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REVIEW

Marek Szpalski
Robert Gunzburg
Michael Mayer

Spine arthroplasty: a historical review

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M. Szpalski (✉)
Department of Orthopedics,
Centre Hospitalier Molière Longchamp,
142 rue Marconi, 1190 Brussels, Belgium
e-mail: marek.szpalski@win.be

R. Gunzburg
Euwfeestkliniek, Antwerp, Belgium

M. Mayer
Orthopädische Klinik-München-Harlaching,
Munich Spine Center, Germany

Abstract Degenerative disc disease is one of the most frequently encountered spinal disorders. The intervertebral disc is a complex anatomic and functional structure, which makes the development of an efficient and reliable artificial disc a complex challenge. Not only is the disc function arduous to reproduce, but there are important consequences associated with the conception and the choice of materials that will have to bear the loads. Biochemical problems have complicated things even more. Two different principles have been applied in the realisation of a discal replacement: a metallic and/or polyethylene prosthesis allowing mainly mobility or a prosthesis enabling the reproduction of viscoelastic properties. Of course some devices attempt to combine both principles. In this paper we will try to present, in chronological order, an overview of the designs published in the literature as well as in the patents granted in this field. The very fact that such a long list of implants, based on highly varied principles, has been proposed, and that only very few have reached the level of animal models, let alone human implantation, clearly demonstrates how challenging the task of designing an intervertebral disc replacement is. Proper randomized controlled trials are now on the way, and should help in assessing the efficacy and real place of spine arthroplasty in the treatment of spinal disorders. Only then will spinal surgery join the list of successful joint replacements.

Keywords Spine · Arthroplasty · Artificial disc · Intervertebral disc · Degeneration

Introduction

Degenerative disc disease is one of the most frequently encountered spinal disorders. Disc arthrosis, segmental instability and spondylolisthesis are the principal indications for spinal fusion. However, there is a lack of precision concerning the definition of certain “pathologies” [175], and the relation between degenerative lesions, actual low back pain and the need for fusion is, at best, open to debate [138].

The pain generated by a degenerative joint is linked to its mobility, and the suppression of the latter should induce pain relief at the cost of impaired function. Hence, fusion became the standard treatment in many severe joint disorders (e.g. knee, hip) until the advent of reliable arthroplasty techniques. Arthroplasty allows for pain relief while keeping or restoring function. It was therefore seen as appealing to apply this principle to the spine by replacing a degenerated disc instead of fusing a segment.

Conception of disc arthroplasty

The structure, function and aetiopathogenesis of peripheral joints such as the hip or the knee are fundamentally different from those of the functional spinal unit. The function of a peripheral joint is to allow a wide range of mainly rotatory movements by means of cartilaginous interfaces. The hip biomechanics is relatively simple, and allowed quite early the development of highly efficient and reliable prostheses. The biomechanics of the knee are more complex, and adequate (although still less reliable) implants followed years later.

The intervertebral disc is not a simple cartilaginous interface joint. It is a mixed structure consisting of a peripheral collagenous band (annulus fibrosus) uniting the adjacent vertebral endplates. This band is composed of 15–20 concentric layers of alternating oblique fibres. In the centre lies a core (nucleus pulposus) made of a mucopolysacharide gel and proteoglycans. It is extremely hydrophilic, thus generating a tension on the peripheral annulus like air in a tyre, even in the absence of external loading. This preloading enhances the resistance to external forces and provides a very efficient repartition of compression forces [70]. The highly complex structure of the disc allows small movements along and around the three main axes. As a result, the centre of rotation is constantly modified along two axes simultaneously. These movements are both allowed and constrained by the discal structure itself. Contrary to the case with peripheral joints, whose stability is essentially achieved by ligamentous structures, the disc provides, on its own, a major part of its stability. For instance, the alternating arrangements of collagen fibres in the annulus creates a very efficient system to control and restrict rotation.

Peripheral joint degeneration consists essentially of destruction of the cartilaginous surfaces followed, in time, by subchondral bone destruction and deformation of surfaces. The movement on destroyed cartilaginous surfaces generates pain. Replacement of those surfaces restores function and abolishes pain. In the disc, however, degenerative lesions are much more complex and consist of a decrease in the hydrophilic properties of the nucleus as well as the appearance of annulus tears. Furthermore, the disc is not the sole mobile structure of the functional unit: secondary osteo-arthrosic modifications of the facet joints influence disc degeneration, and vice versa [103].

To complicate matters, the origin of pain in the functional unit is ill understood, and appears to be more complex than in peripheral joints.

All these structural, functional and pathogenic factors make the development of an efficient and reliable artificial disc a complex challenge. Not only is the disc function arduous to reproduce but there are important consequences associated with the conception and choice of materials that will have to bear the loads. The strains are very different from those supported by peripheral implants. In a correctly implanted hip prosthesis, long-term problems arise from surface wear, and recent advances have been achieved in the field of friction coefficients improvement. Implant fracture is mostly due to poor placement or construction faults.

The complex strains supported by an intervertebral disc make it a different challenge. It is estimated that the spine undergoes approximately 100 million flexion cycles during a lifetime [189], not taking into account the slight motion occurring when breathing, estimated to be 6 million a year [105]. Thirty million cycles appears to be the optimal life length of an implant, and 10 million should be the minimum [106]. This represents a very severe demand both for the metallic and elastomer components.

Biochemical problems have complicated things even more. Whereas silicones appeared to be promising composites in the making of viscoelastic implants, they form molecular links with lipids, making them rigid and brittle in the long term [150].

Two different principles have been applied in the realisation of a discal replacement: a metallic and/or polyethylene prosthesis allowing mainly mobility or a prosthesis enabling the reproduction of viscoelastic properties.

Specific challenges are related to the insertion technique: whereas it is relatively easy to cut or ream an acetabulum, a femur or a tibia in order to adapt the surface to the implant, it is much more complex to prepare two vertebrae, where it advisable not to damage the endplates in order to avoid subsidence of the prosthesis. Yet, as osteointegration is facilitated by contact with subchondral bone, the implant has to have a perfect fit.

Finally, there are major problems at the level of implant/bone fixation, which is much more complex than the cementing or press fitting techniques used in peripheral joints. An additional challenge is presented by the significant osteopoenia often found in severe low back pain sufferers [83]. It is desirable to cover the entire surface of the disc to create a better load repartition structure, as this will minimize surface stress. However, it makes the implant bulkier, which makes the surgical technique more arduous.

All these problems largely explain why disc replacement surgery was slow to develop. There is also a difference in the consequence of loss of function. Whereas a hip or knee joint fusion is highly debilitating, the absence of motion of one or even several intevertebral units is of little consequence for the global mobility of the spine, and therefore for the quality of life.

Principles behind disc replacement concepts

Among the different design proposals for intervertebral disc replacement, two key principles can be differentiated:

- Some prostheses mainly aim to reproduce the viscoelastic properties of the disc. These are usually manufactured from various silicones or polymers, although some rely on springs and/or piston systems. Some are injected in monomer form and polymerised in-situ.
- Other prostheses mainly aim at the reproduction of the motion characteristics of the disc. These are usually mechanical devices made from metal and sometimes polyethylene couples. These designs are inspired by the basic principles of peripheral joints prosthesis.

Of course some devices attempt to combine both principles. We will try to present, in chronological order, an overview of the designs published in the literature as well as in the patents granted in this field. At times the choice may seem arbitrary, and some designs touch on different principles. In some cases the patent documents appear a little unclear as to what the real nature of the described device is. Different variations on the basic principle are also often described. While we feel that this is a fairly complete overview of devices designed in this field, there are probably other existing implants that we did not come upon. We will first present implants for which, to our knowledge, no clinical use has been published, and then those, much scarcer, for which clinical data have been reported. In the first category are also implants for which clinical trials are ongoing, but where no results have yet been presented.

Implants patented or published but never clinically used

Devices aimed mainly at restoring the viscoelastic function

In the late 1950s, Nachemson injected self-hardening liquid silicone rubber into cadaver discs and did some basic biomechanical testing to demonstrate a relative restoration of some disc properties. Later, he tried out silicon testicular prostheses, but found that the implants rapidly disintegrated after 20 to 30 thousand cycles of walking load [135, 136, 137].

1955, [181]: van Steenbrugghe patented a series of joint replacement implants spanning nearly all the major joints. Among those drawings is one related to the disc. This prosthesis consists of two cushions which, according to the inventor, can be made in a wide variety of materials.

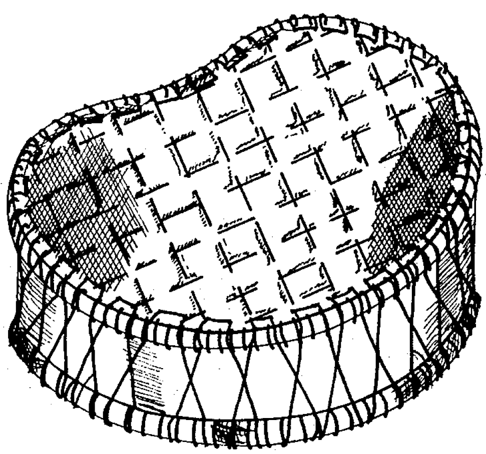


Fig. 1 Original Stubstdat design

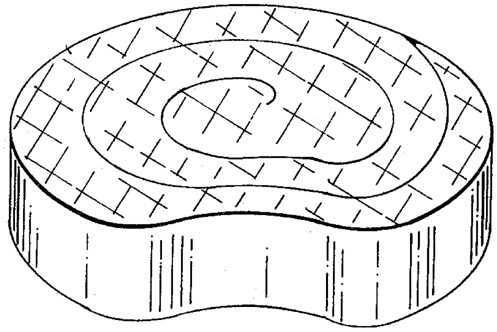


Fig. 2 Variant of the Stubstadt design, showing first helicoidal design

1973, [173]: Stubstad et al. [132] developed several designs approximating the shape and structure of a disc and made of reinforced elastic polymer (Fig. 1). A primate study was undertaken [179], but there does not appear to have been human use. In the same patent application, the authors also propose a coiled implant which, after introduction, wraps into a disc-shaped prosthesis. The same team also describes a spiral implant with elastic memory properties. The width of the coil varies so that it forms an oval shape (Fig. 2). This is the first of the multiple coiled or spiraled implants.

- 1974, [160]: Schneider and Oyen published an experimental work on silicon disc replacement.
- 1974, [92, 93]: Hoffman-Daimler patented an implant consisting of metal endplates with a complex plastic spacer.
- 1975, Froning [57]: discoid bladder-like implant filled with liquid after insertion. It is fixed to the vertebrae with a spike (Fig. 3).
- 1978, Roy-Camille et al. [156]: pre-made silicon disc.
- 1980, Kuntz [109]: simple wedge-shaped implant made of "biologically acceptable material" and inserted by "friction fit". It may be made of metal, hard plastic or elastomers. It enables motion in a sagittal plane.
- 1981, Edeland [42]: folded diaphragm-like device introduced in the disc where it unfolds. Looks like a wheel with four spokes. He also describes a disc containing a hydroscopic agent, which is used to expand the disc after introduction.

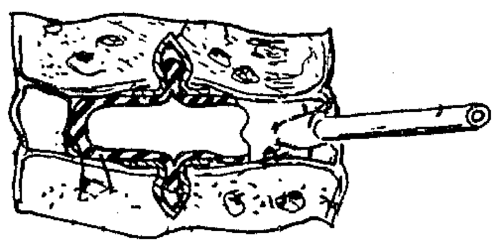


Fig. 3 Bladder-like Froning prosthesis

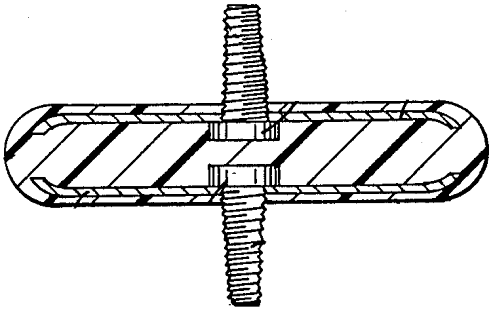


Fig. 4 Downey prosthesis

- 1982, Khvisuyk [102]: silicon cushion between two metallic plates fixed to the adjacent vertebrae with pins.
- 1987, Downey [39]: "flying saucer" shaped cushion made of silicon or polyethylene with an inner core in a more fluid material. Two large central screws attach to the endplates. The screws have opposite-direction threading, so that by rotating the device it threads simultaneously in both adjacent endplates. The placement of such a device would certainly be arduous (Fig. 4).
- 1987, Monson [133]: rubber or silicon implant made of two hollow moulded parts joined and glued together and containing a cavity in which saline solution is injected after implanting, in order to create resiliency and restore height. Suction cup like structures are placed on the upper and lower surfaces of the implant to ensure fixation.
- 1989, Ojima et al. [141]: hydroxyapatite-covered plates with a synthetic polymeric body. Inverted frustum cones are used to anchor the device to the vertebral bodies.
- 1989, Main et al. [118]: a device to replace disc and vertebral body. It consists of two thick rigid housings fixed by anchoring pins and an expandable connecting structure (Fig. 5).
- 1990, Harms et al. [86]: disc consisting of a biocompatible support layer (i.e. silicon rubber) covered on both sides with fibre-reinforced plastic plates. The endplates are made of triazin resin coated with hydroxyapatite-tricalcium phosphate mixture.
- 1990, Frey et al. [54, 55, 56]: compressible elastic hollow body between two anchoring plates. The hollow cavity is compartmented and filled with fluid, which is allowed to circulate.
- 1990, Clemow et al. [34]: disc-shaped spacer made of elastomeric material of varying hardness.
- 1990, Schoppe [162]: fluid inflatable device.
- 1990, Downey [40]: vertebral body replacement including an elastic disc screwed in the endplates.
- 1990, Lee et al. [112, 113, 144]: functional biocompatible intervertebral disc spacer. Laminated horizontal or axial polymer sheets in which changes in the physical parameters modify the flexibility of the disc. This has been one of the most studied devices over time. Many materials were experimented with, mostly silicon composites (C-Flex) or polyurethane (Biothane). In later modifications, porous coatings and hydroxyapatite particles were added to help bone ingrowth. Implantation in rabbits gave encouraging results [16] Hydroxyapatite models were experimented with in a canine model and the results were published in 1994. Poor bonding and high migration frequency was found [183]. Extensive development was conducted in later years with different design variations and materials (e.g. carbon fibres, Dacron), but no clinical use has ever been reported. Insufficient tear and fatigue strength of most rubbers used appeared to be the main stumbling block. The biocompatibility of materials was also not optimal; for example C-Flex has been reported to contain mineral oil, which could leach out [184] and potential carcinogenicity of certain polyurethane composites is talked about.

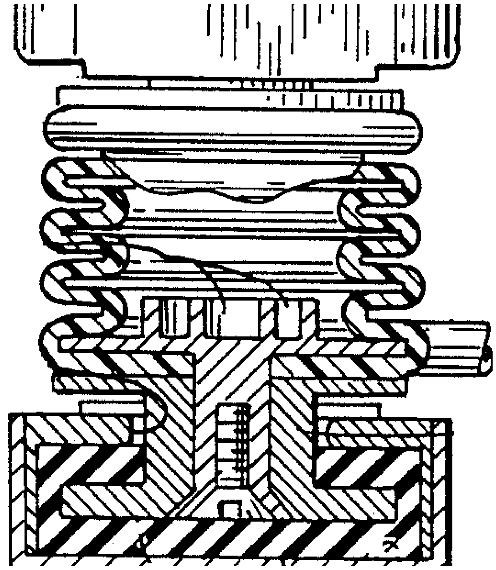


Fig. 5 Main prosthesis

- 1991, Pisharodi [147]: expandable device designed to fill the disc space. It is made of a hollow bag containing springs and small external spikes at both ends of each spring. The prosthesis is folded into a small rectangular package in order to be inserted. Once in place, it opens and expands by filling with liquid or gas (Fig. 6).
- 1991, Bao and Higham [5]: hydrogel beads covered by a semi-permeable membrane to fill the disc, permitting fluids to flow in and out of the implant. The hydrogel beads have a water content of at least 30% and can be made from many different composites. The membrane is made of Dacron or Nylon in a woven form. The surface of the implants can be either smooth or have grooves to increase stability in the intervertebral space, and can be slightly convex. Devices for minimally invasive insertion of beads have also been described [2].

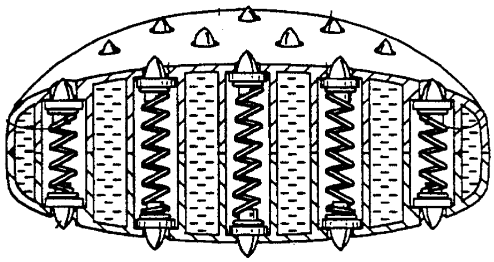


Fig. 6 Pisharodi expandable prosthesis

- 1991, Baumgartner [10]: flexible elastic body coiled in the intervertebral space with a valve capable of receiving a filling medium. The device is filled after being introduced and coiled in the disc space (Fig. 7). Further modifications on the same principles were patented later [95, 96]. The procedure has been baptized "spiral nucleoplasty". It seems to be in clinical experimentation by Husson, but nothing has been published to date.
- 1991, Kaden et al. [99]: a circular or elliptical corrugated tube filled with a viscoelastic material. The ends of the tube are sealed by rigid cover plates. Those plates have holes to allow screwing to the vertebral bodies.
- 1992, Baumgartner [9, 11]: a small elastomeric cylinder core with metallic endplates which have ascending and descending portions that act as stops for compression, translation and bending. The elastomeric core is placed after fixation of the endplates and can be removed.
- 1994, Baumgartner [12]: elastic beads introduced in the disc space, preserving the annulus. They may be introduced directly into the nucleus space or be enclosed within a membrane (Fig. 8).
- 1993, Fuchs et al. [59]: disc-shaped cushion made from elastic material with a bulging periphery (tyre like) sandwiched between two metallic plates screwed into the adjacent vertebrae.

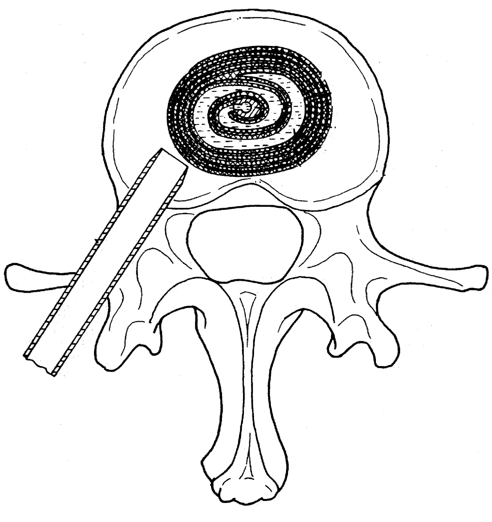


Fig. 7 The first of the Baumgartner and Husson helicoidal discs (spiral nucleoplasty)

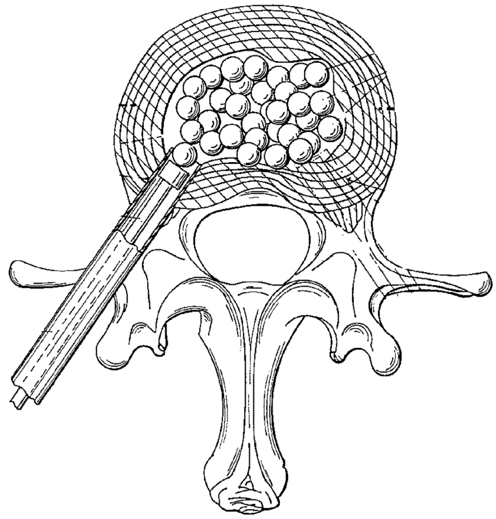


Fig. 8 Baumgartner elastic beads design

- 1994, Oka et al. [142]: composite body comprising layers of polyvinyl alcohol hydrogel and ceramic or metallous porous body allowing bone ingrowth.
- 1994, Grundei [78]: rounded silicon sleeve fitting to a metallic body enabling "partial replacement" of the disc.
- 1994, Popp et al. [148]: disc-shaped device made from a "biocompatible" material. This device has a U or W lateral shape and functions as a spring.
- 1995, Beer and Beer [13]: disc-shaped screwed plates joined by springs protected by an elastomeric covering. The plates have a compressible polymeric core (Fig. 9).
- 1995, Simon et al. [167]: spiraled device rolled around a central core. It has self-adhesive sides and a lengthwise reinforcing radio-opaque structure.
- 1996, Dumas et al. [41]: pair of plates with a helicoidal spring with exponentially increasing stiffness as the space between plates narrows.
- 1996, Bao et al. [6, 7, 8]: hydrogel prosthetic rods absorbing body fluids to fill the interbody nuclear cavity. The hydrogel contains approximately 70% of its uncompressed absorption capacity under physiological

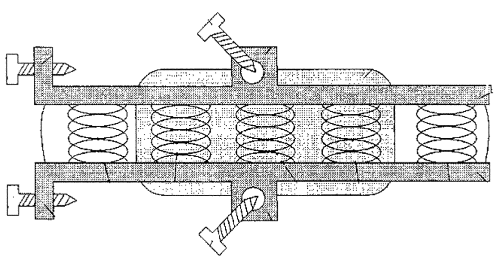


Fig. 9 Beer and Beer spring based implant

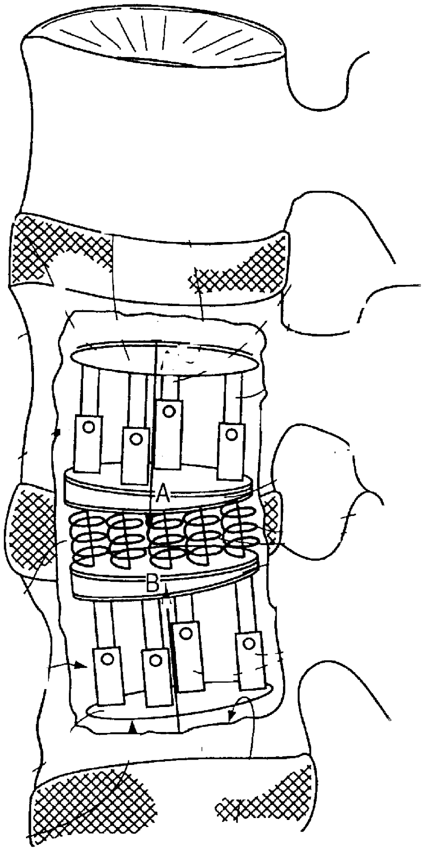


Fig. 10 Buttermann complex spring and pistons prosthesis

load. They reported that this hydrogel nucleus can absorb and release water when submitted to cyclic loading. Another hydrogel prosthetic nucleus shaped implant is also described [90, 91]. It appears that unpublished primate implantations have been realized and showed no adverse reactions, whether local or systemic. A preliminary human study is planned.

- 1996, Buttermann [27]: complex system with preloaded springs allowing preservation of the annulus fibrosus (sic). Looking at the patent drawing, one wonders about the insertion of the implant (Fig. 10).
- 1996, Grammont and Gauchet [75]: deformable capsules with rigid plates and connected by a deformable envelope.
- 1996, Pigg and Cassidy [146]: resiliently deformable material such as a hydrophilic polymer reinforced with physically discreet structures in order to form an in-situ composite.
- 1997, Monteiro et al. [134]: hollow flexible and inflatable capsule filled with radio-opaque "swelling" fluid.
- 1997, Ratron [149]: two plates joined by elastic partitions, implanted in pairs.
- 1997, Dios Seoane [38]: a flexible structure made of osteointegrating material.
- 1997, Bisserie [15]: mirror-like left/right half disc prosthesis consisting of rigid upper and lower spiked plates with elastic cushions in between.
- 1997, Bainville et al. [3]: two metal half envelopes confining a compression cushion with a controlled differential compression. It also utilises an anti-expulsion system to limit the expansion of the elastic cushion.
- 1997, Bouvet [17]: two rigid plates fixed to the bone separated by leaf spring in the shape of a cross and made of elastic material. This device is described as a hip and intervertebral prosthesis.
- 1997, Krapiva [108]: cylindrical flexible hollow nucleus prosthesis, which is folded for insertion and expands in situ. It is then filled with a gel.
- 1999, Graf [71, 72, 73]: three designs. One design consists of an elastic conical core with two grooved rigid covers, the conical shape being meant to help preserve lordosis [71]. The second design appears to be based on the same plates/core principles, but the core is limited to the anterior two-thirds of the disc, and this design allows a greater degree of motion [72]. In a third design, Graf describes a composite device consisting of a posterior damping system fixed with pedicular screws combined with an intervertebral implant (Fig. 11). The latter could be based on different principles: a posterior pivot axis with an anterior damping spring, a rigid ball between concave plates, a ball with hydrophilic gel surrounded by a membrane or an elastic cushion [73].
- 1999, Harrington [87]: pivot ball and socket with shock-absorbing devices between plates screwed into the endplates (Fig. 12).
- 1999, Wardlaw [185]: nucleus-shaped transudative material cover filled with hydrogel material.

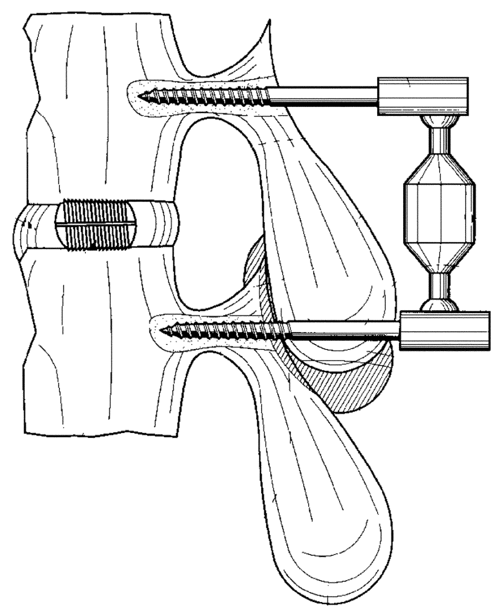


Fig. 11 Graf combined antero-posterior implants

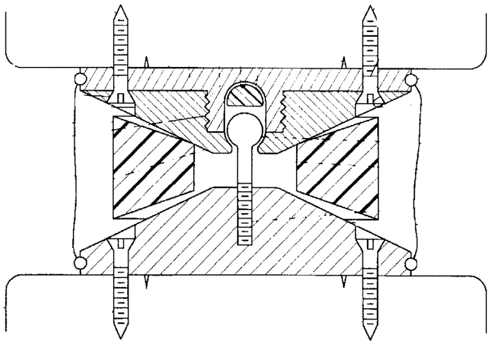


Fig. 12 Harrington ball and socket prosthesis

- 1999, Savchenko et al. [159]: porous titanium plates with an intermediate fluoroplastic nucleus.
- 2000, Cochet [35]: two titanium plates linked by a core and connecting piece with through cells arranged in honeycomb shape.
- 2000, Bryan and Kunzler [22, 23]: resilient intervertebral body maintained by two articulating anterior plates (Fig. 13).

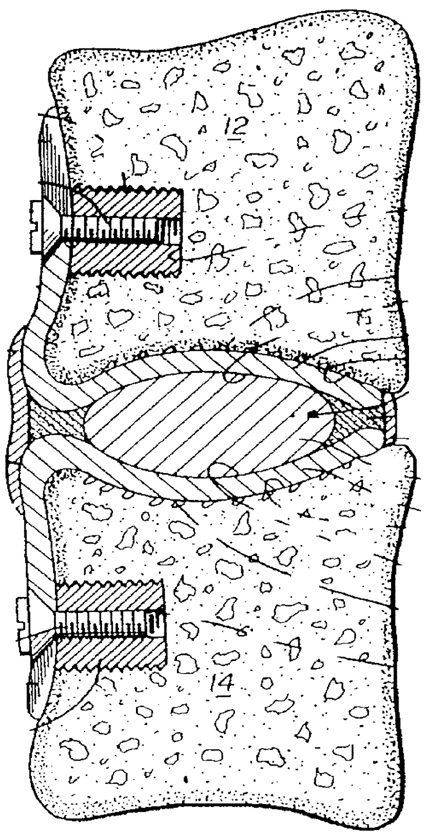


Fig. 13 Bryan and Kunzler prosthesis with disc replacement by "resilient body"

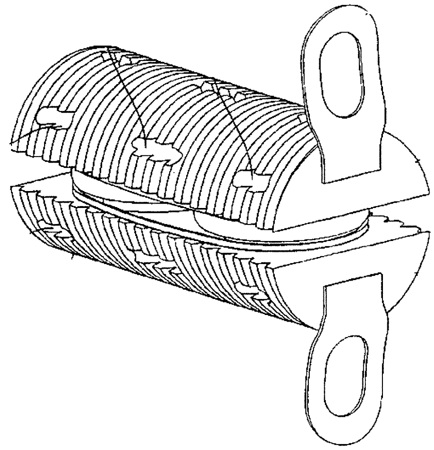


Fig. 14 Bryan and Kunzler cylindric implant

- 2000, Bryan and Kunzler [24]: two threaded hollow half-cylinders screwed to the bodies and containing multiple discoid resilient bodies (Fig. 14).
- 2000, Bryan [20]: "Peanut spectacle" shaped device made of two half "peanut" shells containing resilient bodies.
- 2000, Bryan and Carver [21]: an implant that looks like a combination of the two previous designs: half cylinders filled with peanut shaped resilient bodies.
- 2000, Gauchet and Le Couëdic [64]: disc made of two metal blades screwed to the vertebral bodies surrounding a compressible cushion (Fig. 15).
- 2000, Gauchet [62]: elastic material cylinder surrounding a liquid-filled nucleus between two plates screwed to the bodies.
- 2000, Gauchet et al. [65]: construct of two round plates and an intermediate deformable body in the shape of a four-leaf clover.
- 2000, Lawson [110]: semi-ovoid design. The lower surface is slightly convex and comprises a short peg for cemented fixation in the upper endplate of the inferior vertebra. The superior surface is more convex and ar-

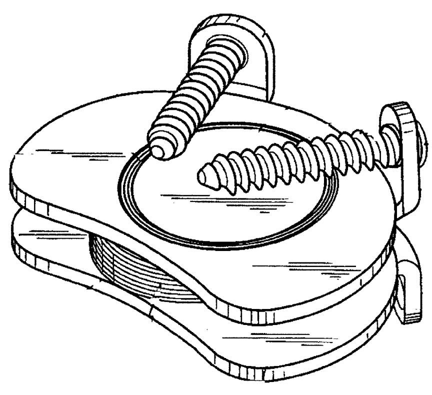


Fig. 15 Prosthesis of Gauchet and Le Couedic

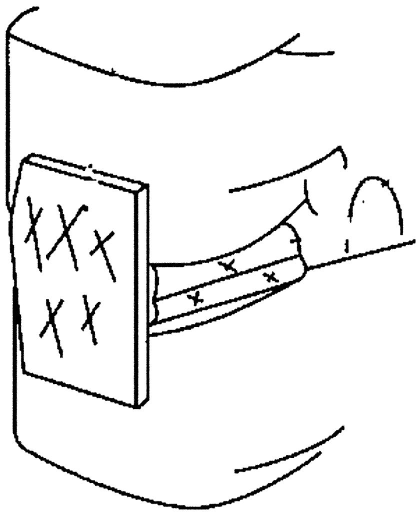


Fig. 16 Jackowski and McLeod elastomeric prosthesis

ticulates with the upper vertebra. The device is placed through an annular flap after curetting nucleus material. The annulus is preserved.

- 2000, Middleton [128]: complex multi-slit disc-shaped device.
- 2000, Jackowski and McLeod [98]: elastomeric material compressed by textile encapsulation and laid in the intervertebral space (Fig. 16).
- 2000, Gauchet [63]: compressible bladder filled with liquid and a compressible material between two plates.
- 2000, Zdeblick and McKay [194]: two rectangular shells with grooved biconvex surfaces for contact with the endplates. A spacer made from an elastic material is sandwiched between the shells.
- 2001, Viart and Marin [182]: two spiked convex plates with a viscoelastic biconcave "tyre like" core.
- 2001, Gau [61]: one or several spheres made from "biocompatible" material moving in a conic cage-like enclosure.
- 2001, Studer and Schärer [174]: another variation of a spiraled device. The spiral is made of "plastic material" containing small hydrogel cylinders. It is meant to be implanted following discectomy.
- 2001, Marcolongo and Lowman [119]: prosthetic nucleus made from blends of polyvinylalcohol and polyvinyl pyrollidone.
- 2001, Minda and Schmidt [131]: fillable soft container or balloon to be filled with fluid or air.
- 2001, Weber and Da Silva [188]: prosthesis including an annulus and a nucleus which can be adapted to the anatomical configuration by stereotactic forming after imaging studies (MRI, CT). The nucleus includes an empty cavity for the introduction of fluid or gel. An optional fibre-optic carriage could transmit laser or electromagnetic rays to stimulate tissue ingrowth from adjacent vertebrae into porosities on the upper and lower surfaces.

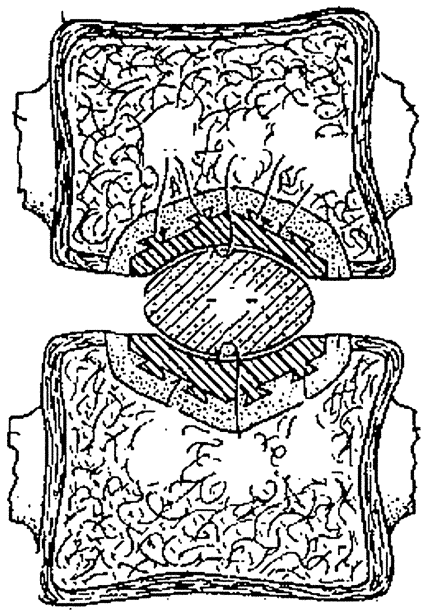


Fig. 17 Weber lumbar prosthesis

- 2001, Banks et al. [4]: implants of different shapes made from synthetic polyamide, polyester, polyethylene, collagen or other plastics. They may have bone fixation anchor and annulus closing features.
- 2002, Kotani et al. [107]: a disc made from a three-dimensional fabric woven from polyethylene fibers and coated with bioactive ceramic on the surfaces. The authors describe biomechanical studies and sheep implantation. They report that the best motion results are achieved when a temporary rigid fixation is used over 6 months.

Devices aimed mainly at restoring the motion function

- 1978, Weber [186]: two polyethylene box-like structures anchored in the adjacent vertebrae, each having a shell-shaped cavity in which a ceramic ovoid core is introduced to enable motion (Fig. 17).
- 1987, Hedman et al. [48, 88]: this is the Kostuik team implant. Made of two titanium springs between cobalt-chromium-molybdenum hinged alloy plates screwed to the bodies. This implant allows good sagittal motion (15°–20°) with very restricted lateral motion (3°–6°). It is designed in six sizes. Fatigue tests to 100 million cycles showed that springs tended to break [89]. Implantation in sheep did not show fibrous ingrowth in the mechanisms [104]. It was never implanted in humans.
- 1989, Keller [101]: two concave spiked stop plates with a biconvex metallic core (Fig. 18).
- 1992, Bullivant [25]: two plates and a core with an inferior convex surface sliding in a concave shape of the inferior plate. A superior flat surface slides against the upper flat plate. It appears to be inspired by the Charité concept.

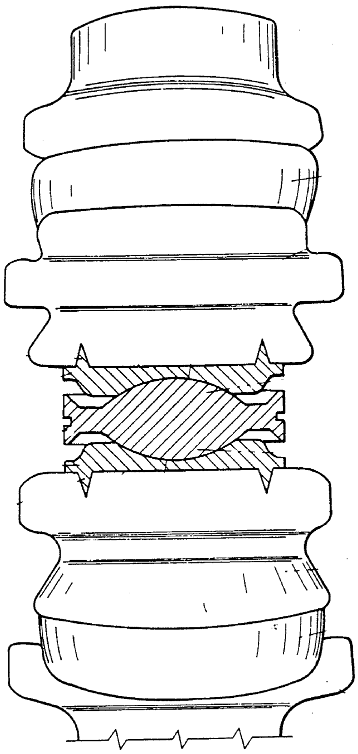


Fig. 18 Keller prosthesis

- 1992, Graham [74]: ball and socket joint fixed to cylinders and flexible spacers inserted in the vertebral body and locked by hemicylindrical plates and screws. The ball and socket provides motion and the spacers compressive function (Fig. 19).
- 1992, Salib and Pettine [158]: eccentric ball and socket joint screwed to the vertebral bodies. It is designed to have six degrees of freedom but no compressive properties (Fig. 20).

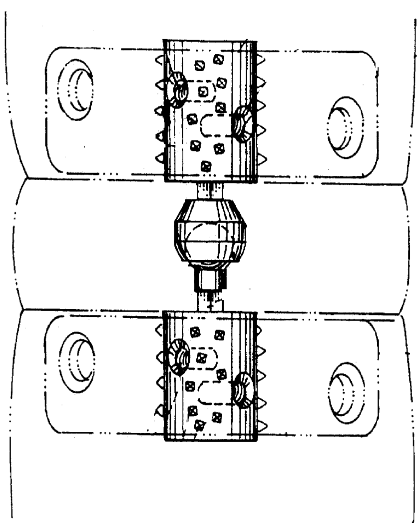


Fig. 19 Graham ball and socket joint

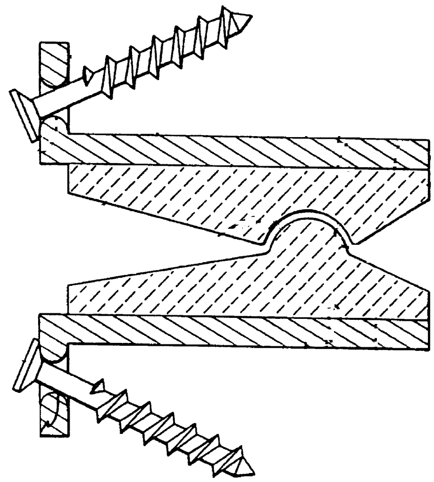


Fig. 20 Salib and Pettine ball and socket design

- 1994, Mazda [124]: two spiked plates between which is placed a centred ball joint with an elastic surrounding cushion.
- 1996, Teule [178]: low-friction prosthesis with a lens-shaped spacer.
- 1997, Yuan et al. [193]: articulated convex/concave implant enabling motion in all planes and fixed through spikes in the endplates.
- 1997, Shinn and Tate [166]: two plates anchored with pins in the endplates and screwed into the anterior wall of adjacent vertebrae. A partial socket is attached to the lower plate and a partial ball is attached to the upper plate to articulate with and be retained by the socket. A peripheric membrane can be added.
- 1998, Xavier et al. [191]: vertebral body replacement allowing motion. Two spiked plates are screwed to the bodies with an articulated ball surrounded by an elastic annulus. They attempt to restrain rotational motion by X-pattern wires between the two plates (Fig. 21).

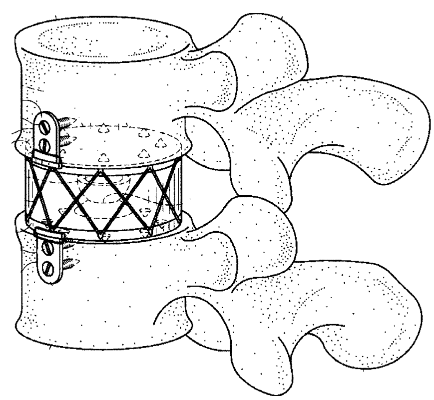


Fig. 21 Xavier wire stabilized prosthesis

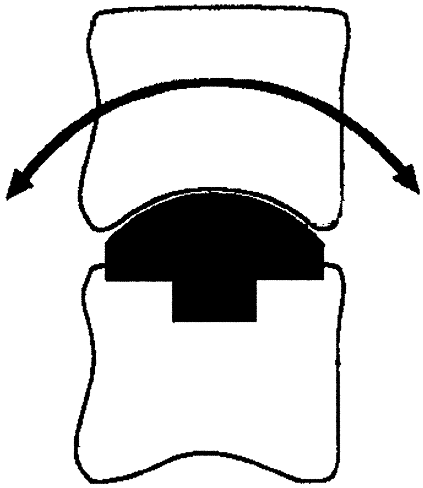


Fig. 22 Sabitzer prosthesis

- 1999, Sabitzer and Fuss [157]: this device has a flat inferior side with a rod for fixation in the inferior vertebra. The upper side is convex and articulates with the lower endplate of the superior vertebra (Fig. 22).
- 1999, Rogozinski [155]: self-centering system with a biconvex core sliding in two concave plates.
- 2000, Shelokov [164]: prosthesis resembling a knee implant with two condyles. An upper double-convex element slides on an inferior double-concave one.
- 2000, Griffith and Erickson [76]: spiked plates with one curved bearing and one plane bearing surface and an intermediate core adapted to those surfaces. It allows for rotation and, optionally, for certain amount of translation.
- 2000, Gordon et al. [69]: two plates, one with a male concave element placed in a female flat element fixed on the other plate. A hemispheric bearing is sandwiched between the two elements. The plates are screwed to the anterior walls of the adjacent vertebrae.
- 2001, Cauthen [31]: two hemi-cylindrical elements with a longitudinal slit on the inferior element in which a rounded ridge on the upper element articulates, enabling sagittal motion (Fig. 23).
- 2001, Betisor et al. [14]: articulated frame with rods and axes and a toothed contact surface.

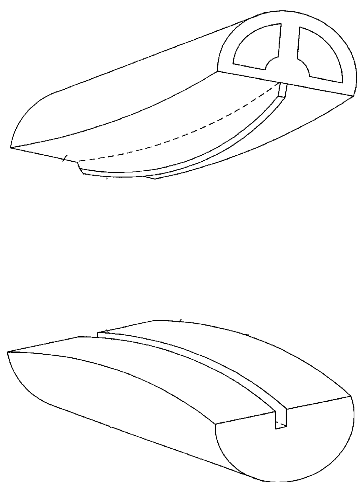


Fig. 23 Cauthen cylindrical slit and rib implant

Cervical disc prosthesis

- 1979, Weber [187]: this implant is similar to his lumbar implant. Two concave structures are anchored in the vertebral bodies with cemented grooved spikes, between which lies a central ovoid core. In the cervical model, the holding plates have a guiding system linking them to avoid expulsion of the core during movements. Each superior and inferior component is fixed with a single cemented spike, which is eccentric in the frontal plane (Fig. 24).
- 1980, Patil [145]: interlocking spiked plates, resembling box cover, linked with springs (Fig. 25).

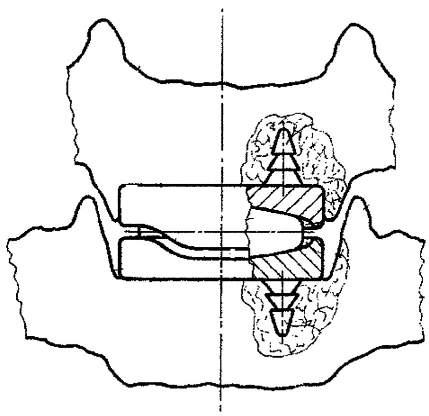


Fig. 24 Weber cervical implant with eccentric cementing

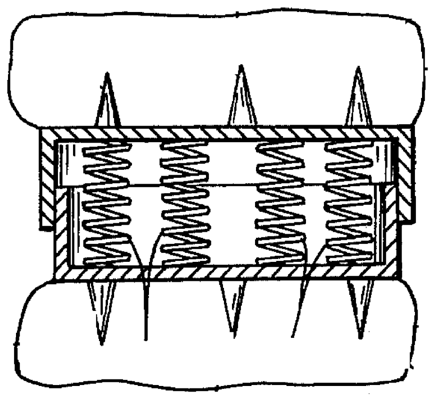


Fig. 25 Patil cervical interlocking plates and springs

- 1995, Lesoin et al. [116]: two plates screwed in the bodies with a large concave/convex articulation.
- 1996, Kehr et al. [100]: sliding prosthesis made of an inferior plate screwed on the side of the vertebra on which is mounted a convex element. The latter can articulate either with the inferior endplate of the upper vertebra or with a concave element fixed to that upper vertebra (Fig. 26).

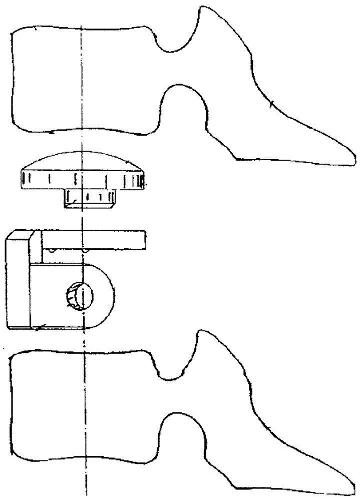


Fig. 26 Kehr cervical implant

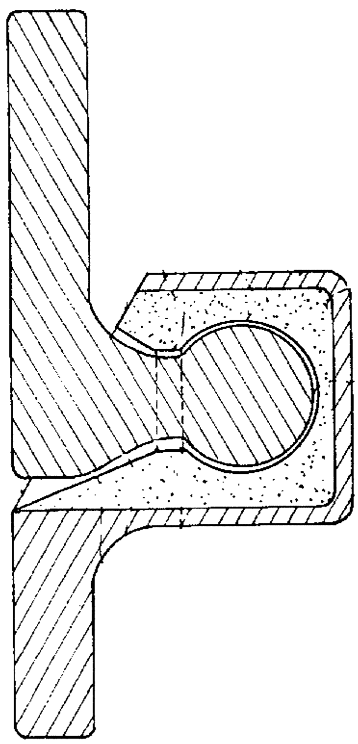


Fig. 27 Ibo "inversed hip" ball and socket implant

- 1998, Ibo and Pierotto [97]: a ball and socket joint screwed in the bodies. It looks like a small total hip replacement (Fig. 27).
- 2000, Cauthen [30]: two threaded half-cylinders with a ball and socket joint in the centre (Fig. 28).
- 2001, Buhler and Ramadan [25]: two spiked plates with ceramic articulation.
- 2001, Medizadeh [127]: two threaded half-cylinders linked by small springs. It looks like a longitudinally split cylindrical cage in which springs have been inserted.

Other designs

- 1996, Navas [139]: two ball joints with a dampening element screwed into adjacent vertebral bodies and linked together to try to reproduce disc behaviour.

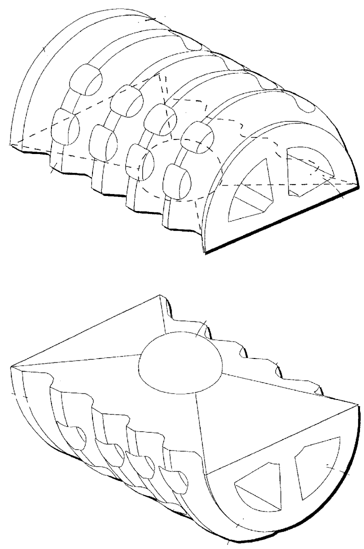
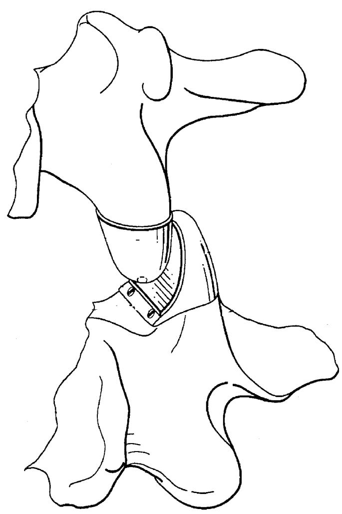


Fig. 28 Cauthen cylindrical ball and socket designs

Fig. 29 Fitz articular facet covers implant



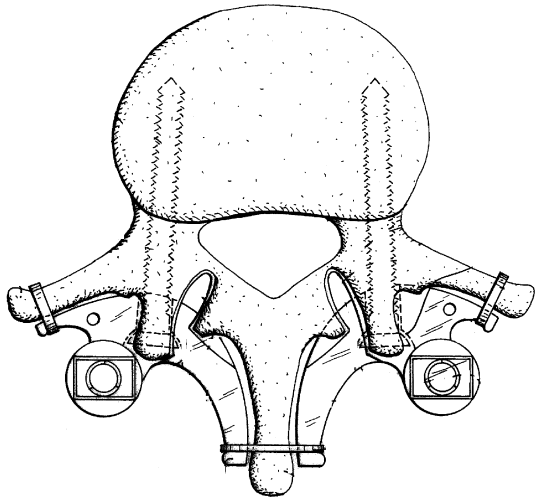


Fig. 30 Martin complex facet replacement

- 1990, Stone [171, 172]: prosthetic disc acting as a scaffold for regrowth of disc tissue made of a dry porous volume matrix of biocompatible and bioresorbable fibres. This matrix establishes a scaffold for ingrowth of intervertebral fibrochondrocytes.
- 1996, Fitz [51]: facet prosthesis with two metal elements capping the superior and inferior facets (Fig. 29).
- 2000, Martin [122]: complex facet joint prosthesis with the joint construct attached to pedicular screws and to the lateral and spinous processes (Fig. 30).
- A number of Chinese patents relating to disc prostheses exist, although we have no precise description [81, 84, 117, 165].

In situ polymerizing devices

A number of attempts to inject substances that polymerize in situ in the intervertebral space in order to restore viscoelastic function have been proposed.

Garcia [60] and Shepperd [18] have described such a procedure. Recently, Felt et al. [47] described a minimally invasive technique to deliver a curable biomaterial such as a two-part polyurethane system. The delivery balloon used also allows for expansion during polymer injection, thus restoring disc height. Preliminary clinical testing is to begin.

Arrowsmith and Milner [1, 129, 130] propose materials that would cross-link upon contact with water or moisture, such as isocyanate prepolymers or silane functionalised polymers or precursors.

However, all in situ curing formulations contain monomer, prepolymers and catalysts, which are generally cytotoxic and/or carcinogenic. Furthermore, they are exothermic. Permanent anchoring may also be a problem.

Some attempts have been made at trying to reform a degenerate disc. Chin Chin Gan et al. [32] describe a disc-shaped porous hybrid device made of disc cells and a bioactive biodegradable material like bioactive glass or synthetic materials coated with bioactive substances.

Experimental animal reinsertions of allograft nucleus pulposus have also been described [140, 143].

Clinical use

Artificial discs that have been used clinically

In spite of the very large amount of different disc replacement designs, only a few have reached the level of clinical implantation, even in primate animal models.

The first human implantation of artificial disc was performed by Fernström in the late 1950s [49]. He was using a metal ball – in fact an SKF ball bearing – and tried to reproduce the "ball joint" mechanism of the disc. Along the same line of thought, Harmon utilises Vitalium spheres, which were commercialised for a short period of time. The Harmon spheres could also have been used as instrumen-

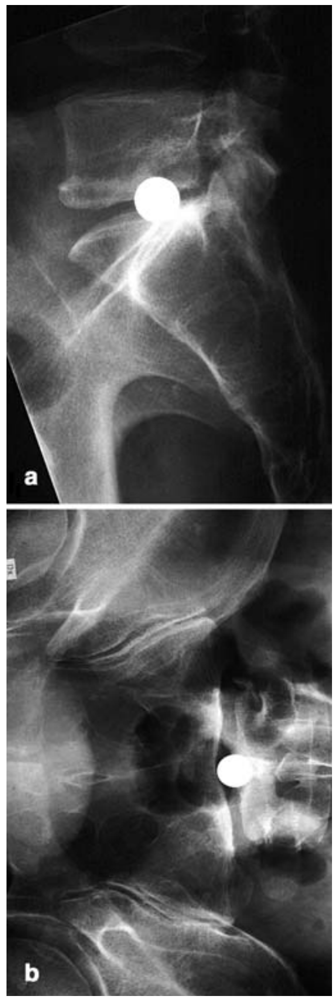


Fig. 31 **A** Lateral and **B** antero-posterior view of an implanted Fernström ball. Note the sinking of the device in the upper endplate (courtesy T. Hansson)

tation for fusion [85]. The Fernström balls seem to have been used in about 250 patients. They created a segmental hypermobility and had a marked tendency to subside into the vertebral endplates and bodies (Fig. 31). McKenzie presented good preliminary results [125] and good long-term results, but the latter in a methodologically dubious paper published in a non indexed and non peer reviewed journal [126]. Fernström himself admitted poor results; the implant was withdrawn and no long-term studies are available [50].

Reitz and Joubert, from South Africa, implanted a metal prosthesis in the cervical spine in the treatment of intractable headache and cervico-brachialgia. No long-term follow-up is available [154].

Fassio designed and patented an elastic, which has a "flying saucer shape" [45]. The central sphere is in silastic and the lateral plateau in uncompressible synthetic resin (Fig. 32). After laboratory testing and primate implantation, they implanted it in three patients in 1977 (Fig. 33) [46]. They stopped because of the destructive posterior approach and subsidence of the implant in the endplates, which created an intraspongious hernia. After 4 years follow-up, there was a marked disc narrowing and absence of motion.

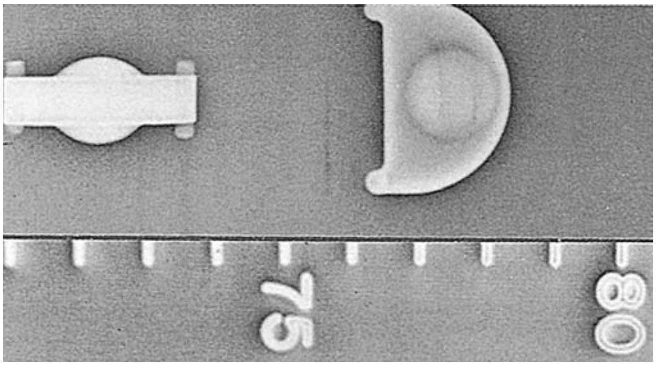


Fig. 32 Fassio silicon implant (courtesy B. Fassio)

It appears that Hou and co-workers used a silicon prosthesis in about 30 patients. Results were not published [94].

Steffee designed a lumbar implant [168, 169, 170], the Acroflex, consisting of a hexen-based polyolefin rubber cushion attached to two titanium endplates. Six patients were implanted and followed up for 3 years, with very average results [43]. Possible carcinogenic properties of a chemical used in the rubber vulcanisation process caused the withdrawal of the implant.

A new design using HP-100 silicon elastomer was proposed by Steffee, Fraser, and co-workers [53, 163] (Fig. 34). Those new implants were third-generation AcroFlex artificial discs. The initial implant, referred to as the Pilot 1 device, had flat endplates and a crescent-shaped protruberance for bony fixation and was used in 11 patients; the subsequent version, with contoured endplates and fins, was called the Pilot 2 device (used in 29 patients). Apart from the metal endplate surfaces, the devices were identical. However, after those first 40 implantations (Fig. 35), it was decided to stop, because of the failure of the device in vivo to live up to the performance demonstrated in laboratory testing, with the development in a number of cases of minor defects in the polyolefin, which were displayed on fine-cut computed tomography scans (accurate to 0.25 mm) after 1 or 2 years [52].

The SB Charité prosthesis was designed in former East Germany in the early 1980s by Schellnac and Büttner-Jans, and was first implanted by Zippel in 1984. Problems of migration and metal fatigue fractures led to the aban-

Fig. 33 **A** Antero-posterior and **B** lateral radiograph of the Fassio implant (courtesy B. Fassio)

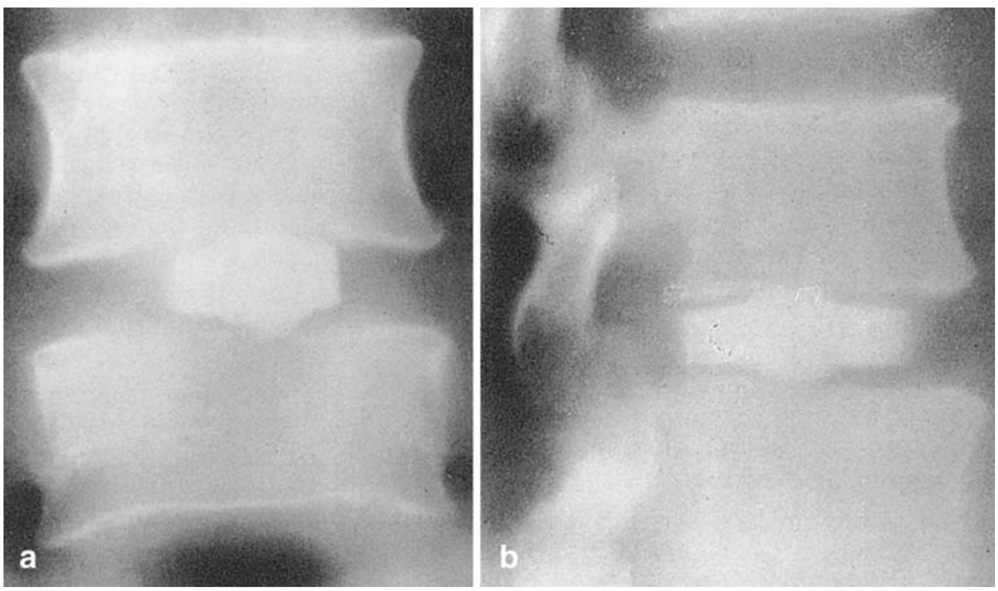


Fig. 34 The Fraser/Steffee second Acroflex implant (courtesy R.D. Fraser)

donment of versions I and II [28, 29]. The Charité III, introduced in 1987, consists of a biconvex ultra-high-molecular-weight polyethylene nucleus with a radio-opaque metallic ring. It interfaces with two endplates of cobalt-chromium-molybdenum alloy coated with titanium and hydroxyapatite and primarily fixed through ventral and dorsal teeth. It has been widely implanted [33, 77, 115, 195], and clinical results are presented elsewhere in this volume.

Ray and Corbin developed a nucleus replacement [151, 152] consisting of dual-threaded cylinders made of semi-permeable, flexible and high-tensile polymeric fibres containing a hydroscopic semi-fluid. Probably due to technical problems in manufacturing a perfectly sealed semi-fluid, this concept was abandoned. Ray et al. then developed the PDN (Prosthetic Disc Nucleus), also a nucleus replacement. It consists of a hydrogel core enclosed in an elastic woven polyethylene jacket, resembling a pillow. Different designs have been patented and used. The annulus fibrosus is conserved during implantation. The hydrogel has hydrophilic properties: it absorbs fluids and expands, and therefore tries to mimic the behaviour of the nucleus pulposus. The design has led to several modifications after a number of device migrations [153]. Preliminary clinical reports have been published [161] and longer-term clinical results are presented elsewhere in this issue.

The Pro-Disc is an articulating disc with polyethylene core. The metal endplates are plasma sprayed with titanium and have two vertical fins for fixation in the endplates. Various clinical trials are currently under way [120, 121], and results are published elsewhere in this issue.

Mathews, Le Huec and al. [123] conceived the Maverick prosthesis, a metal/metal (chrome cobalt) interface implant with a posterior rotation axis. It allows normal motion in sagittal and frontal planes. A multicentric clinical trial is ongoing (Fig. 36).

The Bryan Total Cervical Disc is designed as a low-friction, wear-resistant elastic nucleus. This nucleus is set between and articulates with two titanium plates covered with a porous coating and screwed to the vertebral bodies. A flexible membrane surrounds the construct. It allows range of motion in all planes. The device has been used by several authors, and a paper has been submitted for publication [68]. Another report about this device can be found elsewhere in this issue.

In 1998, Gill and co-workers patented the Bristol cervical disc [66] (Fig. 37). This is a ball and socket type de-

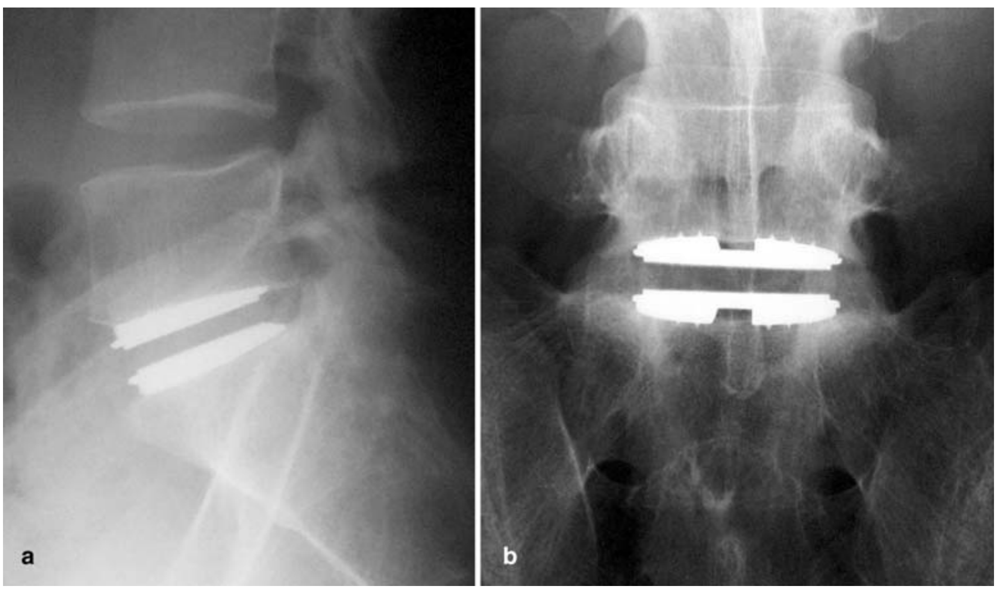


Fig. 35 Lateral radiographic view of implanted second Acroflex prosthesis (courtesy R.D. Fraser)

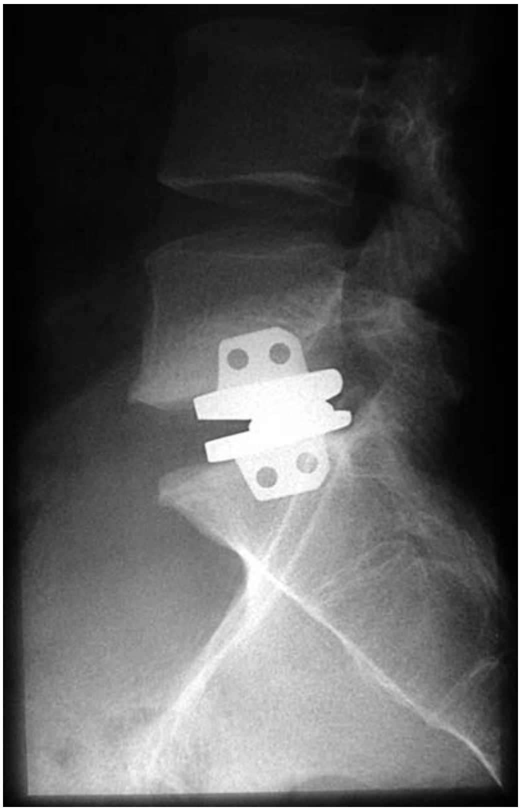


Fig. 36 Antero-posterior radiographic view of the Maverick prosthesis (courtesy J.C. Le Huec)

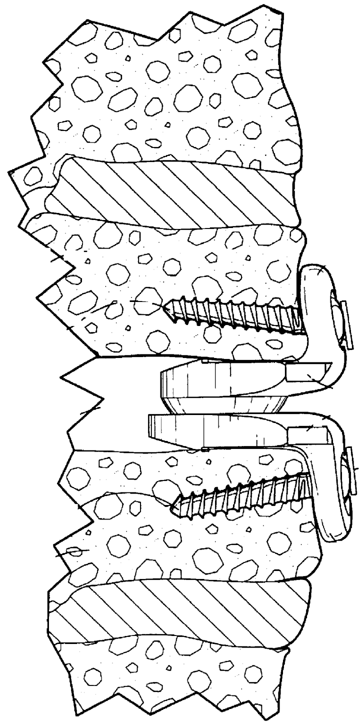


Fig. 37 The Bristol/Gill cervical implant

vice made of stainless steel, which is screwed to the anterior sides of the adjacent vertebral bodies. Cummins reported on 20 patients implanted with the device, and found good results. The device is being clinically evaluated [36].

In 1992, Gjunter [67], from Russia, patented a device with a coiled design. But whereas previous such implants spiraled around a transversal axis, this one spirals around an antero-posterior sagittal axis, to form a resilient flexible cylinder made of a rolled sheet of superelastic porous TiNi alloy [79]. It can be ready coiled or rolled on itself to enable a variation in the diameter. At least one patient has undergone a cervical implantation at the C6/C7 level in Novosibirsk. Results are not known.

Discussion

Proponents of disc prosthesis advance several reasons in favour of spine arthroplasty:

- Preservation of function
- Immediate pain relief
- Frequency of failed fusions
- Possible absence of degeneration at adjacent levels
- Absence of drawbacks linked to autologous bone harvesting

Preservation of function is appealing. However, whereas loss of mobility of a hip or knee is extremely incapacitating, the loss of motion in one, or even several, spinal units is of little functional consequence.

The disc is not, by a long way, the only spinal structure at the origin of nociception [192]. Pain can originate at any of the components of the three-joint complex [103]. In the case of fusion, all structures capable of nociception are fixed, which is not so in arthroplasty. We know that clinical outcome is not necessarily linked to a successful fusion, and that non-union does not preclude a good result [44, 58]. In the literature published to date, the success rate of arthroplasties is comparable to that of fusions. Furthermore, psycho-social factors [82, 190] are known to play a major role in the outcome of any spinal surgery, and the nature of arthroplasty should have a major influence on this aspect. This shows the complex nature of back pain and its relation to surgery. One may wonder whether the poor outcomes are not related to poor indications rather than to the techniques themselves [176].

Some studies have shown a higher degeneration frequency at levels adjacent to a fusion [19, 111]. However, other publications have shown that if imaging does indeed show degeneration, the relation with clinical complaints is very weak [114], and the importance of low back pain is not higher than that in matching-age non-operated patients [37].

Graft harvesting does indeed carry its load of complications and irritations. However, the development in biomaterials and molecular biology will make it possible to use reliable bone substitutes [80, 177].

The very fact that such a long list of implants, based on highly varied principles, has been proposed, and that only very few have reached the level of animal models, let alone human implantation, clearly demonstrates how challenging the task of designing an intervertebral disc replacement is. In the current days of evidence based medicine, adequate prospective clinical trials are imperative. Very recently, leading Dutch orthopaedic surgeons representing the Dutch Orthopaedic Society and the Dutch Spine Society published a warning about uncontrolled clinical implantation in Europe of disc prostheses. They stress the fact that those devices are labelled experimental in the US. In the absence of proper clinical evidence, they consider it should also be seen as experimental in Europe. They denounce the commercial hype through the media, which tends to present these techniques as miracle cures [180].

Proper randomized controlled trials are on the way, and should help in assessing the efficacy and real place of spine arthroplasty in the treatment of spinal disorders. Only then will spinal surgery join the list of successful joint replacements.

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