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: 9 March 2010

Reviewer: Al Richter

Reviewer's report:

The author of this study protocol have chosen a very interesting topic in the discussion of operative treatment of symptomatic spinal stenosis. The question they are trying to answer is if a minimal invasive approach by implanting an interspinous processus device (IPD) can achieve similar good results (in the short time of one year) in the clinical outcome compared to the standard procedure of laminotomy (efficacy, cost effectiveness). As said by the authors published information is limited.

IPD’s can be divided into static and dynamic implants. One of the dynamic interspinous implants is the Coflex™ Device (Paradigm Spine, LCC, New York New York), formerly Interspinous ‘U’’. The authors should point out, that there are two different approaches to achieve the clinical goal, first indirect decompression by implanting an IPD, second implanting an IPD after standard decompression in order to stabilize the segment. The indication of the U-shaped titan Coflex IPD is to stabilize the segment following decompressive surgery. It was first invented in 1994 by the French orthopaedic surgeon Jacques Samani as an alternative to arthrodesis, in order to protect adjacent levels after spinal surgery and for the protection of degenerative segments following decompressive surgery. Due to the Company’s indication the aim of this interspinous device is to unload the facet joints, restore foraminal height and provide stability after decompressive surgery in order to improve the clinical outcome. So using this Coflex implant for indirect decompression (without laminotomy) is a new indication and should be explained and pointed out by the authors. So far this procedure is not recommended by the Company (see indications www.paradigm-spine.de)

In the references i’m missing one publication which is recently available. The study compares prospectively decompression surgery vs additional implanting of a Coflex device. After a follow up of one year no differences in the clinical outcome could be found by the authors. [Richter et al., Eur Spine J 2010 Feb (2) 283-9, Epub 2009 Dec5].

The authors are planning a follow up of 8 weeks and one year as written in the Methods/design chapter. I would prefer an even longer follow up (2 years/ 5 years/ 10 years) to see the long time effect of the implant due to revision rate and clinical outcome (compared also to the literature). In the outcome assessment a follow up of 60 month is described.
In the discussion the aim of this study is “to determine whether the IPD is more (cost-) effective after eight weeks compared to the conventional surgery”. I think the aim of the study should not be restricted to 8 weeks. The effective of the IPD should be analyse in the short- mid- and longtime follow up period.

Inclusion criteria (p20)
“…Patient will be included…

In summery this study protocol is well designed und fulfils high evidence level. Some more explanations have to be made concerning the aim of the Coflex IPD in the so far standard use and the new approach. The aspired follow up period has to be more structured.

Defining the indications for new technologies is an ongoing challenge.