

## Lumbar Partial Disc Replacement

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Back pain is universally shared and causes many doctor visits around the world. About 40% of people aged 25 to 74 suffer from back pain. The consequences of impaired musculoskeletal conditions are drastic and expensive for the patients as well as for the economy: long duration of employee absenteeism, hospitalization, and disability. The number of patients is still increasing, and with it the need for better and optimal treatment options. Even though not all of the patients who suffer from natural disc degeneration need medical treatment, some patients require medical as well as clinical treatment to reduce their severe back pain.

### Disc mechanics and physiology

The intervertebral disc has two important main functions: to provide cushioning and to allow the axial skeleton to remain flexible. Each intervertebral disc consists of two components: the multilayered fibers of the annulus fibrosus and the soft and gelatinous nucleus pulposus in the center.

The annulus consists of multiple laminations or plies [1]. The inelastic collagen fibers of every lamination attach to each adjacent vertebral body in a diagonal orientation [2]. The cushioning effect is created by the fibers and their laminations, which permit bulging under load.

Within the outer annulus, the content of fibers is around 90%; toward the center of the disc, the gel

component increases; and in the center of the disc, the gel component is about 90% and the fibers only about 10%. The internal fibers of the annulus are not connected to the vertebrae but they provide substance to the nucleus mass.

The nucleus consists of collagens and proteoglycans. The proteoglycans provide the tissue with its stiffness and resistance against compression by their interactions with water [3,4]. The water-binding capacity of the nucleus depends on the presence of these hydrophilic proteins. Furthermore the water content varies depending on the external disc load. Under high load conditions, the water squeezes into the adjacent vertebral endplates and it returns under low load. This pumping mechanism is necessary to provide the metabolism to the vessel-free nucleus [5]. Consequently the water content is higher in the morning, after a rest, but in the evening the nucleus has lost some water and the thickness is not so high anymore. Also the composition of the nucleus changes as a result of the normal aging process: In youth the water content is about 80%, but due to a gradual change in the type of proteoglycans the nucleus is more fibrous by the third decade of life. Within this natural progress, the nucleus is usually significantly dehydrated and has lost its mucoid consistence by the fifth decade which explains the loss of height of older people.

Capillaries and free nerve endings, the pain transmitters, can be found only in the outer layers of the annulus. The nucleus and inner annulus are anaerobic, the nutritional exchange of intradiscal metabolites passes through the intact cartilaginous endplate and its channels. The process depends on osmotic differentials and diurnal pumping action. Under low load conditions at night fluid and nutrients are pulled

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into the disc by the hydrophilic nucleus gel and under high load conditions during the day the byproducts exit through the endplate and into the capillary bed.

Under load, the semisolid nucleus pushes radially out from the center of the disc and causes the annulus to bulge [7,8]. By tensioning of the collagen fibers, the annulus dissipates the compressive forces. This lets the intervertebral disc operate as a cushion between each single vertebral body. During this process the inner as well as the outer margins of the annulus bulge outward. However, when the nucleus no longer functions properly, under similar loading the inner annulus bulges or folds inward as the outer margin bulges outward [9]. In case of desiccation of the layers between the laminations, the folding of the annulus can cause tears, delamination, and consequently weaken the disc. The appearance of tears may result in problems with internal disc metabolites. They can escape and reach the outer belt of the pain-transmitting free nerve endings or even the vertebral canal. Already very little quantities of anaerobic metabolites can lead to acute or chronic back or leg pain and little motion of the segment will cause severe pain to the patient. The exchange of wastes and nutrients as well as an intact annulus and nucleus are essential for a healthy and proper functioned disc.

### **Treating degenerative disc disease with a prosthetic nucleus**

After failed conservative therapy, only discectomy and fusion exist as further treatment steps [10]. Discectomy is a good option for people with direct nerve root compression, inflammation, or vascular changes affecting the ganglion or root. But due to the mechanical component that also induces back pain, it is no solution for this component of discogenic low back pain. The segment gets less stable and less functional as more of the nucleus pulposus is removed [11].

Patients with degenerative back pain with failed conservative treatment have received further insufficient treatment, pain treatment, or as a surgical option, fusion surgery. Although fusion procedures relieve pain relatively well, they are very invasive treatments with a relatively high potential of complications, severe collateral damage of surrounding soft tissue structures, and create significant changes to the biomechanics of the segment by eliminating the segment function and mobility permanently. The literature supports a relatively high incidence of adjacent segment degeneration due to these biomechanical changes.

The nucleus pulposus seems to be the starting point of the degenerative cascade in many cases and should be a major treatment target [6]. The idea of partial disc replacement is to replace only the nucleus as the origin for the pain while restoring the biomechanical function of the disc and therefore also the function of the whole segment. Lumbar partial disc replacement is one opportunity to fill the therapy gap in the earlier stages of disc degeneration that exist between discectomy and fusion [12].

### **Development of nucleus replacement devices**

In the early stages (late 1950s and early 1960s) of partial disc replacement, the nucleus pulposus space was instilled or replaced with polymethylmethacrylate (PMMA), silicon, or stainless steel ball bearings [13–15]. Due to a lack of knowledge about disc mechanics, such as pressure, range of motion, migration and subsidence issues, the results from these early procedures were not sufficiently acceptable and none of the devices obtained acceptance at that time.

The Fernstrom ball attempted to preserve motion by replacing the nucleus with stainless steel ball bearings and retaining most of the annulus fibrosis [15]. In general, the results for the Fernstrom ball were good for patients with sciatic pain. Less optimal results were noted for patients who suffered from spondylolisthesis and severe facet arthropathy. In most of the cases major subsidence occurred, causing bad clinical outcome.

About the same time, Nachemson [15] injected silicon and Hamby and Glaser [14] tried injecting PMMA into the disc but had flow control problems and poor outcome. The results of this early research provided a basis for the further development of a nucleus replacement, which would restore biomechanics and biology and prevent further degeneration of the disc.

In the early 1980s, available materials could tolerate the compression and shear forces expected in the disc space, but several devices failed at fatigue testing.

In the last few years, the understanding of the biomechanics of the disc and the degenerative cascade has been elucidated and that led to attempts to reproduce the biphasic and viscoelastic mechanical properties of the nucleus pulposus, using synthetic hydrogels. The hydrophilic nature of these polymers mimics the transport and biomechanical properties of the natural soft tissue, including the intervertebral disc [16,17]. For more than 15 years hydrogel-based

Table 1  
Classification of nucleus disc replacement devices

Device	Material	Constrained and/or predefined geometry	Unconstrained devices	Injectable devices
<b>Soft devices</b>				
PDN	Hypan	x	—	—
PDN-SOLO				
NeuDisc	Hydrogel	x	—	—
DASCOR	Polyurethane	x	—	x
Newcleus	Polycarbonate urethane	—	x	—
Aquarelle	Polyvinyl alcohol	—	x	—
SINUX	Silicone	—	—	x
BioDisc	Protein hydrogel	—	—	x
NuCore	Silk elastin protein	—	—	x
Gelifex	Hydrogel	—	—	x
<b>Hard devices</b>				
Regain	Pyrolytic carbon	x	—	—
CL-Disc	Zirconia ceramic	x	—	—

nucleus replacement devices have been in development and until now various devices as shown below have been produced.

### Types of nucleus replacement devices

Due to the rapid growth of technology there is a multiplicity of implants that are already in clinical use or under clinical trial. In principle, contained devices and devices with predefined geometry can be distinguished from uncontained or injectable devices (Table 1).

#### *Contained and predefined devices*

The Prosthetic Disc Nucleus PDN (Raymedica, Inc., Bloomington, Minnesota) assumes the cushioning function of a normal disc and simultaneously maintains disc height and flexibility. The device is composed of a hydrogel pellet that is surrounded by a polyethylene layer. The pellet absorbs water through which it is able to swell powerfully, restoring or maintaining disc height. The outer polyethylene fibers prevent unlimited swelling and minimize the horizontal spreading. This guarantees the maintenance of the implant shape even when overloading the spine. Each pellet has small platinum-iridium marker wires that are embedded in the hydrogel to visualize the position and orientation of the implants by fluoroscopy during surgery and by ordinary radiograph imaging after surgery [1]. Originally a two-pillow hydrogel, at present a single-pillow hydrogel, the new PDN-SOLO, is used (Fig. 1A, B).

The PDN has been a landmark for the development of nucleus replacement devices and is currently the device with the largest human clinical experience.

The NeuDisc (Replication Medical, Inc., New Brunswick, New Jersey) is another hydrogel device (Fig. 2A, B) that has been introduced recently in human trials. Similar to the PDN device it expands

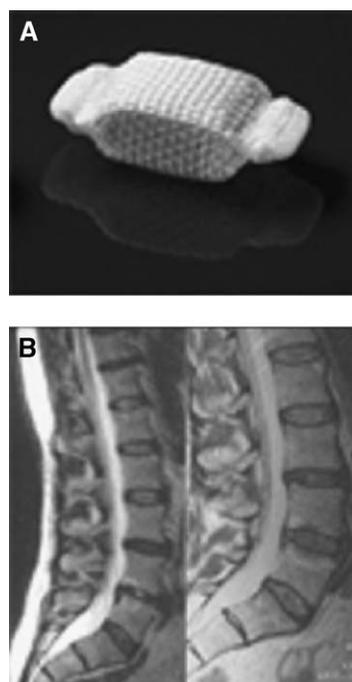


Fig. 1. (A) PDN-SOLO device. (B) MRI PDN-Dual (preoperative, postoperative).

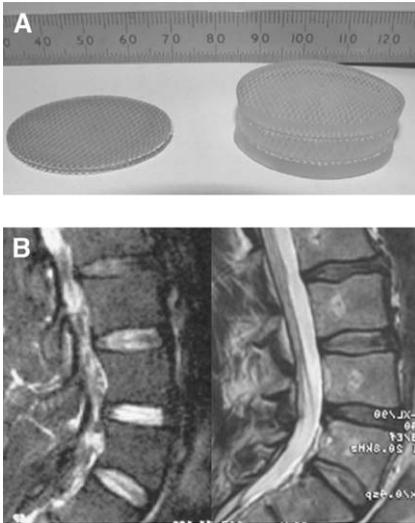


Fig. 2. (A) Neudisc device (preoperative, postoperative). (B) MRI Neudisc case.

preferentially in the axial direction by imbibing water. In contrast to the PDN the NeuDisc is not surrounded by an outer polyethylene jacket but by structured layers that are located inside the device. The proprietary hydrogel is characterized by excellent biostability, biocompatibility, and biomechanical properties and mimics the structural features of the nucleus pulposus [18].

The DASCOR (Disc Dynamics Inc., Eden Prairie, Minnesota) is a balloon device that will be filled with an injectable cool polyurethane polymer. The void is filled completely due to the fact that the polyurethane polymer is delivered under pressure [18]. The polyurethane polymer is contained due to the balloon. First clinical trials are under investigation.

#### Unconstrained devices

The Newcleus (Zimmer Spine, Warsaw, Indiana) is an unconstrained elastic memory coiling spiral made of polycarbonate urethane. The device functions as a spacer with some shock absorbing capability. First clinical trials started in Europe but the device is still under further development.

The Aquarelle (Stryker Corp., Kalamazoo, Michigan), a polyvinyl alcohol hydrogel nucleus replacement, has also undergone significant development and testing. Different from the PDN, the Aquarelle does not need a rehydration period postoperatively because it is implanted in a hydrated state. The device

is viscoelastic and provides uniform pressure across the endplate. In opposite to the PDN device the lifting force is much less.

#### Injectable devices

An alternative to the devices mentioned previously are injectable substances that act more as a void filler.

The SINUX ANR (J&J DePuy, Raynham, Massachusetts) is a liquid polymethylsiloxane polymer that completely fills the void that is left from the removed nuclear material. It cures in approximately 15 minutes into a resilient elastic mass [18].

The BioDisc (Cryolife, Inc., Kennesaw, Georgia) is an injectable protein hydrogel device consisting of a mixture of serum albumin and glutaraldehyde.

The NuCore IDN (Spine Wave Inc., Shelton, Connecticut) is a protein polymer that is created through DNA bacterial synthesis fermentation. As protein polymers do not contain human or animal components, the risk for transmitting or causing diseases is reduced.

The Gelifex (Gelifex, Inc., Philadelphia, Pennsylvania) is a polymer that is liquid at room temperature and solidifies at body temperature.

In addition to these devices, devices made of memory metal stent, peak nucleus devices, and carbon-coated metal devices are under evaluation. None of these devices is in clinical use at present.

#### Indications

To achieve a high surgical success rate, careful patient selection is crucial. Among all of the currently used clinical study protocols for the different devices, the least common denominator are patients between 18 and 65 years old with degenerative disc disease, dominant low back pain, and back or leg pain who have failed conservative treatment. Because the failed nucleus will be replaced and will not be fixed into its position, a relatively intact annulus container with strong mechanical properties must be present. Therefore the disc height reduction should not exceed more than 50% of the original height.

In general, patients with osteoporosis, endplate problems, posterior element disorders (eg, stenosis, facet arthritis, isthmic pathologies), and infection tumors should be excluded.

For the longest used partial disc replacement device, the PDN, a disc height reduction of more

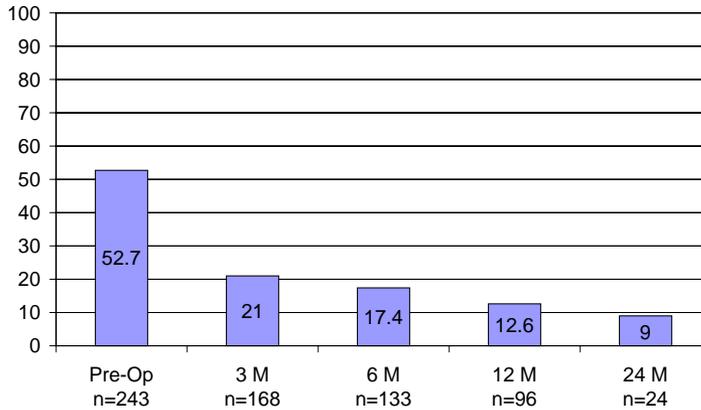


Fig. 3. Oswestry disability scores for patients with PDN device implantation, preoperative to 24 months.

than 50% and a BMI of 30 or greater have been analyzed as a reason for failures.

## Results

Despite extensive information and use of implants, there are long-term studies only from the PDN device. The results of these German/Swedish and Korean studies are available as world data.

A worldwide clinical multicenter study with paired implants on 243 patients has shown marked improvement in pain levels.

The mean Oswestry score preoperative was 52.7. Postoperative the score dropped to 21 at the 3-months follow up, 17.4 at the 6-months follow up, and improved further to 12.6 after 12 months and 9.0 after 24 months (Fig. 3).

The VAS score declined similarly. The mean VAS score before surgery was 7.1, after 3 months 3.0, 6 months 3.0, 12 months 2.5, and it decreased to 1.8 after 24-months follow up (Fig. 4).

In addition, there was also an increase in disc height, which is a prerequisite for segmental stability to minimize nonphysiologic movements that may cause additional tearing of the annulus [19]. For 218 patients, the average disc height preoperative was 8.1 mm. It increased to 10.5 mm after 3 months, the 6 months follow up showed a disc height of 10.3 mm, the 12 months follow up 9.7 mm, and after 24 months the average disc height was 10.2 mm (Fig. 5).

The most common complications that have been reported for the use of PDN implantation are migration/extrusion as well as severe endplate reaction together with subsidence. The overall complication rate reduced from initially 53% to less than 25% due to improved implant design and surgical tech-

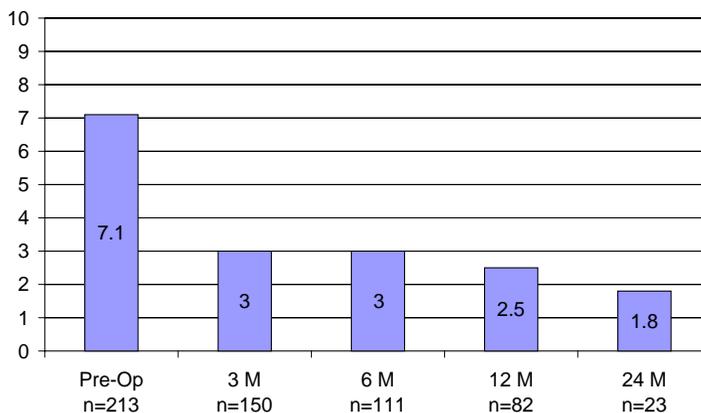


Fig. 4. Visual analog scale (VAS) for patients with PDN device implantation, preoperative to 24 months.

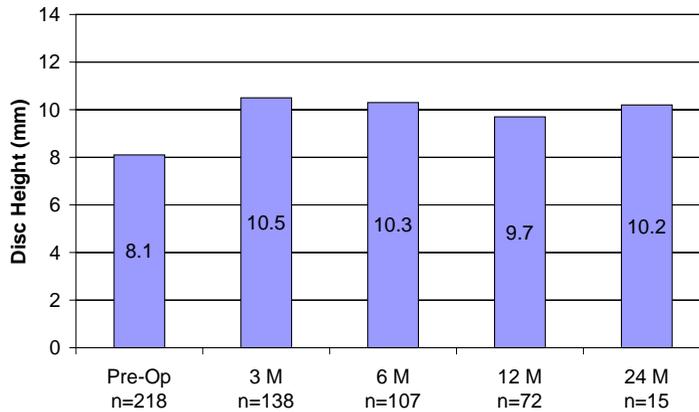


Fig. 5. Disc height before and after surgery.

niques. As a result of the not satisfying clinical outcome, the PDN-SOLO has been introduced. With the PDN-SOLO the overall complication rate could be reduced significantly and is now less than 10%. Also a suitable surgical approach can achieve a considerable reduction of the extrusion rate. By using the anterolateral transposoatic approach (ALPA), the PDN extrusion could be completely reduced [20].

### Summary

Up to now, no standards have been defined with regard to the degree of annulus degeneration and disc height loss up to which a nucleus implant can be successfully implanted.

The nucleus replacement is based on the assumption that the annulus and the endplates are still functioning properly [5]. These considerations have to be included in the patient selection and the indications for surgery. Reaction to the implant tissue interface can occur as well as other problems including wear and implant longevity problems, possible degradation processes within the nucleus material that might lead for re-intervention after 15 to 20 years, and the risk of herniation of the new, artificial nucleus. Therefore the current use of any of these devices should be investigated very precisely also in the near future and the patients should be selected very carefully following the criteria that have been defined in the known literature. Patients with risk factors like decreased bone density, increased BMI, or multilevel degeneration should be excluded. An optimal and careful surgical technique should be performed. Due to the rapidly growing number of new technologies in this field, a certain risk exists

to lose the overview and to evaluate every single technique properly.

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