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A spiral implant as nucleus prosthesis in the lumbar spine

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Abstract Microdiscectomy represents the gold standard in disc surgery on the lumbar spine. The remaining defect in the intervertebral disc space can be filled with a newly developed nucleus prosthesis presented in this paper. This prosthesis consists of polycarbonate urethane (Sulene™ PCU), and takes the form of a memory coiling spiral. It can be easily implanted using the standard microdiscectomy approach with no further tissue damage. Biomechanical tests have shown that anatomical distances can be restored by the spiral for both the facet joints and the endplates. Endplate deformations are not statistically different when compared to intact conditions. Inclusion

and exclusion criteria of an in vivo pilot study are presented. The paper describes the insertion setup for the spiral and the technique of implantation. Five patients have been supplied with the implant to date. The first results on postoperative magnetic resonance images are presented.

Keywords Nucleus prosthesis · Artificial disc · Non-fusion treatment · Spine arthroplasty · Discogenic pain

Introduction

In many cases, low-back pain arises from pathological discogenic changes of the lumbar motion segment. Autopsy studies have shown that by the age of 21, in nearly every second person, at least one lumbar disc is already damaged. Moreover, even in healthy symptom-free adults, disc protrusions and disc herniations are found frequently [1].

With conservative treatment being routinely the initial treatment in discogenic low-back pain, clinical symptoms such as an increasing sensomotoric deficit or a more or less complete cauda equina syndrome as well as therapy-resistant radicular pain may require surgical intervention. So far, microsurgical discectomy, whether performed through an open endoscopic or microscope-assisted procedure, represents the gold standard procedure for herniated discs.

Depending in part on the amount of disc material being removed, more or less dramatic changes may threaten the lumbar motion segment [2, 3, 8, 13]. With progressive loss of the pressure-absorbing function of the disc, the height of the affected segment will be reduced, resulting in a further degeneration of annulus and remaining nucleus. Finally, the segment will collapse, increasing the load on both facet joints, leading to accelerated spondylarthrosis and reduced mobility.

For many decades, several attempts were made to create an efficient implant to replace the herniated or degenerated nucleus, including the concepts of a waterbladder [7], a hydrophilic elastomer [4] and a silicone polyethylene implant [5]. More or less ineffective, these implants never went into clinical studies or into routine use. Recently, the PDN device (Prosthetic Disc Nucleus; RayMedica, Inc., USA), developed by Charles Ray, has been gaining influence [11]. Briefly summarizing, it consists of a hydrogel core with a polyethylene coating serv-

Fig. 1 New spiral implant

ing for nucleus augmentation. However, difficulties in the implantation technique as well as reports on dislocation are important drawbacks that still prevent the routine use of this device.

A different approach was taken in 1997 by J. L. Huson in cooperation with SulzerMedica [9, 10]. They developed an intervertebral spacer for nucleus replacement in the form of a memory coiling spiral (Fig. 1). The memory effect is based on a specifically validated manufacturing process, with modulation of the molecular chains of the basic component – polycarbonate urethane – into a spiral form. Being in rectilinear position before application, the implant will roll automatically into a spiral shape and will cover in situ the intervertebral disc cavity with no fixed mechanical axis.

Material

The basic implant material – polycarbonate urethane (Sulene™ PCU) – is a well-established material in medicine (used, for instance, in other spinal implants and cardiovascular surgery), and has been extensively and successfully tested for biocompatibility and biostability. When comparing polycarbonate urethane with polyurethane (PUR) in a fatigue test model, electron microscopic studies after five million cycles have shown microcracks in PUR, but not in Sulene™ PCU.

When comparing an intact lumbar motion segment with a nucleotomized segment without and with the spiral, biomechanical cadaver tests have revealed that the spiral is able to restore both the cranio-caudal distance of a lumbar facet joint, and the cranio-caudal distance between the adjacent endplates [12]. In additional biomechanical tests comparing intact, nucleotomized and nucleoplastically supported functional spinal units, the effects of axial com-

pression and eccentric loading in different directions were measured, with special emphasis on the endplate deformation [6]. The coiling spiral increased central endplate deformation when compared to nucleotomy. Furthermore, the endplate deformations were not statistically different when compared to the intact condition, with the exception of posterior shear loading. In all biomechanical tests, no implant migration was seen.

Patient selection

At the moment, two main indications exist for nucleus replacement by an implanted spiral (Table 1):

1. Single-level radiculalgia without back pain due to disc herniation
2. Single-level radiculalgia with predominant leg pain and some back pain, due to disc herniation and degenerative disc disease

Both indications must be confirmed by patient history, physical examination and radiographic findings. In both indication groups, conservative treatment, if indicated, must have failed. In addition, in the present pilot study, other inclusion criteria are: a posterior disc height of more than 5 mm (due to the implant height currently available); a symptomatic pathology restricted to one level between L2 and S1; an age limit between 18 and 65 years and, finally, the absence of any associated severe vertebral pathology. Some exclusion criteria are currently in place during the pilot study, which are detailed in Table 2. They

Table 1 Inclusion criteria

Pure disc herniation with leg pain only <i>or</i> disc herniation + degenerative disc disease with predominant leg pain
Candidate for one-level discectomy from L2 to S1
Posterior disc height at affected level ≥ 5 mm
Patient age between 18 and 65 years

Table 2 Main exclusion criteria

Previous spine surgery
Spinal problem at more than one level
Globular disc
Central disc herniation
Pronounced Schmorl's nodules at the involved level
Endplate lesions
Significant spinal, foraminal or lateral recess stenosis
Symptomatic degenerated facet joints
Degenerative spondylolisthesis greater than grade I
Lytic spondylolisthesis
Severe osteoporosis
Bone tumors or congenital bony abnormalities
Active infection
Presence of malignant tumors

Fig. 2 Insertion instrument filled with spiral, guard and pusher: **A** in vitro, using a saw bone model, **B** in situ (due to technical and approach-related improvements, the instrument now is turned around with the handle towards the midline and its open mouth laterally, thus enabling a permanent microscopic visual control of instrument, dura and nerve root while inserting the spiral)

will probably be slowly modified as the implant comes into routine use.

Surgical technique

The complete insertion setup for the spiral consists of five parts: an insertion instrument (subsequently filled with the spiral) with a guard and spiral pusher, a cutting blade and a measuring gauge (Fig. 2). In combination with lumbar disc surgery, an established microsurgical microscope-assisted approach can be used for the application of the insertion instrument. No additional substantial defect of soft tissue or bony structures has to be performed to place the filled insertion instrument. Microdiscectomy should include clearance of the intervertebral disc space, with removal of as much nucleus material as possible, in order to create a cavity with enough space for a large spiral volume. Then, under microscopic control of the neural structures, the loaded insertion instrument is placed into the intervertebral disc space, extending at least half of the diameter of the disc space. The final position of the insertion instrument should be controlled and documented fluoroscopically (Fig. 3). If the insertion instrument is not inserted deep enough, the spiral might not fill sufficiently the anterior part of the cleared intervertebral disc space. Then, by slowly pushing forward the handle of the insertion instrument, the spiral is inserted into the disc space. As soon as the spiral has reached the anterior border of the created cavity, the surgeon feels the insertion instrument moving slowly backwards out of the middle of the disc space with every push. As soon as the insertion instrument does not carry any further spiral material forward, due to the resistance of the completely filled cavity, the insertion process is finished. Using a guard and replacing the spiral pusher by a cutting blade, with a final strong forward movement of the handle of the insertion instrument, the spiral is then cut in the disc space and beneath the level of the posterior wall of the vertebral body. The insertion instrument with the remainder of the spiral is then removed. In both situations – with the insertion instrument still in situ without the cut spiral as well as with the insertion instrument having already been removed

Fig. 3 Loaded insertion instrument in situ in the intervertebral disc space under lateral fluoroscopic control

with the remainder of the spiral – the amount and diameter of covered disc area can be measured. A microscopical control of the end of the spiral should be performed. The end of the spiral should be rotated forward to the anterior part of the disc space in order to avoid any theoretically imaginable dislocation of this end into the spinal canal. Finally, wound closure follows traditional principles, with drainage being not necessary routinely. Mobilisation starts at the latest the day after surgery, without any bracing support. In accordance with valid study guidelines, the position of the spiral is controlled on the second day after surgery by magnetic resonance imaging in axial, frontal and sagittal planes (Fig. 4).

Fig. 4 **A** Preoperative sagittal magnetic resonance (MR) image showing a disc herniation L5/S1 left-side, in a 52-year-old man with typical radicular leg pain. **B** Postoperative axial MR image at postoperative day 4 of the same patient, with the spiral in place

Preliminary experiences

To date, five patients (two female, three male; age range: 24–52 years) have been supplied with a spiral implant. In all cases, a disc herniation with radicular symptoms presented the indication for surgery. Affected levels were L4/5 or L5/S1. In all of these patients, disc surgery and insertion of the spiral were performed without complications. Postoperative rotational CT scans performed in the first patient at 2 years follow-up demonstrated the completely maintained function of the facet joints. All patients were satisfied with the result of the operation, and scored better values in the postoperative VAS and Oswestry score. However, due to both the small number of patients and short follow-up, no statistical analysis has been carried out so far.

Conclusion

In summary, the major advantage of this new implant for nucleus replacement is its easy application due to both the standardized approach and the memory coiling mechanism of the spiral. Due to the spiral shape of the implant, the filling and covering of the intradiscal space is enlarged, resulting in a reduced risk of migration. The larger

surface of the device in situ improves the pressure distribution on both endplates, thereby minimizing the risk of the implant sinking into the endplates. Biomechanical tests have shown a restoration of the kinematics of a lumbar motion segment by the spiral after disc removal when compared to unsupported segments. Both the disc height and the position of the facet joints were restored and/or maintained by the spiral implant. As verified in biomechanical tests, no implant migration occurred. The implant itself sufficiently supports the anterior column of a functional spinal unit under compression conditions. Cadaver studies as well as in vivo surgery showed that the spiral is usable in the established minimal invasive microscope-assisted techniques for both anterior and posterior approaches.

In the clinical pathway for low-back pain, this new spiral implant promotes the philosophy of non-fusion technologies in spine arthroplasty and fills a gap between the semi-invasive non-open procedures, such as intraspinal injections or the IDET technique, and the next step of complete disc replacement by disc prostheses and finally fusion surgery. An international multicenter study is currently underway, focussing on outcome parameters such as subjective improvement of quality of life, objective clinical results and radiological findings, to establish the long-term effectiveness of this new spiral implant.

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