6.610. Trends in Materials for Spine Surgery
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**Glossary**

**Discogenic back pain** Discogenic back pain is also known as lumbar disc pain. The most frequent symptoms of discogenic back pain are lower back pain and spasms.

**Fretting corrosion** Fretting corrosion refers to corrosion damage at the asperities of contact surfaces. This damage is induced under load and in the presence of repeated relative surface motion and wear.

**Hemangiomas** An abnormal proliferation of blood vessels that may occur in any vascularized tissue.

**Laminectomy** Spine surgery that removes the portion of the bone arch on the dorsal surface of a vertebra.
**Abbreviations**

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>AF</td>
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</tr>
<tr>
<td>GAG</td>
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</tr>
<tr>
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### 6.610.1. Introduction

The spine has two main purposes: (1) it must provide a strong mobile central axis to support the skeleton and (2) it must also provide protection for the delicate nerves that travel from the brain to the periphery. A balance between stability and flexibility are essential to achieve this dual purpose. Aging, injury, disease, and genetic conditions can disrupt this balance resulting in back pain with more than 60% of the population experiencing back pain throughout a lifetime.\(^5\) Low back pain alone accounts for 2% of all U.S. physician office visits.\(^7\) Pain can be generated in the spine from damage to several anatomical elements including the vertebral bodies, intervertebral discs (IVDs), facet joints, dura of the nerve roots, ligaments, fascia, and muscles.\(^8\) Stabilization of the spine has been the major focus of surgical interventions to alleviate back pain.\(^4\)

Interventional techniques have evolved from the earliest use of metal screws and plates to correct scoliosis adapted from peripheral extremity repair in the late 1950s.\(^5\) Internal fixation of the spine using pedical screws was first introduced in 1959 by Boucher in Canada.\(^6\) In the 1960s, the advent of bony fusion techniques greatly increased the success of these procedures and currently, advancements are still being made on materials choice techniques greatly increased the success of these procedures and the potential for novel therapies.

Most notable is the development of the vertebroplasty and kyphoplasty procedures developed in the late 1980s for the percutaneous treatment of vertebral fractures (see Chapter 6.611, Injectable Bone Cements for Spinal Column Augmentation: Materials for Kyphoplasty/Vertebroplasty).\(^11\)–\(^13\) The development of materials for spinal procedures has been greatly influenced by advances in technology that permit the visualization of spinal structures, innovations of novel surgical procedures, and a better understanding of the biology and structure of the native tissue. Early materials were adapted from procedures designed for the repair of bones and joints in the extremities; however, as more is understood about the unique structure and mechanical needs of the spine, novel materials are being developed for use in spine specific procedures. Tissue engineering and drug delivery have also motivated the development of new materials with porous and regenerative surfaces. This chapter outlines the current materials utilized in the major surgical interventions (spinal fusion, total disc replacement, and annulus repair) and spinal pathologies as well as the future direction of material development.

### 6.610.2. Anatomy and Physiology of the Spine

#### 6.610.2.1. The Vertebral Column

The human vertebral column or spine functions to transfer loads and bending moments of the head, trunk, and any external loads to the pelvis, allows sufficient physiological movement and flexibility of the upper body, and protects the spinal cord from dangers due to motion and trauma.\(^14\) It also serves as protection to other vital internal organs and as a base of attachment for upper-body ligaments, tendons, and muscles. These functions help explain its form and structure.

The spine consists of 24 individual vertebrae, the sacrum, and the coccyx, and spans from the skull to the pelvis. The vertebrae are stacked on top of each other and are grouped into five distinct regions – there are 7 cervical vertebrae, 12 thoracic, 5 lumbar, 5 fused sacral, and 3 fused vertebrae that make up the coccyx (Figure 1). From posterior perspective, the spine appears to be straight, but lateral view shows four normal curves that mechanically serve to give the spinal column increased flexibility and shock-absorption ability.

The vertebral body is the primary weight bearing area, and adjacent vertebrae are connected by an IVD (Figure 2). The vertebral foramen is the large hole in the center of the vertebra that is surrounded by lamina, forming the spinal canal. The spinal cord runs through this opening and is protected by it. The spinous process protrudes from the central posterior region of the vertebra and acts as a connection point for ligaments. There

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**Osteopenia** A condition in which bone mineral density is lower than normal, but not low enough to be classified as osteoporosis.

**Pseudo elasticity** A reversible response to an applied stress, caused by a phase transformation between the austenitic and martensitic phases of a crystal.

**Vertebroplasty and kyphoplasty** Medical spinal procedures in which a material is injected through a small hole in the skin (percutaneously) into a fractured vertebra and hardens; the goal of the procedure is to relieve the pain caused by osteoporotic compression fractures.

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are pairs of transverse processes which are orthogonal to the
spine and provide attachment for the back muscles. There are also four facet joints on each vertebra that are found in
pairs (one superior and one inferior), interlocking with adjacent
vertebrae to provide stability to the spine. When osteoporosis
occurs in the spine, vertebral collapse, or compression fractures,
may occur (Figure 3). Vertebral compression fractures may also
be caused by hemangiomas, multiple myeloma, and osteolytic
metastases. Multiple fractures lead to a stooped or hunched
posture, chronic pain, and loss of height.

6.610.2.2. The Intervertebral Disc

The IVD separates adjacent vertebrae and acts as a shock
absorber, dissipating energy under loading. The disc is the
largest avascular tissue in the human body requiring nutrients
to enter and waste to be removed primarily through diffusion
and fluid flow. The disc structure is quite complex combining
three distinct regions: the nucleus pulposus (NP), an inner
gelatinous core; the anulus fibrosus (AF), a surrounding
ordered fibrous structure; and the bony endplates that are
partly cartilaginous and partly bony and serve as an interface
between the disc and the vertebral bodies (Figure 4). The
cellular content of the disc is very low, less than ~0.25% of
tissue volume. The extracellular disc matrix plays the main
role in determining the mechanical properties of the disc.

6.610.2.3. The Nucleus Pulposus

The central NP region of the IVD is a gelatinous structure that is
mostly water (77% of wet weight) but also contains a large
constituent of proteoglycans (PGs) (14% of wet weight) which
are composed of charged glycosaminoglycan (GAG) chains
covalently attached to a protein core. Randomly organized
collagen fibers are also present in the NP (about 4% of wet
weight) and associate with the PGs to form a loose network.
Collagen fibers within the NP provide tensile strength while
PGs create a large osmotic swelling pressure and draw water
into the tissue (Figure 5). Charged groups on the GAG chains
of the PGs carry with them mobile counter ions such as Na+
which draw water into the tissue because of the osmotic imbal-
ance generating a hydrostatic pressure within the NP.

6.610.2.4. The Annulus Fibrosus

The AF of the IVD is a structure that serves to contain the
gelatinous NP. The chemical composition of the AF comprises
65–90% wet weight of water, 50–70% dry weight of collagen,
10–20% dry weight of PGs, and noncollagenous proteins such
as elastin. The structure of the AF is laminate in nature, con-
sisting of a minimum of 15 (posterior) and 25 (lateral) concent-
tric layers. The layers are made up of type I collagen fibers which
alternate in angles from 30° at the peripheral AF to 44° at the
central AF with reference to the transverse plane of the disc
(Figure 6). The concentric rings of the AF are referred to as
lamellae, and the spaces between them as interlamellar septae.
Spinal compression generates a hydrostatic pressure in the NP that places the annulus into tension thereby resisting the applied load (Figure 6).\(^{20}\) The AF has a very highly organized structure which results in complex anisotropic behavior with loading. The tensile, compressive, and shear properties of the AF differ in the axial, radial, and circumferential directions. The AF can be further divided into the inner and outer AF on the basis of the structural differences, the inner AF being subjected to higher hydrostatic pressures of the NP than the outer AF which is subject to tensile forces.

6.610.2.5. Intervertebral Disc Degeneration

The IVD of the spine is subject to degenerative changes induced by normal aging as well as injury, loading, or genetically induced accelerated disc degeneration.\(^{21}\) The exact mechanism of IVD degeneration is not well understood; however, possible degenerative cascades have been proposed which lead to eventual changes in disc mechanical properties (Figure 7). Initial changes in the IVD are thought to be brought about by changes in the nutrient flow to and waste product flow out of the nucleus. Calcification of the cartilaginous endplates, the major route of nutrient supply to the disc, leads to harsh cellular environments, subsequently reducing matrix synthesis and increasing enzyme production further reducing PG and collagen content of the disc, in particular in the NP.\(^{21,23,24}\) The loss of PGs in the NP has major effects on the load-bearing behavior of the disc, causing the osmotic pressure of the disc to fall and reducing the disc water content disrupting the NP’s ability to behave hydrostatically under load. Loading can then
lead to inappropriate stress concentrations along the endplate and in the annulus with progressive changes as disc degeneration proceeds (Figure 7).

Changes in stress concentration can lead to damage of the AF as well as the endplates with stress concentrations being associated with discogenic pain. Several manifestations of disc degeneration and damage can be visualized with MRI and are represented in Figure 8. Although these alterations in the IVD are prevalent in the asymptomatic population, disc disruptions have been associated with back pain and are targets for surgical interventions such as spinal fusion, total disc replacement, nucleus replacement, and annulus repair.

6.610.3. Spinal Fusion

Spinal fusion and stabilization utilizes a wide range of devices such as screws, wires, artificial ligaments, and vertebral cages. The instrumentation used in fusion surgery is designed to stabilize the spine during fusion and promote osseous fusion. Material choice for these devices is therefore targeted toward the promotion of bone ingrowth, and immediate mechanical stabilization of the spine. Postoperative imaging and analysis of surgical success is also of importance in material choice for spinal fusion devices. Early spinal fusion devices were based on metals commonly utilized in other orthopedic surgeries such as in hip implants.
Metals are still widely used in spine fusion implants today; however, advances have been made in implant design and material development in order to address the unique needs of the spine including maintenance of spine flexibility and to avoid the occurrence of adjacent area damage.

6.610.3.1. Metals for Spinal Cages and Interbody Spacers

The removal of the IVD in order to address discogenic back pain and disc herniation will lead to the loss of disc height and lead to spinal instability. Cage structures have been developed to assist in implanting allo- and autologous bone graft interbody spacers. These cages enhance stabilization of the spinal segment and prevent postoperative collapse.

The BAK™ interbody fusion system is a cage structure made of porous Ti–6Al–4V shell with a cavity for the placement of bone grafts (Figure 9). This device is implanted centrally or bilaterally between the vertebral bodies. The ends of this device are capped with ultrahigh molecular weight polyethylene (UHMWPE) plugs in order to contain the bone grafts and to minimize adhesion to surrounding nerves and blood vessels. The strength of the titanium material allows for the load bearing function of the spine and protection of the graft material while the implant design which incorporates threading to stabilize the implant, and a hollow center to allow for bone delivery, achieves the other functions of this device. Metals, however, are subject to fatigue failure if the graft does not fuse; also the high modulus of metals can lead to stress shielding and eventual failure of the device to integrate into its surroundings. See Table 1 for some common metals used in spine implants and their material properties.

Cobalt chrome has also been developed into a porous metal sponge for use in spinal surgery. The porous structure was designed to match the structure of cancellous bone and the implant could be loaded axially up to 28.5 MPa. Problems arose, however, with metal ion release because of the high surface area imparted by the porous structure. Released metal ions may increase pain at the implant site and cause loosening of the implant and local bone resorption at the implant site. Decreased pH levels at the implant site can be brought about by the inflammatory response and infection and may also have a deleterious effect on metallic implants causing fretting corrosion.

6.610.3.2. Polymers and Composites for Fusion Cages

In order to address some of the drawbacks of metal fusion cages, composite materials have been developed and utilized in spinal cages. A cage made from a composite of poly ether ketone ether ketone ketone (PEKEKK) with pyrolytic carbon fibers interspersed within the polymer matrix was developed. The material was molded to incorporate teeth located superiorly and inferiorly in order to resist expulsion (Figure 10). Material properties were modulated to better mimic those of bone in order to better support physiological loads as the graft material slowly integrates into the surgical site and in case the graft does not fuse. The cage was designed to have a Young’s modulus of ~17 GPa, close to that of cortical bone. This matched modulus decreases the likelihood of stress

![Figure 9](image_url) The BAK cervical spinal fixation device. A threaded hollow titanium implant that allows bone grafts to be implanted within the shell to facilitate fusion. Ends are capped with UHMWPE to minimize adhesion. Reproduced from Martz, E. O.; Goel, V. K.; Pope, M. H.; Park, J. B. J. Biomed. Mater. Res. 1997, 38, 267–288.

<table>
<thead>
<tr>
<th>Property</th>
<th>ASTM designation</th>
<th>316L SS (cold worked)</th>
<th>Wrought CoNiCrMo</th>
<th>Ti–6Al–4V</th>
<th>Pure Ti (Grade 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (g cm⁻³)</td>
<td>7.9</td>
<td>9.2</td>
<td>105</td>
<td>4.5</td>
<td>4.51</td>
</tr>
<tr>
<td>Elastic modulus (GPa)</td>
<td>193</td>
<td>220–234</td>
<td>1586</td>
<td>100</td>
<td>483–655</td>
</tr>
<tr>
<td>Yield strength (MPa)</td>
<td>690</td>
<td>220–234</td>
<td>785</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Tensile strength (MPa)</td>
<td>860</td>
<td>1793</td>
<td>860</td>
<td>100</td>
<td>550</td>
</tr>
<tr>
<td>Elongation (%)</td>
<td>12</td>
<td>8</td>
<td>10</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Fatigue strength (MPa)</td>
<td>310</td>
<td>500</td>
<td>520</td>
<td>240</td>
<td></td>
</tr>
<tr>
<td>(10⁷ cycles)</td>
<td>(F55 cold worked)</td>
<td>(cold worked)</td>
<td>(forged, annealed)</td>
<td>(as fabricated)</td>
<td></td>
</tr>
</tbody>
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An additional benefit of the nonmetallic implant is the ability to visualize the postoperative implant area because of the radiolucent property of the material.

Polyaryletherketones (PAEKs) are in the family of high temperature thermoplastic polymers and have been widely used for spinal cage implants after their introduction in the 1990s as an improvement over metal devices by Acromed (Cleveland, OH, now DePuy Spine, Raynham, MA). PAEKs consist of an aromatic backbone molecular chain interconnected by ketone and ether functional groups. Specifically, poly(aryl-ether-ether-ketone), PEEK, and poly(aryl-ether-ketone-ether-ketone-ketone), PEKEKK, have been used in orthopedic and spinal implants. The chemical structure of PAEKs allows stability at high temperatures, exceeding 300 °C, resistance to chemical and radiation damage, compatibility with reinforcing agents such as glass and carbon fibers, and greater strength than even metals. Mechanical and material properties for some PEEK formulations in comparison to other commonly used polymer materials are given in Table 2. These materials are also radiolucent making them a good alternative to metallic spine biomaterials.

PEEK and PEKEKK were first used in the development of the Brantigan cage with 68% by weight carbon fiber reinforcement in a 2-year clinical trial beginning in 1989. Clinical results were good with 100% interbody fusion identified. Interbody fusion could be identified because of the radioluency of the PAEK materials which continued to be a major reason for the use of this material (Figure 11).

In addition to carbon reinforced PEEK, neat PEEK is also utilized in the development of spinal cages and implants. Studies have also been conducted to investigate the improvement of PEEK cages to incorporate accelerated fusion performance by adding bioactive materials such as hydroxylapatite or rhBMP-2. Wear and fracture can be potential concerns with the use of PEEK as a load-bearing implant material; however, these concerns are not unique to PEEK. Although debris from wear has been noted in biopsies from carbon fiber PEEK cages, there has been no evidence of an inflammatory reaction making PAEK type materials promising in this application.

PEEK materials have also been investigated for other spine stabilization devices such as posterior dynamic stabilization devices and total disc replacements.

### 6.610.3.3. Wires, Tapes, and Cables in Spinal Fusion

Fusion of single or multiple spinal segments is also accomplished through the use of wires, tapes, and cables to secure adjacent bone segments. The most commonly used wire material is 316L stainless steel (Table 1). Stainless steel is relatively strong, ductile, and relatively inexpensive. Stainless steel 316L is especially preferred because of its resistance to corrosion as a result of low carbon content (0.03% maximum) which prevents sensitization of the stainless steel. Nevertheless, even stainless steel 316L is susceptible to localized corrosion associated with a loss of the protective chromium oxide surface layer. A concern in the use of metal wires for fixation is the possibility of neurological damage as well as concerns that the wire may cut through the bone if the bone is soft, which is especially the case in children. As an alternative, polymer tapes have been introduced such as nylon and woven strands of polyethylene (Mersiline) for use in procedures on scoliotic children.

### Table 2

<table>
<thead>
<tr>
<th>Property (ISO)</th>
<th>Selected lavibio PEEK biomaterials (OPTIMALTI)</th>
<th>UHMWPE</th>
<th>PMMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polymer type</td>
<td>Semicrystalline</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular weight (10^6 g mol⁻¹)</td>
<td>0.08–0.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poisson’s ratio</td>
<td>0.36</td>
<td>0.40</td>
<td>0.38</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.3</td>
<td>1.4</td>
<td>1.6</td>
</tr>
<tr>
<td>Flexural modulus (GPa)</td>
<td>4</td>
<td>20</td>
<td>135</td>
</tr>
<tr>
<td>Tensile strength (MPa)</td>
<td>93</td>
<td>170</td>
<td>&gt;2000</td>
</tr>
<tr>
<td>Tensile elongation (%)</td>
<td>30–40</td>
<td>1–2</td>
<td>1</td>
</tr>
<tr>
<td>Degree of crystallinity (%)</td>
<td>30–35</td>
<td>30–35</td>
<td>30–35</td>
</tr>
<tr>
<td></td>
<td>Unfilled (OPTIMALTI)</td>
<td>30% (w/w) chopped carbon fiber</td>
<td>68% (v/v) continuous carbon fiber</td>
</tr>
<tr>
<td></td>
<td></td>
<td>reinforced (LTICA30)</td>
<td>reinforced (Endolign)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Semicrystalline</td>
<td>Amorphous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2–6</td>
<td>0.1–0.8</td>
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<tr>
<td></td>
<td></td>
<td>0.8–1.6</td>
<td>1.5–4.1</td>
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Testing conducted at 23°C.
**6.610.3.4. Pedicle Screws, Plates, Bands, and Rods for Fusion and Dynamic Stabilization**

Screws, plates, and rods are often used to augment spinal fusion. Screws placed in the pedicles or vertebral bodies act as anchor points for bands, rods and plates working together to restore spinal stability. The screw–bone interface is especially influential in the success of fixations. Surface treatments of metal implants of stainless steel\(^{50}\) or titanium\(^{51}\) have been utilized to increase fatigue life of the implants and promote better integration. Stainless steel fatigue strength is enhanced by the implantation of nitrogen ions by inducing the formation of extremely hard nitrides at the surface of the material while maintaining the bulk properties of the material.\(^{26}\) Titanium can be modified by the introduction of bioactive titania layers of, for example, sodium titanate, calcium titanate, or titanium oxide which induce apatite formation on the implant surfaces and have been demonstrated to enhance osteoinductivity as well as osteoconductivity for improved implant integration.\(^{51}\)

Dynamic stabilization may be an alternative to fusion in some patients and may provide an improvement over fusion by altering load bearing and controlling abnormal motion while maintaining some flexibility. Dynamic stabilization devices incorporate a flexible ligament like component or other spring or mobile joint to allow motion in the spine while controlling movement such as flexion and extension. The diverse functionality of these devices often requires the use of both flexible polymeric materials and more rigid materials such as metals (Table 3).\(^7\)

**Figure 11** (a) Brantigan spine fusion cage and (b) lateral radiograph of a Brantigan cage with a solid fusion. (Note that the Brantigan cage has tantalum microspheres for visualization on radiographs.) Reproduced from Kurtz, S. M.; Devine, J. N. Biomat. 2007, 29, 4845–4899.

**Table 3** Dynamic stabilization devices

<table>
<thead>
<tr>
<th>Category and trade name</th>
<th>Key features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pedicle screws and artificial ligaments</td>
<td></td>
</tr>
<tr>
<td>Dynesys (Dynamic Neutralization System for the Spine); Zimmer Spine, Warsaw, Ind (18)</td>
<td>Semirigid artificial ligament system composed of titanium alloy pedicle screws and polycarbonateurethane spacers connected by polyester cords (artificial ligaments) that are placed under tension</td>
</tr>
<tr>
<td>Graf ligament; Surgicraft, Redditch, England (19)</td>
<td>Nonelastic polyester ligament looped around pedicle screws and placed under tension to prevent rotation while allowing some flexion; if tension is too high, hyperlordosis, foraminal narrowing, and nerve root impingement may result</td>
</tr>
<tr>
<td>IsoBar; Scient’x USA, Maitland, FL</td>
<td>Includes a mobile joint within metal rods</td>
</tr>
<tr>
<td>M-Brace; Applied Spine Technologies, New Haven, Conn</td>
<td>Implanted by using a minimally invasive technique</td>
</tr>
<tr>
<td>Stabilimax NZ; Applied Spine Technologies</td>
<td>Utilizes a dual spring mechanism</td>
</tr>
<tr>
<td>Dynamic Soft Stabilization System (20)</td>
<td>Elliptical metal coil connecting adjacent pedicle screws</td>
</tr>
<tr>
<td>Inter-spinous process decompression system</td>
<td></td>
</tr>
<tr>
<td>Wallis ligament; Abbott Spine, Austin, Tex (21)</td>
<td>Interspinous process distraction device composed of a spacer held between spinous processes with Dacron tape</td>
</tr>
<tr>
<td>X STOP; St Francis Medical Technologies, Concord, NH (22)</td>
<td>Titanium device in two pieces, placed between adjacent spinous processes to hold spine in flexion; can be inserted by using a minimally invasive approach with a local anesthetic and is thus useful in elderly patients with degenerative spinal stenosis</td>
</tr>
<tr>
<td>Diam; Medtronic So famor Danek, Memphis, Tenn</td>
<td>H-shaped silicone device held in place by a mesh band and suture</td>
</tr>
<tr>
<td>Coflex; Paradigm Spine, New York, NY</td>
<td>U-shaped device that controls flexion and extension</td>
</tr>
<tr>
<td>Posterior element replacement systems</td>
<td>Consists of a sphere that slides along a curved plate anchored by pegs passing into the vertebral body</td>
</tr>
<tr>
<td>Total Facet Arthroplasty System; Archus Orthopedics, Redmond, Wash</td>
<td>Posterior elements are removed and a plastic device is implanted and anchored with devices similar to pedicle screws</td>
</tr>
<tr>
<td>Total Posterior System; Implant, Princeton, NJ</td>
<td></td>
</tr>
</tbody>
</table>

Note: Some of the devices listed may not yet have been approved by the FDA for clinical use.

Inducing an abnormal curvature may lead to stress induced osteopenia of the vertebral bodies and spinal degeneration in adjacent spinal levels.\textsuperscript{26}This is, however, in contrast to the needs of a rigid system in order to promote the solid fusion process. Therefore, the use of a system whose rigidity decreases with time is desirable. Bioreabsorbable materials provide promise for such a system. Bioreabsorbable cages have stiffnesses comparable to those of bone, are radiolucent, and resorb over time.\textsuperscript{52} These cages provide the additional benefits of eliminating risks associated with permanent implants such as implant removal on revision surgery. In addition, degradation of the polymer may allow for the incorporation of a drug release system into the implanted device.

The most commonly used biodegradable materials are polyesters derived from poly(\(\varepsilon\)-hydroxy acids) such as poly(lactic acid) (PLA) and poly(glycolic acid) (PGA), and their isomers and copolymers. The chemical backbones of these materials are hydrolytically unstable, and the chains will degrade when placed in aqueous environments such as the body. PLA and PLGA degrade to lactic acid and glycolic acid respectively and are natural, biocompatible metabolic compounds. The strength and degradation rate of these polymers can be modified by the fabrication of copolymer systems. PGA degrades within months and is therefore used only in small amounts in copolymer systems, while PLA is more widely used in spinal implants. Chemical and physical properties of some commonly used PLA and PLA isomers are summarized in Table 4.

The polymer degradation kinetics and mechanical properties can be influenced by the polymer system utilized; however, the implant design and geometry itself has a large influence on the rates and types of degradation experienced by the implant. PLA devices degrade faster when they are less porous, less permeable, and have a bulkier design and wall thicknesses.\textsuperscript{52} Sterilization of the implant can also have drastic effects on the physical and mechanical properties of the polymer. Many conventional sterilization techniques such as steam sterilization can cause melting of the polymer system and therefore cannot be utilized. Ionizing radiation is an alternative sterilization technique; however, this technique can also induce damage in the polymers causing changes in biocompatibility and biomechanical characteristics. Treatment with ethylene oxide or plasma sterilization provides better alternatives and shows limited effect on molecular weight and tensile strength of PLA-based materials.\textsuperscript{13,54} Biocompatibility of PLA and related polymers has generally been demonstrated to be good with the absence of significant toxicity.\textsuperscript{52} A local reduction in pH imparted by the degradation products, however, may be responsible for some adverse tissue reactions such as osteolysis and bone resorption around the implant.\textsuperscript{55}

Bioreabsorbable PLA plates have performed well in comparison to titanium plates in controlled clinical studies. In an original study by Nabhan et al., bioreabsorbable plates made of \(\varepsilon\)-lactic and D,\(\varepsilon\)-lactic acid in the ratio of 80:20 in the INION S-1 Biodegradable Anterior Cervical Fusion System were investigated in a prospective randomized controlled study with 40 patients.\textsuperscript{56} The bioreabsorbable plates in this study were designed to hydrolyze over the course of 2 years. Plates maintained 90% of their initial strength after 6 months, then continued to decrease slowly to 70% after 9 months, and continued to absorb after 2 years. The fusion incidence and rates of fusion were found to be comparable to those of titanium plates but with several added benefits associated with the use of a biodegradable polymer. Advantages of the PLA plates included the radioluency of the plates which allowed visualization of the graft material giving reassurance that the plates had not migrated. The plates were also somewhat flexible and were able to be bent to match the vertebral contours of the patients. Gradual resorption of the plates may allow the fusion to gradually assume the role of structural support and enhance fusion rates while reducing stress shielding.\textsuperscript{56}

### 6.610.4. Total Disc Arthroplasty

The first mode of treatment proposed for the treatment of the majority of patients who suffer from disc degeneration is non-operative care. On the basis of carefully considered guidelines, surgical interventions are recommended in the event that conservative remedies do not address the clinical needs of the patient. Arthrodesis or spinal fusion is the traditionally accepted surgical intervention technique advocated in cases of isolated disc degeneration in the cervical or lumbar spine. The procedure involves the removal of a motion segment through the use of bone grafts and sometimes through internal fixation. Indications for the procedure are instability of a motion segment caused by traumatic injury or degeneration.\textsuperscript{57} A successful fusion procedure eliminates motion that causes pain and offers the ability to restore intervertebral height and alignment.\textsuperscript{58} However, spinal fusion has its limitations, some of which include the following:\textsuperscript{41}

- No significant improvement seen in the success rate of fusion procedures despite the advances made in terms of surgical techniques and instruments;
- Morbidities associated with bone graft harvests during the procedure;
- Accelerated adjacent level disc degeneration;

<table>
<thead>
<tr>
<th>Table 4</th>
<th>Chemical and physical characteristics of PLLA and PLDLLA</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLLA (literature)</td>
<td>PLLA (own use)</td>
</tr>
<tr>
<td>(M_n) (g mol(^{-1}))</td>
<td>240 500</td>
</tr>
<tr>
<td>(M_w) (g mol(^{-1}))</td>
<td>395 500</td>
</tr>
<tr>
<td>(D (M_w/M_n))</td>
<td>1.64</td>
</tr>
<tr>
<td>Intr. visc. (dl g(^{-1}))</td>
<td>2.68</td>
</tr>
<tr>
<td>Inh. visc. (dl g(^{-1}))</td>
<td>2.42</td>
</tr>
<tr>
<td>Crystallinity (%)</td>
<td>13.0</td>
</tr>
<tr>
<td>(T_g) (°C)</td>
<td>60–65</td>
</tr>
<tr>
<td>(T_m) (°C)</td>
<td>173–178</td>
</tr>
<tr>
<td>Degr. time (min)</td>
<td>&gt;24</td>
</tr>
</tbody>
</table>

● Long postoperative recuperation times;
● Increased costs of fusion procedures.

Disc arthroplasty is a surgical procedure that has been getting a lot of attention in the spine community. The procedure aims to potentially eliminate a painful disc while preserving/restoring motion. The goals of arthroplasty include successful pain relief and functional recovery, acceptable levels of morbidity associated with the procedure (equal to or less than those seen in fusion), shorter postoperative recuperation times, and easily implantable surgical techniques. The biomechanical objectives of disc arthroplasty are the restoration of disc function to relieve abnormal stress or strain caused by degeneration. More importantly, it is essential that the procedure does not cause any detrimental biomechanical effects on surrounding structures within the motion segment and on adjacent levels.

6.610.4.1. Material Requirements

In order to understand the material requirements, it is necessary to understand the biomechanics of disc arthroplasty. The following are some of the biomechanical parameters that might be considered while designing a total disc replacement implant:41

● Restoration of mobility while avoiding segmental instability;
● Restoration of correct spinal alignment;
● Protection of adjacent structures from overloading and resultant accelerated degeneration;
● Stability and wear properties of the device.

The material requirements for a TDA prosthesis are discussed according to each component of the artificial disc to be designed, along with some examples where possible.

6.610.4.1.1. Implant endplate

The vertebral endplate is subject to repetitive physiological loads, and therefore, a material chosen for this component needs to be durable enough to withstand such types of loads. Other aspects to be considered include the reactivity of the material, its modulus of elasticity, ultimate tensile strength, imaging characteristics, ease of manufacture, and cost. Commonly used materials for endplates are stainless steel, cobalt–chromium alloys, and titanium alloys.

Stainless steel implants are inexpensive to fabricate, show relatively low corrosion, and have high moduli of elasticity. Cobalt–chromium alloys have properties in between those of steel and titanium alloys. Depending on the alloy, processing of the end product can be tuned to a wide range of strengths and ductility, thus making these alloys versatile in their applicability as implants. However, such implants are more expensive to manufacture. Currently used prostheses have endplates made out of these types of alloys.

Titanium alloys are attractive as implant materials owing to their high biocompatibility. They are also more corrosion resistant than the other two types of alloys. Further, they yield fewer debris particles as detected by imaging with magnetic resonance. Their mechanical properties are closer to those of cancellous bone, but they have higher susceptibility to wear debris generation. Pure titanium implants have not been studied clinically, but titanium coatings are being used currently.

6.610.4.1.2. Bone implant interface

Attachment of an implant to the endplate can be achieved through the use of screws, serrations, or fins. These structures help insert the device, prevent early displacement, and facilitate long term stability. Long term attachment of the device can be facilitated by the presence of microstructured features on the surface of the implant in order to encourage bony ingrowth. Other options for inducing bony ingrowth include titanium spraying or meshes, calcium sulfate coatings, and hydroxyapatite coatings.

6.610.4.1.3. Bearing surfaces

Special attention is to be paid while selecting materials for the bearing surfaces of the implant. The bearing surface usually determines the long term stability of a well-fixed TDA implant. The articulation of these surfaces must allow low friction motion, resist permanent deformation, and show good wear resistance (see Chapter 6.614, Wear: Total Intervertebral Disc Prostheses).

Typically, surgical intervention to correct disc degeneration is performed on patients between the ages of 35 and 50 years. In order to reduce incidence of revision surgeries, the estimated life of a prosthesis is proposed to be over 40 years. Taking into consideration the number and amplitude of load cycles a lumbar disc experiences in a year, it can be assumed that the average adult bends 125,000 (extension and flexion movements) annually and takes about 2 million steps (gait cycles). The device is expected to endure roughly 85 million cycles of loading during its lifetime without significant degeneration. It is recommended that the device be tested for a 100 million cycles of loading. This hypothesis is made after taking into account the implant’s capacity to resist fatigue, and immunologic response to wear particles including their toxicity.

UHMWPE is used as a bearing material in several implants owing to its low creep properties. Even though polyethylene shows wear debris in its use with other joints, animal studies of metal-on-polyethylene disc implants have not shown significant evidence of wear particles.

6.610.4.1.4. General material specifications

Metals are considered to be good candidates for a total disc replacement device owing to their inherent high fatigue strength. Also, metal alloys have been shown to possess good biocompatibility. On the other hand, nonmetallic materials such as polymers and elastomers are also good candidates because of the similarities between their mechanical properties and those of native disc tissue. Over a short period of time, the lower elastic moduli of nonmetals help replicate disc behavior adequately. However, in terms of a long term device, such materials tend to pose a challenge to develop. Overall, the need of the hour is to develop materials that demonstrate both biomechanical applicability and biocompatibility while being user friendly in a surgical environment.

In order to meet the needs for an artificial disc, combinations of both metallic and nonmetallic components have been researched. In most cases, these take the form of metal–polymer–metal sandwiches, wherein the metal portion is used to improve fixation using screws/spikes or porous coatings to promote tissue ingrowth. The polymer component of the fixed implant can provide the flexibility seen in native discs.
6.610.4.2. Discontinued Artificial Discs

6.610.4.2.1. Acroflex

The Acroflex artificial disc was developed in the 1970s by Arthur Steffee. The device represents a leap in the concepts and design of artificial discs. The design of the disc comprises two porous metal end plates coated with titanium and fused to a hyperelastic polymer disc which is made up of a hexane-based polyolefin rubber. The design of the device is such that the vertebral bone is intended to grow into the titanium plates to ensure long-term fixation, while the polymer disc is intended for restoration of flexibility and motion to the functional spinal unit.

The Acroflex device had significant biomechanical advantages. It helped in the preservation of disc height and allowed semiconstrained motion in all modes including compression.

Over the years, there have been three generations of the Acroflex disc developed. Each generation of the device successfully passed the mechanical testing protocols to which they were subjected, only to fail in the short term when implanted in a series of limited human clinical trials.

6.610.4.2.1.1. First generation

The first generation of Acroflex was composed of CoCr alloy and polyethylene as the polymeric core cemented together and implanted through an anterior approach. The disc was tested in cadaveric spines; however, concerns were raised regarding the bone–cement interface, and the device idea was subsequently abandoned.

A cementless design was developed in the 1980s using titanium end plates with a double layer of sintered 250 μm beads to enhance long-term fixation. In this version of the disc, the polymeric core was made out of a polyolefin rubber known as Hexsyn, manufactured by Goodyear for fatigue-resistant biomedical applications.

The device was subjected to preliminary mechanical testing, and despite some incidences of local material failure, the tests were judged to be successful. The next step was animal testing; however, the company was never able to obtain permission to carry out animal studies. Instead, on the basis of in vitro studies to study biocompatibility, a decision was made to proceed to human trials. The device was implanted in six patients and follow-up studies were conducted. However, in 1990 the FDA raised concerns of the use of Hexsyn, which contained 2-mercaptobenzothiazole, a potential carcinogenic. The disc was eventually removed from the market.

6.610.4.2.1.2. Second generation

There is very little information available in the literature about the second generation of the Acroflex device (Figure 12). In this iteration of the design, the polymeric core was composed of a silicone elastomer and clinical trials were performed in eight patients. Data for this generation of studies are not available because of the controversies surrounding the use of the silicone gel in breast implants. Class action lawsuits had been filed against the manufacturer of the silicone (Dow Corning), making the developers of the disc hesitate to publish their findings.

6.610.4.2.1.3. Third generation

The third generation of the Acroflex disc once again used a hexane-based polyolefin rubber core. The endplate design was modified to reduce the profile to facilitate easier implantation. The endplates were made from a Ti–6Al–4V ELI alloy, coated with porous beads made of pure Ti. Mechanical testing was performed on the device and concluded to be satisfactory. Debris testing was not undertaken as the disc had no articulating surfaces.

Animal studies conducted on 20 baboons showed significant evidence of osteointegration into the porous coating after 6 months. There was one case of failure and histological reaction because of the presence of wear particles in one animal.

Pilot human trials were conducted with two groups of patients, with subtle design differences in the endplate of the device. Both sets of trials did not yield significant results to conclude the success of the device.

Eventually, even after three decades of changes to the design and materials used in the Acroflex artificial disc, the device did not achieve significant clinical success. The design concept of using a one-piece nonarticulating artificial disc is very attractive, as it would mimic natural disc function very well. However, this is hindered by the complex loading environment seen in the spine. The device was successful in terms of achieving rapid osteointegration. The biggest hurdle to the success of the Acroflex artificial disc though was the designers’ inability to find a suitable polymeric core material to meet the required needs for an artificial disc.

6.610.4.3. Currently Available Devices

6.610.4.3.1. Charité artificial disc

The Charité Artificial Disc (marketed by DePuy Spine), unlike the Acroflex was designed with the goal of replicating the kinematics of the disc as opposed to the motion. The device...
was designed by Kurt Shellnack M.D., and Karin Buttner-Janz M.D., Ph.D, who were affiliated at the time to the Charité Center for Musculoskeletal Surgery at the University of Berlin. The basic design of the device incorporates two metallic end plates made of cobalt-chromium alloy which are attached to adjacent vertebral bodies, and articulate against a central polymeric core made up of UHMWPE.

The UHMWPE core has two domed (convex) surfaces that help to articulate against the concave metallic endplates. The hypothesis is that in conditions of full flexion or tension, the core is free to translate or rotate when the polyethylene rim of the core contacts the metal rims of the endplates. The device is implanted through an anterior approach. The device provides unconstrained motion during rotation, and semi constrained motion during flexion, extension, lateral bending, and translation, to some extent.

The Charité Artificial disc has undergone four iterations in design since its inception and offers the largest and longest clinical trial of any existing artificial disc. The rationale for choosing an UHMWPE core was because of the outstanding friction and fatigue properties of the material.

6.610.4.3.1.1. SB Charité I and II

Only retrospective clinical data are available for the SB Charité I and II, the first two generations of the device. The first two generations were made up of stainless steel endplates, which had protruding teeth for better fixation. In the SB I disc, the end plates were circular and shaped like bottle caps, while in the SB II they were expanded by providing lateral wings to enhance contact with the vertebral end plates. The SB I and II discs were implanted in 15 and 22 patients respectively and follow-up data obtained after a period of 17.5 years. Follow-up studies revealed a success rate of 87% (13/15) for the SB I disc, and 68% (15/22) for the SB II discs. The success was defined in terms of the absence of long term complications.

The inventors performed mechanical testing on the devices and found that the height of the UHMWPE core was reduced by 10% during testing. They claimed that there was minimal wear and debris formation posttesting; however, it has been seen that their claims are consistent with testing in a single direction, which produces far less wear particles than testing in multiple directions.

6.610.4.3.1.2. SB Charité III

Waldemar Link GmbH and Co. was the company that commercialized the Charité artificial disc, resulting in the third generation SB Charité III (Figure 14). Major changes were made to the endplate material, which was now constructed out of a proprietary CoCr alloy called VACUCAST (0.25% C, 28–20% Cr, 5.5–6.5% Mo, max 0.5% Ni, max 0.5% Fe, 0.4–1% Si, 1% Mn, and the remaining 57.1–69% Co). The back of the alloy was ‘satin’ finished by corundum blasting, and the device was fitted with six sharp teeth to achieve fixation. The UHMWPE core design remained unchanged.

There have been a number of clinical studies undertaken to document the performance of the SB Charité III. In summary, most of these studies have demonstrated that the Charité artificial disc has the potential to preserve motion and survive long term implantation in the body with good to excellent outcomes. However, cohort studies undertaken have shown variability in the complication and success rates of the device, which raises concerns regarding the repeatability and reproducibility of the procedure.

6.610.4.3.2. ProDisc

The ProDisc (Synthes Spine, Paoli, PA) also consists of metallic endplate with an UHMWPE core. Unlike the Charité, the ProDisc is attached firmly to the inferior end plate through a locking mechanism. The convex surface of the polymer core articulates against the superior end plate. There have been two generations of the ProDisc, ProDisc I and II, but only the ProDisc II has been commercialized.

The ProDisc has undergone the second largest clinical trial of any artificial disc after the Charité. The ProDisc I had metallic endplates made of Ti alloy, whose back surfaces were plasma sprayed with a titanium coating to promote bone growth. Follow-up reports for ProDisc I showed some procedure related complications. Minimal wear of the UHMWPE core was detected.

Clinical studies on the ProDisc II have only been short term (17–31 months), with reports of positive outcomes. It is to be noted that the studies for ProDisc are more scientifically sound than the studies for the Charité disc, which has only been retrospectively studied in Europe. Studies on the ProDisc...
II however, are prospective and employ validated outcome measures such as the Oswestry Disability Index, which can be compared with alternative spine procedures (Figures 15 and 16).62

6.610.4.3.3. Maverick

The Maverick total disc replacement device was developed in 2001 by Medtronic Sofamor Danek (Figure 17). Initial prototypes were designed using alumina ceramic, but the commercially available device now features a two piece metal-on-metal design, which comprises superior and inferior endplates made of CoCr alloy. Bearing surfaces are made of CoCr alloy based on ultra low wear rates obtained in hip replacements. The endplates have been treated with hydroxyapatite to promote bone growth.62

Clinical trials of the Maverick disc began in 2002. Two-year follow-up results have been reported so far. Clinical success was reported in 75% of the patients. No revisions or device related complications were reported in this study. Mechanical testing on the disc showed good shock loading, and showed no mechanical damage after 10 million loading cycles. However, wear debris was produced, but the test methods were not published in the literature. On the basis of this, the life span of the device was predicted to be around 31.5 years in vivo, but this claim cannot be validated until further studies are conducted.71,72

Figure 15 Components of the ProDisc. From left to right: superior endplate, polyethylene inlay, and inferior endplate. Source: Synthes Product Literature.

Figure 16 Front and side views of the ProDisc-L artificial disc. Source: Synthes Product Literature.

To sum, the Maverick disc is a good alternative to metal-polymer-metal disc replacements that are currently available. Two-year follow-up studies and biomechanical testing have been reported. Metal-on-metal articulation produces less wear than metal-on-UHMWPE prostheses; however, it also produces metallic wear debris. This can be a cause for concern. Only further studies can tell if the Maverick disc will be clinically successful.

### 6.610.4.3.4. Flexicore

The Flexicore disc manufactured by Stryker Spine is the most constrained of lumbar discs and consists of four CoCr components: a superior and an inferior baseplate, a spherical head that attaches to the superior endplate, and a shield (Figure 18). The device is capable of supporting tensile loading because of the presence of the spherical head. It also contains mechanical stops in order to limit flexion/extension and lateral bending. The device endplates are coated with titanium plasma spray coating to promote bone growth. Mechanical testing has been conducted in tension, compression, and shear. The studies showed that the device is mechanically sound and has strength limits excessive to the load limits for the IVD. Wear testing showed that minimal or no wear damage was seen.

The disc is undergoing a clinical trial at present, but the results are not expected for several years. The success of the Flexicore disc can only be determined when more clinical data become available.

### 6.610.4.4. Future Trends

The field of total disc replacement is a rapidly evolving area of new technologies and techniques, and great strides have been made in the development of spinal implants that are able to replicate and preserve motion in the IVD. The arena of total disc replacement has seen many leaps in terms of achieving short term benefits such as patient satisfaction and speed of recovery.

New implants are being designed, developed, and tested. The near future might hold answers regarding the long term benefits of using total disc replacements, especially the goal of reducing the incidence of adjacent segment degeneration. More comprehensive follow-up studies will reveal the future for these implants.

From a materials standpoint, there have been different design concepts explored. The use of all-metal implants and that of metal–polymer implants have been investigated. At this juncture, it is hard to say which system works better. Each type of design has its own inherent advantages and disadvantages; for example, the main issue with metal–polymer implants is the wear of the polymer core, which can cause early failure of the implant. The all metal implants show excellent wear resistance; however, the generation of wear debris is an issue of concern. The consequences of these wear particles and their corrosion solubility products are unknown at present. There might also be concerns regarding the maintenance of bony attachment with the degradation of bone tissue with age and osteoporosis with respect to these devices.

Nevertheless, the future holds a lot of promise for this field, and as more data are published on the available and developing implants, changes in design and materials can be conceptualized and implemented to meet the objective of achieving a successful implant that will meet all the needs of patients who require total disc replacement.

### 6.610.5. Annulus Repair

#### 6.610.5.1. Procedure

The repair of the AF has seemed to be an intuitive idea for many researchers, but given the limitations posed by the current microscopic and endoscopic surgical techniques, this has not been attempted much. Advanced technologies are being developed to close annulus defects. These could also enhance the use of intradiscal prostheses which are contained by the AF. Efforts are also underway to develop devices that will support the annulus after a disectomy procedure.

#### 6.610.5.2. Mechanical Role

The AF of the IVD is a structure that serves to contain the gelatinous central portion of the disc, the NP. The chemical composition of the AF comprises 65–90% water, 50–70% dry weight of collagen, 10–20% dry weight of PGs, and noncollagenous proteins such as elastin.

The structure of the AF is laminate in nature, consisting of a minimum of 15 (posterior) and 25 (lateral) concentric layers. The layers are made up of type I collagen fibers which alternate in angles from 28° at the peripheral AF to 44° at the central AF with reference to the transverse plane of the disc. The concentric rings of the AF are referred to as lamellae, and the spaces between them as interlamellar septae.

The AF has a very highly organized structure which results in complex anisotropic behavior. The tensile, compressive, and shear properties of the AF differ in the axial, radial, and circumferential directions. The AF can be further divided into the inner and outer AF on the basis of the structural differences, the inner AF being subjected to higher hydrostatic pressures of the NP than the outer AF which is subject to tensile forces.

Age related degradation of annulus tissue manifests in the form of annular tears and fissures, and can ultimately lead to

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Figure 18  Components of the Flexicore artificial disc. Reproduced from Valdevit, A.; Errico, T. *Spine J.*, 2004, 4, 276–288.
disc herniation. Circumferential delamination and the formation of radial fissures can cause the extrusion of the NP material which is contained by the annulus. This is referred to as disc herniation. Herniation can be defined as the localized displacement of disc material beyond the limits of the intervertebral disc space. When this happens from the posterior region of the annulus, the release of chemical inflammatory signals can result in severe pain in the back.

Degeneration of the annulus results in a transfer of load from the NP to the posterior portion of the annulus. To compensate for the added stress, the annulus tends to broaden, which often causes significant protrusion of the disc. This manifests in the form of circumferential disc bulging or focal herniation. Tissue remodeling in the posterior annulus is often accompanied by calcification and other changes that pose a challenge to the treatment of this issue.

In the past, surgical intervention to reverse disc degeneration has focused on re-establishing disc height and geometry, while minimizing the flexibility of the disc. But recently, techniques that seek to retain or restore disc motion are being investigated in a bid to avoid the elimination of spinal segmental motion. Some of these include the replacement of the ‘total disc’ (i.e., the NP and a significant portion of the annulus) with a prosthetic implant. An alternative to this approach is to replace the NP while retaining a major part of the annulus.

Studies have shown that an incision through the annulus can alter the mechanics of the involved disc. Hampton et al. showed that incisions made in the posterior annulus showed limited healing potential and the presence of a persistent defect could form a pathway for the leakage of nuclear fluid into surrounding perineural tissue. This view was reinforced by other researchers who investigated annulotomy techniques in animal models. They found that a box type or window annulotomy technique produces a significantly weaker healing response than a slit or cruciate incision.

On the basis of the results reported, it can be inferred that the AF has a limited capacity for regeneration after an annulotomy. On the basis of the type of annulotomy performed, the healing process leads to the formation of a thin layer of inferior fibrous tissue. The poor regenerative capacity may be due to the fact that the external repairs do not meet the needs of fiber recruitment to withstand the tensile forces applied to the annulus. In order for the annulus to shift between axial loading and circumferential tension, it is necessary that the nucleus suffering damage from an annulotomy or degradation, its ability to retain the nucleus is lowered. In light of the above discussion, we can say that preservation of as much annular tissue as possible should be the goal during surgical interventions to treat disc degeneration.

6.610.5.3. Reported Treatment Methods
6.610.5.3.1. Suture techniques
There have been reports of closing annular defects with sutures after a microdiscectomy. The first instance of suture usage to close annular defects was reported by Yasargil in 1977, wherein he used 7-0 sutures to close a defect made to remove nucleus material. He reported that this method could help prevent adhesions in the annulus, but did not suggest any mechanism for the same. He tested his method on 105 patients, and recorded no reherniations, neurological impairment, or postoperative radiculopathy in them.

Lehmann et al. have reported suture related techniques to close annular defects by using 4-0 sutures to close the flaps of the posterior longitudinal ligament, peridural membrane, and outer fibers of the annulus. In a study conducted in 152 patients, a larger percentage of patients who received sutures had less postsurgery pain compared to those who did not receive them; however, the result was not statistically significant. The investigators did not report on the incidence of reoperation or reherniation.

Cauthen et al. have studied suturing of the annulus with a focus on reducing the rate of reoperations. He studied 254 patients and reported that there was a 21% chance of recurrent disc herniation when the patient did not receive sutures at 2 years. The use of one suture to perform microsurgical suturing showed a decreased recurrence rate of 10% while the use of more than one suture brought it down to as low as 5%.

6.610.5.3.2. Sealant and bulking techniques
Biocompatible tissue adhesives have been used in many areas of the body containing soft tissue, for example, fascial hernias or cardiovascular procedures. Such procedures, however, have not been extended to the AF because of the undesirable effects of adhesion that might occur with neural tissue in the vicinity. Instead, ‘sealing’ biomaterials, which are polymeric solutions that cure in situ, have been injected into the annulus. In concept, these bulking hydrogels are intended to form a sealant which will take on the complex, irregular shape of the AF defect, and may bond strongly to the neighboring tissue around the defect. There have been no clinical reports of such a technique being applied to the annulus; instead, these types of biomaterials seem more applicable to nucleus replacement.

6.610.5.4. Current Technologies
6.610.5.4.1. Xclose™ tissue repair system
The Xclose™ Tissue Repair System marketed by Anulex Technologies, Inc. is an FDA approved technology, and is recommended for reapproximation of soft tissue such as the AF after a discectomy procedure (Figure 19). The system consists of two tension band devices and one knot pusher. The device works by placing tension bands at the annulotomy site and securing them with tension bands.

6.610.5.4.1.1. Material
All implanted components of the device are made up of polyethylene terephthalate.

6.610.5.4.1.2. Procedure
All the components of the kit are provided in sterile conditions and preloaded on disposable delivery instruments. A tension band consists of a pair of nonabsorbable suture loops each of which is attached to a T-anchor. A third loop of suture with a pretied knot is then used to connect the two loops together, while facilitating the tightening of the tension band, which helps to draw the construct together and hence closes the defect in the tissue.

Cadaveric experiments have been performed to study the use of the Xclose™ system. The results were presented at the annual
meeting of the Spine Arthroplasty Society in Berlin. The ability of
the system to remain in place after cyclic loading of the repaired
tissue was analyzed. A partial laminectomy was performed to
make a posterior annular incision. A limited amount of nucleus
was removed (~0.2 cm³), and the incision was repaired using
the Xclose™ system. Nine spinal units were tested in this study.92

Cyclic fatigue loading was performed, consisting of 20 K
cycles of flexion–extension, 15 K cycles of lateral bending,
and 5 K cycles of axial rotation. Calibrated digital macropho-
tography was used to assess the system’s ability to keep the
repaired tissue in place, and the knot slippage was measured to
check for loosening of the suture knots.78

The study showed that all annulotomy defects remained
closed and intact after 40 K cycles of loading. Post cyclic load-
ing, the loosening in the system was minimal and knot slipp-
age was measured to be 0.8 ± 0.7 mm. Also, the system did
not migrate out of the annulus or pull out of the tissue.92

On the basis of the results of the study, we can infer that the
Xclose™ system is a simple and effective method to close annu-
lar defects incurred during a discectomy. The materials used do
not detrimentally affect the repaired tissue, and the system has
shown stability upon cyclic loading. So far, the Xclose™ system
has been implanted in over 6000 patients in the United States.93

The Xclose™ system is undergoing a Phase IV randomized
clinical trial at present, but no clinical data are currently avail-
able. In 2009, the company also launched a Post Market Clinical
study in which 750 patients from 34 facilities around the United
States were enrolled.93 On the basis of data from the clinical
trials, more can be said about the materials that are used to
construct the device and their role in the body post implantation.
Until data from more long term studies in vivo are made avail-
able, the final understanding of this approach cannot be
formulated.

6.610.5.5. Barrier Technologies

6.610.5.5.1. Inclose™ surgical mesh system

The Inclose™ Surgical Mesh System is marketed by Anulex
Technologies (Minnetonka, Minnesota) (Figure 20). The
device is designed to act as a barrier and provide a scaffold
for the repair of soft tissue such as the AF.94 The surgical mesh
implant is made up of a monofilament polymeric braid which
is preloaded on a disposable delivery device.

6.610.5.5.1.1. Materials

The braided mesh is biocompatible, expandable, and com-
posed of polyethylene terephthalate,91 a commonly used poly-
mer in medical devices.75

6.610.5.5.1.2. Procedure

The mesh is a low profile device which enables it to be inserted
into the annulus in a minimally invasive manner. The device is
inserted using a preloaded delivery device supplied with the
kit. The system is secured in place using nonabsorbable surgi-
cal suture anchors.

The cylindrical device is mounted on a delivery instrument
which allows it to extend in a circumferential direction to form
a barrier by latching the cylinder ends together. The mesh
device can be inserted into any tissue aperture, such as an
annular defect, and once deployed into position, it can be
tethered using sutures.75
6.610.5.5.1.3. Studies on the device

In vitro biomechanics studies were conducted using the device, and demonstrated that implantation of the Inclose™ system did not alter segmental spinal biomechanics. The study also showed that the implant position remained intact despite application of complex cyclic loading. In theory, a stable spinal motion segment may be able to reduce risks of herniation in an adjacent disc by avoiding stress redistribution. Also, this study suggests that the repair of the annulus using such a device might indirectly avoid the need of nucleus material removal which is often a solution employed by surgeons to mitigate the effects of disc herniations.

Animal studies on intradiscal implants are faced with complications of downsizing the device in order to accommodate smaller tissue areas. In general, no animal models exist that can accurately represent the exact nature of disc space characteristics as seen in humans and correlate to human clinical use. Despite these limitations, animal models were designed to study the surgical implantation of the Inclose™ device and histological response to the PET mesh.

Peppelman et al. studied Inclose™ implantation in a Nubian goat model and showed that a lateral approach could be used to place the implant safely in the proximity of the annulus. When positioned and affixed properly, the implant remained intact over the course of 12 weeks, as seen using radiography. Also, the device was found to be incorporated histologically without any detrimental effects on the surrounding tissues.

The device was studied after implantation in cadaveric and animal models. On the basis of a report submitted at the Spine Arthroplasty Society in Berlin in 2007, the studies demonstrated that the presence of wear particles was minimal. Also, motion of the implant was negligible and it had no detrimental effects on spinal flexibility. Early findings showed that there were no recurrent herniations when the device was implanted.

Early clinical use of the Inclose™ mesh device has shown promising results. Around 10 patients were implanted with the device after an endoscopic L4-L5 or L5-S1 discectomy. The implant was inserted with minimal disruption to the annulus, with access openings between 3 and 8 mm. There was inadequate length of follow up, because of which long term effects of the implant cannot be predicted yet. However, it was noted that the best technical results were obtained in patients with focal, protruded, and/or extruded disc herniations.

6.610.5.5.2. Barricaid® prosthesis

The Barricaid® Prosthesis device is currently not clinically available in the United States. It is a device aimed at reconstruction of the annulus in the region of disc herniation. The Barricaid® implant works by forming a strong and flexible wall between the AF and NP, where it is implanted.

The salient features of the prosthesis include its ability to create a mechanical barrier that closes the annulus defect, while allowing more nucleus material to be retained in the disc. According to the manufacturers, the device can be implanted quickly, simply, and securely (Intrinsic Therapeutics).

6.610.5.5.2.1. Material

The Barricaid® Prosthesis consists of a woven mesh made of polytetrafluoroethylene (PTFE) supported by a nitinol frame. The frame is made up of a nickel–titanium alloy base, which anchors the annulus and reinforces it while closing the defect. The frame functions as a shape memory alloy, and exhibits pseudo elasticity (Intrinsic Therapeutics).

6.610.5.5.2.2. Procedure

The Barricaid® Prosthesis is implanted into the annulus through a small incision (5 × 10 mm defect) made on the posterior side, as part of a standard limited discectomy, just prior to wound closure (Intrinsic Therapeutics). The device covers a major portion of the mediolateral distance in the posterior AF, and expands cephalad–caudad postinsertion.

6.610.5.5.2.3. Studies on the device

In vitro biomechanical studies have been performed to evaluate the Barricaid® device, and they have demonstrated that the rate of recurrent herniations is decreased. The ability of the device to withstand intradiscal pressure was demonstrated in a study by subjecting the device to complex applied loads, and measuring the intradiscal pressures. The clinical use of the device was also tested, and the study demonstrated that compared to patients who were not implanted with the prosthesis, patients who received the device after a standard discectomy were seen to experience restoration in disc height lost because of the procedure. However, the evaluation of the long term effects of the device in a clinical setting will require longer follow-up studies.

6.610.5.5.3. SpineJet XL

The SpineJet HydroSurgery system is a novel technology that harnesses the power of water in medical applications such as surgery (Figure 21). The system comprises a controlled hair-thin supersonics water jet that can be used as an effective cutting, ablation, and collection device. The advantage of such a system is that it has the power of laser technology and radio-frequency devices, but avoids the damage to tissue that such technologies cause. The SpineJet XL is a percutaneous hydrodiscectomy device that can be used in the minimally invasive surgical intervention of intervertebral disc degeneration. The device aspirates tissue as it is being used, and can be used to remove cartilage and nucleus material.

The device is designed with four cutting surfaces. Annular thinning is accomplished using a windshield wiper motion to scrape the heel and toe of the device along the inner surface of the annulus. Lateral cutting sides are used to scrape cartilage off the endplates to increase the surface area for interbody lumbar fusion.

The device is mainly used for the removal of NP, in order to perform spinal fusion. The system’s use of cold fluid prevents thermal damage to tissue. The design of the device is such that it enables the removal of precise amounts of nucleus tissue without annular puncture or endplate damage.

The device underwent a trial on 13 patients in 2008–2009. Initial results suggested that percutaneous hydrodiscectomy could be a good alternative for the treatment of lumbar degenerative disc disease. However, more clinical data are required to properly assess the device before more widespread use.

6.610.5.6. Material Requirements

On the basis of the discussion of current materials/technologies, we can say that closure of an annulus defect using suture
approximations would require materials that are nonabsorbable, given the nature of an annular defect. With respect to the barrier type of technologies that have been developed so far, the material in question should be able to support the annulus appropriately on the basis of the biomechanical environments it is subject to, without the device getting damaged or causing damage to the annulus; that is, the material has to have mechanical properties matching those of the annulus. Any motion of the device due to functioning of the annulus should not generate any wear particles that might bring about adverse effects in the tissue. Further, considering that such types of techniques are limited by the method of implantation of the device, it is also required that the material in question has properties that enable molding it in a manner that facilitates easy and efficient implantation into the AF.

6.610.5.7. Future Trends

The field of annulus repair is still in its infancy, with data still being collected on implantation of devices that are currently available in the market. However, preserving the integrity of the annulus is an important consideration while repairing the intervertebral disc, as it is the only means of gaining access to the NP. On the basis of the discussion presented above, it is intuitive to try to preserve as much of the annulus as possible as the annulus is responsible for the mechanical properties of the disc. As more follow-up data become available, investigators can look to modifying the currently available technologies to refine their applicability, as well as lay the foundation for the design and development of newer devices that can be implanted minimally invasively, which will help retain the properties of the annulus while allowing access to the NP.

6.610.6. Concluding Remarks

Early spinal implants were based on metals because of the utility of metals in other orthopedic devices. The complex loading nature and function of the spine however necessitated the development of novel materials and techniques in surgical spine interventions. Composite materials and polymers have been utilized in spinal implants as an improvement over metals which do not have matching mechanical properties to the spinal anatomy and are subject to wear. A better understanding of spine anatomy, physiology, and pathophysiology has also led to the development of new materials with several materials being developed specifically for application in the spine. Failure of earlier devices has especially expanded the breadth of materials utilized in spinal interventions. Adjacent level disc degeneration with spinal fusion, expulsion of implant materials through surgical sites, and subsidence of implants into the endplates have driven the development of new surgical techniques and provided the impetus for the development of novel spine materials. This is especially illustrated by the development of in situ curing hydrogel and nonhydrogel nucleus replacements where materials were designed such that they could be delivered with minimal damage to the AF, a major way for nucleus replacement as well as the development of sealants for the AF itself. Another drive in materials for spine implants is the utilization of tissue engineering approaches. Tissue scaffolds that support nucleus and AF cell growth are under investigation; however, major limitations in nutrient supply to the implant after implantation must be addressed before tissue engineering approaches for the IVD can be realized.

References
