Artificial disc: current developments in artificial disc replacement

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For more than 40 years attempts have been made to create an artificial disc. Many designs exist. Options include nucleus replacement and total disc replacement. Few models have reached clinical trials. Two devices are currently undergoing clinical evaluation in Food and Drug Administration trials in the United States. Curr Opin Orthop 2003, 14:138–143

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If pain and disability originate from a disrupted or degenerative disc, is it possible to eliminate the pain and preserve physiologic motion? If a herniated disc is excised, is there a way to replace the physiologic function of the nucleus and thereby thwart the continuation of the degenerative cascade?

The affirmative answer to these questions involves the formation of an artificial disc. Two interventions are possible: a nucleus substitute and a total disc replacement (nucleus and anulus). Both methods require duplication of the natural structure, biocompatibility, durability, and ease and safety during implant placement or removal.

Lumbar nucleus replacements

Nucleus replacement offers two primary advantages over total disc replacement: a less invasive surgical approach and restoration of the anulus to its natural fiber length and tension. The technique may find clinical utility when used in conjunction with open or percutaneous nucleotomy for disc herniation and in early-stage disc degeneration. The anulus must be competent and capable of a degree of healing. In later stage disc disruption, with failure of the anulus, simple nucleus replacement would be ineffective.

The ideal nucleus substitute should be capable of pressure modulation with position change to restore the normal fluid "hydraulic" pumping mechanism to enhance nutrient delivery to the remaining nucleus and the inner anulus. The implant modulus of elasticity and the implant/cavity conformity should be designed to restore normal load distribution. The prosthesis should have sufficient stability in the disc space to avoid excessive motion that could lead to migration and an elevated rate of wear on endplate or implant surface (Table 1).

The PDN artificial nucleus was developed in 1988 by Dr. Charles Ray (Raymedica, Minneapolis, MN, USA) [1]. His initial design called for a hydrogel core surrounded by an outer fiber woven layer made with a bioresorbable material that constrained the ultimate swelling of the hydrogel and attracted tissue ingrowth. The hydrogel component is able to absorb and relinquish water with changes in applied load. The device can also potentially serve as depot sites for medications that elude into the disc space.

Table 1. Goals of nucleus replacement

Retension anulus
Preserve endplate cartilage
Restore normal load distribution
Restore normal hydraulic pumping mechanism
Restore spine kinematics, shock absorption
Minimally invasive implantation

The original surgical protocol called for a trephine to be used, from the posterior approach, to bore a passage into the center of the disc. After nucleotomy, the devices could then be slid into position, side by side, and filled with the gel. The design called for expandable collars that would theoretically protect against device displacement.

The original implants and subsequent modifications have passed Food and Drug Administration guidelines for biologic safety, cytotoxicity, carcinogenicity, and long-term animal implantation all without negative findings [2••]. Biomechanical fatigue studies to more than 50 million cycles under simulated physiologic loads (200–800 N) have been performed successfully [2••].

The first clinical trials using the PDN began in 1996. After inspection of the early results, the initial hydrogel polymer, Hypan 68 (absorbing 68% of its weight in water), was felt to be too rigid, resulting in negative effects on the cartilaginous endplate [2••]. In 1998, Hypan 80 was used to absorb more water and become proportionately softer. An unacceptably high rate of implant migration and extrusion was recognized, with 38% of cases requiring revisional surgery [2••]. This finding led to subsequent changes in design and surgical protocol.

It is now recommended that the two devices be placed sideways in the disc space: one tapered anterior unit and a rectangular posterior unit. To accommodate two units, the endplate anteroposterior diameter must be greater than 37 mm [2••]. The units are connected by tethering sutures. A Solo-PDN (Raymedica, Minneapolis, MN), a broader and thinner single unit, has been recently developed and may ultimately replace the two-unit design in the future.

The annulotomy must be kept as small as possible, using a dilating technique rather than a cut entry. Dr. Rudolph Bertagnoli has recommended the anterolateral transpsoas approach as a means for safe implantation while decreasing extrusion issues [2••]. The postoperative protocol now recommends a brace be worn for 6 weeks.

More than 400 patients, the majority in Europe, have been implanted with the PDN [2••]. There has been minimal clinical outcome data reported on the device. Four-year follow-up data, presented but unpublished, have demonstrated improved mean Oswestry scores (from more than 50 points to less than 10 points) and improved mean pain visual analog scale scores (from 7.0 points to 1.9 point) [2••].

Sixty patients with PDN have been reviewed with postoperative magnetic resonance imaging [3]. Six weeks after implantation, an increase in Modic changes within the vertebral endplate was identified in 27%. At 1 year, such changes appeared in 70%. Advanced degenerative changes at 1 year were seen in 7%. The clinical implications regarding these radiographic changes is yet to be determined.

Although the PDN serves as the prototypic nucleus replacement, other devices have been designed and are advancing through developmental stages. The Newcleus (Sulzer Spine Tech, Edina, MN, USA) is a preformed, curled, spiral-shaped, elastic memory coiling polyurethane elastomer [4]. Lab and animal studies, unpublished, have been completed. A small number of patients have been implanted with the device in Europe and are currently being observed (5).

The Aquarelle disc (Stryker/Howmedica, Rutherford, NJ, USA) is made of a polyvinyl alcohol hydrogel [6]. It is inserted in the dehydrated form through a 5-mm cannula. Water, drawn from the surrounding tissues, fills the membrane to a 70% water content and the prosthesis nearly doubles in size. This *in situ* expansion creates an interference fit. The hydrogel is able to absorb and relinquish water with changes in applied load. Unpublished biomechanical studies have confirmed restoration of disc function after hydrogel implantation [5]. A nonhuman primate study has been completed but remains unpublished. Implanted in a few patients in Europe, early clinical analysis is still forthcoming. Implant containment remains a problem.

The Prosthetic Intervertebral Nucleus or PIN (Disc Dynamics, Minnetonka, MN, USA), is a polyurethane balloon that is inserted into the disc and is then inflated with an incompressible liquid, allowing the size and the shape of the nucleus prosthesis to be significantly altered during implantation and regained/restored after implantation [5]. Lab studies have been completed and remain unpublished. Animal studies are beginning.

Lumbar total disc replacements

Total disc replacements would be used when removal of all possible sources of pain including nucleus and anulus is required and when the anulus has failed and is thought to be unable to heal. Improvements in material and designs specifications are leading slowly toward the ideal total disc replacement. The materials must be evaluated for cytotoxicity and endurance. The design must replicate (as much as possible) the natural disc dynamics, plan for compatibility between materials, use safe insertion

technique, and have a reliable bonding or interface between host and implant (Table 2).

The spine triple-joint complex has six degrees of freedom: (1) compression, (2) distraction, (3) flexion, (4) extension, (5) lateral bending, and (6) rotation. For total disc replacement, the degree of "constraint" refers to the relative range of motion of the prosthetic joint compared with the healthy intact joint within each of these degrees of freedom. An "unconstrained" device provides no mechanical assistance. An "underconstrained" device imposes limits to motion outside the naturally occurring constraint of motion.

With a "physiologically" or "critically" constrained implant, motion is allowed within a physiologic range but is blocked beyond that range. The "overconstrained" prosthesis prohibits natural motion by imposing constraint within the normal range of motion.

Device torsional overconstraint is a topic of ongoing debate. This feature would offload and spare the facets at the expense of increasing stress at the implant–host interface. Currently, most total disc designs are unconstrained or underconstrained and require intact and functioning posterior elements including facets and ligaments for load sharing and biomechanical stability.

All total disc replacements are implanted through an anterior open approach (transperitoneal or retroperitoneal). This approach is similar to that required for an open anterior lumbar interbody fusion. A slightly wider exposure of the anterior anulus may be required, which may result in a greater risk of vascular injury. Postoperative retroperitoneal scarring makes revisional surgery particularly hazardous.

Precise placement of the device is essential. The device "footprint" should cover the largest possible area of the vertebral endplate. The endplate periphery is stronger whereas the center is weaker. In those with osteoporosis, a total disc is contraindicated.

Metal devices

The principle advantage for using an all-metal total disc replacement is the fatigue strength. Many large, bulky, all-metal devices have been designed, the majority not getting much further than the patent application approval. Reminiscent of hip arthroplasty, the Maverick (Medronic Sofamor Danek, Memphis, TN, USA) is a prosthetic device shaped as a ball and socket [7]. Motion while loaded in compression may be expected to cause increased friction and wear debris.

Table 2. Goals for total disc replacement

Remove all disc "pain generators"
Restore spine kinematics
Longevity > 40 years
Safe implantation

Nonmetal materials

Although the principle advantage of metals is their fatigue strength, the primary benefit of using nonmetals such as rubber and the elastomers (silicone, polyurethane, polyethylene) is their greater mechanical similarity to the natural disc. With a lower modulus of elasticity, it is easier to replicate disc dynamics. Difficulties arise, however, when attempting to develop a long-lasting component that has a stable interface between the structure and vertebra.

The 3-DF is a three-dimensional fabric woven by an ultrahigh-molecular weight polyethylene fiber and spray coated with bioactive ceramics on the surface [8•]. The 3-DF disc demonstrates viscoelasticity. No changes have been noted in biomechanical parameters after 2 million loading cycles [8•]. The segmental biomechanics and interface histology have been evaluated *in vitro* and *in vivo* (sheep model) at 4 and 6 months [8•]. Some implant displacements without dislodgment were noted. Those discs implanted with temporary internal fixation (Kanada one-rod SR system, Depuy Acromed, Raynham, MA) were firmly in place and demonstrated a successful bony bond host–implant interface [8•]. Recognizing that the use of temporary internal fixation that requires removal is not practical, work is being directed toward a supplemental bioabsorbable spinal fixation device.

Combination

To overcome the shortcomings found when using metals or nonmetals alone, designs have combined the materials. Most commonly this combination has taken the form of a metal–polymer–metal sandwich disc. The metal tray is used to improve fixation through the use of spikes, tabs with screws, and a porous coating for ingrowth. With the metal endplate component stable and fixed, the polymer center provides the needed flexibility.

The SB Charite (SBC) was developed in 1988 by Drs. Karin Buttner–Janz and Kurt Schellnack (Waldemar LINK GmbH and Co., Hamburg, Germany) [9]. The device has two endplates made of cobalt chromium alloy with projecting anchoring teeth for fixation. A polyethylene oval spacing piece with contours to match the endplates is placed between the metal endplates. The device allows 20° in flexion–extension and lateral rotation (underconstrained), and unlimited motion in axial rotation (unconstrained). Currently used, the third model can be referred to as the SBC III.

A recently presented biomechanical study compared multiple planes of segmental motion in intact cadaveric specimens and after insertion of the SBC III prosthesis [10]. This study demonstrated that the SBC III restored

motion to the level of the intact specimen in flexion–extension, lateral bending, and increased motion in axial rotation. The SBC III showed an average percentage increase in segmental axial rotation of 44%. The increase in axial rotation reflects the excision of the anterior longitudinal ligament required during insertion and the unconstrained nature of the SBC III in axial rotation.

To date, an estimated 5000 patients have had the SBC implanted. The vast majority have been inserted in Europe (United Kingdom, France, Germany, and the Netherlands). Clinical results have been published in several separate series totaling nearly 300 patients observed for relatively brief durations (1–3 years). In December 1999, a United States Food and Drug Administration study enrolling 400 patients was begun. Patients were randomized 2:1, SBC III versus anterior lumbar interbody fusion with stand-alone BAK (Centerpulse, Minneapolis, MN) fusion cages. Enrollment has ended and the study is currently in the follow-up phase with outcomes to be completed in 2 years.

In 1994, Thierry Marnay, a French orthopaedic surgeon, designed the ProDisc (Spine Solutions GmbH, Tuttlingen, Germany) [11]. This device is a cap-cup matching articulation with endplates made of cobalt chrome molybdenum alloy. The convex-bearing surface is made of ultrahigh-molecular weight polyethylene that snaps into the inferior endplate.

Between 1990 and 1993, 64 patients were implanted with the ProDisc [12]. In 1999, 95% were available for follow-up. All implants were reported to be "intact and functioning." There were no removals, revisions, failures, or subsidence. A total of 93% of patients were "satisfied." Enrollment has begun recently in a United States Food and Drug Administration study. The ProDisc will be randomized 2:1 with anteroposterior circumferential fusion. Patients will be observed for 2 years.

Cervical disc replacements

Two cervical disc devices are emerging with early clinical results. Both devices are inserted via an anterior cervical approach. Standard central decompression and foraminotomy must be accomplished as necessary to obtain nerve decompression. The devices do not provide the type or degree of distraction that leads to foraminal dilation. Long-term mechanical and functional durability remain to be determined.

In the 1980s, Cummins performed the pioneering efforts on a simple metal-on-metal ball and socket joint called the "Frenchay" or the "Bristol" cervical disc (Medronic Sofamor Danek) [13,14•]. The device has been redesigned. The lower component has a shallow ellipsoidal saucer to permit translation and rotation. Rotation of the upper component is achieved by allowing the hemisphere of the joint to glide in the saucer. A screw locking mechanism secures each vertebral component to its respective vertebral body.

In biomechanical studies there was no significant difference in the bending stiffness between the intact spine and the spines implanted with the Bristol disc [14•]. The presence of the component did not significantly alter the motion characteristics of the adjacent motion segments [14•]. Cyclic loading to 10 million cycles showed no failure for the 12-mm device when loaded to 150 N, and the 14-mm prosthesis when loaded to 225 N [13].

Because the device contains stainless steel endplate components, no osseointegration will occur. The long-term fixation stability through the screw–tab sites is uncertain. Lucent lines between the device and the endplate, possibly associated with stress shielding, have been identified [13].

A recent study compared flexion and extension cervical radiographs in those patients with the Bristol disc and those who had undergone anterior cervical fusion [14•]. At 12 months, the Bristol disc motion ranged from 2 to 13° with a mean of 7.1°. There was little difference between the preoperative motion before undergoing surgery and the postoperative range of motion after Bristol disc placement. The preexisting degenerative changes in the facet joints and the neighboring spinal ligaments appeared to determine the movement of the artifical disc *in vivo*. The fusion group demonstrated a significant increase in adjacent-level movement at follow-up compared with an overall reduction in adjacent-level movement in those receiving the artificial disc. Some patients experienced postoperative neck pain with extension. Perhaps overdistraction of the anterior column caused excessive load to be transferred to the posterior elements/facets.

A second cervical disc undergoing recent evaluation is the Bryan Cervical Disc (Medronic Sofamor Danek). This device consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. The surface includes a titanium porous coating to encourage bony ingrowth and long-term stability. A polyurethane sheath surrounds the nucleus and is attached to the endplate shell surfaces with a titanium wire, forming a closed compartment that is filled with saline at the time of implantation. Anterior stops on each shell help to prevent posterior migration of the device. The operative technique is exacting. A gravitational reference system is used to establish the center of the disc space. A milling fixture, adfixed to the vertebral body with anchors, precisely controls the powered cutting instruments that prepare the vertebral endplates. The milled vertebral endplates exactly match the geometry of the implant's convex outer surface.

A recently published report reviewed the early clinical results with the Bryan disc [15]. A total of 97 patients were implanted. Data were reported on 60 patients: 30 at 6 months and 30 at 1 year of follow-up. Patient-derived outcomes were determined by the Cervical Spine Research Society and SF-36 instruments. Success was recorded in 90%. There was no measurable subsidence. One device migrated. Flexion–extension ranged from 1 to 21° (average, 9°).

Problem: heterotopic ossification

Perianular ossification occurring after total disc implantation is not uncommon. There is an increased incidence with postoperative bracing and incomplete coverage of the endplate by the device "footprint."

McAfee et al. [16•] have described a usable radiographic classification to define the presence of heterotopic ossification (HO). In class 0, no HO is present. In class 1, HO is present in islands of bone within soft tissue but not between the planes formed by the two vertebral endplates. The range of motion of the vertebral motion segment is not limited. In class 2, HO exists between the two planes formed by the vertebral endplates but the bone does not articulate. HO may possibly affect the vertebral range of motion. In class 3, the range of motion of the vertebral endplates is decreased on flexion–extension or lateral bending radiographs. In class 4, HO causes arthrodesis and ankylosis with continuous bridging of trabecular bone. Less than 3° of motion on lateral flexion–extension radiographs is appreciated.

Problem: longevity and particulate debris

Wear debris occurs any time an implant is used. The question is the magnitude and the clinical sequelae. As seen in total knee and hip long-term outcomes, microscopic fragments can incite the body's immune system and cause destruction of bone at the prosthetic–bone interface. With bone loss, the component stability is affected and a disc device in such an environment may migrate or extrude.

Polyolefin rubber compound particles have been generated *in vitro* and placed in subcutaneous pouches in rats and adjacent to the lumbosacral dura in sheep [17•]. A foreign body reaction was created. No particle migration from the site of implantation was identified. There were no apparent local or systemic toxic effects.

In a nonhuman primate study with the SBC III, histochemical assays showed no accumulation of particulate debris (no titanium, ultrahigh-molecular weight polyethylene, cobalt chrome) and no cytokines (transforming necrosis factor-α, PGE2, interleukin-1 [IL-1], IL-2, or IL-6) [18]. The lack of long-term evaluation or anatomic differences including the absence of synovial fluid in the disc may be the reason why particulates have not been generated

Table 3. Contraindications for artificial disc replacement

Psycho-social issues
Systemic processes (infection, tumor)
Segmental instability, spondylolisthesis
Disc height < 5 mm or > 12 mm
Incompetent posterior elements, facets
Incompetent end plate
Osteoporosis
Obesity (weight > 90 kg, body mass index > 30)

Conclusions

Slowly, the artificial disc is becoming a reality. Surgical indications for use of an artificial disc need to be clarified. Far from becoming a "routine" procedure, disc replacement will best be applied within a defined, narrow clinical window (Table 3).

Future studies must pursue long-term clinical evaluations. Studies must clearly stratify the degree of degenerative change not just within the disc but within the triple-joint complex (disc, facet, ligamentous complex). For accurate comparability, biomechanical terminology and methodology for the artificial disc must become standardized.

Problems to be solved include (1) accurate patient selection criteria, (2) nucleus replacement containment and anular healing, (3) heterotopic ossification prevention, (4) device longevity and particulate debris, and (5) determining optimal device constraint.

References and recommended reading

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