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(54) Title: IMPLANT FOR TOTAL DISC REPLACEMENT, AND METHOD OF FORMING

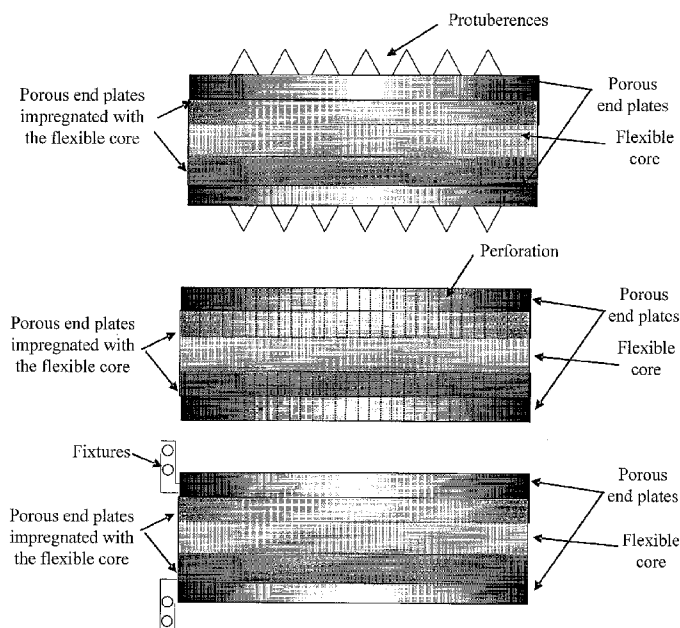


FIG. 4

(57) Abstract: An implant to replace damaged discs while preserving motion between adjacent vertebrae is composed of a flexible core and two porous end plates at the top and bottom of the implant. The porous end plates permit both osseointegration and binding of the flexible core by gross mechanical interlock. The bone integration properties and integration of the flexible core are provided by having pores of a distribution of sizes centered between 25 microns and 2 mm. The primary function of the porous end plates is to bond the flexible core to the vertebrae. The porous end plates are in close contact with the vertebrae to allow bone ingrowth. This provides an integration of the implant and less-constrained movement of the articulation compared to fusion or ball and socket articulations. This implant is simple to manufacture and assemble since it is only composed of a flexible core covered by porous end plates.



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IMPLANT FOR TOTAL DISC REPLACEMENT, AND METHOD OF FORMING

Field of the Invention

5 The invention relates in general to artificial intervertebral disc implants, and, in particular, to an implant having end plates made of a metal or ceramic foam and between the end plates a flexible material, the porosity of the end plates providing a mechanical interlock for both the flexible material and bone for osseointegration, to produce an artificial disc having flexibility, shock absorbing capability, better bonding and longevity, while having a small parts count and inexpensive production.

10

Background of the Invention

15 Implants have been used for many years for the treatment of musculoskeletal disorders, including arthritic disorders, joint replacements (hip, knee, shoulder, extremities), fractures, degenerative disc diseases, craniofacial reconstruction, teeth replacements, etc. Porous metallic coatings were developed in the late 1960's and early 70's to increase friction force between implants and surrounding bone to promote the initial and long term stability through bone ingrowth. These surfaces were initially proposed as a solution to problems encountered with methacrylate based bone cement used for orthopedic implant fixation. Welsh, Pilliar, Cameron, Bobyn and Gallante
20 worked on the initial development and validation of porous coating (titanium, stainless steel, CoCr) that laid the ground for their clinical acceptance in various applications such as hip, knee, and dental applications [1, 2].

25 Research has recently switched from thin porous bead coatings, sintered mesh and thermal sprayed rough coatings to metallic foams. For example, a process has been recently developed at the National Research Council Canada to produce metallic and ceramic foams [3]. The process allows for the production of foams with interconnected porosity. The process is simple and can be used to produce fully porous bodies or coatings on solid implants. The process has been used for the development of titanium, titanium oxide and glass foams for orthopedic and dental applications. Tests have
30 demonstrated the biocompatibility of titanium foams with different *in vitro* models [4, 5, 6]. Tests conducted with mouse macrophages, preosteoblasts and fibroblasts as well as human osteoblasts showed that the material is biocompatible and the large surface area

support cells proliferation. *In vivo* human alveolar bone cultures grown on porous Ti exhibited significantly increased cell and total protein content [6]. Besides, the biocompatibility has been demonstrated in different animal models (rat, rabbit, pig and dogs). Bone grows into the pores and can find its way throughout the thickness of the implants.

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Metallic foams have been used in the development of various treatments (i.e. bone augmentation, graft free vertebra fusion for the treatment of degenerative disk diseases for example). These materials have the advantage of being much more porous than the traditional porous coatings (i.e. sintered beads or mesh, plasma spray coating).
10 The high porosity provides more space for bone in-growth and interlocking, provides more contact surface between bone and the implant and lowers the elastic modulus of the implant to values much closer to those of bone. Levine recently reviewed some uses of metallic foams in joint replacement in Ref. [7] while Schiefer et al. presented the development of porous titanium for the production of dental implants in [8].

15 Besides orthopedic and dental implants, foams have been considered for bone reconstruction. Bone loss or poor bone quality can sometimes impede the use of traditional implants and bone graft procedures can be used to augment the osseous structure. However, the availability of a good graft material represents a problem. Current autograft procedures are invasive and represent significant morbidity. Few good
20 sources of harvesting sites are available and the amount, size and shapes of bone that can be extracted are usually rather limited. While bone graft from donors (e.g. allograft) can be an alternative, their availability, cost, storage and contamination with transmissible pathogens represent significant problems. Calcined bone from animal sources (i.e. xenograft) has been proposed to overcome some of these problems. However, their use
25 also raises ethical concerns and doubts about possible contamination with transmissible pathogens. Accordingly, there is an urgent need to develop a synthetic scaffold. Porous ceramics and bioactive glasses have been proposed as alternatives to auto, allo and xenografts.

30 Porous metal and ceramics have been used in spine surgeries, as taught, for example, by German application DE19858579. They have been used for vertebra fusion as an alternative to bone graft thus avoiding the need to do a graft harvesting procedure. Fusion type implants are different surgically, and conceptually from moving implants and moving implants are associated with different treatments than fusion devices. Fused implants restore the normal space between vertebrae and eliminate pain coming from
35 pinched nerves, but this solution does not, however, restore the motion or the absorption capability of the intervertebral disc.

Recently, different implants have been developed to restore the mobility of the vertebra. Some of the solutions proposed are based on the ball and bearing approach, similar to those used in joint replacement. These solutions usually limit the degree of motion by fixing a degree of rotation. In addition, this solution does not provide the absorption capability of a natural disc.

At the same time, synthetic materials have been developed to mimic the mechanical properties of intervertebral discs. The work has focused on the development of the flexible material. Artificial intervertebral discs were produced using different materials. One of the problems encountered with this approach is the integration and attachment of the flexible material to the adjacent vertebrae.

Flexible disc prostheses design has been previously proposed by [⁹,¹⁰]. The disc consisted of a hexane-based polyolefin rubber core vulcanized to two titanium endplates. The first example of these discs (Acroflex) disc consisted of a hexene-based polyolefin rubber core vulcanized to two titanium endplates. The endplates were coated with sintered 250 micron titanium beads on each surface to provide an increased surface area for bone ingrowth and adhesion of the rubber [¹¹]. However, the implant was not commercialized because a chemical used in the vulcanization process of the rubber (2-mercaptobenzothiazole) was reportedly potentially carcinogenic [¹²]. In addition, tear in the rubber at the junction of vulcanization was also reported due to poor bonding between the end plate and the rubber.

It is known in the art to use metal foams to provide good bone ingrowth of implants, for example, in US 5,571,190 to Ulrich et al. It is known in the art that a wide variety of implants are made better suited to bone ingrowth by using a porous metal foam instead of a solid metal. It is known to coat a metal plate with porous metal foam to improve the adhesion of the plate to bone. For example, Ulrich et al. states:

The implant body or its segments can be formed with throughgoing or blind bores forming part of the structuring described and as means to enable the groove of bone tissue into the implant body in situ. For similar reasons, the implant body or its segments can have a roughened surface to facilitate the growth of tissue into and onto the implant. In addition or alternatively, the implant body can be composed of a porous material, especially a porous metal foam.

There are a variety of artificial intervertebral discs commercially available and more have been proposed. It is known in the art to produce three-layer structured artificial intervertebral discs having solid plates (most often metal) sandwiching a spacer

in between, such as a thermoplastic roller, as is taught by Mitchell in US 2004/0138750 “to facilitate pivotal movement”. Such rigid ball type motion implants are known in the art, but these have several disadvantages over flexible core artificial intervertebral discs.

5 Flexible core artificial intervertebral discs have end plates like the implant taught by Mitchell, but have elastomeric material sandwiched between the end plates. The Bryan TM cervical disc¹³ is an example of this kind of implant. The Bryan cervical disc is an artificial cervical disc made up of two small shell-shaped titanium end pieces, two titanium wires, a plastic nucleus, containing a plastic center disc that is surrounded by a protective plastic sheath and two titanium seal plugs. The Bryan cervical disc has an
10 elastomeric material bonded to one side of the disc and a lubricated surface between an opposing end plate and an opposite side of the elastomeric material.

These discs are structurally somewhat more similar to that of a natural disc, but these artificial intervertebral discs are not without their problems. The nature of the materials used leads to very large material differences in mechanical properties between
15 the core vs. end plates. The load coupling between the hard endplate and the flexible core can be one problem. Delamination disbond of the core from the end plates is another concern. It is noted that a highly resilient device is needed. It is noted that a limited degree of porosity and surface roughness is provided for the Bryan cervical disc by applying a coating thereto. The Bryan cervical disc appears to use the protective
20 plastic sheath and two titanium seal plugs to retain the elastomeric material within between the end pieces, and this leads to various failure scenarios. It will be appreciated that the number of parts, leads to difficulty in assembly of the parts, increased cost, increased number of tests and failure points for such a device, and applies more constraints on the system.

25 In order to provide an artificial intervertebral disc that can safely be implanted and used under the variable conditions of the body, there are severe limitations on what kinds of bonding techniques are available for the implant. Some bonding systems that may be preferred for bonding the flexible core to the porous end plate may be expensive, and alternatives may not provide adequate bonding.

30 Furthermore, there are a wide variety of flexible core material systems known in the art that could advantageously be used. Encapsulated gels (especially as used in so called “hydraulic artificial intervertebral discs”), elastomeric flexible cores, and other composite core systems are known. It would be desirable to provide a mechanism for affixing a wide variety of these cores to an end plate.

Despite the fact that many years have passed since artificial intervertebral discs were first made and used, or that metal foams have been developed and proven, the mechanisms for bonding flexible core materials to end plates remain a problem. Adhesive-based fixing or external wrapping have disadvantages, and provide limited retention of the core and end plates, and also limited retention of bone. The artificial intervertebral discs are expensive to manufacture and there are few flexible cores used because of difficulties with adhering them to end plates.

Summary of the Invention

10 The present invention solves the noted problems observed with previous implants. A total disc replacement implant is provided that is flexible and restores the motion and the absorption capability of the natural disc. The implant is composed of a flexible core between two porous endplates. The end plates have an open pore structure with interconnected porosity that allows bone ingrowth, and implant stability. Finally, the porous end plate permits integration of the flexible core into the porous material on the other side of the endplate, thus providing a good bonding and reducing the risk of failure at the interface between the core and the endplates. Applicant proposes the use of porous metal/ceramic foam end plates to allow the infusion of the flexible core on one side and bone on the other. The integration of the flexible core into the structure of the porous end plates assures a good adhesion bonding between the end plates and the flexible core (compared to solid plates) and bone integration allows a good cohesion between the implant and the adjacent vertebrae. The dual use of the porosity permits better fixation of the core by gross mechanical interlocking of the flexible core and the end plate, while providing improved stress transfer across the interface.

25 The known advantages of the metal/ceramic foam for osseointegration are achieved. The high porosity of the metal/ceramic foam permits the end plates to act as fusion media between the vertebrae and the flexible core and help transferring the loads from the vertebra to the flexible core. For example, in certain situations, the porosity of the end plates may obviate the need for bone grafting, and the porous end plates may be impregnated with growth factor, or other medicinal compounds etc.

Another significant benefit of the present technique is the simplicity and reduced costs of manufacture.

In accordance with the present invention an implant for total disc replacement is provided. The implant includes two porous end plates formed of a metallic or ceramic

foam or any other fully porous open pore material that is: biocompatible, has adequate corrosion resistance, and mechanical properties to sustain the stresses between adjacent vertebrae. The end plates are stacked to sandwich a flexible core such that each end plate has a bone-facing surface facing away from the core, generally opposite a
5 respective core-facing surface. A resilient flexible core material is embedded into both of the end plates at the opposing core-facing surfaces, so that the porous end plates are partially impregnated with the flexible core to provide a good bonding between the porous end plates and the flexible core.

A maximum width and length is preferably similar to, or smaller than, that of a
10 healthy natural disc or nuclei to be replaced. A shape and volume of the implant may mimic that of the natural disc or nuclei. A maximum thickness of the implant may be between 5 and 20 mm; or between 8 and 15 mm.

The porous end plates may be composed of a porous metal, alloy, ceramic and/or
15 a mixture thereof. For example, a titanium foam, a tantalum foam, a nitinol foam (TiNi or NiTi), a stainless steel, or a CoCr foam may be used. Ceramic or other inorganic foams such as bioglass, calcium phosphate, hydroxyapatite, titanium oxide or other ceramics used or considered in orthopedic applications may be used. Furthermore the porous end plates may be composed of a rigid polymer.

The porous end plates may have a pore size distribution with a substantial fraction
20 of the pores between 25 and 2000 microns, or more preferably between 30 and 500 microns such that the end plates are permeable to bone and the flexible core material alike. The porous end plates may be perforated or have fixtures or texture to promote stability, and may be coated, impregnated, or otherwise contain a pharmaceutical agent, biological composition, bone graft, or growth factor to help healing or promote cell growth
25 into the structure. The fixtures may be resorbable.

The flexible core material may be a polymer, an elastomer, a gel, or a composite
structure composed of materials having different stiffnesses, and may be a biocompatible flexible material. For example, silicone, polyurethane, copolymer of silicone and polyurethane, polyolefins, polyisobutylene rubber, polyisoprene rubber, nitrile rubber,
30 neoprene rubber, polyolefin rubber, vulcanized rubber or any other flexible polymer that is biocompatible and able to sustain the load and environment observed between vertebrae may be chosen. The core material may be a composite structure, for example, composed of a central portion having properties that mimic the properties and/or functions of the nucleus and an annular portion that reproduces the function or properties
35 on the annulus. The core material may be a composite structure including at least one spring integrated in the flexible core to mimic the stiffness of natural disc

A method for assembling an implant for total disc replacement is provided. The method involves providing two porous end plates formed of a metallic or ceramic foam or any other fully porous open pore material that is biocompatible, has adequate corrosion resistance and mechanical properties to sustain the stresses between adjacent vertebrae, and infusing a resilient flexible core material into both of the end plates at opposing core-facing surfaces of the end plates, so that the porous end plates are partially impregnated with the flexible core to provide a good bonding between the porous end plates and the flexible core.

Further features of the invention will be described or will become apparent in the course of the following detailed description.

Brief Description of the Drawings

In order that the invention may be more clearly understood, embodiments thereof will now be described in detail by way of example, with reference to the accompanying drawings, in which:

FIG. 1 is a schematic illustration of an implant in accordance with an embodiment of the invention;

FIG. 2 is a schematic illustration of placement of the implant of FIG. 1;

FIG. 3 is a schematic illustration of motion of an implant of FIG. 1;

FIG. 4 is a schematic illustration of alternative embodiments of the invention that incorporate features that may be used to improve bonding to the surrounding bone;

FIG. 5 is a schematic illustration of an alternative embodiment of the invention featuring a two-part composite core having materials of different stiffnesses;

FIG. 6 is a schematic illustration of an alternative embodiment of the invention featuring a two-part composite core consisting of a matrix and fill; and

FIG. 7 is a photograph of a model implant for total disc replacement, and shows three positions of the model between modeled vertebrae.

Description of Preferred Embodiments

A flexible implant of simplified construction and improved durability is provided by infusing a flexible core material into two porous metal or ceramic end plates, providing a mobility zone between the end plates.

FIG. 1 is a schematic illustration of an embodiment of the invention, from a materials perspective. The implant has two opposing end plates 2 between a flexible core 1. Each end plate 2 is composed of a porous metal/ceramic foam. A substantial number of the pores of the foam have minimum dimensions of about 25 microns to 2 millimeters, more preferably 25 microns to 1 mm more preferably 30 to 500 microns, to facilitate ingrowth of bone, to form a fused interlock when implanted, and to permit a mechanical interlock for the flexible core. At a region 3 the porous end plates are infused with the flexible core material. This provides for stress distribution throughout the volume of the end plates 2 that would otherwise be focused on the surface between the core 1 and end plate 2. An enlarged section of the image shows the flexible material of the core 1 infused in the open porosity network 4 of the end plates 2, that is not visible in the whole view.

A shape and thickness of the end plates, and porosity can be chosen to provide a desired mechanical properties of the end plates. Also an alloy of the metal can provide for independent variation of the mechanical properties without varying the porosity. The end plates may be thick enough to permit a desired thickness for integration with the flexible material while providing a desired space for osseointegration. Typically, the thickness of the implant should range between 5 and 20 mm, but is preferably between 8 and 15 mm. The maximum width and length should generally be smaller than those of a natural disc or nuclei. The end plates can also be modular (i.e. made out of smaller plates or segments) to better adapt the surface of the vertebrae.

The porous end plates are preferably made of a ceramic, or more preferably a metallic foam such as a titanium foam, a tantalum foam, a nitinol foam (TiNi or NiTi), a CoCr foam, a stainless steel foam, or any other fully porous metal that is biocompatible, has good corrosion resistance, and the mechanical properties to sustain the stresses observed between adjacent vertebrae. Nitinols are known as shape memory metals, and may be preferable along with other materials that have superelastic properties. The end plates 2 can be composed of ceramic or other inorganic foam such as bioglass, calcium

phosphate, hydroxyapatite, titanium oxide or other ceramics used or considered in orthopedic applications.

5 The endplates can be textured or have additional perforations or protruberences to increase the adhesion with the flexible core and bone, and to provide higher shearing friction against bone.

10 A mobility zone provided between the opposing end plates, contains the flexible core material 1. The end plates can partially or fully cover the surface of the flexible core. The material of the flexible core should be biocompatible and have sufficient mechanical properties to support the load between the vertebrae, even in the most extreme cases. The flexible core materials selected should also withstand the intervertebra environment without deterioration or corrosion.

15 The flexible core can be produced with biocompatible flexible materials. The flexible material can be selected from silicone, polyurethane, copolymer of silicone and polyurethane, polyolefins, polyisobutylene rubber, polyisoprene rubber, nitrile rubber, neoprene rubber, polyolefin rubber, vulcanized rubber or any other flexible polymer that is biocompatible and able to sustain the load and environment observed between vertebrae. The flexible material can also be a gel. The properties of the flexible core must be stable after many cycles of loading and the material must not denature, crumble, or leak harmful fluids or absorb fluids in undesired amounts.

20 The implant geometry in FIG. 1 is schematic, as in fact the implant may have a variety of shapes. For example, the shape may be selected to occupy a space previously occupied by an undamaged natural disc or nuclei. The geometry of the implant can mimic the geometry of the natural disc or nuclei, in static support over a wide range of positions, and also the dynamic support provided during motion, by selection of the core material. The ability to bond a wide variety of materials to the end plates is instrumental in making this possible. Furthermore the geometry may not be designed to resemble or occupy the space of an undamaged natural disc, but may have a different form if it provides better performance, eases manufacturing and/or the surgeries.

30 Assembly of such an implant is preferably made from metallic/ceramic foam parts, machined to size, or molded to size. The flexible core material is introduced in a flowable form, having a viscosity suitable for entry into the porosity network of the end plates. The material may solidify, cure, or become more viscous, and is resistant enough to retain the end plates in place.

FIG. 2 schematically illustrates bone growth within an implant, and a location for the implant. Surgical operations for implanting artificial disks are well known in the art. The mobility zone, unlike ball joints or other mechanical joints, permit limited motion with 6 degrees of freedom. By controlling a shape, and dimensions of the mobility zone, different degrees of motion in the respective dimensions can be favored or limited. By providing more core material in two dimensions and less in the third, as shown, a high resistance to shearing motions across the end plates is provided to limit motion in these directions.

FIG. 3 schematically illustrates the typical motions of the implant. The structure provided with the porous end plates with the flexible core is known to better mimic the natural motion of discs. Unfortunately other structures of this kind are known to be more expensive to produce, and/or have problems at the interface between the end plates and core. Such problems include partial slippage or complete delamination. Alternatively expensive machining procedures for patterning surfaces to provide a desired mechanical interlock can be made. Advantageously the porous end plates being made of a foam or foam-like high porosity material naturally possess the desired surfaces for mating with bone or with a variety of elastomeric or rubbery materials.

FIG. 4 schematically illustrates a variety of embodiments that incorporate features that may be used to improve bonding to the surrounding bone. The end plates can have gross surface features such as textures, or additional perforations (second figure), or protuberances (first figure) to increase the adhesion with the flexible core and bone. The third figure shows additional fixtures for the implant. Naturally other additional features could be used. The protuberances or fixtures may be resorbable and therefore temporary.

The mobility zone does not necessarily have to be monolithic. There can be differentiated regions. For example a core can be wrapped in a sheath material. The material does not have to be isotropic, in particular cylindrical, radial or helical arrangements may be preferred for certain embodiments. The medium could have graduated density or other properties as a function of distance from the end plates, or a central axis of the core material.

FIG. 5 schematically illustrates a two-part flexible core consisting of first and second materials, the first material effectively radially surrounding the second. This provides an option for controlling certain motions to certain degrees. This embodiment provides a closer model of a natural disc, which includes an annulus surrounding a nucleus.

FIG. 6 schematically illustrates a two-part flexible core consisting of a matrix and fill. Structuring of the matrix can permit control and limit of the motion between the end plates. This may be an effective means for modifying the properties of the flexible material.

5 It will be appreciated that springs or other structural elements may be included in the flexible core, as will be appreciated by those of skill in the art.

Examples

10 An exemplary implant illustrating the concept is photographed in FIG. 7 (top). The implant was produced with two titanium foam end plates produced with the process described in the patent [¹⁴]. Industrial silicone was the material used for the flexible core. The porous end plates were partially impregnated into the porous structure of the titanium foam. The impregnation was done by placing a first titanium foam disc in a mold of the same diameter as the disc, applying a thick layer of the silicone, covering the
15 silicone with the second end plate in the same manner, and applying a pressure in such a way that the silicon was partially impregnated with the silicon. The pressure was applied by hand for a few seconds. Both the top and bottom surface of the implant present porous titanium surface not filled with the flexible core in such a way that space is available for bone ingrowth.

20 The resulting implant is flexible. As shown in FIG. 7 [bottom] two artificial vertebrae coupled with the model implant is subject to stresses and deforms according to various states of flexure in a manner that is realistic.

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Other advantages that are inherent to the structure are obvious to one skilled in the art. The embodiments are described herein illustratively and are not meant to limit the scope of the invention as claimed. Variations of the foregoing embodiments will be evident to a person of ordinary skill and are intended by the inventor to be encompassed by the following claims.

Claims:

1. A implant for total disc replacement comprising:
 - two porous end plates formed of an open pore material that is biocompatible, has adequate corrosion resistance and mechanical properties to sustain the stresses between adjacent vertebrae, the end plates being stacked to sandwich a flexible core such that each end plate has a bone-facing surface facing away from the core, generally opposite a respective core-facing surface; and
 - a resilient flexible core material embedded into both of the end plates at the opposing core-facing surfaces, so that the porous end plates are partially impregnated with the flexible core to provide a good bonding between the porous end plates and the flexible core.
2. The implant of 1 wherein:
 - a maximum width and length is similar to, or smaller than, that of a healthy natural disc or nuclei to be replaced;
 - a shape and volume of the implant mimics that of the natural disc or nuclei;
 - a maximum thickness of the implant is between 5 and 20 mm; or
 - a maximum thickness of the implant is between 8 and 15 mm.
3. The implant of 1 wherein the porous end plates are composed of a porous metal, alloy, ceramic and/or a mixture thereof.
4. The implant of 1 wherein the porous end plates are composed of a titanium or titanium alloy, a tantalum or tantalum alloy, a shape memory or superelastic material such as nitinol (TiNi or NiTi) or similar alloys, a stainless steel, a CoCr based alloy.
5. The implant of 1 wherein the porous end plates can be produced with ceramic or other inorganic foam such as bioglass, calcium phosphate, hydroxyapatite, titanium oxide or other ceramics used or considered in orthopedic applications.
6. The implant of 1 wherein the porous end plates have a pore size distribution with a substantial fraction of the pores between 25 and 2000 microns, such that the end plates are permeable to bone and the flexible core material alike.
7. The implant of 1 wherein the porous end plates have a pore size distribution with a substantial fraction of the pores between 50 and 500 microns, such that the end plates are permeable to bone and the flexible core material alike.

8. The implant of 1 wherein the porous end plates are perforated to increase permeability.
9. The implant of 1 wherein the bone facing surface of the porous end plates are coated, impregnated, or otherwise contain a pharmaceutical agent, biological composition, bone graft, or growth factor to help healing or promote cell growth into the structure.
10. The implant of 1 wherein the porous end plates are textured to provide the initial stability of the implant.
11. The implant of 1 wherein the porous end plates have fixtures to help the fixation of the implant and provide initial stability.
12. The implant of 11 wherein the fixtures are resorbable.
13. The implant of 1 wherein the flexible core material is a polymer, an elastomer, a gel, or a composite structure composed of materials having different stiffnesses.
14. The implant of 1 wherein the flexible core material is a biocompatible flexible material.
15. The implant of 1 wherein the flexible material is selected from silicone, polyurethane, copolymer of silicone and polyurethane, polyolefins, polyisobutylene rubber, polyisoprene rubber, nitrile rubber, neoprene rubber, polyolefin rubber, vulcanized rubber or any other flexible polymer that is biocompatible and able to sustain the load and environment observed between vertebrae.
16. The implant of 13 wherein the composite structure is composed of a central portion having properties that mimic the properties and/or functions of the nucleus and an annular portion that reproduces the function or properties on the annulus.
17. The implant of 13 wherein the composite structure is composed of at least one spring integrated in the flexible core to mimic the stiffness of natural disc.
18. A method for assembling an implant for total disc replacement, the method comprising:
providing two porous end plates formed of an open pore material that is biocompatible, has adequate corrosion resistance and mechanical properties to sustain the stresses between adjacent vertebrae; and
infusing a resilient flexible core material into both of the end plates at opposing core-facing surfaces of the end plates, so that the porous end plates are

partially impregnated with the flexible core to provide a good bonding between the porous end plates and the flexible core.

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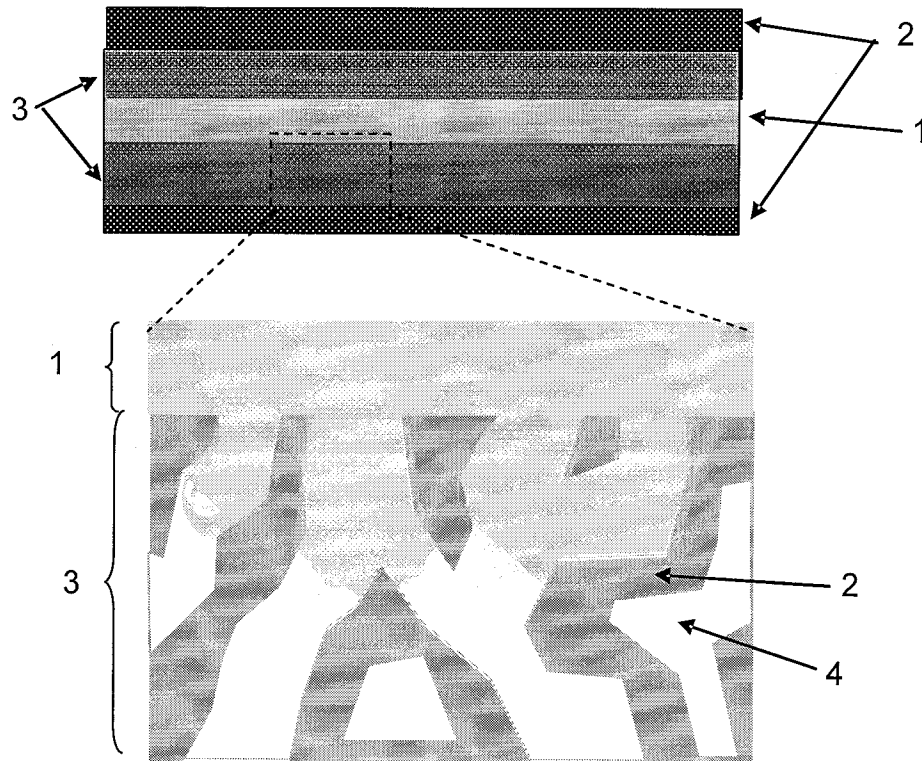


FIG. 1

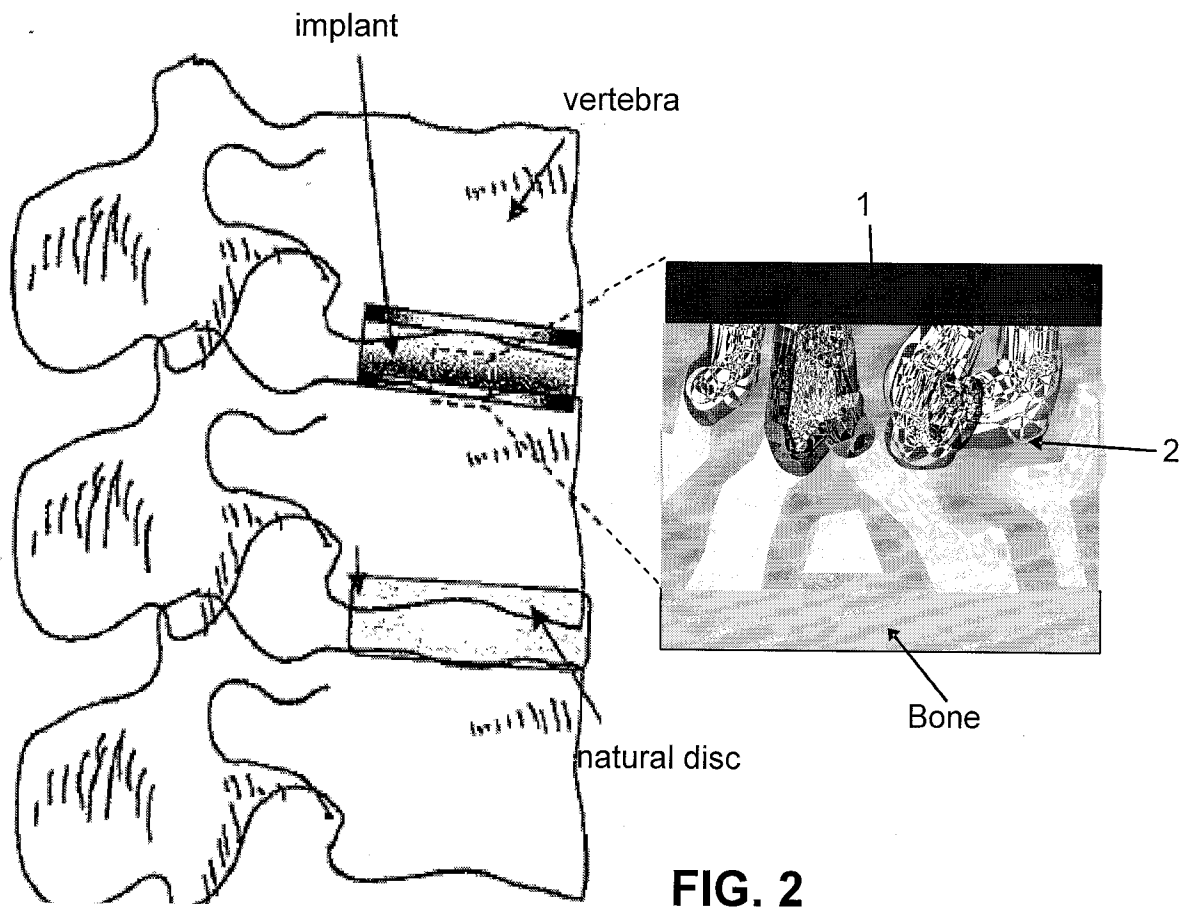


FIG. 2

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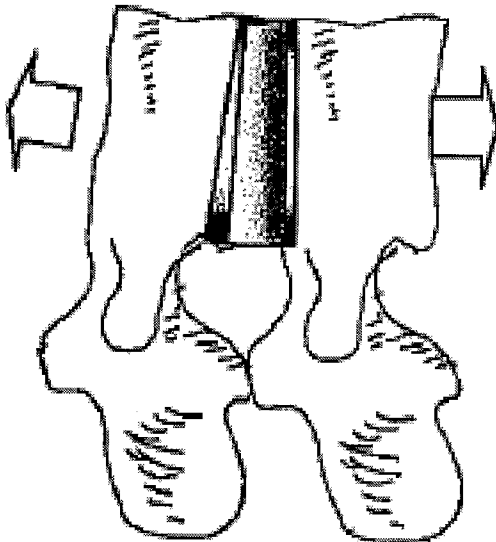
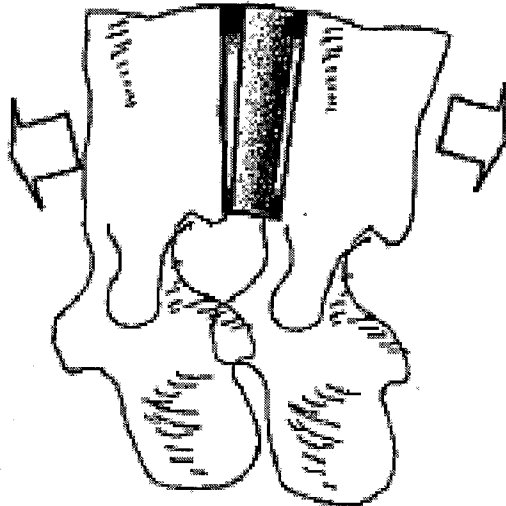
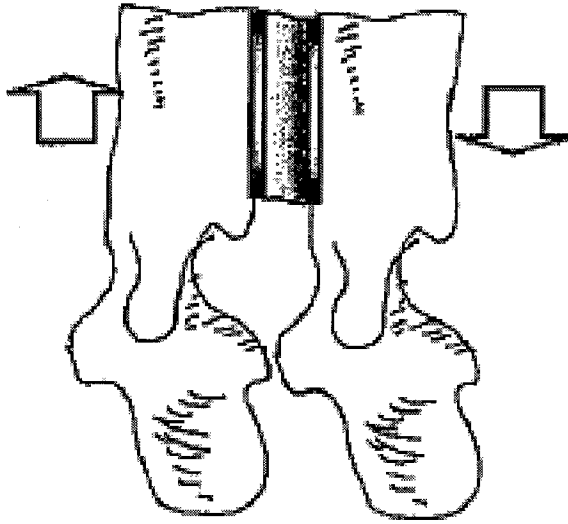


FIG. 3

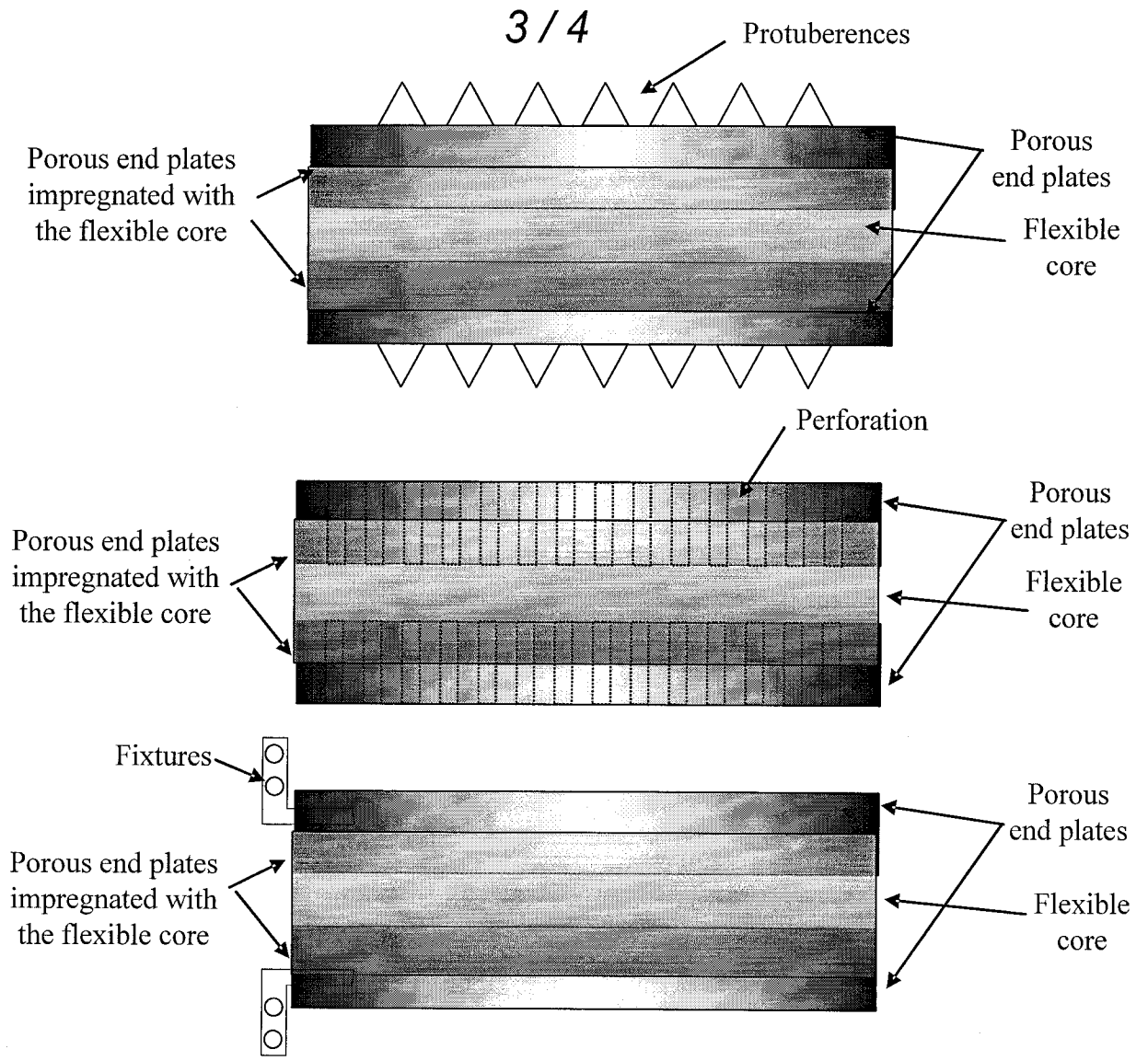


FIG. 4

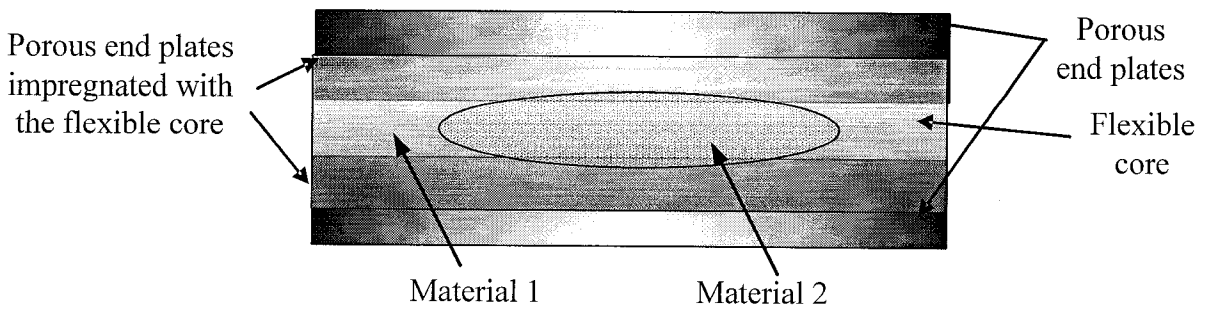


FIG. 5

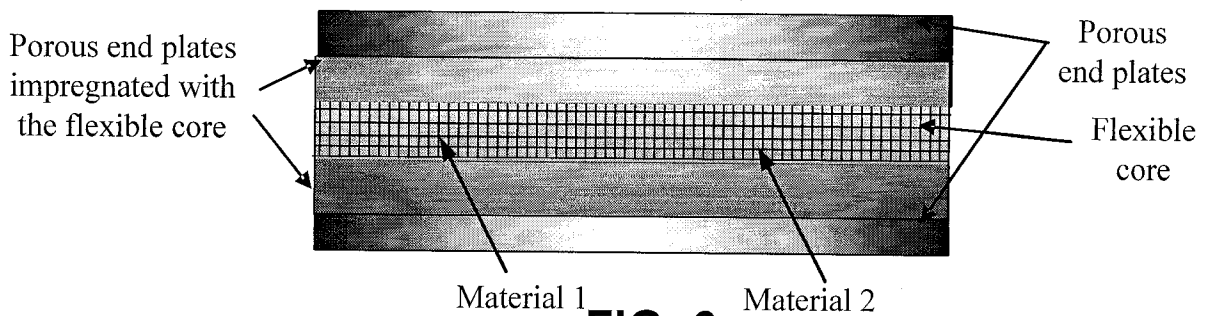


FIG. 6

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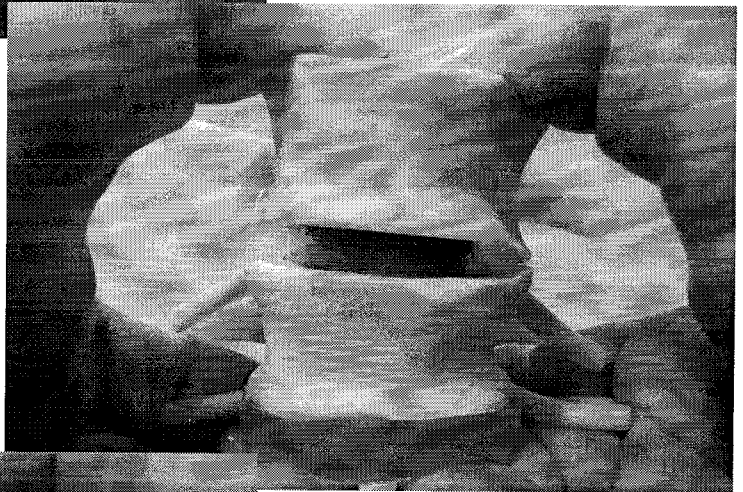
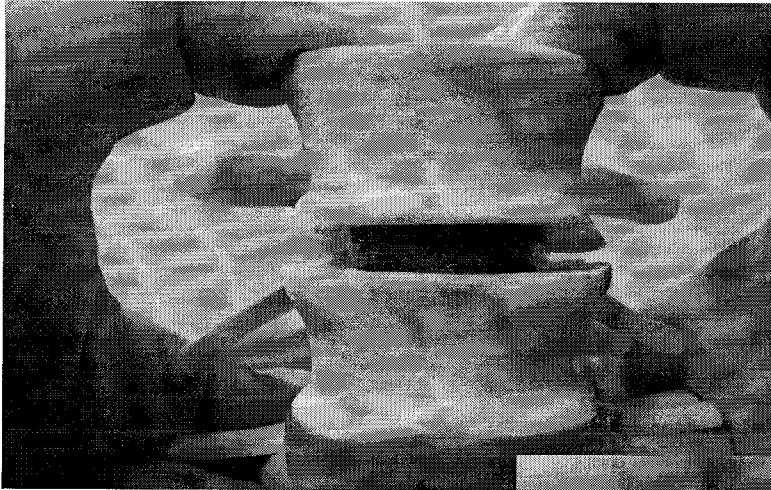


FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2010/000148

<p>A. CLASSIFICATION OF SUBJECT MATTER IPC: <i>A61F 2/44</i> (2006.01) , <i>A61L 27/02</i> (2006.01) , <i>A61L 27/14</i> (2006.01) , <i>A61L 27/54</i> (2006.01) , <i>A61L 27/56</i> (2006.01) , <i>A61L 27/58</i> (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC</p>		
<p>B. FIELDS SEARCHED</p>		
<p>Minimum documentation searched (classification system followed by classification symbols) IPC :A61F 2/44 (2006.01), A61L 27/2,14,54-58 US Cl.: 623/17</p>		
<p>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched</p>		
<p>Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used) EPOQUE, Delphion, Espacenet, Canadian Patent Database: -keywords: intervertebral, disc, endplates, core, porous, impregnate, infuse, bonding</p>		
<p>C. DOCUMENTS CONSIDERED TO BE RELEVANT</p>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US5071437 (STEFFEE) 10-December-1991 (10-12-1991)	1-16, 18
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X	US5458643 (OKA et al.) 17-October-1995 (17-10-1995) Entire document	1, 18
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A	US5545229 (PARSON et al.) 13-August-1996 (13-08-1996)	1
A	US5961554 (JANSON et al.) 05-October-1999 (05-10-1999)	1
A	US5986169 (GJUNTER) 16-November-1999 (16-11-1999)	1
A	FR2865128 (VENTIMIGLIA) 22-July-2005 (22-07-2005)	1
<p><input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.</p>		
<p>* Special categories of cited documents :</p>		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	
<p>Date of the actual completion of the international search 30 March 2010 (30-03-2010)</p>		<p>Date of mailing of the international search report 16 April 2010 (16-04-2010)</p>
<p>Name and mailing address of the ISA/CA Canadian Intellectual Property Office Place du Portage I, C114 - 1st Floor, Box PCT 50 Victoria Street Gatineau, Quebec K1A 0C9 Facsimile No.: 001-819-953-2476</p>		<p>Authorized officer Hoan Huynh (819) 934-3467</p>

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Information on patent family members

International application No.
PCT/CA2010/000148

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