PROSTHESIS FOR SPINAL REPAIR


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ABSTRACT

A shaped article comprising at least a core element having generally flat top and bottom surfaces, the core element being made of elastic polymer and preferably reinforced. Presently preferred forms of the article are those in which the core element has a covering element secured to one or, in some cases, to both flat surfaces and providing an outer surface of an open-pore tissue-ingrowth-receptive material. Another preferred form of the prosthesis comprises a curved, flat, bar-like element shaped into a spiral configuration, so that the overall appearance approximates a flat disc. Still another version includes a plurality of flexible, curved, bar-like elements with configurations which allow them to lie side by side so as to occupy the interior space of a natural disc from which the nucleus pulposus has been removed. When any form of the prosthesis is used to replace a diseased or damaged spinal disc, proper spacing of the adjacent vertebrae is maintained and the prosthesis provides resistance to compressive forces imposed on the spine, as well as preserves the natural flexibility of the spine.

40 Claims, 26 Drawing Figures
1 PROSTHESIS FOR SPINAL REPAIR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of application Ser. No. 214,344, filed Dec. 30, 1971 now abandoned, which in turn is a continuation-in-part of application Ser. No. 109,101, filed Jan. 25, 1971, now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to spinal disc prostheses. Surgical art has recognized the need for a functional spinal disc prosthesis for replacement of or compensation for degenerative or damaged spinal discs which should or must be removed. The prevailing procedure for such disc surgery has been partial or total excision of the disc material, either without or with replacement of the removed disc with a plug or wedges of bone taken from the crest of the iliac bone, which are driven or fitted between adjacent vertebrae to maintain normal spacing and to achieve bony fusion. This procedure has been attended with an unacceptably high failure rate. There has often been as high as 80% recurrence of the symptoms within two to five years. Recurrent pain has stemmed from recurrent sources, among them post-operative failure of fusion or resorption and settling of the graft site and additional bending stress imposed upon discs adjacent to the fusion; each of these factors has tended to apply undesirable pressure on the nerve passages which interface the vertebrae both longitudinally and transversely. Recurrence is believed often to be associated with the settling of bone around the grafted wedges or plugs for several reasons:

1. The iliac crest is a poor source of load-carrying bone, because it consists mainly of porous cancellous bone, poorly strengthened by hard cortical bone. Additionally, the entire cross-section of the vertebra against which the wedges bear is also cancellous bone, with the exception of a narrow peripheral ring of cortical bone around the outside of each vertebra.

2. The grafted bone segments often fail to cover as much load-bearing area as the natural disc which they replace, and this failure to cover promotes resorption due to high unit contact pressures.

Cortical bone exists only in the exterior shells on the outside of bones and becomes well developed only when the bone is under stress, as in a leg bone. Iliac crest bone receives practically no stress and so is not well developed. An iliac bone plug may have the advantage of providing an excellent fit, but this may be outweighed by the disadvantages of inadequate area, little cortical contact, and poor mechanical strength, and the area close to the spinal cord is not repaired.

Additionally, it has been very difficult for the surgeon to select and then to shape an ideally sized bone graft, because of the limitations on the geometry of the donor graft site and because of the degree of manual dexterity required to achieve proper shape of such a graft.

A refinement of existing graft procedures provides a simpler technique of using a single cylindrical bone plug cut with a hollow coring device; the surgeon is benefited by simplification of the bone fitting.

Another earlier proposed procedure, but one practiced only in a few cases where the patient was in terminal state otherwise, was to encase the affected portion of the spine in acrylic plastic or to introduce liquid acrylic plastic into a specially prepared bone trough, suitably lined and formed by removal of at least one degenerative disc, and to harden the plastic in situ. The objections to such procedure are obvious, and the safety of the plastic material was not proven. Nor was the prosthetic treatment intended to return a patient to work and to relatively normal living.

Other earlier procedures employed metal devices as substitutes for either disc or entire vertebrae or both. One such approach sought to accomplish rigid fixation by bridging across the affected vertebra and disc with a U-shaped metal brace that was specially shaped so as to fasten to the vertebrae in a manner similar to the fastening of dental bridges. Another such device employed a large steel ball that was interposed between adjacent vertebrae in an attempt to provide a wide range of motion. The bridging technique produced "satisfactory" results in two cases, but the ball technique failed early, due to high contact loads and an unyielding metal-to-tissue interface which produced necrosis and resorption of bone. Neither approach was able to restore normal disc function, as can be done with the present invention.

SUMMARY OF THE INVENTION

This invention concerns a shaped spinal disc prostheses and, more particularly, a synthetic prosthesis of this type which is resilient, rugged, strong, durable, capable of resisting compressive forces, compatible with body fluids and tissues, and equipped to attach itself where desired to adjacent tissues through natural tissue ingrowth.

The synthetic prosthetic disc of this invention has a flattened kidney shape to conform to the shape of the total natural disc it is intended to replace in a human or animal spine, and has a shape which conforms more or less to the space in a spinal disc from which the nucleus pulposus has been removed.

In its simplest form the prosthetic disc may be a reinforced resilient block of elastomer, such as silicone rubber or polyurethane, interposed between the natural surfaces of the cavity from which the replaced disc has been excised. This simple prosthetic disc is retained in place by reconstructed natural tissue surfaces, such as the cortical plate of the vertebral bodies, and the anterior and posterior longitudinal ligaments. The elastomer may be unreinforced or may, for better resistance of compressive forces, be reinforced, e.g., by an annular ring of laminated fibrous material such as Dacron filaments embedded in the silicone elastomer.

In a more complex configuration, the prosthetic disc of this invention may more nearly duplicate the construction and function of the natural disc which it is intended to replace. It may then comprise a resilient central core element and have at least one open-pore, tissue-ingrowth-receptive surface positioned to abut the exposed bony surface of an adjacent spinal vertebra. The core element may have side and end walls to contain the core.

In one form, the core of this more complex configuration may be a solid resilient pure biocompatible elastomer, either unreinforced or reinforced, to which a reinforced peripheral side wall and two flattened or oblate reinforced end walls are vulcanized and bonded.

In another form, the core may comprise biocompatible viscoelastic liquid contained between reinforced
side and end walls that provide a sealed chamber or pressure vessel capable of containing the core fluid and resisting undesirable deformation under compressive loading, while enabling natural motion and shock mitigation.

The peripheral or side wall may have a plurality of layers of a medical elastomer, such as silicone rubber, reinforced with embedded fibrous material, either polymeric such as Dacron filaments or metal. The whole is all vulcanized and bonded together and to the central core.

In still another form, the prostheses may comprise a more or less elongated, flexible, bar-like element formed into a spiral or coiled configuration which at the time of installation may be unwound and threaded through a small opening into the hollow space of a natural disc from which the nucleus pulposus has been removed. Once installed, elastic action causes the prostheses to assume its original spiral shape and is retained by the annulus fibrosis of the natural disc as well as by tissue ingrowth, and subsequent scarring.

Another form of the prostheses comprises two or more crescent shaped bar-like elements which may also be threaded through a similar small opening one after another into the hollow space of a disc following removal of the nucleus pulposus until the space is occupied and the elements lie closely packed one against another.

Research has shown that normal spinal discs enable angular flexion between 2° and 5° in everyday activity. When flexing or bending in this manner (when stooping over, for example) tensile stresses concentrate first at the edge or periphery of the disc. The central portion of the disc may not share any significant amount of this stress. If the flexion is carried to excess, as in an accidental fall, the edge stress exerted on a prosthesis may result in tearing the natural tissue which has grown into the porous fiber surfaces of the implanted disc prosthesis, which, as stated, preferably has exterior tissue-ingrowth surfaces. Repeated rupture of the tissue bond may excite adverse tissue response, irritation, or development of thick non-adherent fibrous growth. Relief from this situation can be obtained by a special form of prosthetic disc according to this invention. The core element of this special form does not have a vertically reinforced side wall; instead the side surface of the core element is preferably indented so as to create relatively flexible resilient edges which then follow the motion of adjacent vertebral through a wider-than-normal angular movement without creating large tensile stresses in the tissues. Such as prosthetic disc may be described as a "disc for gymnasts" or for very active persons. The net effect is a spreading of the stress over a wider peripheral area so as to reduce the stress per unit area to a more acceptable level. This form of the prosthesis provides a center core which is relatively rigid or stable so far as vertical displacement or vertical loading is concerned, but it is capable of deflection angularly in lateral and anterior-posterior planes. The indented configuration of the side surface additionally avoids bulging at this portion of the prosthesis and thus avoids making painful contact with adjacent nerves.

The problem of exaggerated stress at the edge of the prostheses which can lead to tearing of the tissue ingrowth bond at these edges can also be alleviated by the use of a disc prosthesis in which only one of the flat surfaces, i.e., either the upper or lower surface, is completely covered with a tissue-ingrowth-receptive surface. The opposite surface may be entirely smooth and incapable of supporting tissue ingrowth or it may be smooth at its edges and have a small centrally located area of ingrowth receptive material.

In those forms of the prosthesis having tissue-ingrowth receptive material on both outer surfaces, these may be provided by two outer or covering elements substantially alike in construction, so that a description of one suffices for both. Such an outer element comprises a resilient component, with one or two layers from 0.010 inch to 0.100 inch thick of silicone elastomer or the like. One layer may have an exterior surface of open-woven fiber. The resilient component is covered by a stitchable component, i.e., one adapted to retain stitching, such as at least one layer of Dacron mesh or a mesh of other suitable material or a velour, thus forming a stack or sandwich of the described layers. An open-pore, tissue-ingrowth-receptive fabric, such as Dacron mesh or velour, also compatible with body fluids, is applied as a covering over the stack or sandwich, covering the outer surface of the outermost layer of stitchable ingrowth material and the side walls of the stack, so that the tissue-ingrowth-receptive fabric will be in contact with adjacent vertebral surface when emplaced. In order to aid mechanical fitting and to invite deeper and more substantial tissue ingrowth, such mesh, velour, or other fabric covering may be irregularly thickened, e.g., by pleating or by mechanical brushing and fluffing the fibers, to create a deeper pile, more conformable to the irregularities of the cavity left by the excised disc. These pleat rows advantageously may be sewn or stitched to the underlying mesh layer and also sewn together at a folded-over portion over the lowermost rubber layer of the end wall, using a stitchable thread or filament, such as Dacron filament.

The term "compatible" used in this specification has several meanings. First, there is its chemical aspect, for compatible materials are those which are not unduly attacked by body chemistry, including attack by body fluids. Second, is a physiological aspect, for compatible materials do not adversely affect the body chemistry by reaction with or degrading of body tissues and fluids. Third, is a mechanical aspect, compatibility on a mechanical level with the bone, soft tissue, and so on. Compatible elastomer is compliant, soft, yielding, flexing and stretching like the natural tissue it replaces, absorbing shock without crushing adjacent tissue and distributing loads over wide areas. Compatible fibrous material is strong, flexible, bondable to the elastomer, and relatively immune to wear and breakdown from the intended use. The fibrous material used for tissue ingrowth has a pore size (150 micron or 0.006 inch or larger) to enable invasion by fibroblasts and tiny blood vessels and deposit thereby of calcium, phosphorous, and other bond-building materials carried in the blood stream. It is also desirable for the fibrous material to trigger the "foreign body" response in mild degree — as does Dacron — in order to stimulate faster healing and fibrous encapsulation by body tissue.

The two outer or covering elements, each of which also conforms in horizontal cross-sectional shape to that of the disc to be replaced, and conforms to the shape of the core element, are assembled with the core into a "sandwich" with the core as the central element and with the fully covered face of the outer element remote from the core and facing outwardly. The fully
covered face is thus adapted to abut a surface of a vertebra when the device is emplaced in a spinal column to replace a diseased or damaged disc. Up to this time the elastomeric elements have not been vulcanized, and the assembly is then vulcanized to join the three elements firmly together, along with the fabric coating. Thereafter the assembly is thoroughly stitched together entirely around the periphery, the stitching being spaced inwardly from the outer surface edges and being done with a suitable polymeric filament or thread, such as Dacron, being sewn through in an "X" pattern such that resilient stretching and compression can take place longitudinally along the spine, as in a bellows or accordion.

The core element may have reinforced elastomer secured to its peripheral side wall to contain that portion of the core. In forms of the core element which do not have separately attached wall reinforcement, the side wall surface may be flat, but preferably it should curve concavely from its upper surface to its lower surface to create a grooved side wall so that the edges of the wall extend beyond the innermost portion of the wall surface. The two outer or covering elements may be secured to this core element in a manner similar to that described above. Stitching, such as in an "X" pattern, may be spaced around the periphery but set back from the outer surface edges sufficiently so as to be inside the innermost portion of the curved side wall.

In those forms of the prosthesis which have only one covering element of open-pore fabric either on the upper or lower surface, the core element preferably should contain reinforcement, for example, fabric mesh. In this way, the single covering element, in addition to being made to adhere to the core element by vulcanization, may be more securely attached by stitching running through both the covering element and the core element. The surface not bearing a covering element should have a coating of elastomer of about at least 1 mm. thickness.

The covering of Dacron mesh or other open-pore fabric such as Dacron velour and Teflon mesh or velour, titanium wool, porous carbon or porous ceramic, is receptive to or invites tissue ingrowth, such as fibrous or bony ingrowth, and thus after emplacement in a spine abutting a pair of vertebrae is typically within 4 to 8 weeks, permanently affixed to the adjacent vertebrae by such ingrowth.

The outermost layer of the core element may be made from a reinforced metal screen capable of integration with the elastomer used and having stitches passing through its pores. Specially stiffened end plates may be desirable, at least in some instances.

One advantage of this invention is its provision of a preformed, shaped disc prosthesis or replacement which is sufficiently resilient to absorb most shocks to which a spine may normally be subjected, which has high compressive strength and high tensile strength, and which enables relatively normal flexing and twisting of the spinal structure. The prosthesis of this invention restores the proper spacing between vertebrae and thus helps to hold the spine in place, reducing or eliminating pressure on or constriction of the nerve channels. The maintenance of the intervertebral disc space by the prosthesis prevents degenerative changes about the facets and other posterior spinal elements.

The article is easily made sterile and is easily kept sterile for use. Another important advantage is that use of the prosthesis of this invention in lieu of fusion reduces the mechanical stress on adjacent discs during flexion.

The strengths of the components are quite satisfactory for the use to which the article is to be put. For instance, the tensile strength of silicone rubber is about 1000 p.s.i., and that of Dacron fiber about 20,000 p.s.i.; whereas cortical bone has a tensile strength ranging from about 10,000 to about 20,000 p.s.i., with about the same relative compressive strengths. The maximum compressive load to which a spinal disc is normally subjected has been found to be 350 p.s.i., although much higher loadings can be encountered under extraordinary circumstances. For example, it has been reported that loadings of 1000 p.s.i. can occur in catapult ejection of pilots of jet aircraft. Thus, it can be seen that the components each have strengths exceeding thosenormally or extraordinarily required in the spine. It appears that the prosthesis of this invention has a safety factor of 4 to 5 as related to normal compressive loading, e.g., 350 p.s.i.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention and one mode of carrying it out will be illustrated by the more specific description thereof below and by the annexed drawings, wherein:

FIG. 1 is a view in perspective of a spinal disc prosthesis embodying the principles of the present invention.

FIG. 2 is an exploded vertical cross-sectional view of the article taken on the line 2--2 of FIG. 1.

FIG. 3 is a top plan view, partially cut away to show side wall detail in section, and taken on the line 3--3 of FIG. 2.

FIG. 4 is a view in side elevation showing the article of this invention in place between two vertebrae.

FIG. 5 is a view in front elevation taken along the line 5--5 of FIG. 4.

FIG. 6 is a view in side elevation and in section of a modified form of central core having a viscous liquid interior.

FIG. 7 is a diagrammatic view showing how heavy compressive loading may be exerted against the postero r wall of a spinal disc.

FIG. 8 is a view in perspective of a modified form of central core with box sutures providing reinforcement to protect against the pressures illustrated in FIG. 7.

FIG. 9 is a view in perspective of another modified form of central core having a posterior reinforcement.

FIG. 10 is a diagrammatic view illustrating how the prosthesis of this invention reduces the mechanical stress on adjacent discs.

FIG. 11 is a top plan view, partly broken away and shown in section of a modified form of prosthetic disc embodying the principles of this invention.

FIG. 12 is a view in elevation taken along the line 12--12 in FIG. 11, and partly broken away and shown in section.

FIG. 13 is a view similar to FIG. 12 of a further modified form of prosthetic disc of this invention.

FIG. 14 is a top plan view of another modified form of prosthetic disc of the invention.

FIG. 15 is a view in elevation taken along the line 15--15 in FIG. 14, partly broken away and shown in section.
FIG. 16 is a view in elevation of another modified form of prosthetic disc embodying the principles of this invention.

FIG. 17 is a top plan view of the prosthetic of FIG. 16.

FIG. 18 is a view in vertical cross section of a stack of layers that may be used to make the core element of FIG. 16.

FIG. 19 is a view in side elevation showing what happens to the prosthetic disc of FIG. 16 when a bending moment is applied to its top and bottom surfaces.

FIG. 20 is an enlarged view in perspective of another modified form of prosthetic disc embodying the principles of the invention.

FIG. 21 is a top plan view of the prosthetic disc of FIG. 20.

FIG. 22 is a view in section taken along the line 22—22 in FIG. 21.

FIG. 23 is an enlarged view in perspective of yet another modified form of prosthetic disc embodying the principles of the invention.

FIG. 24 is a top plan view thereof, partially broken away and shown in section.

FIG. 25 is a view similar to FIG. 12 of still another modified form of prosthetic disc embodying the principles of the invention.

FIG. 26 is another view similar to FIG. 12 of yet another modified form of prosthetic disc embodying the principles of the invention.

DETAILED DESCRIPTION OF SOME PREFERRED FORMS OF THE INVENTION

The present invention will be described with reference to the accompanying drawings, which show some embodiments thereof, but it will be understood that these are illustrative only and are not intended to be limiting.

With reference to the drawings, an article or device according to this invention may include a central or core element 15, a top element 11, and a bottom element 12, the latter two being of substantially the same construction. In this embodiment a side wall 13 of the core 11 is preferably made of a plurality of layers of silicone elastomer. A very good such silastomer for this purpose is available in commerce under the trademark Silastic, made and sold by Dow Corning Corporation. Other compatible elastomers, such as polyurethane, may be used. Each layer 14 is preferably reinforced with a mesh of Dacron filaments, and suitably this wall 13 can be made by winding a suitable reinforced strip of such rubber several times around a shaped center portion 16 of the core 15, applying heat to vulcanize and weld the whole together. Other compatible material may be used. The central portion 16 may be of clear rubber of the same type or of a like type, reinforced or not, preferably cast into the proper shape, so that the wound strip automatically assumes the desired kidney or disc shape. Lest this shape be distorted under load, localized reinforcing techniques are available to limit deflection into sensitive areas, as will be described below in connection with FIGS. 7 to 9.

The top element 11 preferably comprises a bottom layer 17 of silicone elastomer, which may be of the same type as in the core 15, and this layer 17 is preferably unvulcanized at the time of assembly. Disposed above the bottom layer 17 is a central layer 18, which may also be silicone elastomer but in many instances is preferably a perforate reinforcing plate of metal or rigid plastic. Disposed above the central layer 18 is an upper layer 19 of silicone elastomer reinforced with a sheet of Dacron velour or similar fabric; preferably, this upper layer 19 is vulcanized before assembly. Above the layer 19 are one or more layers 20 of a suitable fabric, such as Dacron mesh, having an open porous weave to invite tissue ingrowth. A covering or coating 21 of like material, such as Dacron mesh, is folded across the top layer 20, preferably in pleats 22 and is thoroughly stitched by means of thread or filament 24, preferably also of Dacron, to the mesh layers 20 and to the velour in the layer 19. This covering 21 is brought down over a side wall or edge 25 of the element 11 and folded back partially over a surface 26 of the lower still unvulcanized layer 17, which, upon assembly, abuts an upper surface 27 of the core element 15. The folded-over edge 28 of the coating 21 is secured in place by running a filament, preferably also of Dacron, through it, drawing it up tightly as in a purse-string closure, and securing the ends of such filament. The lower element 12 may be and preferably is exactly like the upper element 11, except that its layers 17', 18', 19', 20' and 21' are in reverse order, so that the elements 11 and 12 form covering layers for the core 15, with the Dacron mesh coatings 21 and 21' facing outwardly in each instance, the inner face 26' of the as yet unvulcanized layer 17', abutting a lower face 30 of the core 15 and the face 26 of the as yet unvulcanized layer 17 of the upper element 11 abutting the upper face 27 of the core 15, as indicated above.

In completing the final article 10, after the elements 11, 15 and 12 have been assembled in that order, the article 10 is thoroughly stitched together through the fabric 21 at the sides and top by a filament 29 to join all parts firmly together, preferably using an X-pattern through stitch. Then the assembly is subjected to vulcanizing heat which acts to weld the surfaces 26 and 27 and 26' and 30, respectively, together, while the other unvulcanized layers are also vulcanized together and are also welded to adjacent surfaces.

The open-pore fabric coatings 21, 21' face outwardly, and when the article 10 is placed between two vertebrae 31, 31' as shown in FIGS. 4 and 5, the coatings 21, 21' abut the lower and upper faces 32 and 32', respectively, of the vertebrae 31 and 31'. The article 10 is of sufficient resilience and depth of pile to adapt itself to any small irregularities in the vertebral surfaces; also, the surgeon is at liberty to resect more bone, as required to clear an adequate cavity for the disc, and the prosthesis may be made intentionally oversized to facilitate such surgery. The prosthesis 10 acts to hold each vertebra in position and in proper alignment with respect to the spinal cord 33. After about four to eight weeks of immobility, firm fibrous tissue developed at the vertebral surface will have grown into surfaces 21, 21', interlocking the article 10 and the abutting vertebrae.

The preparation for the retroperitoneal surgery may be the same as in abdominal surgery. A retroperitoneal-anterior or anterior-lateral approach is used to expose the disc spaces. The great vessels and ureters are identified and protected. The anterior longitudinal ligament is incised transversely and opened like a door to expose the injured or degenerated disc. The disc, end plates, and adjacent bones are removed with a curette, chisel, rongeurs, or power drill. The bone is trimmed so that,
upon insertion of the prosthesis, the original spacing between vertebrae is restored. Temporary fixation devices, such as wire or plastic sutures may be set through the bone and prosthesis. The anterior longitudinal ligament and a portion of the annular ligament are then closed with sutures. The overlying fascia, soft tissue, and skin are closed. The patient is kept at bed rest for three weeks and then ambulated in a lumbo-sacral corset.

To summarize the functions of the prosthesis 10 and of its various elements:
1. The fabric coverings 21 and 21' provide tissue ingrowth surfaces.
2. The depth of the pile provided by the fabric layers 20, 21 and 20', 21' enable deeper ingrowth and also make the prosthetic disc 10 conformable to the cavity left by the excised disc.
3. The outermost silicone elastomer layers 19 and 19' preferably have as their outer surface the open-pore velour. These layers 19 and 19' serve a double purpose, for the velour adds to the depth of the pile that assists tissue ingrowth, and the silicone elastomer, having been vulcanized before assembly, inhibits the migration of raw silicone into the pile during the subsequent vulcanization of those silicone layers that have not been previously vulcanized.
4. The reinforcing ply 18 or 18' adds to the stiffness of the article 10 and may carry, when required, stiffer reinforcement such as a suitable screen wire, impregnated with the raw silicone elastomer that is to be vulcanized after assembly. This structure provides end plates that bridge across the softer cancellous bone and prevent the greater strength of the prosthesis 10 from adversely affecting the cancellous bone in each of the adjacent vertebrae.
5. The raw silicone elastomer layers 17 and 17' serve, when vulcanized after assembly, to bond the various components together into a unitary assembly. 6. The central portion 16 of the core 15 provides an elastomeric bulk for spacing the vertebrae to the original anatomical spacing.
7. The annular reinforced core side walls 13 resist the tendency of the disc 10 to become flattened under compressive loading.
8. The walls 13 are impregnated with silicone so that they resist tissue ingrowth, which would bind the prosthetic vertebral disc 10 and prevent the desired natural action.
9. The through-and-through X-pattern stitching 29 ties all the layers together and provides a strong, elastic, mechanical connection, to reinforce the chemical bond produced by vulcanization.

An important feature of the invention is that in some instances the core unit 15 itself, after vulcanization, is a complete prosthetic unit in itself, needing no units 11 or 12 for completion and omitting all of the tissue- ingrowth-promoting material. The unit 15 is then simply inserted between two intact natural end plates that, in this instance, are left attached to each of the two vertebrae between which the unit 15 is inserted.

Modifications of the core unit 15 are also significant.

FIG. 6 shows a core unit 15A having the same layers 13 as in the core 15, but these layers 13 enclose a sac-like container 40 of solid elastomer or other suitable material encasing a visco-elastic fluid polymer 41 such as another form of silicone. So long as the core 15A has a polymer that has resilience and is not too hard nor too liquid, the requirements are met, whether the core unit 15A comprises the complete prosthetic unit or is part of the more complex unit 10.

A common failure of the natural disc, due to heavy compressive loading, is through herniation of the posterior wall, the pressure being exerted as shown in the diagrammatic view of FIG. 7. This pressure may cause extrusion of the nucleus into painful contact with adjacent nerves. To prevent this type of failure, the prosthetic disc of this invention may have suitably reinforced posterior wall, as shown by way of example in FIGS. 8 and 9. Both of these show structures where the posterior wall 44 of the prosthetic disc is kept from deforming into a rounded shape, by ballooning according to the laws of thin-wall pressure vessels.

In FIG. 8 a core unit 15B is provided with a series of “box” sutures 45 of suitable material, such as Dacron. These sutures 45 hold the core 15B in its kidney-like shape and are assisted by the great resistance to posterior deflection already provided by the woven mesh and cloth incorporated in the end plates 11 and 12, where they are present, a bi-directional weave resisting deflection in the plane of the end plates.

In FIG. 9 the core 15C has its posterior wall 44 stiffened by a shape reinforcing member 46 of metal or strong rigid plastic.

An important advantage of the invention over the prior art is illustrated in FIG. 10. One side of this view shows a series of vertebrae 50, 51, 52, 53, in which the vertebrae 51 and 52 have been fused together, as by a prior art treatment, in which the disc was removed. As a result, the adjacent discs 54 and 55 have to flex considerably. The other side of FIG. 10 shows a series of vertebrae 60, 61, 62, 63, with the prosthetic disc 10 between the vertebrae 61 and 62. As a result the adjacent discs 64 and 65 have to flex considerably less to reproduce the equal amount of spinal flexion, the intervertebral distance X in the invention obviously being less than the corresponding distance Y in the prior art.

Further modifications of the core element 15, shown in FIGS. 11–15, are especially pertinent when core unit is used as a complete prosthetic element in itself.

The core element 15D of FIGS. 11 and 12 is shaped as a spinal disc, as are all forms of this invention. In it silicone or other suitable elastomer 70 is reinforced by a plurality of layers 71 of fabric. It may be a substantially flat laminated sandwich of silicone 70 and Dacron 71, with silicone covering all the exposed surfaces. There may be from two to twenty plies of Dacron.

The core element 15E of FIG. 13 has silicone elastomer 72 reinforced by randomly chopped fibers 73, which may be of Dacron.

The core element 15F of FIGS. 14 and 15 is made by spirally wrapping a strip 75 of Dacron covered with silicone elastomer 76, and again as in all instances the exposed surfaces are silicone, the fabric being fully covered.

Another modified form of the prosthetic spinal disc 80 is illustrated in FIGS. 16 to 19. It utilizes two outer covering elements 81 and 82 that are essentially the same as elements 11 and 12 of FIG. 2. However, its core member 83 may be a single piece of biocompatible elastomer molded into a suitable shape and preferably indented at its side surfaces, as by the concave surface 84. The core member 83 preferably has at least a portion of its interior reinforced with fabric, for exam-
ple, woven Dacron mesh, or with fibers, e.g., Dacron fiber. One method of forming the disc prosthesis 80 is to stack several layers of silicone elastomer, each essentially kidney-shaped but of varying overall length and width dimensions, as shown in FIG. 18. Preferably, the outer layers 90 and 91 and also in most cases the next-to-out layers 92 and 93, are of elastomer containing reinforcing mesh 94 to strengthen those portions of the finished core element 80 to which the top element 81 and lower element 82 are secured. Then the inner layers 95, 96, and 97, which are smaller in area then the layers 90 and 91, are of unreinforced elastomer, such as the same silicone elastomer, to enable better yielding. After the stack of FIG. 18 has been made, the outer elements 81 and 82 are placed on the top and bottom of the stack of silicone layers, and the assembly is placed in a suitable press mold and cured or vulcanized, typically at about 320°F. for an hour or more, at which time the outer elements 81, 82 and the layers 90 through 97 of the core have fused 93 to form a unitary member 83 with a smoothly-curved indented or concaved side surface 84. The various elements of the disc prosthesis may be further secured by stitching, preferably by X-stitches 86 near the peripheral edges of the outer elements 81 and 82 extending through the core 83.

As shown in FIG. 19, an uneven load or bending moment M applied to the core members 81 and 82, leaves the central portion 87 unaffected but compresses the prosthesis 80 at one side 88 while stretching it somewhat at the other side 89.

If desired, the core 83 may be made with its top and bottom surfaces parallel, or they may be molded to diverge so that in the finished prosthesis 80, the upper surface of 81 is inclined in one direction or another to the lower surface of 82, i.e., from front to back or back to front, not side to side. A modification of prosthetic member 10 can be used to accomplish essentially what prosthetic member 80 is designed to do; namely, to avoid tearing of tissue bonds at the edges of the prosthesis as a result of extreme flexing stresses. This modification may comprise substantially the same elements as those in prosthetic member 10 except that only one covering element 11 or 12 is secured to the core element 15. For example, FIG. 25 shows a prosthetic disc 98 which consists of the core member 15D of FIG. 12 in combination with the bottom element 12 of FIG. 2. It has no member corresponding to the top element 11. The laminations 70 of elastomer alternate with the laminations 71 of fabric to provide the reinforced core 15D with good strength and ability to withstand compression. The element 12 has the covering or coating 21 of tissue-ingrowth-receptive material 21', but the upper surface 99 of the disc 98 is an elastomeric surface that prevents tissue ingrowth there. Tissue ingrowth thus occurs only on one side of the prosthesis, so that during severe flexing of the spine following emplacement of this modified prosthetic member 98, there is no possibility of tearing at the junction between the ingrowth tissue and the open-pore fabric covering 21'. The prosthetic disc 98 nevertheless remains intact and cannot be displaced since it is secured by tissue growth to the vertebra on that one side.

FIG. 26 shows modified form of prosthetic disc 35, combining a core 15D like that of FIG. 12, a top element 11 like that of FIG. 2, and a lower element 36, which structurally is like the bottom element 12 but is much smaller in area and is confined to the central portion of the lower surface 37 of the core 15D. The lower surface 37 is elastomer and is not receptive to tissue ingrowth. The tissue-ingrowth attachment to the element 36 with its fabric covering 38 of Dacron or the like is not torn away during movement of the patient because it serves only as a central anchorage. The effect is similar to that in the prosthesis 98.

Whereas the foregoing specific embodiments of the spinal disc prosthesis of this invention are of a shape which requires that they be installed retroperitoneally, some surgeons prefer to use the posterior approach for repair of spinal discs. However, the area in the operative field available for inserting a prosthesis is necessarily confined to a space very little more than a square centimeter. Generally, most of the disc problems stem from the rupture of a portion of the posterior wall of the annulus fibrosus whereby the nucleus pulposus is allowed to extrude through the rupture site and press against nerve trunks thus causing pain. In those cases where it is advisable to maintain the natural disc space, current corrective measures include removal of the herniation, removal of the nucleus pulposus through the rupture site, and filling the intervertebral space with wedges of iliac bone. As has been mentioned earlier, the use of iliac bone wedges has an unacceptably high failure rate and other attendant problems.

Certain embodiments of the prosthesis of the present invention allow the surgeon to repair a damaged disc with a prosthesis which will maintain intervertebral spacing, resist compressive forces, and at the same time permit the surgeon to install it despite the limitation in space available to him in a posterior surgical approach to the spine.

One of the preferred embodiments is best shown in FIGS. 20-22 wherein a prosthetic member 100 comprises a flexible spirally-wound bar-like element 101 which can be made to extend into a long generally straight shaped object by unwinding, but it will recoil back into its originally spiral configuration on its own by virtue of its elastic memory created at the time the prosthesis is made. The overall appearance of the coiled structure generally is that of a more or less flat oval-shaped disc. The number of windings or coils which make up the complete prosthesis may be as few as one or it may have several coils, preferably about two or three. In the embodiment as illustrated in the drawings, it has two coils and a portion of a third coil. When viewed horizontally, the width of the coils generally vary, so that the coils when in contact with each other will form an oval-shaped member. For example, the width of the coil at position 102 is smaller than the width at position 103, the net result being that an object is created which has a minor and a major axis. The outside terminal end 104 of the prosthesis is generally tapered so that the coiled structure may assume a more or less smooth non-interrupted periphery at this portion of the prosthesis.

The bar-like element 101 of the coils comprises a core 105 of elastomeric polymer such as Silastic which is impregnated with reinforcement means 106 such as Dacron mesh. An outer coating 107, generally of the same material as the core, covers the core 105 completely. The top surface 108 has an open-pore tissue-ingrowth-receptive layer 109, which may be the same
material as the outer coating 107 or may be some other material such as fabric or metal mesh secured to the outer layer 107 and core 105 by vulcanization and by fabric stitches running through the reinforced core 105 and open-pore layer 109. Preferably, a core-stiffening member 110, which may be a hard plastic or metal piece, is embedded in the outer terminal portion of the prosthesis as shown by phantom lines in FIG. 21. This helps to prevent the prosthesis from bulging through the rupture site of the annulus fibrosis after the prosthesis has been installed. Substantially the entire length of the coiled core 105 may additionally be embedded in it a form-retaining member (not shown) such as a metal spring to assist the bar-like element in returning to the spiral configuration after it is released from an extended position. The bottom surface of the bar-like element 101 may also be covered with an open-pore material; although this is not critical in the proper functioning of the prosthesis. In addition, the side wall 111 of the outer terminal portion of the prosthesis may have an open-pore tissue-receptive surface to promote the growth of tissue and seal the rupture site in the posterior portion of the annulus fibrosis.

The prosthesis 100 may be made in a variety of sizes and shapes depending on which particular disc in the spine is to be repaired. Generally, they are roughly about one-fourth of an inch thick from top to bottom and the width at the widest point is not much more than three-eighths of an inch. Thus it is readily apparent that the unique spiral configuration of the prosthesis 100 allows it to be unwound into a smaller cross-sectional shape so that it can be introduced through a small aperture of a hollowed-out spinal disc, and then it will automatically rewind into a solid space-filling replacement of the resilient nucleus pulposus formerly contained in the disc.

Another alternative to the replacement of the nucleus pulposus is provided by a prosthetic disc 120 shown in FIGS. 23 and 24. The prosthetic disc 120 comprises two segments, 121 and 122, formed to fit together in a nesting arrangement so that together they may occupy the space created by removal of the nucleus pulposus from a spinal disc. Although only two members 121 and 122 are shown, the composite disc 120 may be formed by more than two segments of narrower width provided the combined widths of the nesting segments results in a composite structure which fills the space in a hallowed-out disc. Generally, the width of the widest portion of any segment should not be much greater than about three-eighths of an inch, and the thickness from top to bottom is roughly about one-fourth of an inch. Segments 121 and 122 need not be identical in shape or length, but the concave wall surface 123 of segment 121 and the convex wall surface 124 of segment 122 should have approximately the same degree of curvature. The walls 123 and 124 may be straight up and down, or they may have other configurations such as the wall 123 having a vertical concavity and the wall 124 having a vertical convexity so the two walls may fit snugly together.

The construction and materials used in the formation of the segments 121 and 122 are similar to that described for the bar-like element 101 of the prosthetic disc 100. A core 125 of elastomeric polymer is preferably reinforced as with fabric mesh 126, and the entire peripheral wall 127 surrounding the core 125 is a smooth coating of elastomeric polymer. The latter may also be reinforced internally as with fabric mesh. Preferably, only one surface, either the top or bottom, is coated or covered with an open-pore tissue-ingrowth receptive material 128. The covering of the material 128 is secured by vulcanization and/or stitching to the core 126. The core in either segment may additionally have rigidifying means, heretofore described, embedded within it.

Means for stabilizing the prosthesis may be incorporated as by one or more cords 129 extending from the segment 121. After the two segments 121 and 122 have been inserted into the space of a hollowed-out disc, the cords 29 on the segment 121 may be tied around the segment 122 so as to help maintain the two segments as a composite entity.

To repair a ruptured disc with either prosthesis 100 or 120, the procedure for the posterior approach to repair of the disc is followed. After the interlaminar space is exposed, laminectomy is performed to gain better access to the disc space and to provide an opening of approximately a square centimeter through which the nucleus pulposus will be removed and the prosthesis inserted. The spinal dura and nerve root are identified, the root is dissected free, and together these are retracted laterally to expose the herniation.

Dissecting through the posterior longitudinal ligament and annulus fibrosis at the rupture site, the loose fragments of nucleus and annulus are removed utilizing suction, forceps, and curette.

The disc space is carefully debrided, preserving the cartilaginous end plates and the annulus thus creating a space sufficient to accommodate either form of the prosthesis.

One should be taken that the end plate that will be adjacent to the ingrowth surface of the prosthesis is scraped clean of loose tissue and left with a bleeding surface to promote fixation of the prosthesis by tissue ingrowth.

The spiral prosthetic disc 100 is extended and inserted through the opening and allowed to coil upon itself thereby filling the void in the intervertebral disc.

Alternatively, if prosthesis 120 is used, the anterior segment 121 is inserted into the anterior disc space, followed by the posterior segment 122, care being taken that the two segments abut each other snugly and fill the space provided without stressing adjacent tissues. The two segments may be further stabilized by tying them together by cords 129 or by suturing to one of the adjacent vertebrae or other available tissue.

The wound is closed in layers insuring that proper hemostasis is obtained.

Thus, either prosthesis 100 or 120 prevents instabilty of the spine, maintains proper spacing between vertebrae, and minimizes mechanical bending loads on adjacent discs which was not possible heretofore with fusion procedures of the past.

To those skilled in the art to which this invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the spirit and scope of the invention. The disclosures and the description herein are purely illustrative and are not intended to be in any sense limiting.

We claim:

1. A resilient shaped prosthesis for replacement of a damaged or degenerated spinal disc, comprising:
a spinal-disc-shaped element having two generally flat faces, and
wherein said element is a laminated sandwich of horizontal shaped sheets of elastomer and horizontal shaped sheets of fabric-reinforced elastomer, all outer surfaces consisting of elastomer.

2. A resilient shaped prosthesis for replacement of a damaged or degenerated spinal disc, comprising: a spinal-disc-shaped element having two generally flat faces, and
wherein said element comprises a spirally-wound strip of fabric coated with and bonded by elastomer, all outer surfaces consisting of said elastomer.

3. A resilient shaped prosthesis for replacement of a damaged or degenerated spinal disc, comprising: a spinal-disc-shaped element having two generally flat faces, wherein said element is a laminated sandwich of horizontal shaped sheets of elastomer and horizontal shaped sheets of fabric, and said spinal-disc-shaped element has, affixed to one said face of said element, an outward-facing covering of tissue-ingrowth-receptive, open-pore material.

4. The prosthesis of claim 3 wherein said material is on both said faces.

5. The prosthesis of claim 4 wherein said element has a concave side wall surface cotermianous with an outer edge of said element at said faces and indented in between them.

6. A resilient, biocompatible, shaped prosthesis for replacement of a degenerated or damaged spinal disc including in combination: a spinal-disc-shaped core element having a central portion of viscoelastic fluid polymer encaised in a protecting and confining sac with two generally flat faces, a spinal-disc-shaped first closure element affixed to one said face of said core element, and a spinal-disc-shaped second closure element affixed to the other said face of said core element, each of said closure elements having a flat elastomeric portion resting against one said face, and an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, all of said elements being firmly affixed together.

7. A resilient, biocompatible, shaped prosthesis for replacement of a degenerated or damaged spinal disc including in combination: a spinal-disc-shaped core element having a central portion of unreinforced elastic polymer with two generally flat faces and a surrounding wall of reinforced polymer affixed to said central portion, a spinal-disc-shaped first outer element affixed to one said face of said core element, and a spinal-disc-shaped second outer element affixed to the other said face of said core element, each of said outer elements having a flat elastomeric portion resting against said one face, and an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, all of said elements being firmly affixed together.

8. The prosthesis of claim 7 wherein said reinforced surrounding wall is silicone elastomer reinforced with a mesh of fabric filaments.

9. The prosthesis of claim 8 wherein said surrounding wall has a posterior portion and additional means for rigidifying said posterior portion.

10. The prosthesis of claim 9 wherein said additional means comprises box sutures linking said posterior portion to opposite portions of said wall.

11. The prosthesis of claim 9 wherein said additional means comprises a rigid strip lying against the interior surface of said posterior portion.

12. The prosthesis of claim 7 wherein said surrounding wall is plurality of layers of silicone rubber, each layer being reinforced with Dacron mesh.

13. A resilient, biocompatible, shaped prosthesis for replacement of a degenerated or damaged spinal disc including in combination: a spinal-disc-shaped core element having a central portion of elastic polymer with two generally flat faces, a spinal-disc-shaped first outer element affixed to one said face of said core element, and a spinal-disc-shaped second outer element affixed to the other said face of said core element, each of said outer elements having a flat elastomeric portion resting against one said face and comprising a plurality of silicone rubber layers in stacked arrangement, and an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, all of said elements being firmly affixed together.

14. The prosthesis of claim 13 wherein a reinforcing metal screen is incorporated into one of said silicone rubber layers.

15. The prosthesis of claim 13 wherein the outermost said silicone rubber layer is provided with an outer surface of Dacron velour.

16. A resilient, shaped prosthesis for replacement of a degenerated or damaged spinal disc, comprising: a spinal-disc-shaped element having two generally flat faces and having a central portion consisting of elastic polymer compatible with body fluids and tissues, and a surrounding wall of reinforced elastomer affixed to said central portion.

17. The prosthesis of claim 16 wherein said polymer is a solid elastomer.

18. The prosthesis of claim 16 wherein said reinforced surrounding wall is of silicone elastomer reinforced with a mesh of fabric filaments.

19. A resilient, shaped prosthesis for replacement of a degenerated or damaged spinal disc, comprising: a spinal-disc-shaped element having two generally flat faces and having a central portion consisting of elastic polymer compatible with body fluids and tissues, and a surrounding wall of reinforced elastomer affixed to said central portion, and wherein said polymer is a visco-elastic fluid encaised in a protecting and confining sac.

20. A resilient, shaped prosthesis for replacement of a degenerated or damaged spinal disc, comprising: a spinal-disc-shaped element having two generally flat faces and having a central portion consisting of elastic polymer compatible with body fluids and tissues, and a surrounding wall of reinforced elastomer affixed to said central portion, and said reinforced surrounding wall being made of silicone elastomer reinforced with a mesh of fabric fil-
a posterior portion and additional means for rigidifying said posterior portion.

21. The prosthesis of claim 20 wherein said additional means comprises box sutures linking said posterior portion to opposite portions of said wall.

22. The prosthesis of claim 21 wherein said additional means comprises a rigid strip lying against the interior surface of said posterior portion.

23. A resilient, shaped prosthesis for replacement of a degenerated or damaged spinal disc, comprising:
   a spinal-disc-shaped element having two generally flat faces and having a central portion consisting of elastic polymer compatible with body fluids and tissues, and a surrounding wall of reinforced elastomer affixed to said central portion, and
   wherein said surrounding wall is a plurality of layers of silicone rubber, each layer being reinforced with Dacron mesh.

24. A resilient, shaped prosthesis for replacement of a damaged or a degenerated spinal disc including in combination:
   a spinal-disc-shaped core element having two generally flat faces, a central portion of silicone elastomer, initially unvulcanized, a spinal-disc-shaped first outer covering element affixed to one said face of said core element, and a spinal-disc-shaped second outer covering element affixed to the other said face of said core element, each of said covering elements having a stack of flat elastomeric layers, with an inner initially unvulcanized layer resting against one side face and an initially vulcanized outer layer, and an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, secured to said outer layer, all of said elements being firmly affixed together by vulcanization together after assembly of said initially unvulcanized elastomeric layers and portions.

25. The prosthesis of claim 24 wherein said core element has a surrounding wall of silicone elastomer reinforced with fabric and initially vulcanized.

26. The prosthesis of claim 25 wherein said surrounding wall has a posterior portion and additional means for rigidifying said posterior portion.

27. The prosthesis of claim 26 wherein said additional means comprises Dacron box sutures linking said surrounding wall.

28. The prosthesis of claim 26 wherein said additional means comprises a rigid strip lying against the interior surface of said posterior portion.

29. The prosthesis of claim 25 wherein said surrounding wall is a spirally-wound plurality of layers of silicone rubber, each layer being reinforced with Dacron mesh.

30. The prosthesis of claim 24 wherein a reinforcing metal screen is incorporated into a central, initially unvulcanized elastomeric layer between said outer layer and said inner layer.

31. The prosthesis of claim 24 wherein said outer elastomeric layer is provided with an outer surface of Dacron velour.

32. A resilient, biocompatible, shaped prosthesis for replacement of a degenerated or damaged spinal disc including in combination:
   a spinal-disc-shaped core element having a central portion of fabric-reinforced elastic polymer with two generally flat faces of said polymer, a spinal-disc shaped outer element coterminous in area with said core element affixed to one said face only of said core element and having an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, all of said elements being firmly affixed together.

33. A resilient, shaped prosthesis for replacement of a damaged or a degenerated spinal disc including in combination:
   a spinal-disc-shaped core element having first and second generally flat faces and comprising fabric-reinforced elastomer, said faces having outer surfaces of said elastomer, a spinal-disc-shaped first outer covering element coterminous in area with and affixed to said first face of said core element, and a much smaller spinal-disc-shaped second outer covering element affixed to the central portion only of said second face of said core element, each of said covering elements having an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, secured to said outer layer, all of said elements being firmly affixed together.

34. A resilient, shaped prosthesis for repair of a degenerated or damaged spinal disc, comprising:
   a spinal spina-disc-shaped member having two generally flat faces and comprising a specially-covered bar-like elastomeric element compatible with body fluids and tissues, capable of being unwound into a long generally straight form and inherently tending to recoil itself, upon release, into its spiral spinal-disc shape.

35. The prosthesis of claim 34 wherein said elastomeric member comprises fabric-reinforced elastomer.

36. The prosthesis of claim 34 having an outer covering of tissue-ingrowth-receptive material on at least one said face.

37. The prosthesis of claim 34 having a core-stiffening yielding member embedded in at least its outermost terminal portion to aid in preventing bulging.

38. A resilient, shaped prosthesis for repair of a damaged or a degenerated spinal disc including in combination:
   a generally spinal-disc-shaped assembly having two generally flat faces and comprising a plurality of curved segments arranged to nest in a horizontal manner when in place so as to provide said flat faces, each said segment being sufficiently narrow for installation through a narrow opening.

39. The prosthesis of claim 38 having an outward-facing covering of tissue-ingrowth-receptive, open-pore fabric, secured to one said face on each said segment.

40. A resilient, shaped prosthesis for replacement of a damaged or degenerated spinal disc, comprising:
   a spinal-disc-shaped element having two generally flat faces, wherein said element comprises a spirally-wound strip of fabric coated with and bonded by elastomer and said element has, affixed to one said flat face, an outward-facing covering of tissue-ingrowth-receptive open-pore fabric.

* * * * *
UNIVERS STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 3,867,728
DATED : February 25, 1975
INVENTOR(S) : James A. Stubstad, James R. Urbaniak, and Paul Kahn

It is certified that an error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Col. 1, line 36, "iliac" should read --iliac--.
Col. 3, line 52, "Such as prosthetic" should read --Such a prosthetic--.
Col. 8, line 24, "20°" should read --20'--.
Col. 11, line 66, "shows modified" should read --shows a further modified--.
Col. 15, line 49, which is line 1 of claim 7, "biocompatible" should read --biocompatible--.
Col. 16, line 11, which is line 2 of claim 12, "is plurality" should read --is a plurality--.
Col. 16, line 13, which is line 1 of claim 13, "biocompatible" should read --biocompatible--.
Col. 17, line 32, which is line 13 of claim 24, "one side face" should read --one said face--.
Col. 18, line 27, which is line 3 of claim 34, "spinal" should read --spinal--.

Signed and Sealed this second Day of September 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

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Commissioner of Patents and Trademarks