Chapter 20
Advances in Biomaterials that Led to the Artificial Disc

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INTRODUCTION

It is undeniable that advances in biomaterial technology were indispensable to the development of the artificial disc. However, that does not explain the whole story. A more accurate statement would reflect the fact that artificial discs became a reality only as a result of the confluence of advancements in thought, techniques, and biomaterials; each part of the triumvirate playing an equally important role. This chapter provides a review of the contributions provided by each of these factors that allowed the artificial disc to reach fruition.

POTENTIAL ADVANTAGES AND DISADVANTAGES

Interbody fusion has been successful in the treatment of degenerative disc disorders. However, this success is often tempered by the acceleration of degenerative disc changes at levels adjacent to the fused segment. Hilibrand et al. have documented the occurrence of symptomatic adjacent-segment disc degeneration at a relatively constant incidence of 2.9% per year (10).

Ostensibly, an artificial disc was designed to replace the abnormal degenerated disc while obviating the problems associated with fusion. The potential benefits of arthroplasty include maintaining motion, restoring disc height, and correcting spinal malalignment. The preservation of intervertebral motion may also restore normal loading on facet joints, ligaments, endplates, and adjacent vertebral segments. Taken together, these benefits may allow patients to achieve relief of their neck or back pain after arthroplasty. Potential disadvantages of the artificial disc include implant subsidence, implant migration out of the disc space, and material wear debris. The material's durability must also be considered. Revision surgery for an artificial disc can also be fraught with danger.

DESIGN REQUIREMENTS OF ARTIFICIAL DISC

Ideally, an artificial disc should mimic the characteristics of the physiological intervertebral disc as much as possible. In particular, this includes viscoelastic properties that allow the disc to respond to the natural forces at work in the spine.

An ideal artificial disc should also preserve "normal" motion at the intervertebral joint. The physiological intervertebral disc allows rotation, translation, and bending motions in multiple planes. However, there is a finite range of motion that can be tolerated before injury results. The geometry, dynamics, and kinematics of the artificial disc should mirror these characteristics while also being able to constrain motion to prevent unstable motion.

A disc implant should also be biocompatible. It should be made of materials that will not elicit an excessive inflammatory or allergic reaction. Further, it should not be organotoxic or carcinogenic. On the contrary, its material properties should promote osseointegration at the bone–disc interface to integrate the disc into the intervertebral space and lessen the risk of graft displacement.

Once implanted, an artificial disc should also last a long time without the need for replacement. It should be made of durable materials that are able to withstand the forces to which a spine is subjected. The disc must also tolerate the stress of repetitive joint motion without wearing down prematurely. It has been estimated that an intervertebral joint undergoes 80 million motion cycles during the course of 40 years (11). Neurosurgeons need to become familiar with the science of tribology and its application to spinal arthroplasty.

Lastly, the ideal artificial disc should be made of materials that are imaging friendly. Because correct intraoperative positioning of the artificial disc depends on fluoroscopic guidance, it should be made of materials that are x-ray compatible and do not cause much imaging artifact. Minimizing imaging artifact will also facilitate postoperative radiographic follow-up.

EVOLUTION OF THE MODERN ARTIFICIAL DISC

Although most people think of arthroplasty as a recent phenomenon, the first attempts at disc replacement occurred half a century ago. Since that time, a myriad of disc replacement technologies have been introduced, with varying degrees of success. These implants have encompassed a wide range of techniques concerning the biomaterials, type of articulation, design of bearing surfaces, method of fixation, and kinematics.

In 1955, Cleveland reported 14 patients in whom he implanted a methyl-acrylic device into the intervertebral space at the time of discectomy (2). This was followed by Harmon's use of vitallium spheres in 13 patients from 1959 to 1961 (9). These implants, which were inserted in the lumbar spine through an anterior retroperitoneal approach, led to instances of spontaneous fusion rather than maintaining motion. As a result, this technique was stopped because of legal issues. Another pioneer was Fernstrom of Sweden, who, in 1966, published results of patients in whom he implanted a solid stainless steel sphere through a posterior approach at the time of lumbar discectomy (5). Remarkably, these procedures were done under local anesthesia. This is just a short list of the motion-preserving intervertebral devices that have been tried and abandoned. Other failed techniques include those involving beads, gels, sutures, springs, and ball-and-sockets.

Currently, there are four types of artificial discs being studied:

1) Composite
a) Bryan Cervical Disc (Spinal Dynamics Corp., Mercer Island, WA)
b) Prestige LP (Medtronic Sofamor Danek, Memphis, TN)
c) Charite (Depuy Spine, Inc., Framingham, MA)

2) Mechanical
a) Prodisc (Synthes-Stratec, West Chester, NY)

3) Elastic
a) AcroFlex-100 (Depuy Spine, Inc.)

4) Hydraulic

a) Prosthetic Disc Nucleus (Raymedica, Inc., Bloomington, MN)

These disc prostheses use a variety of materials, including stainless steel, titanium, metal alloys, silicone, or hydrogel. Each material has advantages and disadvantages; titanium provides very little imaging artifact, but is not reliable as a bearing surface; cobalt-chromium makes a superior bearing surface, but has poor imaging characteristics. There is also a variety of articulations being used. The most common include a metal-on-metal articulation or two metal endplates sandwiching a polyethylene core. Metal-on-metal articulations may lead to metallic or metal ionic debris. The ceramics in metal-ceramic discs may shatter. Metal-plastic disc may be complicated by plastic wear or cold flow.

Cervical Arthroplasty

The anatomic cervical disc is approximately 4 to 7 mm in height. The typical cervical motion segment allows 10 degrees of flexion and extension, 11 degrees of lateral bending, 7 degrees of axial rotation, and 2 mm of translation.

Cummings et al. first reported on a two-piece stainless steel disc replacement called the Bristol Disc (Cummins, Bristol, United Kingdom) (Fig. 20.1A), which articulates via complementary concave and convex parts that are secured to the bone with ventral screws (3). They implanted the device in 20 patients with cervical spondylosis, 19 of whom had adjacent-level congenital or surgical fusion, and postoperative x-rays showed motion at the joint in 16 of the patients. Despite changing from one screw per component to two screws during the study, there was still a high complication rate: three partial screw pullouts, two broken screws, one joint subluxation, one hemiparesis caused by drill injury, three patients with mild persistent dysphasia, and one reoperation to remove a device that was loose. The high morbidity was partly attributed to the use of a uniformly sized device and the high profile of the device.

Since that initial report, the Bristol-Cummins disc has undergone many revisions, and the latest iteration is called the Prestige LP (Fig. 20.1B–D). To address the high complication rate of its predecessor, the Prestige disc comes in various sizes to accommodate patient variability. It also has a much lower profile and, because of bilateral notched rails on both the superior and inferior plate, does not require the use of screws to secure the device. Studies are currently underway to evaluate the safety and efficacy of this device.

The Bryan Cervical Disc (Fig. 20.2) consists of a low-friction, wear-resistant, elastic polyurethane nucleus sandwiched between two titanium plates with rigid wings and a porous coating. It has been implanted in Europe with promising results. Bryan published the results of 97 patients in whom the Bryan disc was implanted for the treatment of single-level degenerative disc disease (1). In the 12-month follow-up examinations, using Odom's criteria, 70% of the patients had excellent results, 4% had good results, 13% had fair results, and 13% had poor results. Similar figures were observed at 24-month follow-up exmainations. Goffin et al. prospectively enrolled 30 patients to undergo Bryan cervical disc implantation and found that after 1 year, the rate of clinical success was 90% with the measured mean flexion–extension range of motion of 9 ± 5 degrees (8). There were no cases of graft subsidence or evidence of spondylotic bridging at the implanted disc space. Evidence of anterior–posterior prosthesis migration was detected in one patient, but no devices required revision or explantation. This prosthesis is also currently undergoing clinical trials in the United States.

The Prodisc-C (Synthes-Stratec) (Fig. 20.3) has two CoCrMo endplates with a midline keel and an ultra-high

molecular weight polyethylene (UHMWPE) core. Enrollment in studies involving this device closed in September 2004, and results are forthcoming.

Lumbar Arthroplasty

A lumbar motion segment typically allows 12 degrees of flexion and extension, 8 degrees of lateral bending, and 7 degrees of axial rotation. The SB Charite disc (Depuy Spine, Inc.) has emerged as the most widely used artificial disc since its inception in the early 1980s. Named after its designers and the German hospital where it was tested, the SB Charite disc was originally composed of two metal endplates surrounding a polyethylene core. However, a high incidence of implant fracture was encountered. Currently, the SB Charite III disc (Fig. 20.4) is made of two CoCrMo endplates that sandwich a biconvex UHMWPE sliding core. This unconstrained design allows the core to translate dynamically and, therefore, requires intact facet joints to support shear force. On the other hand, this design forgives slightly off-center positioning. The third generation SB Charite has been used in Europe since 1987, with one study involving 100 patients followed for 10 years reporting 90% good-to-excellent outcome and a 91% return-to-work rate; no device failures occurred. In the United States, Geisler et al. recently published the results of a multicenter trial of 304 patients randomized to undergo Charite disc (n = 205) or BAK cage (n = 99) placement, and compared their results against the fusion literature (7). With a follow-up of 24 months, the Charite disc preserved segmental motion and had a lower complication rate than found in the BAK group. The Charite group also had a superior percentage change in visual analog pain scores (VAS) and equivalent mean percentage changes in Oswestry disability index (ODI) scores when compared with the fusion literature.

The original Prodisc prosthesis, designed with an articulating polyethylene surface between two titanium plates with two vertical fins, was first implanted in 1989. The second generation Prodisc consists of a monoconvex polyethylene core that slides into a caudal plate and articulates with a rostral plate (Fig. 20.5). Both the superior and inferior plates are made from a CrCoMo alloy, have a single midline keel, and are coated with a pure titanium Plasmapore surface to encourage osteointegration. The monoconvex configuration of the core allows the Prodisc to be inserted with less distraction than required for the Charite disc, and the ball-and-trough articulation results in a semiconstrained kinematic behavior. Zigler et al. prospectively randomized patients to undergo Prodisc implant (n = 28) or 350°F fusion (n = 11) (13). With more than 6 months of follow-up, the Prodisc group had significantly ($P < 0.05$) less blood loss, shorter operative time, shorter hospital stay, and more improvement in ODI scores. They also noticed a trend toward greater patient satisfaction with Prodisc versus fusion. Others have found that Prodisc and fusion patients reach the same levels of improvement in ODI and VAS ratings after 1 year, but that the arthroplasty patients arrive at those endpoints faster than fusion patients (4). This potentially translates to a shorter postoperative recovery and a quicker return to work and daily activities.

The Maverick disc (Medtronic Sofamor Danek, Inc., Memphis, TN) is a metal-on-metal articulation with a semiconstrained kinematic design that is currently undergoing clinical trials.

The AcroFlex disc was initially made of a rubber core vulcanized to two titanium endplates, exhibiting constrained kinematics. At the 3-year follow-up, mixed outcomes were reported for the six patients who received this device, two had excellent outcomes, one good, one fair, and two poor (6). One poor result was caused by a tear in the rubber at the junction of vulcanization. Furthermore, the vulcanization process involved the use of chemicals that were possibly carcinogenic in rats. The second generation AcroFlex-100 consists of an HP-100 silicone elastomer core bonded to

two titanium endplates (Fig. 20.6).

The most widely studied nucleus replacement device is the Prosthetic Disc Nucleus (PDN), which consists of a hydrogel core constrained within a woven polyethylene jacket (Fig. 20.7). The hydrogel core is compressed and dehydrated during manufacturing to minimize preimplantation size. After implantation, the outer UHMWPE jacket allows fluid to pass through to the core, which absorbs fluid and expands. Most expansion occurs in the first 24 hours, but maximal expansion takes up to 5 days. The property of the PDN facilitates disc space distraction. The flexible but inelastic woven jacket constrains horizontal and vertical expansion to some extent, yet permits the hydrogel core to deform and reform in response to changes in compressive forces. Platinum-iridium wire markers inserted in the core allow radiographic identification of the device. The PDN can be inserted via either an anterior or a posterior approach. Clinically, Schonmayer et al. reported on 10 patients treated with the PDN with a minimum follow-up of 2 years (12). Significant improvements were observed in both the Prolo and ODI scale scores, and segmental motion was preserved.

CONCLUSION

Spinal arthroplasty offers an attractive alterative to spinal fusion. Maintenance of segmental motion and prevention of symptomatic adjacent level degeneration are the ostensible goals of the myriad of prosthetic disc technologies that have been designed. Although some of the early indications are encouraging, longer term data will be required before we will know whether these goals are achieved.

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Fig. 20.1 A, the Bristol disc. B, the Prestige LP disc.

Fig. 20.2 The Bryan cervical disc.

Fig. 20.3 The Prodisc-C.

Fig. 20.4 A, the SB Charite disc III. B, anteroposterior and C, lateral x-rays of an implanted SB Charite disc.

Fig. 20.5 A, the Prodisc. B, anteroposterior and C, lateral x-rays of an implanted Prodisc.

Fig. 20.6 The AcroFlex-100 disc.

Fig. 20.7 The PDN