New disc prosthesis maintains spine mobility

Background:

Lumbar disc replacement is a rapidly expanding surgical treatment modality for long-standing back and leg pain due to intervertebral disc degeneration. Compared to fusion surgery, it has the advantage of preserving segmental mobility, but convincing evidence of superiority over fusion surgery is missing.

As part of this research project, I participated in the development of a new intervertebral disc prosthesis, with several international patents attached to the design of the prosthesis, the instrumentation and the insertion technique. The Kineflex (Centurion) lumbar disc is a mechanical, un-constrained, re-centering disc prosthesis developed in South Africa. After the development and manufacturing of the disc, prototype test racks were custom-made at the premises of the manufacturer and the disc was extensively tested for mechanical wear and fatigue.

The first implantation took place in October 2002. I prospectively captured all cases performed by our centre, with documentation including demographic data, co-morbidities, clinical history, symptoms and signs. The completed consent forms were filed. The outcome was monitored, pre-operatively and in follow-up, with complete radiological documentation of all radiographs on JPEG files. Clinical outcome results were documented using two different internationally validated questionnaires as well as our own questionnaire, which expands further on work and demographic details, previous operative and conservative treatment, and satisfaction with the treatment outcome.

The aim of the project was to develop a disc prosthesis that is suitable and safe for human implantation into the lumbar spine disc space, even in severely advanced disc degeneration, and to verify this in the outcome studies presented in this thesis. Existing indications and contra-indications for artificial disc replacement were critically evaluated regarding their validity for this particular implant.

Results:

Chapter 3 elaborates on the extensive pre-clinical mechanical wear and fatigue testing protocol to which the Centurion (Kineflex) lumbar disc prosthesis was subjected. The results of this testing protocol, together with our early clinical outcome results, formed the basis for the awarding of the European quality recognition (CE-Mark). In these extensive *in vitro* studies, we were able to show the durability of the Kineflex disc prosthesis in the long term. This, together with our initial clinical outcome results, formed the basis for the acceptance into a “prospective, randomized, multicenter

Food and Drug Administration investigational device exemption study of lumbar total disc replacement with the KINEFLEX Lumbar Artificial Disc *versus* the CHARITÉ™ Artificial Disc".

Chapter 4 is compiled from an invited submission to a new book on motion preservation surgery in the human spine, edited by leading spine surgeons in the field (James J Yue, Rudolf Bertagnoli, Paul McAfee, and Howard An) and published by Elsevier Publishers: Chapter 42: Kineflex. In this chapter, an overview is given of the ideas behind the Kineflex disc development, as well as of the insertion instrumentation used for disc implantation. It further reports on early clinical outcome results of the first patients implanted with the device in our centre (the first 40 implantations worldwide were all performed by me).

Chapter 5, our first peer-reviewed international publication, reports on clinical and radiological two-year outcome results of our first 100 patients. With the Kineflex implant, we could demonstrate equally good radiological placement accuracy in patients with severe and less severe disc degeneration of the index level, rendering the implant suitable even in severe degeneration of a spinal motion segment.

Chapter 6 and Chapter 7 of this thesis consist of two further peer-reviewed publications. They both report on so-called "off-label" patient sub-groups in our disc replacement series.

In Chapter 6 we present the second published series on a larger group of patients presenting with adjacent segment disease after previous lumbar fusion surgery as well as the first publication, which investigated the radiological changes in alignment parameters secondary to the disc replacement surgery in this patient group.

Chapter 7 consists of the first published series on patients with "degenerative spondylolisthesis" treated with disc replacement surgery. A detailed description of the operative reduction technique is provided, which is unique to the Kineflex disc and its insertion instrumentation. In this pilot study, two-year results on a limited patient group are presented.

This thesis concludes with the overall discussion in Chapter 8. It outlines the current knowledge on artificial disc replacement and places my results into perspective with recent discoveries published in the literature. It finishes with my assessment of what future research should concentrate on.