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 colleague,

The widespread use of interspinous implants have been implemented without any strict indication. The senior authors have a wide experience with the X-stop device for the indication of neurogenic claudication. The trial was designed for the X-stop. When the coflex device was launched we saw the personal better results compared to the X-stop device for the "good" indication neurogenic claudication with the indirect decompression.

So in my personal opinion the Coflex works better than the X-stop device for the indication of neurogenic claudication and is used widely for this indication. We elaborately discussed the study and the protocol with, by the reviewers mentioned, Paradigm Spine. As such the company believed in the indication and saw the advantages in gathering evidence by performing a randomized trial. Therefore the same Paradigm Spine very generously sponsored this study, in which we independently from the Coflex firm are able to analyze the results.

Last but not least, as a Spine Neurosurgeon and Epidemiologist I do have great reservations and sorrows about surgical indications for so called facet pain. In my opinion the indication of facet joint pain is worthless and deserves closer attention by good designed randomized trials instead of the widespread use of this expensive implant. The relieve of the facet joints by the use of Coflex to diminish low back pain of facet joint movement pain is a very grey area and should be evaluated by a separate randomized trial. With all respect to all surgeons who use this implant for this indication, this is a very difficult discussion between experts. Evidence Based Medicine should be applied to all facet joint surgeries if facet joint pain exists at all? As far as I do know this is also sponsored and actually performed right now in your country. I am not aware of a publication with the design of the study.

So to summarize, the indication INC for Coflex is widely used and replaces X-stop in a lot of countries. As we are believers in Health Technology Assessment we do want to critically evaluate new technologies. As such, Paradigm spine sponsors this trial, which protocol cannot be changed. If a disagreement about this point still exists I do propose to the editorial board that my colleague Richter and I have a phone conference.

Sincerely yours,

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