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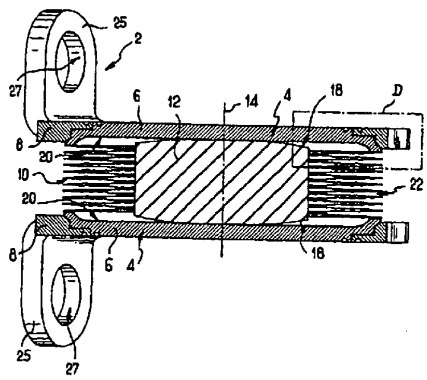

(57) Abstract

The invention concerns an intervertebral disc prosthesis (2) comprises two plates (4) and a bladder (10) interposed between the plates, the bladder comprising a compressible body (12) and containing a compressible fluid.

(57) Abrégé

La prothèse de disque intervertébral (2) comporte deux plateaux (4) et un coussin (10) interposé entre les plateaux, le coussin comportant un corps compressible (12), le coussin renfermant un fluide. Le fluide est compressible.

INTERVERTEBRAL DISK PROSTHESIS

The invention relates to intervertebral disk prostheses.

According to document EP-0 277 282-A1 an intervertebral disk prosthesis is known, comprising two plates and a cushion interposed between them. The cushion comprises a compressible body delimiting a cavity filled with an incompressible fluid. This prosthesis is essentially incompressible in the axial direction and allows only a relative inclination of the plates. This behaviour is different from that of a healthy, natural intervertebral disk.

It would be desirable to provide a disk prosthesis which is different in type and which allows closest approximation to the mechanical properties of a healthy, natural intervertebral disk.

According to the invention an intervertebral disk prosthesis is envisaged comprising two plates and a cushion interposed between the plates, the cushion comprising a compressible body and the cushion containing a fluid, in which prosthesis the fluid is compressible and extends normal round about the body.

Thus the compression of the cushion effects the compression of the body and that of the fluid. Since the compression properties of the body and the fluid can be different, their combination allows a very close approximation to the mechanical properties of a healthy, natural intervertebral disk. More particularly, when a suitable choice of material is made for the body, a curve of the mechanical reaction to a compression of the cushion as a function of a variation in a dimension of the cushion in the direction of compression can be obtained, having a hysteresis shape close to that associated with a healthy, natural disk.

Advantageously, the fluid has a pressure such that it is more compressible than the body.

This difference can thus be utilized to approximate as closely as possible the mechanical properties of the healthy, natural disk.

Advantageously, the fluid comprises a gas.

Advantageously, the cushion is arranged such that a fluid pressure is applied directly to the plates.

Advantageously, the body comprises a viscoelastic material, especially of silicone.

The aforementioned curve having a highly pronounced hysteresis shape can thus be obtained.

Advantageously, the body is in contact with the plates.

Advantageously, the body has at least one end having a contact zone with one of the plates, the prosthesis being arranged such that the contact zone has a surface area which increases whenever a stressing of the plate in the direction of the body in increased.

For the lowest compression values, the mechanical reaction of the prosthesis upon the compression of the body thus varies very little as a function of the dimensional change in the cushion in the direction of compression. In other words, the aforementioned curve is little inclined relative to the horizontal for low compression values and little force is provided in the initial operation. This property reproduces that of a healthy, natural disk.

Advantageously, the contact zone is defined by a face of the plate and an end face of the body, one of the two faces, especially the face of the body, being curved and convex and the other face being flat.

Advantageously, the contact zone is defined by a face of the plate and an end face of the body, the two faces being curved in at least one common direction and being respectively concave and convex, the concave face having at least one radius of curvature greater than a corresponding radius of curvature of the convex face.

As a result of this configuration, the variations in mechanical reaction, such as previously mentioned, can be effected. Moreover, when the body is free to shift laterally relative to the plate, as will be seen later, this configuration guarantees the relative centering of the two faces. For example, after the two faces have been mutually offset, these curvatures enable them to re-center automatically.

Advantageously, the body has at least one end in contact with one of the plates, this end being free to move relative to the plate in a direction parallel to the plate.

Advantageously, the end is accommodated in a recess of the plate and apt to form a lateral stop for the body.

The lateral displacements of the body relative to the plates can thus be limited, or even barred.

Advantageously, the cushion comprises a shell containing the fluid and arranged such that it has a cross-sectional area parallel to the plates which is essentially invariable when variation occurs in a compression of the cushion between the plates.

Advantageously, the cushion comprises a shell containing the fluid and extending round about and at a distance from the body.

The erosion of the body by the shell in the course of its movement, and the dispersion of particles of the body, are thus prevented.

Advantageously, the shell forms a spring, especially a compression spring.

The shell thus influences the reaction of the cushion whenever this is compressed.

Advantageously, the cushion is arranged to exhibit a hysteresis-shaped curve of mechanical reaction to a compression as a function of a variation in a dimension of the cushion in the direction of the compression.

Advantageously, the cushion is arranged such that the reaction to the compression grows less markedly for relatively low reaction values than for relatively high reaction values.

Advantageously, the cushion is arranged such that the reaction to the compression diminishes more markedly for relatively high reaction values than for relatively low reaction values.

Advantageously, the cushion is arranged such that the reaction to the compression has higher values when it grows than when it diminishes.

Advantageously, the prosthesis is intended for the lumbar region of the spine.

Other characteristics and advantages of the invention are yet to appear in the following description of a preferred embodiment and of two variants, given by way of non-limiting examples. In the appended drawings:

- Figure 1 is a perspective view of a prosthesis according to the invention;
- Figure 2 is a axial section along the plane II-II of the prosthesis of Figure 1;
- Figure 3 is an enlarged scale view of a detail D of Figure 2;
- Figure 4 is a curve indicating the compression force F applied by the two plates to the cushion as a function of the variation in the distance separating them;
- Figure 5 is a sectional view of a detail of an illustrative embodiment of the prosthesis; and

- Figure 6 is a simplified view analogous to Figure 2 showing a second illustrative embodiment.

The intervertebral disk prosthesis 2 according to the invention is here particularly intended for the lumbar region of the vertebral column of the human body. It comprises two flat plates 4 having the general shape of a posterior hilar kidney in horizontal projection. Each plate 4 comprises a central, circular dish 6 and a ring 8 extending round about the dish in the plane of the latter. At rest, the two plates 4 extend parallel to one another, facing each other at a distance apart with their contours in coincidence. On each plate 4, the ring 8 and the dish 6 each have a groove 27 for the reception of a seal 31.

The disk prosthesis 2 comprises a cushion or intermediate part 10 interposed between the two plates 4. The cushion comprises a compressible solid body 12, here in viscoelastic material, for example in silicone. This body has a Shore-A hardness advantageously within the range 60 to 100, and here of approximately 80. The body 12 has a shape of revolution about its main axis 14. It has a cylindrical lateral face 16 and two axial end faces 18 generally perpendicular to the axis 14 and of slightly spherical convex shape. Each face 18 therefore has two identical curvatures in mutually perpendicular planes. The body 12 is disposed coaxially with the dishes 6. Each dish 6 has a flat inner central face 20 perpendicular to the axis 14 and in contact with one of the respective axial ends 18 of the body 12. The convex spherical face 18 of the body thus rests on the flat face 20 of the plate. The body 12 rests without anchorage on each of the plates 4 such that it is movable relative to each of these plates in a direction parallel to the plates, that is to say perpendicular to the main axis 14. The transmission of lateral stresses from the one to the other of the vertebrae is thus prevented.

The cushion 10 additionally comprises a bellows 22. The bellows surrounds the body 14 coaxially to the latter and at a distance therefrom. It has a symmetrical shape of revolution about the axis 14. Its wall has, in profile, undulations 24 allowing the length of the bellows 22 to be varied in the axial direction 14 without any essential variation in the area of its section transversely to the axis 14. In the case in question, this bellows, like the plates 4, is produced in titanium or an alloy of titanium, such that it has a certain axial rigidity and forms a compression spring. It can equally be deformed in a direction perpendicular to the axis 14 or can be twisted about the axis 14 or about any axis whatsoever perpendicular to the latter.

The bellows 22, at its two axial ends, has rims bonded to respective rims of the dishes 6 projecting beyond the inner face 20. The bonding is realized in a leaktight manner such that the bellows 22 defines with the two dishes 6 a variable-volume, leaktight shell extending around the body 12. This shell contains a fluid, in the case in question a gas which is here air. The undulations 24 nearest to the body 12 extend at a distance from the latter to allow a free circulation of gas from the one to the other of the dishes 6.

The bellows 22 has, in the case in question, ten convolutions, that is eight outer ridges in addition to two ridges for securement to the plates. It here has an outer diameter of around 30 mm and an inner diameter of around 17 mm. Its height, when the prosthesis is free from load, measures 10 mm. The wall of the bellows can be produced by means of one, two or three leaves, each 0.1 mm thick, and the sum of the thicknesses of which forms the thickness of the wall. The bellows here has a rigidity of around 1.6 N/mm in its own right.

Each ring 8 comprises two lugs 25 projecting beyond an outer face of the plate 4 perpendicularly to the plane of the plate. Each lug 25 has an orifice 27 traversing it right the way through in the direction of the center of the dish and, on a face of the lug 25 opposite to the plate 4, a spherically shaped indentation. The orifices 27 allow the reception of a bone screw 26 having a head 28, a lower face of which has a male spherical shape cooperating with the female indentation of the lug 25 to allow free orientation of the screw 26 relative to the associated lug.

In order to produce a short-term anchorage of the disk prosthesis 2 in the spine, the screws 26 might be anchored in the spondylus of the vertebrae adjacent to the disk to be replaced.

Nevertheless, a so-called "long term" anchorage might be envisaged, in which, moreover, the surfaces of the plates 4 in contact with the adjacent vertebrae are lined with hydroxyapatite, or with any other substance known per se which is able to stimulate bone growth. Prior to lining, the said surfaces might be treated to obtain a more or less porous surface condition, having anchorage points for the bony tissue, in order to ensure a better interface with the said bony tissue.

The path of the curve C has been represented in Figure 4, indicating the intensity of a compression force F applied to the cushion 10 (that is to say on the two plates 4), disregarding their deformability, virtually nil, in the axial direction 14, as a function of the variation in length l of the cushion in the axial direction 14 (or, indeed, in the distance between the two plates). This curve equally represents the mechanical reaction R of the cushion 10 under the same conditions.

This curve C is not linear. Moreover, it has a hysteresis shape: the curve Ca indicating the increase in the compression F from the zero origin being distinct from the curve Cd indicating the decrease in the compression F up to the origin, and extending in its entirety above it. This pronounced hysteresis shape is due principally to the viscoelastic material of the body and subsidiarily to the association in the cushion 10 between the body 12 and the fluid.

In addition, the curve Ca, relating to the increase in the compression force F, exhibits a gently sloping portion Ca1 from the origin O, then a more heavily sloping portion Ca2. The curve Cd illustrating the diminution in the compression F exhibits for the highest values of the force F a markedly sloping portion Cd1, then for the lowest values of the force F a more gently sloping portion Cd2. The presence of a gently sloping portion in the vicinity of the origin for the curves Ca and Cd is due principally to the configuration of the contact faces 18, 20 of the body 12 and of the plates 4, the effect of which is to increase the surface area of the mutual contact zone between each plate and the body, generally in the form of a disk, whenever the force F is increased. This increase occurs until the maximum surface area of the contact zone is reached, when the whole of the face 18 is touching the plate 4.

The connecting points Ja and Jd respectively form the junction between the curves Ca1 and Ca2 and Cd1 and Cd2. On the curve Ca, the point Ja corresponds to the force F for which the maximum contact surfaces between the plates and the body are reached. Likewise, on the curve Cd, the point Jd corresponds to the force for which these surfaces cease to be at a maximum.

The prosthesis will be able to be configured such that the point Ja corresponds to a value of Δ1 lying between

25% and 75% of the maximum variation in length envisaged for the prosthesis during use.

With reference to Figure 5, it will be possible to envisage in one illustrative embodiment, (otherwise exhibiting the other characteristics of the prosthesis of Figure 1) that the face 20 of each plate 4 facing the body 12 has a recess 32, here in the shape of a << U >>, forming a lateral stop, in which recess the corresponding axial end 18 of the body comes to be accommodated. The lateral relative displacements of the body 12 relative to each plate 4 are thus limited to a certain range, or are even totally barred.

In the variant shown in Figure 6, the face 20 can be curved and concave in one or two directions, as is the case here, and the face 18 can be curved and convex in the corresponding direction(s), the radius of curvature of the face 20 being, for each direction, greater than that of the face 18 in the corresponding direction. The two faces 18, 20 are here spherical. The radii of curvature of the surfaces 18 and 20 will lie, for example, within the range 70 to 80 mm, and 140 to 200 mm respectively. Such an arrangement allows the two faces to be centered automatically, whilst permitting a relative lateral displacement of the body 12 relative to the plate in any direction whatsoever perpendicular to a longitudinal direction of the spine.

In the embodiment shown in Figure 2, the two ends of the body 12 have a contact surface 18 with the associated plate of variable surface area and making it laterally movable relative to the body.

By contrast, in the variant shown in Figure 6, only one of the ends 18 of the body 12 exhibits this property. The other end, the lower one in Figure 6, has a circular, flat shape, with a contact zone with the associated plate which is invariable and fixed relative to the latter.

Of course, numerous modifications might be made to the invention without departing from the scope thereof.

The fluid might be a liquid, or even a mixture of a liquid and a gas, the latter being, for example, weakly soluble in the liquid.

The body might have an elliptical shape in cross section to the axis 14.

The inner face 20 of the plates 4 might be convex, the axial end face 18 of the body 12 being flat, or concave with a greater radius of curvature than that of the face 20 of the plate. The two contacting faces of the plate and the body might be convex.

The curvature of the faces might be limited to a single plane.

The characteristics relating to the envelope 22 (spring effect, distance to the body 12) might be effected independently of the other characteristics.

The claims defining the invention are as follows:

1. Intervertebral disk prosthesis, comprising two plates and a cushion interposed between the plates, the cushion comprising a compressible body and the cushion containing a fluid, wherein the fluid is compressible and extends round about the body.

2. Prosthesis according to claim 1, wherein the fluid has a pressure such that it is more compressible than the body.

3. Prosthesis according to claim 1 or 2, wherein the fluid comprises a gas.

4. Prosthesis according to any one of claims 1 to 3, wherein the cushion is arranged such that a fluid pressure is applied directly to the plates.

5. Prosthesis according to any one of claims 1 to 4, wherein the body comprises a viscoelastic material, especially of silicone.

6. Prosthesis according to any one of claims 1 to 5, wherein the body has at least one end having a contact zone with one of the plates, the prosthesis being arranged such that the contact zone has a surface area which increases whenever a stressing of the plate in the direction of the body is increased.

7. Prosthesis according to claim 6, wherein the contact zone is defined by a face of the plate and an end face of the body, one of the two faces, especially the face of the body, being curved and convex and the other face being flat.

8. Prosthesis according to claim 6, wherein the contact zone is defined by a face of the plate and an end face of the body, the two faces being curved in at least one common direction and being respectively concave and convex, the concave face having at least one radius of curvature greater than a corresponding radius of curvature of the convex face.

9. Prosthesis according to any one of claims 1 to 8, wherein the body has at least one end in contact with one of the plates, this end being free to move relative to the plate in a direction parallel to the plate.

10. Prosthesis according to claim 9, wherein the end is accommodated in a recess of the plate and apt to form a lateral stop for the body.

11. Prosthesis according to any one of claims 1 to 10, wherein the cushion comprises a shell containing the fluid and arranged such that it has a cross-sectional area parallel to the plates which is essentially invariable when variation occurs in a compression of the cushion between the plates.

12. Prosthesis according to any one of claims 1 to 11, wherein the cushion comprises a shell containing the fluid and extending round about and at a distance from the body.

13. Prosthesis according to claim 11 or 12, wherein the shell forms a spring, especially a compression spring.

14. Prosthesis according to any one of claims 1 to 13, wherein the cushion is arranged to exhibit a hysteresis-shaped curve of mechanical reaction to a compression as a function of a variation in a dimension of the cushion in the direction of the compression.

15. Prosthesis according to claim 14, wherein the cushion is arranged such that the reaction to the compression grows less markedly for relatively low reaction values than for relatively high reaction values.

16. Prosthesis according to either of claims 14 and 15, wherein the cushion is arranged such that the reaction to the compression diminishes more markedly for relatively high reaction values than for relatively low reaction values.

17. Prosthesis according to any one of claims 14 to 16, wherein the cushion is arranged such that the reaction to the compression has higher values when it grows than when it diminishes.

18. Prosthesis according to any one of claims 1 to 17, wherein the prosthesis in question is a lumbar intervertebral disk prosthesis.

19. Intervertebral disk prosthesis substantially as hereinbefore described with reference to the accompanying drawings.

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Patent Attorneys for the Applicant

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Melbourne\004325467 - Printed 7 July 2003 (17:47)

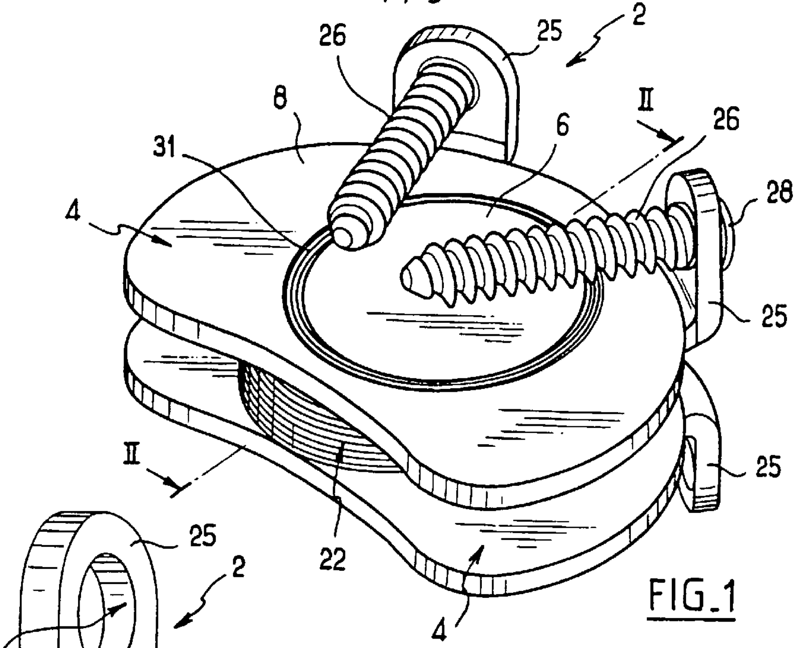

FIG.1

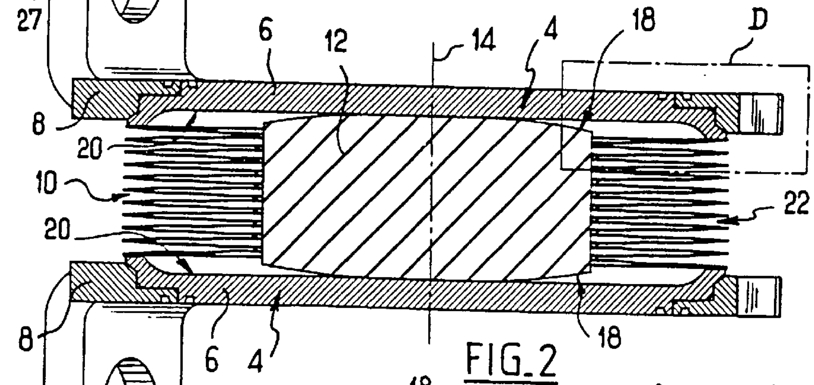

FIG.2

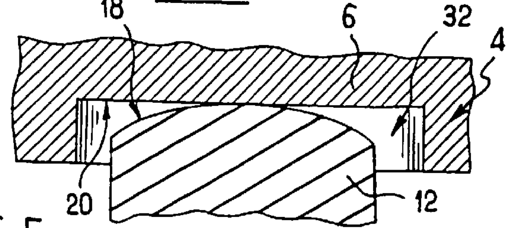

FIG.5

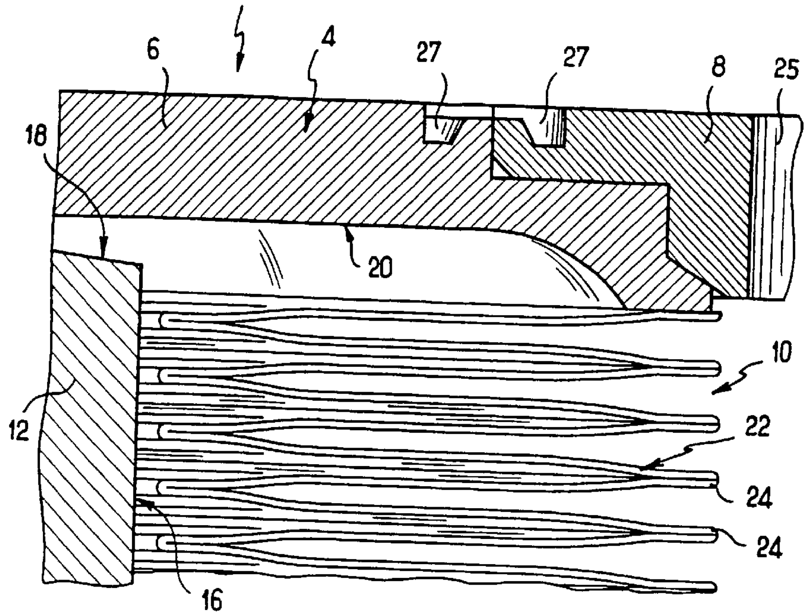
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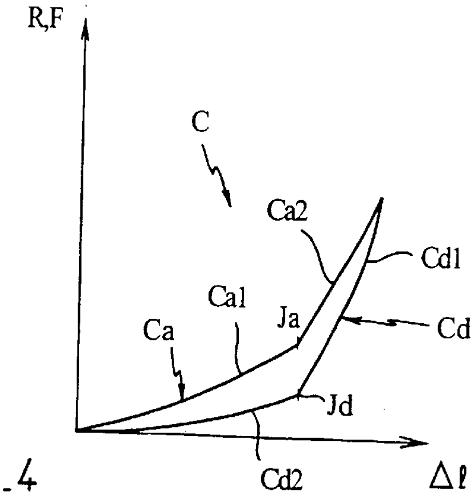
FIG_3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Ca2
Cd1
Ca1
Ja
Cd
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Jd
Cd2
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FIG_4

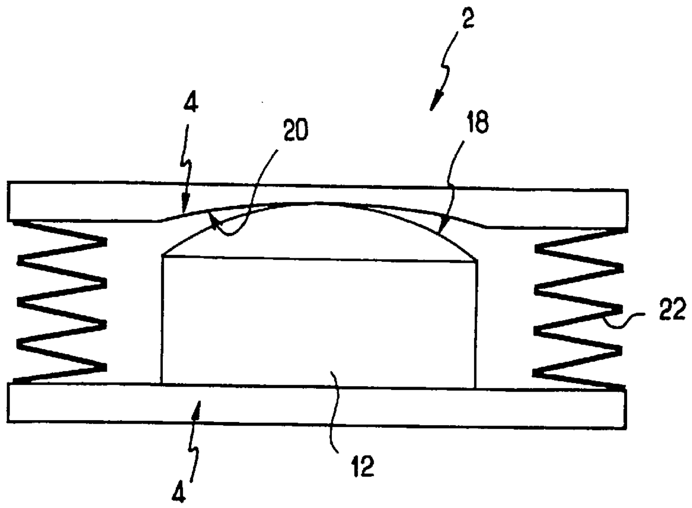

FIG_6