Development of a Biomimetic and Radiopaque Prosthetic Implant for the Nucleus Pulposus

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Introduction

Debilitating low back pain is an immense societal problem. In many cases, the pain can be attributed to an intervertebral disc problem, such as *hernia nucleus pulposus* (HNP). In a small but significant subset of these patients, the annulus fibrosus ring is still competent, except -of course- for the herniated part. In such cases, a treatment option can be to replace the herniated nucleus by a prosthetic implant, and to repair the annulus fibrosus structure. Nucleus replacement is an emerging approach, and a variety of implant designs and concepts have been introduced already[1,2].

Several years ago, our research group has reported on a new concept to replace the nucleus pulposus[3,4]. The new prosthesis consists of a radiopaque (iodine-containing) hydrogel that is implanted in dry form. Swelling occurs in situ, i.e. post implantation. The prosthesis is designed in such a way that it will fill the entire nucleus cavity after swelling. It was hypothesized that this is a mandatory condition to achieve physiological stress distribution within the disc, and –hence- to minimize the risk for implant migration. Furthermore, the implant was engineered in such a manner that adequate physical-mechanical properties and fatigue resistance are realized. Here, we report the first results of an implantation study in which the new nucleus prosthesis was implanted in a canine lumbar spine model.

Methods

Two groups of canine spinal specimens were used, one consisting of ten L1-L5 specimens (L2L3-group), the other consisting of ten L5-S1 specimens (LS-group). Each specimen was tested in the native state, after nucleotomy alone (L2L3-group) or nucleotomy combined with dorsal laminectomy (LS-group), and after insertion of the NPP. Range of motion, neutral zone and neutral zone stiffness were determined in flexion/extension, lateral bending and axial rotation. The overall condition of the prosthesis was visually assessed post biomechanical testing.

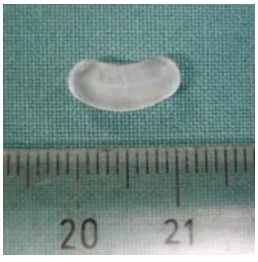

Figure 1.Photograph of the nucleus pulposus prosthesis (NPP).

Results

Load-displacement testing demonstrated that both nucleotomy alone and combined with dorsal laminectomy led to significant instability, and that implantation of the novel NPP resulted in significant restoration of stability. However, stability was restored to the native state for only a few parameters. Moreover, the NPP had sustained considerable damage in 44.4% of the L2L3-group cases and in 50% of the LS-group cases.

Conclusions: The NPP has the ability to significantly stabilize the L2-L3- and lumbosacral spinal segment after surgical decompression. However, the NPP is susceptible to significant damage, resulting in a decreased restorative ability and herniation of NPP material.

Conclusions

This cadaver study reveals that the new nucleus prosthesis can restore stability and functionality of the decompressed spinal segment. However, many of the specimens sustained considerable damage due to biomechanical testing. Three plausible factors for this damage are: (1) physical mechanical characteristics of the biomaterial, (2) improper annular closure and (3) excessive mechanical forces during the implantation procedure. Integrity of the implant and confinement inside the nuclear cavity are essential conditions for the safety and functionality of this concept; therefore, future studies need to include: (1) improvement of the physical-mechanical characteristics of the NPP biomaterial, (2) development of an NPP insertion device, and (3) improvement of the annular closure. These improvements of this NPP concept are prerequisites for safe, future applications *in vivo*.

References

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