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Nucleus prosthesis: a new concept

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Abstract In a large number of low-back pain patients, the pain is related to disc herniation or prolapse of the nucleus pulposus. Although the pathogenesis is still the topic of debate, the nucleus seems to play an important role not only in the progression of low-back pain, but also in its treatment. Numerous surgical treatment solutions have been patented or described in the literature; however, only a few seem promising and are in use today. After the development of numerous ideas, for instance metallic implants, the

concept of a compressible material encased by a strong, inelastic outer layer emerged as the logical conclusion. Specific requirements during operation and during the entire life of the implant have to be taken into consideration in developing new solutions. In this paper, the development of the nucleus prosthesis will be discussed and a new concept presented.

Keywords Low-back pain · Disc replacement · Nucleus prosthesis · Nucleus prolapse

Introduction

Back pain is a major reason for consultations. Almost 15 million visits to a doctor were counted in the US for this diagnosis, making low-back pain the fifth leading diagnosis cluster [10]. Behind the diagnosis “non-specific backache”, accounting for 57% of low-back pain diagnoses, the most specific categories were 12.5% “probable degenerative changes” and 11.1% “herniated discs”. These figures emphasize the size of the problem related to mechanical low-back pain. Although the pathogenesis of mechanical low-back pain related to degenerative disc disease is still the topic of debate, the nucleus seems to play an important role. It is not only the centre of spinal motion segments, but also the origin of the degenerative cascade, and therefore the target of old and new treatment options.

The nucleus: origin and target

Origin of pain development

The nucleus pulposus is the central soft and gelatinous region of each intervertebral disc, surrounded by multilayered fibres of the annulus fibrosus. It is situated closer to the posterior border of the annulus fibrosus than to the anterior one [15]. The main organic structural components are collagens and proteoglycans. While collagens account for less than 20% of the dry weight of the central nucleus, proteoglycans represent as much as 50% in a child. The proteoglycans provide the tissue with its stiffness and resistance against compression by their interactions with water [6]. The presence of these hydrophilic proteins is the reason for the water-binding capacity of the nucleus (swelling pressure). The equilibrium of water content also depends on the external disc load. Increased loads squeeze water into the adjacent vertebral endplates. Unloading leads to return of water. This pumping mechanism provides the metabolism to the vessel-free nucleus [3]. Consequently, the fluid content of the nucleus shows diurnal

variations. In the morning after rest, the turgor, and with it the thickness, is higher; by the evening the nucleus has lost some turgor.

The water content of the nucleus is highest in youth, at about 80%, and decreases gradually with age [12]. It starts reducing in the fourth decade due to a gradual change in the type of proteoglycans [2]. Loss of height is the consequence. In an experimental study by Brinckmann and Grootenboer [5], for instance, about 1 g of tissue loss in the nucleus pulposus led to a loss of height of approximately 0.8 mm. This influences the load sharing between nucleus pulposus, annulus fibrosus and facet joints. The decrease in interdiscal pressure reduces the engagement of the nucleus in the load flow, thus increasing the portions of the load carried by the annulus fibrosus and facet joints. Finally, it may result in damage to the joint cartilage, reactive hypertrophy and inflammation, and the neuroforaminal space of the exiting nerve roots may be impaired as well. The increasing load and the tissue alterations of the annulus fibrosus are the base for radial tears, cracks and fissures. The nucleus will finally prolapse if the mechanisms for self-healing are insufficient. The deformation of a nerve root clinically imposes radicular pain. In contrast, the irritation and inflammation of the facet joints lead to so-called pseudoradicular pain.

Since, in many cases, the nucleus pulposus seems to be the starting point of the degenerative cascade, it should also be the treatment target. But in the past, surgical interventions consisted either in a decompression of the nerve roots alone, in a fusion of motion segments or in a combination of both. All methods lead to an improvement in the clinical symptoms for a certain time. However, these methods do not solve the real problem. The problems are shifted to the adjacent motion segments because of the fusion or the contrasting instability of the segment [21].

Treatment target

The idea of restoring the biomechanical function of the disc by replacing only the nucleus as the cause of degeneration and pain seems very elegant, but has several limitations. The nucleus replacement is based on the assumption that the annulus and the endplates are still functioning properly [3]. This boundary condition has an important impact on patient selection and the indications for surgery. Potential patients are young and without many accompanying degenerative changes in the spine. Implanting an artificial substance into the spine of a young patient, however, raises questions about the longevity of the implant [13]. Wear problems, known from total hip replacements [20], and possible degradation processes within the nucleus material may lead to a need for re-intervention after 15–20 years. Furthermore, the risk of herniation of the new, artificial nucleus has to be minimised. The likelihood of this event should be lower than that of a normal

prolapse [19]. The latter requirement has a direct impact on the surgical technique. While inserting the nucleus, the intraoperative damage to the annulus fibrosus must be kept to a minimum.

Numerous solutions have been patented or described in the literature, but only a few seem promising and are in use today. Initially attempts were made by injecting an acrylic mass [7, 9], and this was later followed by silicone [19]. Roy-Camille et al. used a latex bag to reduce the probability of material herniation and to decrease fatigue behaviour [18]. Nucleus replacement by means of metallic implants was attempted, but was abandoned because of migration and subsidence problems [8].

The concept of a compressible material, encased by a strong, inelastic outer layer, emerged as the logical consequence of the first ideas, and was first tested in vivo by Hou et al. [11], and brought to clinical use by Ray and Corbin [17]. However, clinical studies that prove the long-term efficiency of the device have yet to be done. More recent work is directed towards the development of materials (e.g. hydrogel) that better mimic the physiological behaviour of the nucleus [13, 16] and towards reducing invasiveness during insertion of the nucleus. This latter aim should be achieved by using devices with a memory effect. They are guided into the central disc cavity in a straight shape, but return to their pre-formed (in most cases spiral) structure [4, 14] once they are within the cavity. This solution offers two interesting features: the opening for the insertion of the implant is minimal, while the risk of a re-prolapse is reduced because of the overall size of the nucleus prosthesis after implantation. However, this exciting idea requires an excellent interaction between the materials used and the structure. The shear strength of the spiral's elastic contents, which is not an issue in homogeneous devices such as the PDN, becomes a major issue. Furthermore, delaminating between core and cover of the spiral has to be prevented. When using a hydrogel for the core, the cover sheath has to be guaranteed to remain intact.

New treatment concept

All above-mentioned requirements for a nucleus replacement were taken into consideration during the development of a new nucleus prosthesis design. Mathys Medical Ltd has realised a concept using a “snail” design for the final implant. A complex manufacturing process has been developed to specify the memory effect of the device, and to ensure that it has the required biomechanical properties such as shear strength, etc. The opening required by this specific design is minimal. Insertion into the disc is possible through a cross-stitched incision of the annulus. A tube is used to guide the straight-shaped prosthesis into the cleaned cavity of the disc. The insertion is possible through a percutaneous or minimal open posterior as well

as a retroperitoneal approach. Once inside the empty cavity of the former nucleus, the device can return to its snail shape. Different lengths and diameters allow for compensation in disc height or diameter [1]. No intraoperative shortening of the device is necessary. The hydrogel of the nucleus prosthesis will start to swell after insertion. The prosthesis thus mimics diurnal changes and creep behaviour under mechanical load. As a consequence, the annulus fibrosus should be protected from overload. The core material possesses elastic and reversible plastic behaviour. Unlike other core materials such as polyurethane, nutrients can be transported via the nucleus to the annulus fibrosus. The materials used for both device components are biologically inert, to minimise adverse reactions.

The next steps towards a device for clinical use will include extensive biomechanical testing with respect to complex three-dimensional and fatigue behaviour. Next year, the biocompatibility will be tested before the first clinical studies. A clinical multicentre study will follow.

Conclusions

The newly developed nucleus prosthesis by Mathys Medical Ltd has biomechanical and biological properties that come very close to those of the original nucleus. The intraoperative damage to the surrounding tissue, especially the annulus fibrosus, is minimal, thus reducing the risk of herniation of the nucleus prosthesis. However, the indication for this device has to be established very carefully with respect to accompanying damage of the disc.

The proposed concept may find its place as a first – even prophylactic – treatment option for disc herniation. Especially in young patients, it can offer a long-term solution without limiting further treatment options. If the degeneration of the affected disc continues, replacement of the whole disc or even a fusion is still possible at a later time.

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