbar spinal stenosis at one or more levels”. We share Kook Jin Chung’s opinion, Therefore, a subgroup
analysis is conducted to investigate whether treatment effect varies over subgroups (age over and under 60 years) of patients.

Secondly, Kook Jin Chung and Al Richter ask why we do not do a flavectomy. Al Richter even states the possibility of different types of interspinous devices (IPD): an indirect decompression device and stabilization device. Firstly, like many more biomechanical studies, Wilke et al concluded in their analysis in 2008 that the tested interspinous decompression devices (Coflex, X-stop, Wallis and Diam) had the same effect on flexion and decompression. The Coflex U-shape was claimed to give an indirect decompression (Paradigm Spine). It is true that some studies compare a wide decompression and postero-lateral fusion with decompression and Coflex fixation. However, as stated in Paradigm Spine’s initial statement’s indirect decompression U-shape, combined with the results of the biomechanical studies’ conclusion of the interchangeability of the most interspinous devices, we planed to test the clinical relevance of the indirect decompression. Many studies have been done with Coflex and other devices such as the Diam and the X-stop, comparing conservative treatment compared to IPD surgery. We plan to take the research one step further, like Strömquist et al presented in his poster presentation at the Annual Meeting of the North American Spine Society in 2007: indirect decompression versus conventional decompression. Furthermore, we would like to make clear that Paradigm Spine is funding our Trial and approved with our operation technique in the IPD group.

Kook Jin Chung also asks us how we deal with covariates that will influence the shuttle walking test. Like in all randomization procedures, the influence of covariates in the shuttle walking test will be limited by randomization.
Like David H Lim, Al Richter has some comment on our follow-up period. Like many less invasive treatments, IPD claim to shorten hospital stay and less muscular damage. Therefore, we took a short-term outcome (eight weeks) and a long term outcome (one year). Al Richter asked why we did not have any long-term follow-up points. We want to refer to table 4 (flowchart) in which we include a follow-up until 60 months to give answers about the long term follow-up, such as Al Richter suggested, in patients with lumbar spinal stenosis treated by indirect process decompression.

The reviewer’s own article (Richter et al., Eur Spine J 2010) will be included in our meta-analysis and systematic review (now in progress) and is now also included in our revised manuscript. We thank you for kindly suggesting this article as a reference in our manuscript.

David H Kim had some comment about our precautions to keep patients blinded. David H Kim assumes that we take standard radiographs in our postoperative follow-up. However, standard radiographs are not standard postoperative care in The Netherlands. Surgical time will differ, but as stated in our manuscript, all patients will have general anesthesia. So combining anesthetic time and operation time, total time will not differ much. In the first year of inclusions, nor the patients or the family guessed the blinded chosen therapy right based on total time of surgery. However, we share the concerns of David H Kim for keeping the patient blinded.

Indirect decompression in patients with spondylolisthesis will be performed until type I. In our opinion, spondylolisthesis type 2 and typ3 will require fixation. This is not possible due to patient blinding. Fixation will elongates operation time and will
increase the scar size. In patients with osteoporosis implanting an interspinous device will be difficult (see Miller et al) and will lead mostly to failure. Therefore, patient groups were excluded.

The last question of the reviewers was about our design (non-inferiority design versus superiority design). We believe that an expansive implant and procedure should only be implanted when it is prove superior to the standard therapy. When the coflex is proven non-inferior, one would accept a 15% less effective treatment as equal compared to a far less expansive treatment. That is the consequence of taking a non-inferiority design for answering the research question.

We hope that we have answered all the reviewers’ questions. Enclosed please find our revised manuscript entitled ‘The Felix Trial: Double-blind randomization of interspinous implant or bony decompression for treatment of spinal stenosis related intermittent neurogenic claudication’, which we would like to be reconsidered for publication in the BMC Musculoskeletal Disorders. We hope that it does meet your standards to appear in the BMC Musculoskeletal Disorders.

The authors state that all procedures will be performed in accordance to national and international laws. Furthermore the manuscript is not currently under consideration elsewhere.

Kind regards,

Wouter A. Moojen