

REVIEW

The artificial disc: theory, design and materials

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Low back pain is one of the most common medical conditions in the Western world. Disc degeneration, an inevitable process of aging, of variable rate and degree, is one of the major causes of low back pain. Currently, there are two major surgical interventions for treating conditions related to the degenerative disc: discectomy and fusion. Although discectomy and fusion produce a relatively good short-term clinical result in relieving pain, both these surgical treatments alter the biomechanics of the spine, possibly leading to further degeneration of the surrounding tissues and the discs at adjacent levels. Over the past 35 years, a tremendous effort has been made to develop an artificial disc to replace the degenerated disc. The goal is the restoration of the natural biomechanics of the segment after disc excision, thus relieving pain and preventing further degeneration at adjacent segments. However, the artificial disc faces a complex biomechanical environment which makes replication of the biomechanics difficult and long-term survival challenging to designs and materials. The purpose of this article is to examine the factors of importance in designing a disc replacement. Topics covered include the structure and function of the natural disc, the changes that occur with disc degeneration and existing methods of treatment for the degenerative spine. The progress in achieving a functional, long-lasting disc replacement is outlined. Copyright © 1996 Elsevier Science Limited

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STRUCTURE AND FUNCTION OF THE SPINE

The function of the spine is unique because it serves two distinct and apparently conflicting roles. First, it must provide a strong, yet mobile, central axis onto which the appendicular skeleton is applied. Second, it must protect the delicate nerves travelling from the brain to the periphery. The proper blending of mobility and stability is essential to fulfil these goals simultaneously^{1,2}.

The dual function is realized by a linked structure containing a series of 24 mobile vertebral bones connected by nearly 75 stable articulations that control motion. Motion is allowed in three planes: flexion–extension, axial rotation and lateral bending. Like any joint, the articulations may face large and varying loads with physiological movement and ultimately may degenerate and fail. Indeed, ailments of the ‘overextended’ spine are frequent, accounting for the fifth most common reason for time lost from work and physician office visits, just after the common cold³.

To some extent, the approaches to treatment of spinal

disorders are similar to those followed for degenerative ailments of the knee and hip. As in hip and knee joints, degeneration of articulations in the spine leads to pain, deformity and altered function. Early treatment consists of modifying activities, decreasing weight-bearing stresses with a cane or a crutch or providing external stabilization in the form of splints or braces. By holding the joint rigid, the inflammatory effects of abnormal joint movement can be decreased. Arthrodesis, the term used to describe an operative fusion, effectively obliterates the joint, provides stability and decreases pain. However, the biomechanics of adjacent joints are affected as stresses are concentrated at the junction between the mobile and immobile parts of the structure.

For the hip and knee, joint replacement has become a successful treatment to maintain natural function lost with degeneration and deformity. The achievements to date have required a knowledge of joint biomechanics, a design that approximates the natural structure and materials that can withstand the significant stresses over long periods of time. Many challenges remain, including implant fixation, biocompatibility, particle wear and longevity.

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Over the past 35 years, a parallel effort has been expended in the spine with artificial disc technology. However, successes have been harder to realize. To understand the unique material and design demands facing the artificial disc, one must review the natural structure, the mechanical environment, the patterns of degeneration and the aetiology of pain. The efficacy of the alternative treatments to disc replacement has to be covered in order to place the approach of disc replacement in context.

The triple joint complex

Adjacent vertebrae are linked by three articulations known as the 'triple joint complex'^{4,5}. This is a tripod with the cube-shaped vertebral bodies in the front sandwiching an intervertebral disc and matching facet joints posteriorly (*Figure 1*). The primary function of the disco-vertebral joint is to transmit compressive load while still providing flexibility. Posteriorly, the two paired facet joints have overlapping articular processes similar to shingles on a roof. Like the hip and knee, these facet joints have a smooth cartilage surface, lubricating joint fluid and a covering capsule. The facet joints allow small degrees of flexion and extension, limit rotation and ultimately serve to protect the disc from translational shear stresses.

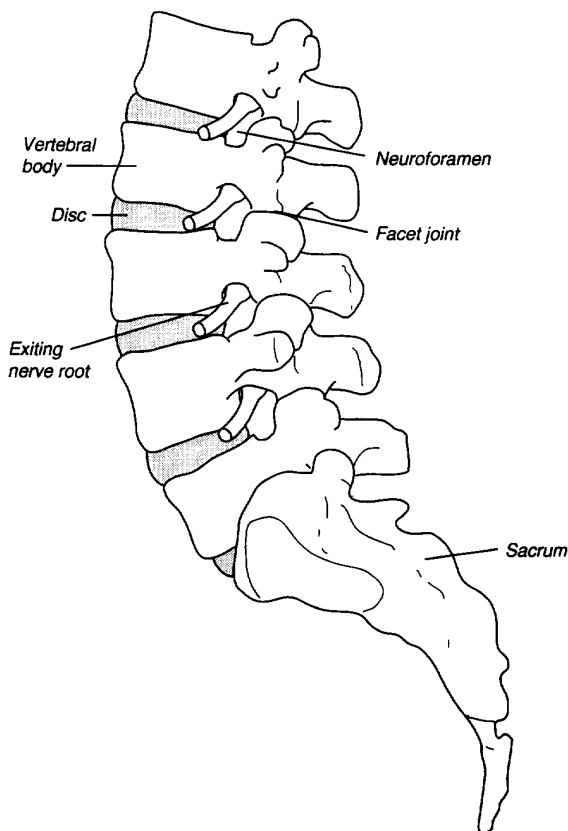


Figure 1 Anatomic structure of lumbar spine.

The disco-vertebral joint

The disc is a composite structure made up of the nucleus pulposus core surrounded by the multi-layered fibres of the annulus fibrosus⁶ (*Figure 2*). The nucleus is 80% water in youth and gradually desiccates with age. Water is drawn into the nucleus by the presence of hydrophilic proteins called proteoglycans⁷. Collagen protein fibres criss-cross the nucleus in an irregular fashion, creating a firm, gel matrix. Cells known as chondrocytes inhabit the zones between protein bundles. There is no blood supply directly to the disc after 3 years of age⁸. Nutrients for the chondrocytes must pass by diffusion across the disc after release from end-capillaries in adjacent vertebra during cyclic loading⁹.

The structure of a disc is analogous to that of the automobile tyre. The annulus, with successive layers oriented in alternating directions, surrounds the nucleus. These layers are placed under tension as the nucleus absorbs water and swells⁹. Superiorly and inferiorly are two thin layers of vertebral cartilage end-plates. Unlike the tyre, in which the air is completely sealed, these plates have multiple perforations that allow the exchange of water and nutrients. The water binding capability of the nucleus (swelling pressure) is dependent on its chemical composition and at any given condition the equilibrium water content of the nucleus is dependent on the actual external load on the disc. When the load on the disc is increased and kept at a high level, the pressure within the nucleus will also increase and it will cause the water in the nucleus to be squeezed into the adjacent end-plates and removed by the vertebral capillaries. With recumbency, the nucleus pressure decreases and water returns. This creates an effective pump or 'bellows' which provides a circulation bringing nutrients and removing products of metabolism.

The neural elements

Nerve roots exit at each level. They pass laterally through passages known as neuroforamina, under the facet joints and superior to the disc (*Figure 1*). Narrowing of the disc space is therefore accompanied by a decrease in the size of the neuroforamina as the two vertebral bodies are allowed to come closer together.

Most of the structures of the spine are innervated, with the exception of the nucleus and the inner layers

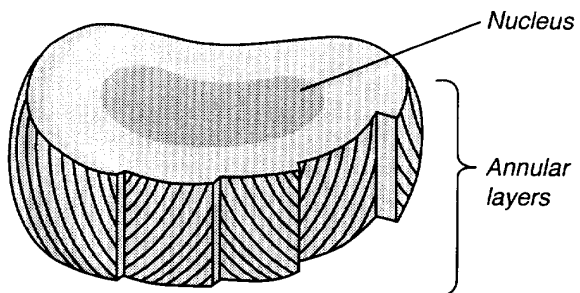


Figure 2 Structure of intervertebral disc.

of the annulus¹⁰. Kuslich *et al.*¹¹ performed lumbar procedures on awake patients with the use of local anaesthetic. By direct probing of structures, he was able to identify painful loci. The outer layers of the annulus are richly innervated by branches of the sinu-vertebral nerve. Many believe that injuries to the annulus stimulate this nerve and that this is the origin of most back pain.

The degenerative cascade

Aging is a normal, not pathological, process. Beginning at approximately 30 years of age, there is a gradual change in the types of proteoglycans and a loss of overall water content^{12,13}. As the nucleus dehydrates and shrinks, the load on the nucleus decreases while the load on the annulus increases^{14,15}. Like the tyre, the multi-layer structure of the annulus performs well when it is inflated and is susceptible to delamination and damage when it is flat. Radial tears, cracks and fissures occur first within the annulus¹⁶. Some of these may heal, given the right environment. However, if healing does not occur, the nucleus may migrate from the centre of the disc to the periphery through the tear. This expansion of the nucleus within and between the fibres of the annulus causes stretching and delamination of the annular layers and results in back pain by stimulation of the sinu-vertebral nerve. The nucleus may ultimately transgress all retaining layers of the annulus, resulting in a 'disc herniation'. The herniated disc material may mechanically deform a nerve root, resulting in 'radicular pain' that travels down the length of an extremity in the distribution of the particular nerve. The nucleus, avascular and previously sheltered from the body's immune system, now becomes 'recognized' and elicits an inflammatory response^{17,18}.

With age, vertebral end-plates become sclerotic and less porous, making transfer of water and nutrients difficult. Products of metabolism accumulate, creating an acidic environment. This pH change, in concert with immunoglobulins and inflammation producing prostaglandins, is the chemical change which can produce back pain¹⁹.

A disc without a competent nucleus is unable to function properly. Like a flat tyre, the desiccated disc loses central pressure and collapses^{20,21}. The normally taut, retaining annular fibres sag, allowing bulging of the redundant strands. Loss of disc height means less space in the neuroforamen for the exiting nerve root²⁰. There is compromised stability and increased motion between vertebra^{4,22}. To maintain stability, the components of the spine, including ligament, bone and facet joint capsule, thicken and hypertrophy¹³. This extra tissue results in a reduction of the space available for the nerves and is termed 'spinal stenosis'²².

The facets, which normally experience 16% of the compressive load²³, must take on increasing portions of the compressive stress owing to the disc degeneration²⁴. Wear occurs at the facet joints with abrasions of the articular cartilage, inflammation and capsular laxity. With the facets impaired, the disc is subjected to shear stress, which will accelerate disc degeneration.

Since the spine is a cooperative system of elements, it follows that altering the structure and mechanics at one location significantly increases the stresses experienced at adjacent locations, thus initiating a degenerative cascade⁵. Adjacent levels may simultaneously be in different stages of degeneration²⁵.

CURRENT METHODS OF TREATMENT OF LOW BACK PAIN

Pain may occur at any stage of the degenerative continuum: from a simple annular tear, to complete disc degeneration, deformity, instability and compromise of the neural elements. For the majority of ailments, conservative measures are in order. With time, studies on serial radiological imaging have shown a decrease in the size of herniated disc fragment²⁶. This is accompanied by a diminution of symptoms.

Operative intervention is indicated when: (1) conservative measures fail; (2) when radiographic imaging indicating nerve compression is consistent with the historical, physical and neurological findings; and (3) when hypermobility becomes frank instability and physiological stress of normal movement directly damage the neural elements, or threaten to do so. Surgical methods for degenerative lumbar conditions include decompression (relieving pressure on nerve elements by excision of disc, hypertrophied bone or ligament), fusion or a combination of both.

The primary purpose of discectomy is to excise any disc material which compresses the spinal nerve causing pain, sensory changes or weakness in the distribution of the effected nerve. The traditional posterior approach, open discectomy surgery, requires removal of a small portion of lamina and ligament (ligamentum flavum) with an incision into the posterior annulus. Methods finding increasing clinical utility include percutaneous techniques which allow removal of the disc material through small (4.5–6.0 mm or less) cannulae, thus potentially lessening damage to the annulus, bone and ligament during the surgical approach. Discectomy is successful in relieving the radicular pain caused by a herniated disc. However, such surgery alone is unable to restore the nucleus to its original load sharing capacity and makes long-term results more questionable²⁸. Disc degeneration and its sequelae are allowed to continue, and perhaps are accelerated by the surgical intervention. This can lead to alterations in spine stability^{29–31}. Ultimately, progressive disc narrowing, increased compressive stress on the annulus, advanced degeneration and spinal stenosis may evolve over the years after the surgery.

Fusion means eliminating a motion segment between two vertebrae by use of bone graft and sometimes by the use of internal fixation. This procedure is performed for gross instability of a motion segment resulting from traumatic injury or degeneration. It is also performed by some surgeons to abolish motion at a painful, but stable, degenerative disc. Ablation of the joint removes the source of chemical irritants, eliminates instability and hopefully the pain which these factors produce.

The success rate of spinal fusion, however, is poorly defined in the literature and varies in a very wide range between 32% and 98%³². Biomechanical study also shows that fusion alters the biomechanics of the spine and causes increased stresses to be experienced at the junction between fused and unfused segments³³. This promotes degeneration and begins the cycle anew³⁴.

PROSTHESES: THE IDEAL SOLUTION TO LOW BACK PAIN

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

An affirmative answer to the above questions involves the utilization of an 'artificial disc'. Two types of intervention are possible: (1) total disc replacement (nucleus and annulus) and (2) a nucleus pulposus substitute. Both methods require duplication of the natural structure, significant durability to last greater than 40 years³⁵, and ease and safety during implant placement or removal.

Total disc replacements would be used when removal of all possible sources of pain, including nucleus and annulus, is required and when the annulus has failed and is felt to be unable to heal. Designs to date include: (1) low friction sliding surface like the ball and socket; (2) spring and hinge systems; (3) contained fluid-filled chambers; and (4) discs of rubber and other elastomers.

Nucleus substitutes should restore disc height and return annular fibres to their natural length. Restoring the normal load distribution among the nucleus, the annulus and the facet joints may allow healing of the annulus and prevent degeneration of the facet joints. The substitute should be capable of pressure modulation with position change recreating the disc 'bellows' effect.

Improvements in material and design are moving slowly toward the ideal solution. Material properties to be considered are biocompatibility, endurance and resistance to long-term compressive creep. The design should replicate natural disc dynamics, plan for material compatibility within the device to minimize wear if several components are used, utilize a safe insertion technique, and have a reliable bonding or interface between host and implant.

Total artificial disc replacement

Metals

The principle advantage for using an all-metal total disc replacement is the inherent high fatigue strength of these materials. Hellier *et al.*³⁵ and Hedman *et al.*³⁶ believe a material should withstand fatigue test loading up to 100 million constant amplitude cycles, this being equivalent to a 40 year life span. They believe only metals have this longevity. Biocompat-

ibility of alloys, such as stainless steel, titanium and its alloys and cobalt-chromium alloys, has been demonstrated in other orthopaedic applications.

An all-metal disc spacer was disclosed in US Patent 2,677,369 in 1954 by Knowles³⁷. It is a solid device serving as a wedge between the spinous processes posteriorly. It was meant to provide an alternative path of compressive load bearing through the posterior elements, diverting stresses away from the degenerative disc. It does not restore any natural flexibility to the disc. Therefore, the device cannot be considered a true 'artificial disc'. Devices which do not allow motion at the segment are not further reviewed.

Patil³⁸, in 1982, developed a disc composed of upper and lower cup-shaped plates which effectively distribute compressive forces to the entire end-plate. These plates were anchored to the bone by a series of spikes which emanated from the plates. Multiple springs were arranged between the plates. Stainless steel was suggested. Springs were gauged to withstand 12 lb (~5.4 kg) of force. No detailed experimental results have been published on this device.

Baumgartner³⁹ suggested decreasing the articulations between multiple parts and returned to a one-piece component made from a strong, yet relatively elastic material such as titanium. In this design multiple overlapping slits are carved out of the metal block forming two opposing combs. The tines interdigitate with loading. Sheppard^{40,41} described a single component meant for use in the cervical spine, shaped like a bullet and made of either titanium or a ceramic.

Single component designs, however, are unable to replicate the complicated motion of the natural disc with its constantly changing centre of rotation. Hedman *et al.*⁴² developed a device that used two springs coiled between plates with a posterior hinge allowing flexion and extension (*Figure 3*). The springs were made of titanium alloy and were designed to provide adequate stiffness in both flexion and extension. Hot isostatically pressed (HIPed) cobalt chromium alloy, with high carbon content to improve

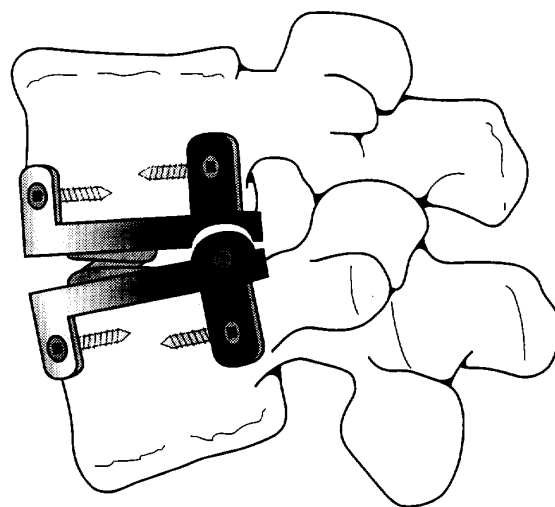


Figure 3 Artificial disc designed by Hedman *et al.*^{42,43}.

wear characteristics, was employed in the remainder of the device. Vertically projecting tabs were placed at the front and side of the plate members, through which screws could be placed for fixation. In a sheep model, Kostuik⁴³ showed, at least in the short term, that fibrous tissue does not grow between the hinges or around coils. Such ingrowth would be expected to significantly interfere with the disc mechanics.

Reminiscent of hip arthroplasty design and materials, Salib and Pettine⁴⁴ created a prosthetic device shaped as a ball and socket and made out of a zirconium oxide ceramic. Fibrous tissue growth between components was less likely. Base plates supporting either the ball or socket component were fixed through tabs to the vertebra. Six degrees of freedom were allowed. However, motion while loaded in compression might be expected to cause increased friction and the generation of wear debris.

Non-metallic materials

Whereas the principle advantage of metals is their fatigue strength, the primary benefit of using non-metallic materials such as polymers and elastomers (silicone, polyurethane) is their mechanical similarity to the natural disc. With a lower modulus of elasticity, it is easier, in the short term, to replicate disc dynamics. Difficulties, however, arise when attempting to develop a long-lasting component which has a stable interface between the structure and vertebrae.

In 1956, van Steenbrughe⁴⁵ described a multi-component disc encompassing intermediate cushions inlayers with plastic bodies of varying shapes. The method of anchoring was not included in the design specifications.

In 1975, Stubstad *et al.*⁴⁶ utilized all synthetic materials for a prosthetic disc. Silicone elastomer or other elastomers such as polyurethane were formed into the general kidney-shape of the nucleus, comprising the fluid-filled core element between flat superior and inferior elastomeric plates. A covering weave of Dacron[®] fibres simulating the annulus was suggested. Pores allowing for tissue ingrowth and ultimate component fixation could be created in this weave. Similarly, Downey^{47,48} developed a disc with a central core, bordered by end-plates held by two fixation screws. The core was filled with a soft polymeric foam, while the end-plates were constructed with a more rigid silicone.

Weber⁴⁹, in 1978, designed a three-component disc prosthesis consisting of two supporting bodies with matching central concave recesses articulating on either side of a central spacer body. Polyethylene was suggested for the support bodies, with a bioceramic used to create the spacer. Later, the design was enhanced by the addition of overlapping edges ventrally and dorsally on the support bodies to prevent the spacer body from dislodging during extremes in movement⁵⁰.

Edeland⁵¹ suggested a similar design to Weber's with a nucleus comprised of a porous silicone inserted between two polyethylene base plates. He also proposed several other intervertebral space designs, including a squeezed-together, circular silicone nucleus surrounded by a silicone annulus

and a silicone nucleus supported by a tubular stick coiled silicone or polyethylene annulus replacer⁵². He recognized the need for materials to demonstrate biomechanical applicability and biocompatibility, while being user-friendly in surgical application⁵¹.

Monson⁵³ proposed an all-rubber design consisting of two hollow halves joined together with adhesive and a central cavity subsequently inflated with saline. Dove *et al.*'s design⁵⁴ called for a plastic reinforced with carbon-fibre and shaped as a rigid horseshoe. Material alternatives listed by Dove include epoxy resin, calcium nitride, titanium, stainless steel, ceramic, polyethylene hydroxyapatite and polyethylene hydroxybutyrate. Staggered holes were made available along the inner rim for screw placement.

Fischer's concept⁵⁵ called for significant versatility. Rod-shaped cushion bodies could be assembled in varying designs, including a U-shape or triangular shape. The cushions could be filled with either liquid (silicone oil) or gas.

The disc of Lee *et al.*⁵⁶ and Parsons *et al.*⁵⁷ uses a soft elastomer central core, reinforcing fibre sheets with specific alternating fibre orientation in six to 15 laminae embedded in a second elastomer. Two stiff end-plates using elastomer, metal or hydroxyapatite frame the core (*Figure 4*). This appears to be the first time that compression-torsional stiffness was taken into consideration in the design of an artificial disc. By selecting the appropriate materials, this component can mimic both the compressive modulus and the compressive-torsional stiffness of the natural disc. The disc has been extensively studied *in vitro*, *in vivo* and with finite-element models⁵⁸⁻⁶⁰. Throughout the research three different biomaterials were used: silicone rubber, polyurethane and, most recently, a thermoplastic multicomponent design made of a polysiloxane modified styrene/ethylene-butylene/styrene block copolymer known as C-Flex (Concept Polymer Technologies, Clearwater, FL, USA)⁶¹.

A 'sandwich' design was adopted by Tadano *et al.*⁶².

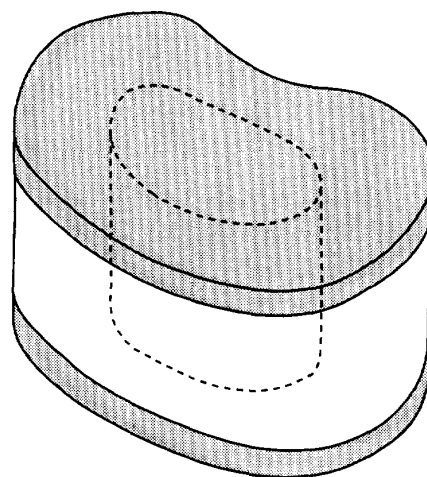


Figure 4 Artificial disc designed by Lee *et al.*⁵⁶, Parsons *et al.*⁵⁷ and Langrana⁵⁷.

Their design consisted of two 3-mm plates with an interposed 8 mm semicircular 'disc' with a radius of 40 mm. The central portion used a silicone elastomer with a Young's modulus of 1.0 MPa and Poisson's ratio of 0.1 covered by an outer skin layer of 1.25 mm with a Young's modulus of 14.0 MPa and Poisson's ratio of 0.4. Because of their demonstrated ability to form strong bonds with osseous tissue, glass ceramics containing apatite and wollastonite were suggested as the material for the end-plates.

Most recently, Stone⁶³ had set out to 'regenerate the disc'. This is done by the establishment of a dry, porous, volume matrix using a scaffold of biocompatible and bioresorbable fibres (glycosaminoglycans) created by recombinant DNA technology. That regeneration can occur in humans has yet to be proven.

Combination of metallic and non-metallic materials

To overcome the shortcomings found when using metals or non-metals alone, other inventors have combined the materials. Most commonly this has taken the form of a metal-polymer-metal sandwich disc. A metal tray is employed to improve fixation through the use of spikes, tabs with screws or porous coating for ingrowth. With the component thus stable and fixed, the polymer may provide the needed flexibility.

Frey and Koch made three different designs for the artificial disc. The first was a kidney-shaped body of either synthetic material or metal covered with a multi-layered wire mesh (titanium) for bone ingrowth⁶⁴. Their second model called for a compressible plastic (polyurethane) with a hollow centre forming a toroidal ring⁶⁵. Non-compressible fluid of varying viscosity could be placed in the chamber. With loading, this fluid would be squeezed into interconnecting channels of the ring, allowing localized pressure modulation. As in Stubstad's design, a reinforcing weave of synthetic hydrocarbon fibres was used with addition of a titanium wire-mesh anchoring system. Their latest design is an all-metal disc⁶⁶.

Similar to Frey and Koch's second design, Khvisyuk *et al.*⁶⁷ used an elastomer for the ring and a gel-like liquid to fill the ring. Fixation was through pins and screws on the metal end-plates.

The LINK[®] S Charité offers the largest and longest clinical trial of any existing artificial disc⁶⁸. It was developed by Büttner-Janzen *et al.*⁶⁹⁻⁷⁰ and Zippel⁷¹ in the mid-1980s. The prosthesis has undergone several major design, structural and manufacturing modifications from SB Charité I to SB Charité II and eventually to SB Charité III, which is currently marketed in Europe⁶⁸. The current design has two concave end-plates made of cobalt-chromium alloy. The plates have spikes or teeth to be fixed without cement to the vertebral body. A bioconvex polyethylene oval spacing piece with contours to match the end-plates is placed between them (Figure 5). Hysteresis was seen with the polyethylene (Chirulen[®]) at 4.2 kN with incipient irreversible deformation occurring between 6 and 8 kN due to cold flow⁷⁰.

Griffith *et al.*⁶⁸ reported a multi-centre retrospective study of the clinical results of the SB Charité disc on 93 patients in whom a total of 139 model III prostheses

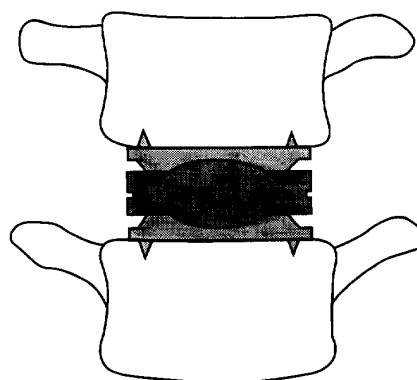


Figure 5 LINK[®] SB Charité artificial disc⁶⁹⁻⁷¹.

were implanted. The predominant operative indication was for degenerative disc disease, usually occurring at L4-L5 and L5-S1. The average length of follow-up was 11.9 months (range 1-37 months). Ninety-two percent of the group had preoperative back pain. Twenty percent of these patients had resolution of pain postoperatively. Forty to fifty percent reported a reduction in leg pain. Leg pain had increased in 6-9%. Revision procedures were required in 3%.

In the United States, Steffee has gained initial clinical experience through the implantation of a device in six patients. This disc substitute consists of a hexene-based, carbon black-filled, polyolefin rubber core vulcanized to two titanium plates⁷². Fixation is accomplished with a porous coating promoting ingrowth and four 7-mm cone-shaped posts which extend into the vertebral body (Figure 6). Of the six patients within the preliminary clinical series, there were two failures with fracture of the rubber core⁷³⁻⁷⁵. After learning that the disc in the initial study contained a chemical, 2-mercaptobenzothiazole, used in the rubber vulcanization process, which is possibly carcinogenic in rats, they have eliminated this chemical in the rubber process⁷⁵. This disc became the first artificial disc approved by the FDA for clinical

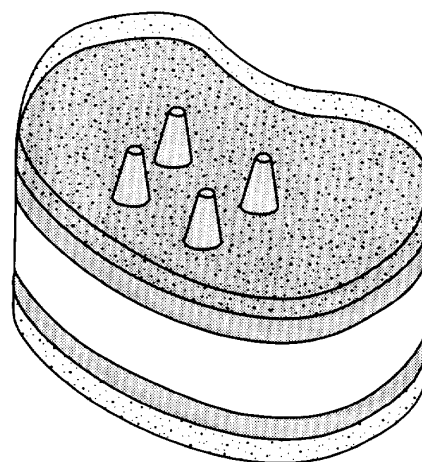


Figure 6 Artificial disc designed by Steffee *et al.*⁷²⁻⁷⁵.

use under the guideline of Investigational Device Exemption (IDE).

Fuhrmann *et al.*⁷⁶ used a circular or elliptic corrugated tube terminated on each side by an end-plate. The tube is filled with a viscoelastic material composed of a polymerizable material which is introduced in liquid form. Motion would occur through bending in the corrugated tube, with elastic recoil provided by the central material.

Pisharodi⁷⁷ disclosed an artificial disc, containing multiple springs enveloped by a silastic sheath. Either air, saline or a mineral oil can be injected to expand the sheath after placement within the disc space. Many spikes cover the surface to assist in component fixation.

Main *et al.*⁷⁸ have created a dynamic prosthetic vertebral body to replace a resected vertebral body and the adjacent intervertebral discs. The design has a rigid metal housing arising from end-plates. The housings form a chamber with a suspension plate surrounded by silicone rubber (Durometer 70 on the C scale). The device is inserted, then a central bellows is expanded with acrylic cement which solidifies as a column replicating the body and connecting the end-plate housing constructs where motion is allowed. Pins are used for fixation. Based on a similar principal, Hirayama *et al.*⁷⁹ designed their disc comprising a pair of metal end-plates with a medical synthetic polymer, such as silicone rubber, polyvinyl alcohol or polyurethane sandwiched between through-connecting members.

More recently, a cap-cup matching articulation was designed by Marnay⁸⁰. A polyethylene cap and titanium cup mimic a hip arthroplasty. Oka *et al.*⁸¹ placed a polyvinyl alcohol (PVA) hydrogel between a porous ceramic or metallic body. Similar to many other 'sandwich' designs for an artificial disc, a recent design by Baumgartner⁸² had an upper and a lower titanium alloy support for attachment to adjacent vertebrae and an elastic separator.

Nucleus substitutes

Rather than replacing the entire disc, several investigators have described prostheses that simply replace the nucleus. This approach offers several advantages over total disc replacement: (1) a less invasive surgical approach and (2) restoration of the annulus to its natural fibre length and tension. For these procedures to be effective, the annulus must be competent and prevented from further degeneration. The technique may find clinical utility if used after open or percutaneous nucleotomy for disc herniation or in early-stage disc degeneration. Late-stage disc disruption, with failure of the annulus, is a contraindication for nucleus replacement.

In the early 1960s, Nachemson and others developed the concept of nucleus replacement. This began with the injection of a self-curing silicone into the disc space in cadavers⁸³. In 1974, Schneider and Oyen^{84,85} performed similar studies as Nachemson. In 1977, Roy-Camille *et al.*⁸⁶ attempted to contain medical grade silicone within a latex bag during injection into a human cadaveric disc. The silicone was polymerized in 3–7 min. Fatigue tests lasting 200 h were conducted on the resultant disc and no deterioration of the disc was

noticed. Fassio and Ginestie⁸⁷ reported the first clinical study of the silicone nucleus in a monkey model. By critically assessing the stress distribution at the interface between the intervertebral disc and the vertebral body, Horst⁸⁸ improved the design of the silicone rubber nucleus device, which had a better positive locking and more uniform stress distribution. More recently, Ashida *et al.*⁸⁹ conducted a biomechanical study of an artificial silicone nucleus using cadaveric monkey spines. Garcia and co-workers⁹⁰ injected a mixture of diisocyanate and long and short polyols into the nucleus cavity to form successfully polyurethane elastomer *in situ*.

After biomechanical study and animal studies in a monkey model⁹¹, Hou⁹² has implanted a preformed silicone nucleus of horseshoe shape into over 30 patients with maximum follow-up of 4 years. To our knowledge, this is the first large human clinical study using silicone rubber for nucleus replacement. The details of this study, unfortunately, have not yet been published.

Concurrent to the development of an artificial nucleus with elastomers, there have been several groups of researchers who used simple metal balls of varying sizes to replace the nucleus after discectomy. They include Reitz-Joubert⁹³ and Fernström^{94–96}. These solid ball devices were meant to serve as a spacer that allowed movement of adjacent vertebrae. They did not, however, restore the natural flexibility of the disc. Problems included migration and subsidence of the balls into the vertebral bodies as pressure was not evenly distributed, and no pressure modulation was possible with position change.

Edeland⁵¹ presented the principle of hydrophilic-hydroelastic intervertebral interposium to be used as a nucleus replacement after discectomy surgery. However, no experimental work on this type of implant has been performed since it poses difficulties in the selection of suitable materials.

The majority of subsequent efforts, however, have been toward developing contained systems that allow for a more accurate and reproducible fabrication and prosthetic placement. While replicating the natural properties of the nucleus, Froning⁹⁷ first developed a plastic device with a central, collapsible bladder. Fixation was through stud-like protrusions.

Kunze created a nucleus replacement to be used in the cervical or lumbar spine. It is shaped like a fish with fin-type tail and a body with a convex contour to match the concave end-plates. Transverse grooves provide a friction fit in concert with the broadened flange-tail⁹⁸.

In addition to several total disc designs, Baumgartner also proposed a nucleus prosthesis comprising an elastic liquid-tight body which can be inserted into the disc space through a tube. The elastic body can then be filled with an incompressible medium through a valve which is connected to the body⁹⁹.

Ray and Corbin¹⁰⁰, in 1988, introduced dual disc cylinders which rested side-by-side (*Figure 7*). The outer layer was constructed with a fibre weave using bioresorbable material which attracted tissue ingrowth. A trephine is used, from the posterior approach, to bore a passage into the centre of the disc. After nucleotomy, the cylinders are then slid into position

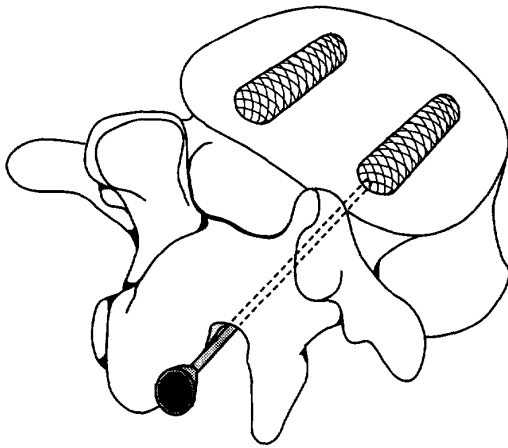


Figure 7 Artificial nucleus implant designed by Ray and Corbin¹⁰⁰.

and filled with a thixotropic gel (Brookfield viscosity between 100 and 10000 cps at 6 rpm). Expandable collars protect against capsule displacement. The capsules can also serve the dual purpose of depot sites for medications that can elute into the disc space. A predictable release of therapeutic agents including growth factors to facilitate healing and anti-inflammatory agents may prove beneficial¹⁰¹.

Bao and Higham concentrated on reproducing not only the mechanical properties of the nucleus but also its physiological properties. Delivery of nutrition and removal of products of metabolism rely on the flow of fluid through the disc space during cyclic loading. Therefore, replacing the nucleus with an elastomer without significant water content, such as silicon or polyurethane, would decrease the nutrition supply to the disc. This might lead to a deterioration in the strength of the annulus over time. To overcome this problem, Bao and Higham^{102, 103} developed a hydrogel intervertebral nucleus (*Figure 8*). Hydrogels have been widely used in other medical application since the discovery by Wichterle and Lim of the remarkable biomedical properties of poly(2-hydroxyethyl methacrylate) in 1960¹⁰⁴. By properly selecting hydrogel materials, Bao and Higham have made a hydrogel nucleus implant containing about 70% water content under physiological loading conditions. The hydrogel has the required mechanical properties and can absorb and release water with changes in the applied load similar to the natural nucleus material. Biomechanical studies have confirmed restoration of the disc anatomy and function after implantation of a hydrogel nucleus^{105, 106}.

CONCLUSIONS

In our attempt to duplicate the disco-vertebral joint, we come to recognize the strengths, weaknesses and hidden complexities of the natural system. Compared to the status of hip and knee joint replacement, the development of a functional artificial disc is in its infancy. The complexities which underlie disc mechanics, physiology and degeneration create

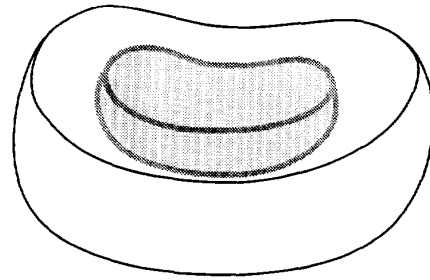


Figure 8 Artificial hydrogel nucleus designed by Bao and Higham^{102, 103}.

challenges for the orthopaedist, neurosurgeon, engineer and material scientist.

For total disc replacement, it is important to select materials and create designs which possess the required biocompatibility and endurance while providing kinematic and dynamic properties similar to the natural disc. To create such an identical match is critical to minimize the further degeneration of the facet joints and discs at adjacent levels. Due to the complexities of the disc structure, a total disc with single component design would be expected to have limited utility.

The nucleus replacement, because it seeks to replace only part of the disc, involves simpler components and means of implantation when compared to the total disc. This approach, however, is based on the assumption that the annulus and the end-plates are still functional. Therefore, it is important that the nucleus implant can resume not only its mechanical role but also the physiological function of the natural nucleus. The nucleus must provide the means of transporting nutrition and removing by-products of metabolism to prevent further degeneration. Without this, the avascular annulus would be expected to deteriorate over time, progressively losing its mechanical strength.

The surgical techniques developed to implant the device, total disc or nucleus substitute must be safe and reproducible. Techniques of extraction for component revision should be available.

In the course of development of an artificial disc/nucleus there is also another important issue which should be mentioned here, i.e. whether there is a suitable animal model for the disc/nucleus device. It is generally agreed that there is no animal which matches the loads and motions on the spine with that of the human^{43, 107}. Ape and kangaroo are thought to be the closest models for the human lumbar spine^{43, 107}. However, there are limitations in using these models for artificial disc research due to either expensive cost or government protection. For this reason, among all the devices reviewed above, only less than a handful of groups have conducted animal studies. For the three devices which are currently in human clinical use, Steffee's disc has never been tested in any animal model⁷⁵; no animal study has been reported for the Link SB Charité disc and Hou only conducted an animal study in monkey on a very small scale (four animals) and for a relatively short

term (15 months)⁹¹. Even for those groups which have conducted animal studies, such as the dog study by Lee *et al.*⁶⁰ and the sheep study by Kostuik⁴³, it should be understood that the primary purpose of the animal study is the development of the surgical technique and studying the tissue reaction of the implant with the surrounding tissues (biosafety/biocompatibility) rather than studying the efficacy of the implant.

If prevention of degeneration is not possible, then the future will continue to be drawn toward procedures that can restore natural form and function. The most promising designs and material choices in artificial disc technology are most likely those which duplicate not only the natural form but also its function.

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