The concept of disc reconstruction with a prosthetic device that maintains motion and alignment is not new; attempts at disc replacement date back to the 1960s. As a result of both a process of trial and error and an analysis of biomechanics, disc replacement will soon be clinically available. The use of arthroplasty eliminates the need for fusion and theoretically prevents abnormal stress at adjacent levels. If adjacent-segment degeneration could be reduced, spinal arthroplasty would have a distinct advantage over arthrodesis. The purpose of this paper is to review the design of disc prostheses, the materials used for their manufacture, and technical concerns that remain regarding their in vivo degradation and the potential immunological response.

**OVERVIEW**

*Theory of Spinal Arthroplasty*

The belief that spinal fusion leads to accelerated degeneration of adjacent disc levels is widely held. A new direction in treating degenerative disc disease surgically is the development of a functional disc prosthesis that offers the same benefits as fusion while providing motion and protecting adjacent-level discs. Keeping in mind that any new device or arthroplasty in the future should provide relief from objective neurological symptoms and signs, provide stability, withstand biomechanical forces, reduce pain by excision of the nucleus pulposus, and still provide normal range of motion, we have reviewed the available devices and those awaiting imminent approval.

To date, disc replacement design technology has produced two types of prostheses, the unconstrained and the constrained. The unconstrained model has a core bearing that permits rotation and some degree of translation in all three anatomical axes (x, y, and z). In contrast, constrained devices have a fixed axis of rotation such that both the x-axis (anteroposterior) and y-axis (medial to lateral) translations are limited, but there are no restrictions in rotational motion. The constrained design concept is thought to minimize x-axis (anteroposterior) movement at the treated facet level, potentially reducing stresses on these structures.

Theoretically, the use of a prosthetic disc preserves the normal range of motion in the interspace and protects against adjacent-level degeneration. It should be understood, however, that accelerated degeneration caused by increased stress at adjacent disc levels after fusion has only been postulated; it has not been documented or proven experimentally. Whether this theory is accurate or whether adjacent-level disease reflects the natural disease process is unclear at this time.

*Normal Disc Anatomy, Physiology, and Degeneration*

The intervertebral disc is a structure consisting of a peripheral collagenous band (anulus fibrosus) uniting adjacent vertebral endplates. In the center lies the nucleus pulposus, composed of a mucopolysaccharide gel and...
proteoglycans. Peripherally the anulus is a collagenous band composed of 15 to 20 concentric layers of alternating oblique fibers. The highly complex structure of the disc allows small movements along the x, y, and z anatomical axes. The alternating arrangements of collagen fibers in the anulus fibrosus make an efficient system to control motion, especially rotation, while still providing stability.

Degenerative disc disease has some similarity to degenerative joint disease such as arthritis of the hip, but it also has unique features. In its early stages the hydrophilic properties of the nucleus are diminished. The anulus also develops tears and loses ability to contain the nucleus. Later the bone endplates become sclerotic and irregular and eventually resemble the end stage in any diarthrodial joint degeneration. The origin of pain in the degenerative spine is complex and less understood than in peripheral joints that have degenerated. It is believed that both the anulus fibrosus and nucleus pulposus contribute to the generation of spinal pain; removal or surgery extensive enough to alter these structures significantly is thought to relieve pain.

**Biomaterials Used in Joint Replacement**

Disc arthroplasty designs have been heavily influenced by orthopedic joint arthroplasty, with the majority of recent designs using a combination of polymers and metals. Polymers provide a low-friction surface for articulation as well as some degree of “shock absorption,” which promotes a host–tissue response that has the wear stimulates the formation of an inflammatory reaction to the wear debris. Particulate debris generated by prosthetic wear, formation of wear debris, and tissue corrosion resistance, and some have been used for disc arthroplasty.

Factors determining disc arthroplasty survivability are similar to those for joint replacement technology, and include prosthetic wear, formation of wear debris, and tissue reaction to the wear debris. Particular debris generated by wear stimulates the formation of an inflammatory reaction, which promotes a host–tissue response that has the ability to invade the bone–implant interface. This commonly results in progressive local bone loss that threatens the fixation of implanted devices. Despite their high resistance to corrosion, all metal alloy implants corrode in vivo. When this degradative process is severe enough it can damage the structural integrity of the implant, and corrosion products are potentially toxic.

Disc replacement designs incorporate cobalt-chromium-molybdenum alloy endplates that are externally coated with titanium for bone ingrowth. The metallic endplates are fixed to polymeric cores and motion takes place between articulating polymer surfaces.

Corrosion resistance is important in selecting metals for disc arthroplasty. Alloys are protected from the progressive degradation of corrosion by the formation of a protective surface oxidative film. The Laplace law, a discussion of which is beyond the scope of this article, can be used to predict the behavior of the metallic surfaces in an in vivo fluid environment. Nevertheless, based on data from the Laplace law and other complex physical, chemical, and material science computations, many joint arthroplasties are performed with a cobalt-chromium-molybdenum alloy.

**Surface Coatings**

Several surface coatings have been designed to improve bone ingrowth. These include titanium, porous cobalt-chromium or titanium beads, titanium wire mesh, plasma-sprayed titanium, and newer bioactive nonmetallic materials such as hydroxyapatite or other calcium phosphate compositions that have been developed to create a tighter interdigitation between implant and bone. This minimizes motion at the implant–bone junction as well as corrosion.

**Wear Analysis**

Based on studies of failed devices used in orthopedic joint replacement surgery, it has been determined that prosthetic debris is the leading factor causing prosthetic loosening and requiring revision surgery. Wear debris is formed over time with any prosthesis. All wear debris causes a foreign-body reaction that induces an inflammatory response, which results in progressive local bone loss (osteolysis) and possible prosthetic loosening and failure.

The mechanism of debris generation involves the loss of particles from the prosthesis as a consequence of friction between moving surfaces. Any articulating materials, if placed under a sufficient load, will generate debris. The wear rate can be calculated using the following formula:

\[ V = KF_x \]

where \( V \) is volumetric wear (mm³/year), \( K \) is a material constant of the material couple, and \( F_x \) is the contact force, and \( x \) the distance of travel (in millimeters). The harder the material the less it will wear, and if different materials are articulated, the harder of the bearing materials will wear less rapidly. In a metal-on-polymer pair, the polymer wears almost exclusively, whereas in a metal-on-ceramic pair, the metal wears to a greater extent. Volumetric wear can be directly related to the number of particles released in vivo.

Clinical wear rates have been seen to increase in patients with hip replacements, based on the patient’s weight, the geometry and size of implants, and the mechanical properties of implant materials. There is limited information regarding pure metal wear in spinal arthroplasty. Nevertheless, in a recent study reported by Hellier, et al., the authors showed that the best metal for minimizing wear was the cobalt-chromium-molybdenum alloy. This alloy provided for the smallest amount of wear debris, with a mean wear volume rate of 0.09 to 0.126 mm³/million cycles in wear simulation with lumbar disc replacement. If one assumes that 1 million simulator cycles is representative of 1 year of clinical use, the rate of wear per year is estimated to be 0.96 mm³/year. This compares very favorably (two orders of magnitude less) to wear observed in orthopedic joint arthroplasty. For example, numerous clinical studies have shown wear rates ranging from 50 to 100 mm³/year in hip arthroplasties. From these studies it appears that wear degradation in disc arthroplasty will not be as big a problem as it is in hip replacement. It is a concern, however, that wear debris and any resultant inflammatory reaction would occur in close proximity to neural structures.

The Charité artificial disc (Depuy Spine, Inc., Rayn-
ham, MA) was originally developed at the Charité Clinic in Berlin, Germany. In 1982, through cooperation between leading orthopedic spine specialists and the staff at Waldemar Link GmbH, a European medical device manufacturer based in Hamburg, Germany, the first artificial lumbar disc was implanted. The Charité consists of two endplates made with a cobalt-chromium alloy enclosing an ultra–high molecular weight polyethylene core.

Recently, Anderson and colleagues performed an in vitro wear test of the Bryan Cervical Disc prosthesis (manufactured by Spinal Dynamics Corp., Seattle, WA [a division of Medtronic, Inc., Minneapolis, MN]) in a cervical spine simulator. Biological response to wear was assessed in chimpanzee and goat animal models. These researchers showed that particulate wear generation took place at the rate of 1.2 mg/106 cycles, with the loss of prosthetic height occurring at 0.02 mm/106 cycles in vitro. This compared favorably with orthopedic joint replacement in vitro data. Wear debris was present in the peri-articular and epidural spaces in some animals. More importantly, there was no significant inflammatory response observed and no wear material was found distant from the implant in draining lymph tissue, the liver, or the spleen. As a result, the investigators were able to conclude that the Bryan disc has satisfactory wear characteristics and does not produce a significant inflammatory response.

The Prestige disc (Medtronic, Inc.) is not made from the metal-on-polymer articulation that other designs use and instead features metal-on-metal articulation, in which endplates and articulating surfaces are constructed of stainless steel or titanium. The design of metal-on-metal was used to eliminate polyethylene wear debris, which generates a more aggressive inflammatory response. A downside to this type of articulation is that the amount of metallic debris generated is several orders of magnitude higher than a metal-on-polymer articulation that other designs use and does not produce a significant inflammatory response.

Corrosion, Metallic Wear, and the Host Immune System

All metals implanted into a biological system corrode and release metal ions. The more motion there is in a prosthesis–bone interface, the higher the rate of corrosion due to continual degradation and reformation of new oxide layers that have no protective coating against degradation. Metal-on-metal articulating surfaces are also a major source of released metal ions. As a result, the immune system can be activated and microscopic implant particles released by corrosion also become embedded in local tissue and are recognized by the host immune system. These particles are bound by proteins and are eventually transported to immune tissue. Although most implant alloys are chemically inert elements, in vivo they can become toxic through biochemical conversion. They can be converted through a series of immunological interactions to form metallic moieties forming haptens, which can elicit an immunological reaction.

Stainless steel alloys corrode the most of all alloys used in arthroplasty. In recent studies investigators have found that there is an eightfold increase in the incidence of corrosion when dissimilar metal junctions are used, compared with only 7% of cases studied in which similar metal junctions were implanted. The results of these studies indicate that the actual material can play an important role in corrosion and that we need to evaluate carefully the effects of different metal alloys and the impact they have on the host immune system.

Nickel, cobalt, and chromium are essential trace elements that are required for normal homeostasis. In larger amounts than has ever been documented to be associated with surgical arthroplasty, nickel leads to dermatitis and is carcinogenic. Cobalt is known to cause polycythemia, thyroid dysfunction, cardiomyopathy, and is carcinogenic. Chromium and vanadium can cause both cardiac and renal dysfunction as well as psychosis. The nonessential metallic alloys can also be toxic. Titanium can induce pulmonary disease in people with inhalational exposure as well as platelet dysfunction. Aluminum produces bone marrow suppression, renal failure, and neurological dysfunction, possibly including Alzheimer disease. These toxicities result from extremely high circulating concentrations of the elements or their inhalation, and it is unlikely that such levels would result from prosthetic implant degradation. There is no study to date that demonstrates a cause and effect relationship between arthroplasty devices and toxic levels of metal release, but these data should not be forgotten.

There are several cell types, including macrophages, osteoblasts, osteoclasts, fibroblasts, and endothelial cells as well as immune cells that are stimulated by the corrosion particles. The role of corrosion, Metallic Wear, and the Host Immune System in corrosion and that we need to evaluate carefully the effects of different metal alloys and the impact they have on the host immune system.
CONCLUSIONS

With the emerging technology of spinal arthroplasty, a variety of new clinical problems may arise in the very near future. The purpose of this paper was to review the design of disc prostheses, the materials used for their manufacture, and technical and theoretical concerns that remain regarding their use in vivo. We have focused on the effects of particulate and ionic debris associated with spinal implants. Meticulous clinical follow-up evaluation of these patients will be necessary to identify not only gross mechanical failure but also less obvious loosening associated with a debris-induced immune response. In addition, we will have to continue to monitor potential systemic effects resulting from disc arthroplasty vigilantly, as is currently done for similar orthopedically implanted materials.

Disclaimer

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Future of spinal arthroplasty: a biomaterial perspective


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