



US 20070299524A1

(19) **United States**

(12) **Patent Application Publication**
Rivin

(10) **Pub. No.: US 2007/0299524 A1**

(43) **Pub. Date: Dec. 27, 2007**

(54) **ARTIFICIAL INTERVERTEBRAL DISC**

(60) Provisional application No. 60/535,741, filed on Jan. 13, 2004.

(76) Inventor: **Evgeny Rivin**, West Bloomfield, MI
(US)

Publication Classification

Correspondence Address:

**GIFFORD, KRASS, SPRINKLE, ANDERSON &
CITKOWSKI, P.C**
PO BOX 7021
TROY, MI 48007-7021 (US)

(51) **Int. Cl.**

A61F 2/44 (2006.01)

(52) **U.S. Cl.** **623/17.13; 623/17.14; 623/17.15;
623/17.16**

(21) Appl. No.: **11/759,609**

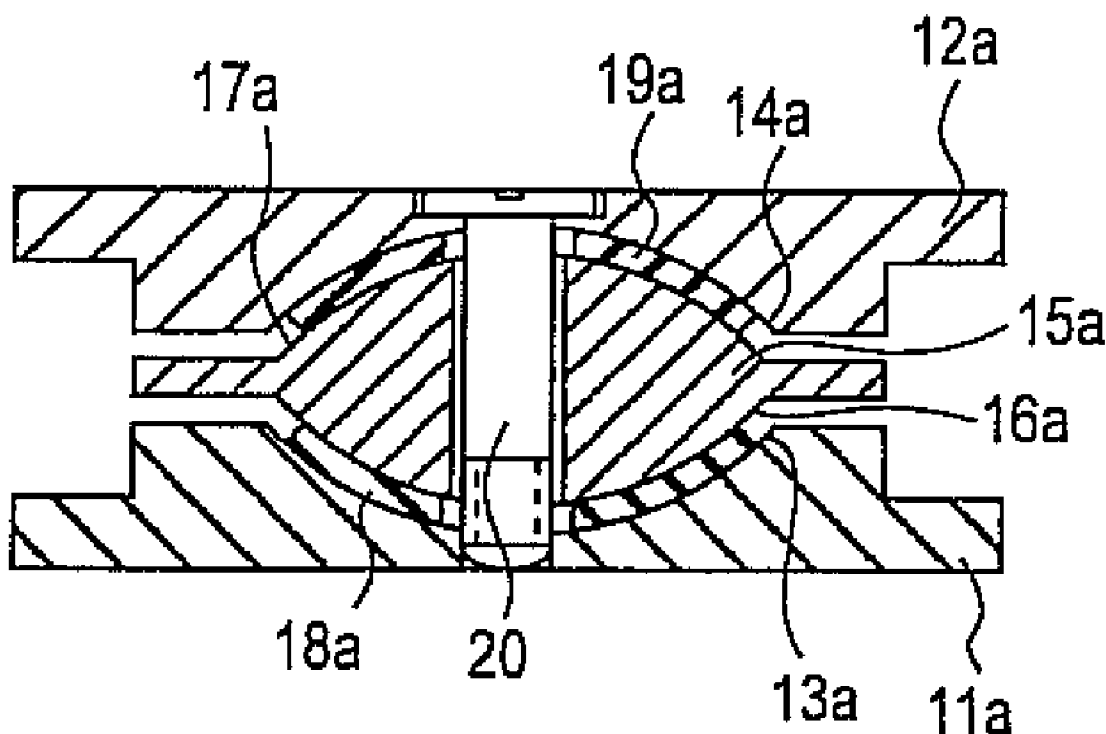
(57) **ABSTRACT**

(22) Filed: **Jun. 7, 2007**

Related U.S. Application Data

(62) Division of application No. 11/037,629, filed on Jan. 12, 2005, now Pat. No. 7,235,103.

The instant invention proposes an artificial intervertebral disc providing for angular displacements between adjacent vertebrae wherein these displacements are accommodated by internal shear in an elastomeric layered element residing between the upper and lower bases attached, respectively, to the upper and lower adjacent vertebrae, without sliding.



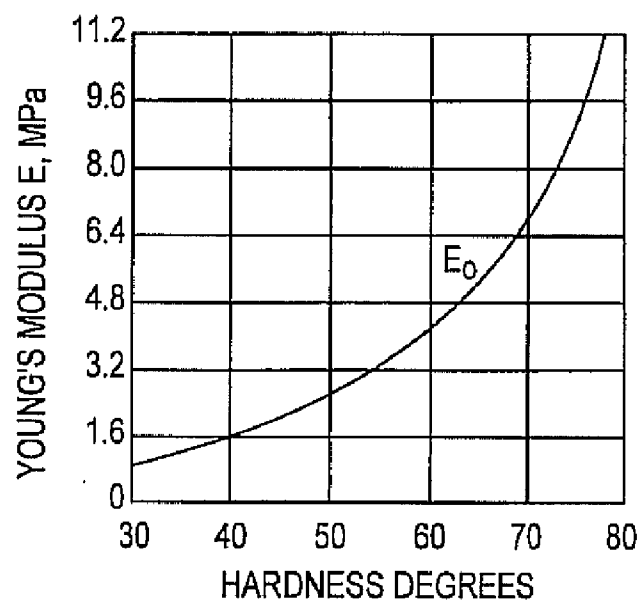


FIG. 1

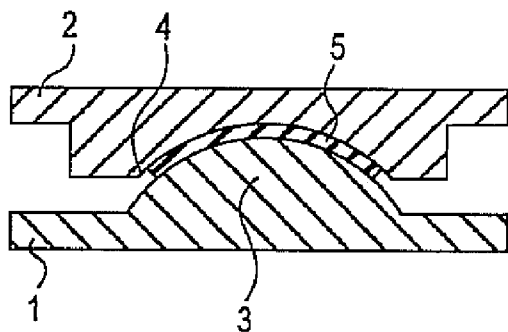


FIG. 2

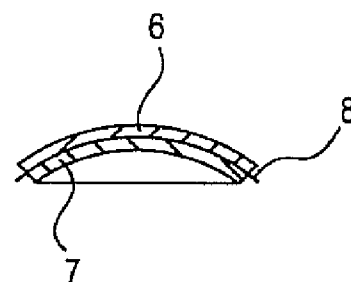


FIG. 3

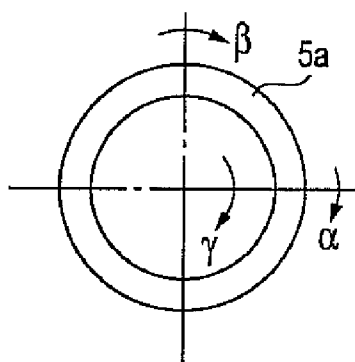


FIG. 4

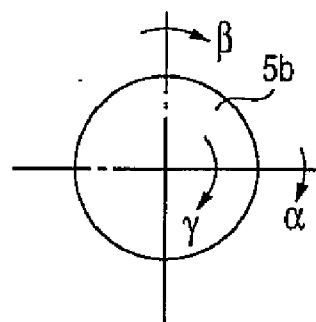


FIG. 5

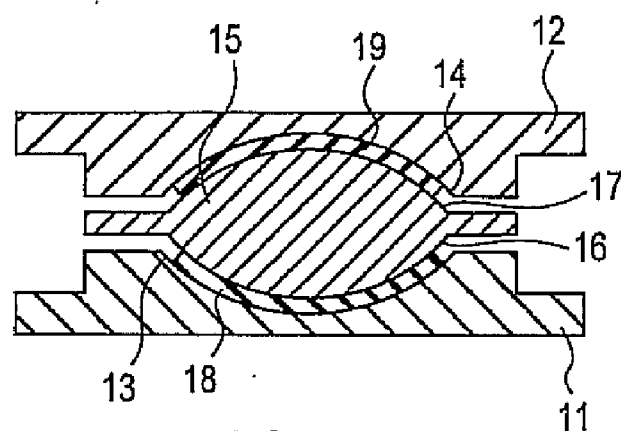


FIG. 6

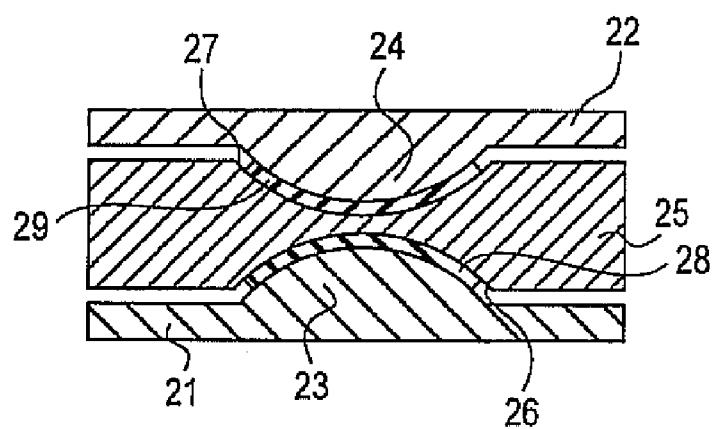


FIG. 7

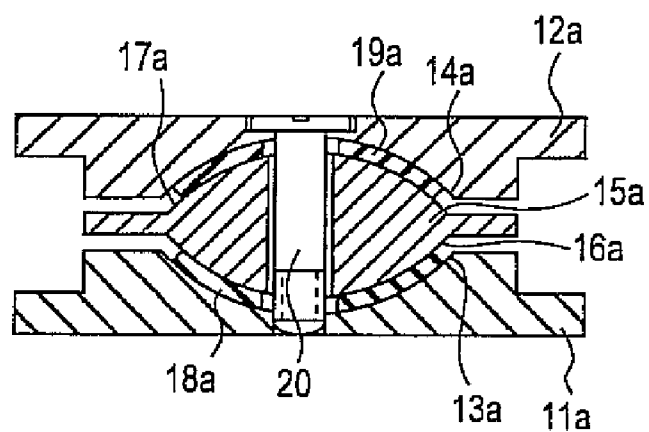


FIG. 8

ARTIFICIAL INTERVERTEBRAL DISC

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application is a divisional of U.S. patent application Ser. No. 11/037,629 filed Jan. 12, 2005, which claims priority of U.S. Provisional Application Ser. No. 60/535,741 filed Jan. 13, 2004.

FIELD OF THE INVENTION

[0002] The invention relates to designs of artificial intervertebral discs for prosthetic and dummy applications.

BACKGROUND OF THE INVENTION

[0003] Intervertebral disc prosthetics must comply with several requirements, often contradicting each other. These requirements are derived from studies on natural intervertebral discs. The prosthetic artificial disc should provide angular mobilities with specified ranges and stiffness values (two bending mobilities, fore-and-aft and side-to-side, and torsional around the axis of the spine), while accommodating large and varying axial (vertical) loading; it is desirable that the stiffness values are not significantly influenced by the changing vertical loads. Dummies are mock-ups of human bodies designed to simulate behavior of human bodies in extreme circumstances, e.g. crash dummies. Dummies are not, usually, equipped with all individual vertebrae simulating the human spinal column but have structural elements rather crudely simulating the human spine. These structural elements will also be called "vertebras" in this specification. Maintaining the structural characteristics of artificial intervertebral discs in close similarity to the natural discs is very important in order to adequately simulate behavior of the human bodies in the course of the dummy-based experiments.

[0004] There are various proposed designs of artificial intervertebral discs attempting to simulate structural characteristics, especially stiffness values and ranges of motion of the natural discs. The most widely used designs comprise spherical joints generated by a concave spherical socket engaged with a fitting convex spherical protrusion. Both surfaces are usually made from a low friction plastic capable of sliding without lubrication. While providing mobility in various angular directions and capable of accommodating axial loads, these designs have several shortcomings.

[0005] These artificial discs do not have elastic characteristics resident in the discs of the natural spinal column in any of the three angular directions. The natural elastic resistances to the motions approximately proportional to the deformation angle are replaced in these prosthetic or artificial discs by frictional resistances, practically independent on the motion magnitude.

[0006] Secondly, the motion resistances in all three directions (the friction forces) are increasing with the increasing axial force in the spinal column (which varies in the wide range). This also results in some unnatural feelings, since the elastic resistance forces in the natural spinal column are not significantly dependent on the axial force.

[0007] Another shortcoming of the state-of-the-art prosthetics is an unavoidable difference between static and dynamic friction coefficients in spherical joint. This makes

the motion resistance different in the beginning of the movement and in the process of movement, since the static friction coefficient is greater than the dynamic friction coefficient.

[0008] Yet another shortcoming, which is also a result of frictional interaction in the spherical joint, is inevitable wear of the sliding connection. The wear is enhanced by sometimes high axial pressures in the spinal column which are too high for sliding plastic contacts. The wear process creates worn-out particles which are contaminating the area around the disc and may increase the friction forces if accumulated in the sliding connection.

[0009] The subject invention eliminates the listed shortcomings.

SUMMARY OF THE INVENTION

[0010] The instant invention proposes an artificial intervertebral disc providing for angular displacements between adjacent vertebrae wherein these displacements are accommodated by internal shear in an elastomeric layered element residing between the upper and lower adjacent vertebrae, without sliding.

[0011] The preferred embodiment of the invention has upper and lower rigid bases attached, respectively, to the upper and lower adjacent vertebrae. One of the bases has a spherical convex protrusion and another has a coaxial concave spherical socket, with these two spherical surfaces having the common center. The elastomeric layered element is placed between and attached to these convex and concave spherical surfaces.

[0012] In another embodiment of the proposed artificial intervertebral disc, both upper and lower bases have concave spherical sockets and an intermediate rigid element has two coaxial convex spherical protrusions on its upper and lower sides, with the upper protrusion being coaxial with and having the common center with the concave spherical socket on the upper base, with the lower protrusion being coaxial with and having the common center with the convex spherical socket on the lower base, and the elastomeric layered element consists of two elastomeric layers, one of which is placed between and attached to the two upper spherical surfaces and another is placed between and attached to the two lower spherical surfaces.

[0013] In another embodiment of the proposed artificial intervertebral disc, both upper and lower bases have convex spherical protrusions and an intermediate rigid element has two coaxial concave spherical sockets on its upper and lower sides, with the upper socket being coaxial with and having the common center with the convex spherical protrusion on the upper base, with the lower socket being coaxial with and having the common center with the convex spherical protrusion on the lower base, and the elastomeric layered element consists of two elastomeric layers, one of which is placed between and attached to the two upper spherical surfaces and another is placed between and attached to the two lower spherical surfaces.

[0014] Yet another embodiment of the proposed artificial intervertebral disc is characterized by having means for preloading the elastomeric layered element in compression.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 shows a correlation between elastomer (rubber) hardness measured by standard measuring tool—Shore Durometer at its “A” scale and Young’s modulus of the elastomer.

[0016] FIG. 2 shows a cross section of the proposed artificial intervertebral disc with elastomeric layered element placed between the spherical socket in the upper base and the spherical protrusion in the lower base.

[0017] FIG. 3 gives a cross section of spherical elastomeric element constructed as a laminate with two layers of rubber and one intermediate layer of a rigid material.

[0018] FIG. 4 shows a plan view of the elastomeric element shaped for providing a relatively high angular stiffness of the artificial disc around the spinal axis as compared with its bending angular stiffness values.

[0019] FIG. 5 shows a plan view of the elastomeric element shaped for providing a relatively low angular stiffness of the artificial disc around the spinal axis as compared with its angular bending stiffness values.

[0020] FIG. 6 depicts the axial cross section of the artificial spinal disc having an intermediate double-convex element interacting with the lower and upper bases via elastomeric layered element.

[0021] FIG. 7 depicts the axial cross section of the artificial spinal disc having an intermediate double-concave element interacting with the lower and upper bases via elastomeric layers.

[0022] FIG. 8 illustrates modification of artificial discs with intermediate elements, as shown in FIGS. 6 and 7, which can be axially preloaded before insertion.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] A “rigid” component in this specification means a component having significantly lesser deformations than the elastomeric element(s) connecting these components. Specifically, “rigid” is defined here as having the Young’s modulus at least ten times greater than the Young’s modulus E_0 of an elastomer having hardness H60 on scale A of Shore Durometer. This corresponds, in accordance with the industry-accepted correlation shown in FIG. 1, to the Young’s modulus $E \approx G > 10E_0 = 40$ MPa, where G is the shear modulus.

[0024] Four embodiments of the proposed disc design are shown in FIGS. 2, 6, 7, and 8.

[0025] FIG. 2 shows an artificial disc comprising lower base 1 and upper base 2, both made of a metal, plastic, or other rigid material. One of the bases has a convex spherical protrusion 3 (shown on the lower base 1), while another base (top base 2 in FIG. 2) has a concave spherical socket 4 coaxial with protrusion 3. Bases 1 and 2 do not have a direct contact, and the space between protrusion 3 and socket 4 is filled with elastomeric element 5 which constitutes a layer or a laminate (see below) of uniform thickness, attached by known means (bonded, glued, mechanically attached, etc.) to both convex and concave spherical surfaces of protrusion 3 and socket 4. Elastomeric element 5 is shown in FIG. 2 as a “solid” rubber layer, contacting with the full surface area

of socket 4 and protrusion 3. However, it can be designed with smaller area, as shown in FIGS. 4, 5 below. While an elastomeric element comprising one layer of rubber is shown in FIG. 2, it can be embodied as a rubber-metal laminate. Such a laminate comprising two layers 6 and 7 of rubber with thin layer 8 made of metal or other material rigid in extension, such as strong fabric, between the layers of rubber is shown in FIG. 3.

[0026] Bases 1 and 2 in FIG. 2 are attached, respectively, to the lower and upper adjacent vertebrae (not shown). It is preferable that the centers of both convex and concave spherical surfaces coincide at one point, thus minimizing the resistance forces for angular displacements between the connected vertebrae. Spherical elastomeric layer or laminate 5 is conforming spherical surfaces of protrusion 3 and socket 4, and can have a shape providing for desirable stiffness values in different directions. For example, layers 5a and 5b of the same spherical radius shown in FIGS. 4 and 5, respectively, in the plan views are shown to have the same surface area, but different shapes, annular in FIG. 4 and solid of a small diameter in FIG. 5. As a result, they have the same angular (shear) stiffness in two bending directions shown as α and β , but layer 5a, FIG. 4, has significantly higher stiffness than layer 5b, FIG. 5, in y direction (torsional stiffness, rotation about the spine axis). Other shapes of elastomeric element 5 in FIG. 2 may be beneficial in special cases.

[0027] While the artificial intervertebral disc shown in FIG. 2 has the convex spherical protrusion on the lower base and the concave spherical socket on the upper base, this arrangement can be reversed and the socket can be part of the lower base, while the spherical protrusion is made on the upper base.

[0028] If the artificial disc is intended to be used as a prosthetic device, then bases 1 and 2 as well as elastomeric element 5 must be made of bio-compatible materials.

[0029] In operation, an angular bending displacement between the adjacent vertebrae in α and/or β directions would induce the same angular displacement between lower 1 and upper 2 bases attached to these vertebrae. The relative angular displacement in α and/or β directions between bases 1 and 2 having, respectively, convex and concave spherical surfaces centered at the same point and separated by elastomeric layered element 5, will be accommodated by a shear deformation of element 5. The shear resistance associated with this deformation will be of an elastic nature characteristic for elastomeric (rubberlike) materials and is approximately proportional to magnitude of the shear deformation and to shear modulus $G = E_0/3$ of the elastomeric material. Axial forces in the spinal column cause compression deformation of the layered elastomeric element.

[0030] Numerous experiments have shown that the compression forces cause only a slight increase in the shear resistance, especially for thin layers of the elastomeric materials.

[0031] Since there is no direct sliding contact between the upper and lower bases, there is no friction and no wear in the proposed artificial disc system, which operates in a close similarity to the natural intervertebral disc.

[0032] FIG. 6 illustrates another embodiment of the proposed prosthesis, comprising lower base 11 and top base 12

attached to the respective adjacent vertebrae. Each base has socket **13**, **14**, respectively, each socket having concave spherical surface. Intermediate element **15** has two convex spherical protrusions **16** and **17** with all four spherical surfaces being coaxial in the undeformed (initial) condition of the artificial disc. The elastomeric element comprises two elastomeric layers (shown) or laminates as presented in FIG. 3. The space between protrusion **16** and socket **13** is filled with elastomeric layer/laminate **18** of uniform thickness, attached (bonded, glued, etc.) to both convex and concave spherical surfaces of protrusion **16** and socket **13**. The space between protrusion **17** and socket **14** is filled with a elastomeric layer/laminate **19** of uniform thickness, attached (bonded, glued, etc.) to both convex and concave spherical surfaces of protrusion **17** and socket **14**.

[0033] FIG. 7 illustrates yet another embodiment of the proposed artificial intervertebral disc, comprising lower base **21** and top base **22** attached to the respective adjacent vertebrae. Each base has spherical protrusion **23**, **24**, respectively, each protrusion having convex spherical surface. Intermediate element **25** has two concave spherical sockets **26** and **27** with all four spherical surfaces being coaxial in the undeformed (initial) condition. The elastomeric element comprises two elastomeric layers (shown) or laminates as presented in FIG. 3. The space between socket **26** and protrusion **23** is filled with elastomeric layer/laminate **28** of uniform thickness, attached (bonded, glued, etc.) to both concave and convex spherical surfaces of socket **26** and protrusion **23**. The space between socket **27** and protrusion **24** is filled with an elastomeric layer/laminate **29** of uniform thickness, attached (bonded, glued, etc.) to both concave and convex spherical surfaces of socket **27** and protrusion **24**.

[0034] FIG. 8 shows an embodiment of the proposed prosthesis similar to the embodiment shown in FIG. 6 wherein the spherical joint is preloaded (and held captive) by means of preloading member **20** (a bolt is shown but other known designs of preloading elements can be employed). The preloading element **20** is attached to lower base **11a** and top base **12a**, but does not have a contact with intermediate element **15a**. The artificial disc can be preloaded with a specified load before insertion into the spinal column, resulting in modification of the axial stiffness.

[0035] A similar preloading system can be applied to the embodiment shown in FIG. 7.

[0036] It is readily apparent that the components of the artificial intervertebral disc disclosed herein may take a variety of configurations. Thus, the embodiments and exemplifications shown and described herein are meant for illustrative purposes only and are not intended to limit the scope of the present invention, the true scope of which is limited solely by the claims appended thereto.

1. An artificial intervertebral disc, comprising:

lower and upper bases, each made from a rigid material and each attached, respectively, to the lower and upper adjacent vertebrae,

said lower and upper bases having relative mobilities in three angular coordinate directions,

with all these relative mobilities resulting from shear deformations within at least one elastomeric layered element attached to said lower and upper bases,

wherein both of said rigid lower and upper bases have co-axial concave spherical sockets, and an intermediate rigid element is inserted between said lower and upper bases, said intermediate rigid element having on its opposing lower and upper sides, respectively adjacent to said lower and upper bases, convex co-axial spherical protrusions, these protrusions being co-axial with the concave spherical sockets on the lower and upper bases, with center points of said spherical protrusion on the upper side of said intermediate rigid element and said spherical socket on the upper base approximately coinciding, with center points of said spherical protrusion on the lower side of said intermediate rigid element and said spherical socket on the lower base approximately coinciding, with the lower part of elastomeric layered element residing between and attached to said concave spherical socket on said lower base and said convex spherical protrusion on the upper side of said intermediate element, and with the upper part of elastomeric layered element residing between and attached to said concave spherical socket on the upper base and said convex spherical protrusion on the upper side of said intermediate element.

2. The artificial intervertebral disc of claim 1, wherein both of said rigid lower and upper bases have co-axial convex spherical protrusions, and an intermediate rigid element is inserted between said lower and upper bases, said intermediate rigid element having on its opposing lower and upper sides, respectively adjacent to said lower and upper bases, concave co-axial spherical sockets, these sockets being co-axial with the convex spherical protrusions on the lower and upper bases, with center points of said spherical socket on the upper side of said intermediate rigid element and said spherical protrusion on the upper base approximately coinciding, with center points of said spherical socket on the lower side of said intermediate rigid element and said spherical protrusion on the lower base approximately coinciding, with the lower part of elastomeric layered element residing between and attached to said spherical protrusion on said lower base and said spherical socket on the upper side of said intermediate element, and with the upper part of the elastomeric layered element residing between and attached to said spherical protrusion on the upper base and said spherical socket on the upper side of said intermediate element.

3. The artificial intervertebral disc of claim 1, wherein each of said upper and lower elastomeric layered elements comprise one layer of an elastomeric material.

4. The artificial intervertebral disc of claim 2, wherein each of said upper and lower elastomeric layered elements comprise one layer of an elastomeric material.

5. The artificial intervertebral disc of claim 1, wherein said upper and lower elastomeric layered elements are preloaded in compression before insertion between the vertebrae.

6. The artificial intervertebral disc of claim 2, wherein said upper and lower elastomeric layered elements are preloaded in compression before insertion between the vertebrae.