A61F 2/44 (2006.01)

PCT/CA2009/001603

11 November 2009 (11.11.2009)

English

English

US

20 November 2008 (20.11.2008)

KINETIC SPINE TECHNOLOGIES INC. [CA/CA]; c/o Foothills Hospital, 1403-29th Street N.W., Calgary, Alberta T2N 2T9 (CA).

HURLBERT, R., John [CA/CA]; 36 Church Ranches Close, Calgary, Alberta T3G 1C1 (CA). DUPLESSIS, Stephan, J. [CA/CA]; 303 Church Ranches Rise, Calgary, Alberta T3R 1B1 (CA). SEKHON, Lali [US/US]; 4367 Dundee Road, Reno, Nevada 89519 (US).

CHARI, Santosh, K. et al; Blake, Cassels & Graydon LLP, 199 Bay Street, Suite 2800, Box 25, Commerce Court West, Toronto, Ontario M5L 1A9 (CA).

Declarations under Rule 4.17:
— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(H))
— with international search report (Art. 21(3))

ARTICULATING INTERVERTEBRAL DISC PROSTHESIS

FIG. 22

An artificial intervertebral disc for implantation between two adjacent vertebrae includes superior and inferior shells connected in a ball and socket arrangement. The inferior shell preferably incorporates a convex portion that cooperates with a concave portion on the superior shell. A resilient nucleus is provided within an enclosure defined by the opposing inner surfaces of the shells and biases the shells against each other. The ball portion can be provided in either fixed or slidable arrangement. The superior and inferior shells are also provided with cooperating male and female portions whereby the shells positively engage each other, thereby preventing separation, but allowing any desired articulation there-between. The artificial disc of the invention includes various resistance means for restricting and limiting the range of rotational and translational motion between the shells.
ARTICULATING INTERVERTEBRAL DISC PROSTHESIS

CROSS REFERENCE TO PRIOR APPLICATIONS

[0001] The present application claims priority from US patent application number 12/274,685, filed November 20, 2008, which is a Continuation in Part of PCT application number PCT/CA2008/001 114, filed June 12, 2008, which claims priority from US Provisional application number 60/934,277, filed June 12, 2007. The entire contents of the aforementioned prior applications are incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the field of spinal implants and, more particularly, to intervertebral disc prostheses allowing various degrees of articulation.

DESCRIPTION OF THE PRIOR ART

[0003] The spine is a complicated structure comprised of various anatomical components, which, while being extremely flexible, provides structure and stability for the body. The spine is made up of vertebrae, each having a ventral body of a generally cylindrical shape. Opposed surfaces of adjacent vertebral bodies are connected together and separated by intervertebral discs (or "discs"), comprised of a fibrocartilaginous material. The vertebral bodies are also connected to each other by a complex arrangement of ligaments acting together to limit excessive movement and to provide stability.

[0004] The main function of the discs is load bearing (including load distribution and shock absorption) and motion. Through their weight bearing function, the discs transmit loads from one vertebral body to the next while providing a cushion between adjacent bodies. The discs also allow movement to occur between adjacent vertebral bodies but within a limited range thereby giving the spine structure and stiffness. Such movement includes translation and rotation in positive and negative directions as well as many combinations thereof. Thus, intervertebral discs allow for various complex movements or articulations to occur between adjacent vertebrae.

[0005] Due to a number of factors such as age, injury, disease etc., it is often found that intervertebral discs lose their dimensional stability and collapse, shrink, become displaced, or otherwise damaged. It is common for diseased or damaged discs to be replaced with prostheses and various versions of such prostheses, or implants, as are known in the art.
One of the known methods involves replacement of a damaged disc with a spacer into the space occupied by the disc. However, such spacers also fuse together the adjacent vertebrae thereby preventing any relative movement there-between.

More recently, disc replacement implants that allow movement between adjacent vertebrae have been proposed. Examples of some prior art implants are provided in the following US patents: no. 5,562,738 (Boyd et al.); no. 6,179,874 (Cauthen); and no. 6,572,653 (Simonson).

In addition to the artificial discs mentioned above, the present inventors have proposed various improved disc prostheses that provide a variety of intervertebral movements as well as means for simulating normal movement restrictions as would be found in natural spinal structures. Examples of the present inventors’ disc prostheses are described in the following U.S. patent application numbers: 11/978,804; 11/978,872; and 60/934,277. These prior applications are incorporated herein by reference in their entirety.

In developing artificial intervertebral discs it is desired to allow the disc a wide range of articulation while preventing separation of the disc components and/or extreme motion in any given direction.

SUMMARY OF THE INVENTION

In one aspect, the present invention provides an implant for replacing intervertebral discs.

In another aspect, the invention provides an artificial intervertebral disc that allows adjacent vertebrae a range of motions in various planes. Such motion may be limited to a predetermined range, within which movement of adjacent vertebrae does not lead to deterioration of neighbouring spinal structural components.

In another aspect, the above-mentioned motion about various axes can be coupled to more closely simulate natural movement.

In another embodiment, the invention provides an artificial disc that includes a means of preventing separation of the two main components forming the disc.

Thus, in one aspect, the invention provides an artificial intervertebral disc for implantation between adjacent superior and inferior vertebrae of a spine, the disc comprising:
- a superior shell, an inferior shell, and a means of biasing the superior and inferior shells apart;
- the superior and inferior shells being moveable with respect to each other over two or more articulating surfaces;
- the inferior shell having a superior surface comprising a posteriorly positioned convex portion;
- the superior shell having an inferior surface opposing the superior surface of the inferior shell, and comprising a posteriorly positioned concave portion, opposite the convex portion;
- the convex and concave portions being in articulating cooperation to form a ball and socket joint;
- at least one of the convex or concave portions having at least one male portion and the other of the convex or concave portions having a corresponding number of cooperating female portions adapted to receive and positively engage the at least one male portion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The features of the invention will become more apparent in the following detailed description in which reference is made to the appended drawings wherein:

[0015] Figure 1 is a schematic illustration of the range of motion of a vertebra.

[0016] Figure 2 is a side elevation of an artificial intervertebral disc according to one embodiment of invention.

[0017] Figure 3 is a top view of the disc of Figure 2.

[0018] Figure 4 is a side or lateral cross sectional elevation of the disc of Figure 2 taken along the sagittal plane IV-IV shown in Figure 5.

[0019] Figure 5 is top or superior cross sectional view of the inferior shell of the disc of Figure 2 taken along the axial plane V-V shown in Figure 6.

[0020] Figure 6 is a front or anterior cross sectional view of the disc of Figure 2 taken along the coronal plane VI-VI shown in Figure 5.

[0021] Figures 7 and 8 are cross sectional elevations of the disc of Figure 2 implanted in a spine and illustrating the disc in extension and flexion positions, respectively.
Figure 9 is a side or lateral cross sectional elevation of the disc of the invention according to another embodiment taken along the sagittal plane IV-IV shown in Figure 10.

Figure 10 is a top or superior cross sectional view of the inferior shell of the disc of Figure 9 taken along the axial plane X-X shown in Figure 11.

Figure 11 is a front or anterior cross sectional elevation of the disc of Figure 9 taken along the coronal plane XI-XI shown in Figure 10.

Figure 12 is a side perspective elevation of the disc of the invention according to another embodiment.

Figure 13 is a side perspective elevation of the disc of Figure 12 with the inferior and superior shells separated.

Figure 14 is a top perspective elevation of the inferior shell of Figure 12.

Figure 15 is a side perspective elevation of the disc of Figure 12 in a state of flexion.

Figure 16 is a side cross sectional elevation of the disc of Figure 15.

Figure 17 is a side perspective elevation of the disc of Figure 12 in a state of extension.

Figure 18 is a side cross sectional elevation of the disc of Figure 17.

Figure 19 is a rear cross sectional elevation of the disc of Figure 12 in a laterally extended state.

Figures 20 and 21 are side elevations of nuclei of the invention.

Figure 22 is a side cross sectional elevation of a disc of the invention according to a further embodiment.

Figure 23 is a posterior cross sectional elevation of the disc of Figure 22.

Figure 24 is a top perspective view of the inferior shell of the disc of Figure 22.

Figures 25 to 27 and 31 are side cross sectional views of further variants of the disc of Figure 22.
[0038] Figures 28 and 29 are posterior cross sectional views of further variants of the
disc of Figure 22.

[0039] Figure 30 is a side cross sectional view of a further variant of the disc of Figure
22.

DETAILED DESCRIPTION OF THE INVENTION

[0040] In the following description, the terms "superior", "inferior", "anterior", "posterior" and "lateral" will be used. These terms are meant to describe the orientation of the implants of the invention when positioned in the spine. Thus, "superior" refers to a top portion and "posterior" refers to that portion of the implant (or other spinal components) facing the rear of the patient's body when the spine is in the upright position. Similarly, the term "inferior" will be used to refer to the bottom portions of the implant while "anterior" will be used to refer to those portions that face the front of the patient's body when the spine is in the upright position. With respect to views shown in the accompanying figures, the term "coronal" will be understood to indicate a plane extending between lateral ends thereby separating the body into anterior and posterior portions. The term "sagittal" will be understood to indicate a plane extending anteroposterior thereby separating the body into lateral portions. The term "axial" will be understood to indicate a plane separating the body into superior and inferior portions. It will be appreciated that these positional and orientation terms are not intended to limit the invention to any particular orientation but are used to facilitate the following description.

[0041] The present invention provides artificial discs or implants for replacing intervertebral discs that are damaged or otherwise dysfunctional. The implants of the present invention are designed to allow various degrees of motion between adjacent vertebral bodies, but within acceptable limits.

[0042] Figure 1 illustrates the complexity of vertebral movement by indicating the various degrees of freedom associated therewith. In the normal range of physiological motion, vertebrae extend between a "neutral zone" and an "elastic zone". The neutral zone is a zone within the total range of motion where ligaments supporting the spinal bony structures are relatively non-stressed; that is, the ligaments offer relatively little resistance to movement. The elastic zone is encountered when the movement occurs at or near the limit of the range of motion. At this zone, the visco-elastic nature of the ligaments begins to provide resistance to the motion thereby limiting same. The majority of "everyday" or typical movements occurs within the neutral zone and only occasionally continues into the elastic zone. Motion
contained within the neutral zone does not stress soft tissue structures whereas motion into
the elastic zone will cause various degrees of elastic responses. Therefore, a goal in the
field of spinal prosthetic implants in particular, is to provide a prosthesis that restricts motion
of the vertebrae adjacent thereto to the neutral zone. Such restriction minimises stresses to
adjacent osseous and soft tissue structures. For example, such limitation of movement will
help to minimize or otherwise reduce facet joint degeneration.

[0043] In general terms, the present invention provides an implantable spinal prosthesis
for replacing intervertebral discs. The implant of the invention is generally comprised of
cooperating inferior and superior portions, or shells, that are moveable relative to each other
and being separated along at least a portion thereof by a resilient, force absorbing nucleus.
The relative movement between the components of the disc of the invention includes various
degrees of freedom but is generally limited to a specified range. That is, the prosthesis is
provided with various "soft" and "hard" stops to limit motion between the vertebrae adjacent
thereto. In particular, the artificial disc of the invention provides for rotation, flexion,
extension and lateral motions that are similar to normal movements in the neutral and elastic
zones (i.e. the movements associated with a normal or intact disc). In addition, the device of
the invention also allows various combinations of such motions, or coupled motions. For
example, the disc of the invention can be subjected to flexion and translation, or lateral
flexion and lateral translation, or flexion and rotation. Various other motions will be apparent
to persons skilled in the art given the present disclosure.

[0044] Figures 2 and 3 illustrate an artificial intervertebral disc 10 according to an
embodiment of the invention. As shown, the disc 10 includes a superior shell 12 and an
inferior shell 14 and comprises anterior 16 and posterior 18 ends. The outer superior and
inferior surfaces, 13 and 15 respectively, of the shells 12 and 14 may be provided with
desired surface structures or shapes as may be needed for enhancing or facilitating
implantation in the space between the neighbouring vertebral body structures. For example,
in the embodiment shown, the superior outer surface 13 of the superior shell may be
convexly shaped. In addition, the surfaces 13 and 15 may be provided with any known
coating or surface treatment to facilitate and/or cause bony in-growth and/or to otherwise
promote adhesion to the adjacent bone structures. Such coatings etc. will be known to
persons skilled in the art. In addition, the outer surfaces of the shells 12 and 14 may be
provided with further anchoring devices for securing the disc 10 to the adjacent bone
structures. Such devices may include, for example, screws, spikes, holes or pins (not
shown) for facilitating or enhancing implantation of the invention between adjacent vertebral
bodies.
In addition, the disc 10 of the invention can be adapted for use in association with artificial vertebral bodies. In such case, the disc 10 of the invention may be provided with various anchoring means such as keels and the like (not shown) that can be used for securing to artificial vertebral bodies. An example of such an artificial body is provided the present applicant's co-pending PCT application published under number WO 2006/1 16850, the entire contents of which are incorporated herein by reference. In general, the disc 10 of the invention may be provided with any external surface or surface means that would facilitate attachment to an adjacent surface of an artificial vertebral body when the two structures are in combination. The attachment means may allow some degree of relative movement between the artificial disc and artificial vertebral body. Thus, although in one embodiment (as shown in Figures 2 and 3), the outer inferior surface 15 is provided with a curved geometry to adapt to a naturally occurring vertebral body, it may equally be provided with a different structure that is adapted to engage or cooperate with a surface of an artificial vertebral body. Both the artificial disc and the artificial body may be designed so as to allow such cooperative arrangement there-between.

As shown in Figures 3 and 5, the disc 10 of the invention is preferably provided with a generally oblong, oval or elliptical configuration when viewed from the top (superiorly) or bottom (inferiorly). This shape of the disc will be understood by persons skilled in the art to be preferred in terms of maximising surface contact with the adjacent vertebral bodies. However, various other shapes, sizes and proportions will be possible. As also shown, the disc 10 may preferably be provided with a specific external shape that may be different superiorly and inferiorly. For example, the external aesthetic characteristics illustrated in the figures attached hereto may facilitate implantation in existing bone structures by reflecting the natural shape of the adjacent vertebral structures. However, it will be appreciated that the invention is not limited to any shape or size. In addition, it will be appreciated that the external shape of the disc illustrated in the accompanying figures may not be needed or suitable for use with artificial vertebral bodies.

The disc 10 is shown in sagittal cross section in Figure 4. As shown, the inferior and superior shells 12 and 14 are arranged in a cooperative manner to form the disc 10. Between the shells 12 and 14 is provided a resilient nucleus 20. As shown in Figures 4 to 6, the inner (or superior) surface of the inferior shell 14 includes a raised convex portion 22 proximal to the posterior end 18. The convex portion 22 cooperates with a concave portion or surface 24 provided on the inner (or inferior) surface of the superior shell 12 to form a ball and socket type of joint, as discussed further below. As will be understood, such a joint allows for the shells 12 and 14 to be in articulating cooperation thereby allowing relative movement between the shells.
movement in various directions. As shown in Figures 4 and 5, in one embodiment, the convex portion or ball 22 may be located at the posterior end 18 of the inferior shell. The posterior and anterior ends, 19 and 21, of the ball 22 are preferably truncated or squared off. As will be understood by persons skilled in the art and as described further below, the shape, position and dimensions of the convex portion 22 and/or concave portion 24 can be adjusted depending upon the desired range or extent of motion, or axis of rotation.

The inferior shell also includes an upward extending outer wall 26 thereby resulting in a well, 28 bounded between the convex portion or ball 22 and the outer wall 26, within which is contained the nucleus 20. As shown in Figure 5, the well 28 of the illustrated embodiment generally has a "U" shaped structure with the arms of such "U" extending posteriorly. The nucleus 20 is preferably provided with a similar structure so the nucleus conforms to the shape of the well 28 and is accommodated therein. However, as will be understood and as discussed further below, the well 28 and/or the nucleus 20 may be provided with other shapes to achieve the same function.

As illustrated in Figures 4 and 6, the superior shell 12 is provided with a downward extending posterior portion 30 the inferior surface of which comprises the aforementioned concave surface 24 or socket. As discussed above, the concave surface or socket 24 of the superior shell 12 is adapted or designed to cooperate with the convex portion or ball 22 of the inferior shell so as to form an articulating joint there-between. The superior shell 12 also includes a downward extending rim 32 at least along the anterior end thereof. The rim 32 is sized to lie in front of, or anteriorly of, the wall 26 of the inferior shell. As will be discussed further below, this arrangement serves to provide a "hard stop" for flexion and extension movements, that is, a movement wherein the superior shell is moved anteriorly or posteriorly over the inferior shell. The disc shown in Figure 4 illustrates the superior shell 12 in a position where the rim 32 thereof contacts the wall 26 of the inferior shell thereby preventing any further posterior movement of the superior shell 12. It will be understood that the rim 32 and wall 26 of the shells do not need to be continuous or extend along the entire periphery of the respective shells.

As shown in Figures 4 and 6, the superior shell includes a recess 29 surrounding the posterior socket portion 24. The recess 29 is generally the same shape as the well 28 of the inferior section whereby the recess and well 28 combine to form an enclosure for the nucleus.
As shown in Figure 6, the superior shell 12 may preferably also be provided with a pair of downward extending tabs 34, 36 on the lateral ends thereof. The tabs 34 and 36 are adapted to be received within slots 38 and 40, respectively, the slots being provided on the lateral ends of the inferior shell 14. As taught for example in the present applicant's co-pending PCT application published under number WO 2006/1 16852, this type tab and slot arrangement serves to provide a "hard stop" for lateral bending motions as well as axial rotation motions.

More specifically, in the case of lateral motions, as can be seen in Figure 6, the slots 38 and 40 extend deeper into the inferior shell 14 than the length of the tabs 34 and 36. Thus, a lateral or side to side movement between the superior and inferior shells will cause the terminal end of one of the tabs to contact the base of the respective slot thereby preventing any further movement in that direction. In the case of axial rotation, the slots 38 and 40 will be sized to be wider than the tabs 34 and 36, thereby allowing the superior and inferior shells to be rotated over the ball 22 and socket 24 joint formed there-between until the side edges of the tabs 34 and 36 contact the side walls of the table 38 and 40. Further details concerning such tabs and slots are provided in applicant's aforementioned co-pending application. It will understood that the ovoid shape of the disc itself may also provide any necessary "stop" for rotation motion, thereby avoiding the need for the tabs (34, 36) and slots (38, 40). It will also be understood that the disc 10 may be unconstrained with respect to rotational movement or, alternatively, may be designed to inhibit any rotational movement. The degree of permissible rotation of the disc will depend on various factors as will be known to persons skilled in the art.

As shown in Figures 4 and 6, the resilient nucleus 20 serves to provide resistance to relative movement of the inferior and superior shells 12 and 14. For example, as shown in Figure 4, the nucleus 20 resiliently biases the anterior ends of the shells 12 and 14 apart from each other wherein, due to the resilient nature of the nucleus, a compressive force applied to the anterior portion of the disc causes the anterior portions of the shells to be brought closer together. This type of motion of the shells would occur, for example, during a flexion movement (i.e. where the superior shell 12 is moved anteriorly with respect to the inferior shell 14).

Figure 6 illustrates an optional structure wherein outer angled edges are provided on the superior and inferior shells 12 and 14, primarily at the respective lateral ends thereof. As shown, the superior shell 12 includes downwardly angled edges 37a and 37b on the opposite lateral ends while the inferior shell 14 includes upwardly angled edges 39a and
39b. The edges 37a and 37b are arranged in opposing manner to the edges 39a and 39b, respectively. As illustrated, the arrangement of the edges 37 a,b and 39 a,b would result in a pincer-like function when the disc 10 is compressed laterally (i.e. along the coronal plane). This arrangement serves to shear any scar tissue that may form around the disc 10 once implanted and subjected to normal movements.

[0055] Figures 7 and 8 illustrate a flexion movement of the invention. As shown, the disc 10 is illustrated in its implanted state within the intervertebral space created after excision of a damaged or diseased intervertebral disc. The disc 10 is shown in an extended position in Figure 7 and in a flexion position in Figure 8. As can be seen, in the extended position, Figure 7, the superior and inferior shells 12 and 14 are in the position shown earlier in Figure 4 and the nucleus 20 is contained within the enclosure formed by the wall 28 and recess 29. However, as the superior vertebra is moved anteriorly in a flexion motion, the socket 30 of the superior shell 12 is slidably moved over the ball 22 of the inferior shell 14. As shown in Figure 8, in the course of such flexion motion, the anterior wall of the socket portion 30 impinges against the resilient nucleus 20, which in turn is forced against the wall 26 of the inferior shell 14. As also shown, in the course of the flexion motion, the volume of the enclosure 29 containing the nucleus 20 is reduced as a result of the socket 30 of the superior shell 12 sliding over the ball 22 of the inferior shell. As illustrated, in this manner, the anterior end of the superior shell is vertically lowered thereby constricting the volume of the enclosure 29. As will be understood, such flexion movement can be continued until the nucleus is no longer compressible within the enclosure, at which point further flexion is prevented. Such compression of the nucleus would be understood to serve as a "soft" stop for the respective motion between the shells.

[0056] In one possible embodiment of the invention, the disc 10 may also utilize the tabs 34, 36 and slots 38, 40 described above as a "hard stop" for flexion movements. That is, in order to limit flexion, the tabs and slots may be sized to permit only a certain degree of movement until the anterior edges of the tabs 34, 36 contact the anterior walls of the slots 38, 40, at which point, further flexion is prevented.

[0057] In the flexion movement discussed above, the contact surface between the nucleus 20 and the inner walls of the recess 29 may be subjected to frictional forces. As such, the invention provides for the walls of the recess 29 to be provided with any known coating or treatment etc. to minimise such frictional forces thereby preventing damage to the nucleus 20.
Figure 8 also illustrates the curvature of the ball or convex portion 22. As shown, the ball 22 preferably comprises a spherical surface having a radius "r" originating from a point P within the inferior vertebra. As illustrated, the point "P", which defines the instantaneous axis of rotation for the disc 10, is situated in the posterior portion of the inferior vertebra. This positioning is a result of the posteriorly positioned point or articulation formed by the ball 22 and socket 24.

In certain cases, the implantation of an artificial disc may also require realignment of the adjacent vertebrae to alleviate a specific pathology. For example, the vertebrae may need to be realigned to restore lordosis. As will be understood, the present invention allows for the instantaneous axis of rotation of the disc to be positioned at various desired locations depending upon the need. The repositioning of the axis of rotation can be accomplished, for example, by changing the geometry and location of the ball 22 provided in the disc 10 of the invention. That is, by changing the shape of the ball 22 the instantaneous axis of rotation can be moved anteriorly or posteriorly. Thus, in the illustration of Figure 8 for example, the point P can be moved in the anterior or posterior directions by adjusting the position of the ball 22 and the associated socket 24. In addition, it can also be understood that the curvature of the ball 22 may also be adjusted either together or independent of the location thereby also permitting the vertical positioning of the point P to be varied. For example, by reducing the radius "r" discussed above, it will be understood that the instantaneous axis of rotation (i.e. point "P" illustrated in Figure 8) can be vertically raised so as to lie closer to the inferior shell 14 of the disc 10. In such position, the shear stresses applied to the facet joints between the adjacent vertebrae can be reduced.

In a further embodiment, the curvature of the convex portion 22 may be of various non-spherical shapes. For example, by adjusting the curvature to be more pronounced at the anterior end, the convex portion 22 may be adapted to act as a motion inhibitor to flexion. It will be understood that such adjustments to the convex portion or ball 22 can be made for one or more motions while still maintaining the desired ball and socket arrangement.

As indicated above, the resilient nucleus 20 provides an increasing resistance to flexion. Since such resistance is dependent upon the compressibility of the material comprising the nucleus, it will be understood that the degree of flexion can be tailored by choosing the appropriate characteristics of such material. For example, a nucleus made of a less compressible material or a nucleus that occupies more volume of the enclosure in which it is contained will have a reduced range of motion. As described above, the nucleus 20 is
preferably provided with a generally "U" shaped structure so the nucleus more readily
conforms to the shape of the generally "U" shaped well 28. However, as will be understood,
the well 28 and/or the nucleus 20 may be provided with other shapes to achieve the same
function. For example, in one embodiment, the nucleus 20 may be contained solely in the
anterior section of the well and not within the arms of the "U" shape. For example, the
nucleus may have an elongate (i.e. oval, ovoid or oblong) structure. In such case, it will be
understood that the well 28 or the enclosure 29 may be provided with a wall or other such
barrier means to prevent displacement of the nucleus. In another embodiment, the nucleus
may comprise a generally round structure that is located only at the anterior portion of the
disc. In such case, it will be understood that the "soft" stop offered by the nucleus may only
be effective in flexion movements. In the above description, the nucleus has been referred
to as a singular body. However, in other embodiments, the nucleus may be provided in one
or several pieces since the resilient nature of the nucleus would enable it to assume the
shape of the well (or specific section of the well) once the superior shell has been combined.
For example, in one embodiment, the nucleus may be provided in three segments
corresponding to an anterior segment and two lateral segments. In yet another embodiment,
the nucleus may be provided in two segments, each of which is located in the lateral
sections of the enclosure of the disc (such as within the two arms of the "U" shaped well). In
such case, it will be understood that the nucleus may only be effective as a "soft" stop for
lateral bending movements. If, however, the two nucleus segments are elongated towards
the anterior section of the disc, it will be understood that at least some degree of a "soft stop"
would be provided for flexion movement. In general, the nucleus of the invention preferably
provides a "soft" stop for flexion and lateral compressive movements. Thus, on this basis
and in view of the present disclosure, various other modifications of the shape and size of
the nucleus and/or well will be apparent to persons skilled in the art.

Although the above discussion has focussed on flexion, it will be understood that
the disc of the invention also allows for various other individual or coupled movements. For
example, as mentioned above, the invention allows for controlled lateral movements of the
vertebrae adjacent to the disc 10. In the embodiment illustrated in Figure 6, a nucleus 20
having a generally "U" shaped structure includes arms of the "U" that are provided within
lateral positions of the enclosure formed by the superior 12 and inferior 14 shells. That is,
the arms of the generally "U" shaped nucleus occupy the lateral portions of the well 28. In
this arrangement, it will be understood that during a lateral (i.e. side to side) movement, one
of the lateral ends of the disc will be subjected to compression. This is also illustrated in
Figure 19. This movement will result in compression of the lateral section of the nucleus
corresponding to the side that is under compression. As discussed above with respect to
flexion and extension, the resilient nature of the nucleus would serve also to gradually limit
the amount of lateral compression until a maximum amount of nucleus compression occurs.
This therefore provides the "soft" stop for lateral movement. Such movement can be
controlled as indicated above by selecting the appropriate choice of material for the nucleus
and/or by the volume of nucleus contained within the enclosure of the disc. As discussed
above, although a nucleus having the aforementioned "U" shaped structure may be
preferred, the artificial disc of the invention may also be provided with a nucleus of any
geometry. For example in the case where the nucleus comprises an oval, ovoid or
otherwise oblong structure, it will be understood that at least some degree of lateral
compression would still occur thereby allowing such nucleus to provide the above mentioned
"soft" stop for lateral movements. Alternatively, the nucleus may be designed to provide a
"soft" stop only for flexion and extension movements. Such options will be apparent to
persons skilled in the art upon reviewing the present disclosure.

[0063] In another aspect, the various "hard stops" of the disc 10, as discussed above,
 can be tailored to provide more or less range of motion depending on the need of the patient
 and upon the natural motion requirements of the vertebrae in question.

[0064] Another embodiment of the invention is illustrated in Figures 9 to 11 wherein like
elements are identified with the same reference numerals as above. Elements that are
similar but include variations are identified with the same reference numeral but with the
letter "a" added for clarity.

[0065] As shown in Figures 9 to 11, the general structure of the disc 10a is similar to that
described above. In addition, the superior shell 12 comprises the same structure discussed
above. However, the inferior shell 14 is modified to provide a means for dynamically varying
the instantaneous axis of rotation. More specifically, in the embodiment shown, the fixed
convex or ball portion 22 of the inferior shell 14a is replaced with a moveable core 54 having
a convex superior surface. As shown in Figures 9 to 11, the inferior shell 14a is provided
with a recess 50, which, in one embodiment, is located at the posterior end 18 of the inferior
shell 14 and generally centrally between the lateral ends thereof. However, based on the
present disclosure, it will be understood that the recess 50 can be located at any position
depending upon the need. The recess 50 includes a generally planar base 52 and is
adapted to receive the moveable, or floating core 54. The core 54 has a generally flat
inferior surface 56 that is capable of sliding over the base 52 of the recess 50.
As shown in figures 9 to 11, the core 54 comprises a convex superior surface 58 that is adapted to cooperate with the concave or socket portion 30 of the superior shell 12. Thus, the convex surface 58 serves the same function as the convex surface 22 discussed above. In a preferred embodiment, the convex superior surface, or ball, 58 of the core 54 has a spherical shape with an axis of rotation, such as point "P" discussed above, which, when implanted, lies within the inferiorly adjacent vertebral body. In addition, as with the embodiment discussed above, the geometry of the convex surface 58 of the core can be tailored to position the instantaneous axis of rotation (i.e. point "P", not shown) at any desired location. However, the embodiment of Figures 9 to 11 allows a further variability of the positioning of such rotational axis by providing a recess 50 that includes one or more dimensions that are larger than the core 54. For example, in one embodiment, the recess 50 may be larger than the core as measured in the sagittal plane thereby allowing the core 54 to slide anteroposteriorly, which, as will be understood, would translate the instantaneous axis of rotation in the course of normal movement of the patient. The degree of such sliding motion can be pre-determined by providing as little or as much clearance as needed between the core 54 and the recess 50.

In the embodiment illustrated in Figures 9 to 11, the size of the recess 50 across the coronal plane is very close to that of the core 54 thereby preventing any lateral shifting of the core while still allowing anterior-posterior movement. However, in another embodiment, the recess 50 of the inferior shell 14a may be sized to allow such lateral movement of the core as well. Thus, by sizing the recess 50 as needed the core 54 can be allowed a freedom of movement in sagittal and/or coronal planes.

The disc of the invention can be made with a variety of materials as will be known to persons skilled in the art. For example, the shells may be manufactured from metals (such as stainless steel, titanium, titanium alloys, nickel-titanium alloys, such as Nitinol™, cobalt-chrome alloys, etc.), porcelain, and plastic and/or thermoplastic polymers (such as PEEK™) or any combination thereof. In addition, it will be understood that the "ball" of the inferior shell and/or "socket" of the superior shell may be made from materials that are the same or different from the remainder of the respective shells. For example, the "ball" may be made of titanium while the "socket" and both shells are made of PEEK. Various other combinations of materials will be known to persons skilled in the art.

The nucleus 20 of the invention has been described generally as comprising a resilient material. In one embodiment, such material comprises a hydrogel, which is a material known in the art. However, alternative materials may also be used for the nucleus.
For example, the nucleus may comprise mechanical springs (for example made of metal), hydraulic pistons, a hydrogel or silicone sac, rubber, a polymer or elastomer material, or any other such resilient material or device. One example of a suitable polymer material for the nucleus would be carbothane. Generally, the nucleus is made from resiliently compressible materials that serve to limit movement between the superior and inferior shells 12 and 14, 14a as described above and to provide a force for returning the disc 10, 10a to its neutral position.

219382141

[0070] Another embodiment of the invention is illustrated in Figures 12 to 21 wherein elements similar to those described above are identified with the prefix "1". As shown, the disc 110 according to the illustrated embodiment includes a superior shell 112 and an inferior shell 114. The outer surfaces of the artificial disc 110 may be provided with any shape or surface treatment as may be required. For example, as discussed above, the superior surface 113 of the superior shell 112 may be provided with a shape that conforms to the shape of the vertebral body that the disc 110 will contact when implanted.

[0071] Figure 13 illustrates the disc 110 in the open state, wherein the superior 112 and inferior 114 shells are separated. In both Figures 12 and 13, the nucleus of the disc is not shown. As can be seen in Figures 12 and 13, tabs 134 and 136 are provided on the lateral sides of the superior shell 112 and function similarly to the tab structures discussed above. As with the embodiment discussed previously, the inferior shell 114 of disc 110 is provided with a pair of slots 138 and 140, with one slot being provided on each lateral side of the inferior shell 114. As above, the slots 138 and 140 are adapted to receive the tabs 134 and 136, respectively, when the shells 112 and 114 are assembled to form the disc 110. In the embodiment of Figures 12 and 13, it can be seen that the slots 138 and 140 are sized so as to have a width that is greater than the width of the associated tabs 134 and 136. As discussed above, such an arrangement serves to allow some degree of translational movement of the tabs 134 and 136 within the associated slot 138 and 140. Such a freedom of movement between the slots and tabs allows the superior and inferior shells 112 and 114 to rotate with respect to each other thereby allowing a degree of axial rotation movement of the spinal segment wherein the disc 110 is implanted. It will be understood that the degree of rotational movement may be tailored by sizing either the slots or tabs. Although a single tab on each side of the disc has been described, it will be understood that any number of tabs may be provided for achieving the same result. Further, in other embodiments, the positions of the tabs and slots may be reversed wherein the tabs are provided on the inferior shell and the slots are provided on the superior shell.
Figure 13 also illustrates the generally "U" shaped well 128 defined by the outer wall 126 of the inferior shell 114. As discussed above, the well 128 accommodates the nucleus (not shown in Figures 12 and 13) of the disc 110. Figure 14 illustrates the inferior shell 114 wherein the nucleus 120 is accommodated within the well 128 shown in Figure 13.

The inferior shell 114 shown in Figures 13 and 14 includes a convex surface or ball 122 that cooperates with a convex surface (not shown in Figures 13 and 14) of the superior shell 112 in the same manner as described above.

As described with respect to the previous embodiments, the superior shell 112 is provided with a rim 132 on the anterior end 116 thereof. The rim 132 extends in a direction towards the inferior shell 114 when the disc 110 is in the assembled and implanted state. In one embodiment, as shown in Figures 12 to 14, the inferior portion of the inferior shell may be provided with, or extended to form, a lip 202 extending anteriorly and adapted to be positioned under the inferior edge 201 of the rim 132. As will be described further below, the lip 202 would serve as a further hard stop for the disc 110 during a flexion motion.

The slots 138 and 140 of the inferior shell are defined by anterior walls 203, 205 and posterior walls 204, 206, respectively. As discussed above, the slots 138 and 140 and the tabs 134 and 136 are respectively sized so as to allow the tabs to move within the respective slots when the disc 110 is subjected to an axial rotation movement. In such movement, it will be understood that the anterior edge of one of the tabs will abut the anterior wall of its associated slot while, simultaneously, the posterior edge of the other of the tabs will abut the posterior wall of its associated slot. When the disc 110 is rotated in the opposite direction, it will be understood that the opposite edges and walls will be abutting.

Figures 15 and 16 illustrate the disc 100 during a flexion (i.e. posterior to anterior) motion. As shown and as discussed above, during such motion, the superior and inferior shells articulate over the ball and socket type of connection formed between the convex surface (or ball) 122 of the inferior shell 114 and the concave surface (or socket) 124 of the superior shell 112. It will be understood that such articulation occurs for all translational and rotational movements that occurs between the shells 112 and 114. As shown in Figure 16, during flexion, the superior shell 112 articulates over the inferior shell 114 thereby resulting in compression of the nucleus 120 between the body of the socket portion 124 and the outer wall 126 of the inferior shell 114. The flexion motion is capable of continuing until the resilient nucleus 120 is no longer capable of being compressed. It will be understood that the compression of the nucleus 120 serves as a gradual or "soft" stop for such flexion.
motion. However, in order to provide a "hard" stop, the embodiment illustrated in Figures 15 and 16 are provided with other features. For example, as discussed above, the inferior shell 114 may be provided with a lip 202 that extends anteriorly underneath the inferior edge 201 of the rim 132 of the superior shell 112. As shown in Figures 15 and 16, in such an arrangement, flexion motion of the disc 110 is prevented upon the inferior edge 201 contacting the superior surface of the lip 202. Alternatively or in combination, the anterior walls 203 and 205 of the slots 138 and 140, respectively, may also be sized so as to abut the anterior edges of the tabs 134 and 136, respectively, to serve as a hard stop for flexion movement. This feature is illustrated in Figure 15 wherein the disc 110 is shown in the full flexion state and wherein the anterior edge of the tab 136 abuts the anterior wall 205 of the slot 140 (it will be understood that the tab 134 similarly abuts the anterior wall 203 of the slot 138).

[0077] Figures 17 and 18 illustrate the disc 110 of the embodiment in an extension (i.e. anterior to posterior) movement. In Figure 18, the nucleus 120 has been omitted for clarity thereby illustrating the well 128. As discussed above, the "hard" stop for the extension motion occurs when the posterior surface of the rim 132 contacts the anterior surface of the wall 126. As shown in Figure 18, such contact occurs generally at the superior edge of the wall 126; however, it will be understood that this will depend upon the degree of clearance provided between the rim 132 and the wall 126. That is, if the separation between the rim 132 and the wall 126 is smaller than that illustrated, the contact region between the two during extension will be positioned inferiorly. Figure 17 illustrates a further hard stop for the extension motion involving the tabs 134 and 136 and the respective slots 138 and 140. That is, as discussed above with respect to flexion, during extension, the posterior edges of the tabs 134 and 136 are moved towards the posterior walls 204 and 206 of the slots 138 and 140, respectively. Thus, as will be understood, such movement would be prevented from progressing upon the posterior edges of the tabs 134 and 136 contacting the posterior walls 204 and 206 (i.e. a "hard" stop is reached).

[0078] Figure 19 illustrates the disc 110 of the embodiment (but without the nucleus 120) in a lateral (side to side) motion between the superior and inferior shells 112, 114. As shown in Figure 19, a right to left movement of the superior shell 112, with respect to the inferior shell 114, involves an articulation of the socket 124 over the ball 122. Such movement is continued until the inferior edge 207 of the tab 136 contacts the base 208 of the slot 140 at which point, further lateral movement is prevented. It will also be noted in Figure 19 that the wall 126 provided on the inferior shell 114 is tapered upwardly. As will be understood, this arrangement will be preferred in order to allow the tab 134 to rise during the right to left
movement without contacting the wall 126. The above description has focused on a right to
left movement; however, it will be understood that a similar stop will be encountered during a
left to right lateral movement as well. As also illustrated in Figure 19, during a lateral
movement, one side of the disc is compressed and, in the result, any portion of the nucleus
(not shown) that may be present in the well 128 or enclosure, would be subjected to
compression and thereby offer a “soft” stop for such movement.

[0079] It should also be noted that although the above description of the disc 110 has
discussed specific movements in single planes, various combinations of movements will be
possible with the present invention.

[0080] Figures 20 and 21 illustrate various alternate embodiments of the nucleus
according to one embodiment of the invention. For clarity, the two embodiments of these
figures are indicated as 120a and 120b, respectively. In the embodiments shown, the nuclei
120a and 120b are shown as having a generally “U” shaped structure with the arms of the
“U” shape extending towards to posterior end 118 of the disc (not shown). The nuclei 120a
and 120b have inferior surfaces 210a, 210b and superior surfaces 211a, 211b, respectively.
As shown, the inferior surfaces 210a and 210b are generally planar and are adapted to be
accommodated within the well of the inferior shell of the disc (as discussed above). In the
embodiments shown in Figures 20 and 21, the anterior (i.e. in the direction of 116) portion of
the nuclei 120a, 120b are provided with thickened sections whereby the anterior ends of the
superior surfaces 211a, 211b of the nuclei rise above the posterior ends. In Figure 20, the
superior surface 211a is further provided with an inclined shape. With the structure of the
nuclei shown in Figures 20 and 21, it will be understood that a greater separation force will
be offered by the nuclei to space apart the superior shell from the inferior shell. Further, by
concentrating such separation force on the anterior end (116) of the disc, the nuclei of
Figures 20 and 21 cause the spinal segment in which the disc is implanted into the neutral
position when the individual is upright. That is, the increased separating force applied to the
anterior end of the disc will allow a degree of compression (such as to accommodate the
weight of the individual’s head) and still result in the segment to assume the neutral position.
It will be understood that this feature may be of importance primarily for discs implanted into
cervical spinal segments or where accommodation is desired to account for compression of
the nucleus due to overlying weight. The specific situations where such an accommodation
is required will be apparent to persons skilled in the art.

[0081] The artificial discs (e.g. 10, 10a etc.) discussed above include various features.
In one aspect, the discs may include various structural components to accommodate
individual and coupled movements such as axial rotation, lateral bending, and flexion/extension. In the result, the prosthetic disc of the invention generally reproduces neutral zone and elastic zone movements associated with a natural intact disc. Further, the invention allows for unconstrained and/or partially constrained coupled movements by means of engineered end-points that prevent excessive or non-physiological movement. The fully constrained stop mechanisms (i.e. the "hard stops") ensure that movement is, for example, not extended past the elastic zone.

[0082] In another aspect, the discs may be generally wedge shaped in the sagittal plane so as to integrate with and promote a lordotic spine configuration. Such an implant may be used in cases where spinal re-alignment is sought. For example, the disc may have a larger height at the anterior end as compared to the height of the posterior end to provide the aforementioned wedge shape. Similarly, such a difference in height may also be provided between the lateral sides of the disc, that is, in the coronal plane. This type of configuration may be used, for example, to correct a malalignment such as scoliosis.

[0083] In another aspect, one or both of the shells of the disc may be provided with a generally spherically curved external surface so as to provide the disc of the invention with an ovoid or semi-ovoid curvature in the coronal plane. This structure maximises disc to bone surface area and thereby promotes bony in-growth. Such structure also maximises prosthetic occupation of the disc space while stabilizing the disc against bone after implantation.

[0084] Various "hard stops" are provided to inhibit excess lateral, rotational and extension movement between the shells.

[0085] The external surfaces of the superior and inferior shells may be curved or spherical (i.e. ovoid, elliptical) or straight (i.e. squared) for insertion into bi-concave or rectangular discectomy sites at any area of the spine. The external surfaces may optionally be provided with anchoring ribs or keels for securing the disc to adjacent bone structures or to other artificial spinal structures.

[0086] In one embodiment, the superior shell may be larger in diameter, as taken in the sagittal plane (i.e. the anterior-posterior direction), than the inferior shell so as to better approximate the "normal" condition.

[0087] In one embodiment, the outer surface of the disc of the invention can be provided with one or more markings or physical features to render same opaque under radiography.
As will be understood, such features would aid in post-operatively verifying the alignment and/or positioning of the implant.

[0088] The footprint of the disc is preferably maximised in both the coronal and sagittal planes to help eliminate subsidence. As will be understood, the size of the discs of the invention will vary to accommodate various sizes of discs in the normal spine.

[0089] As discussed above, the ball and socket-like joint formed between the superior and inferior shells allows for complex relative motions there-between. The "ball" portion can be provided with a variety of geometries (e.g. radii of curvature) and in a variety of positions over the inferior shell to create different axes of rotation based on the need. It will be understood that a concomitant positioning of the socket portion of the superior shell will also be made in order to provide the ball and socket joint arrangement described above. In other embodiments, the ball portion may be moveable in one or more planes within a constrained space so as to allow the instantaneous axis of rotation to be dynamically variable and allow for greater variability in the range of motion provided by the disc of the invention.

[0090] In one embodiment of the invention, the "ball and socket" portion of the disc may include an interlocking, or male and female arrangement that prevents separation of the two shells while allowing the desired level of articulation there-between. An example of this arrangement is illustrated in Figures 22 to 24, which depict a variation of the disc shown in Figures 4 or 16. As shown in the embodiment of Figures 22 to 24, the "ball", or convex portion 322 provided at the posterior end 318 of the inferior shell 314 includes a stem 400 extending away from the inferior shell 314 in a direction towards the superior shell 312, when the shells 312 and 314 are in combination. The opposite end of the stem 400 includes a second convex portion 402 having a superior convex surface 404. In one aspect, the curvature of the convex surface 404 may correspond with the curvature of the convex portion 322. However, as will be understood from the discussion below, the invention is not limited to such an arrangement. In the embodiment shown in Figure 24, the convex portion 402 generally comprises a curved, disc-shaped element. Figure 23 illustrates the convex portion 402 in a posterior view.

[0091] As illustrated in Figures 22 to 24, the superior shell 312 is provided with a concave surface 324 similar to the surface 24 shown in Figure 4. The concave surface 324 is adapted to contact and engage the exposed surface 406 of the ball 322. The arrangement between the surface 406 of the ball 322 and the concave surface 324 will be understood to be the same as the ball 22 and concave surface 24 of the embodiment of
Figure 4, for example. That is, such arrangement allows articulation over the respective
curved portions of both elements. However, as shown in Figures 22 and 23, the illustrated
embodiment of the invention provides a superior shell 312 having a further pair of articulating
surfaces. Specifically, the superior shell 312 is provided with a second concave surface 408
that is adapted to engage the convex surface 404 of the convex portion 402. As will be
understood, the surfaces 408 and 404 combine to provide a further cooperating pair of
articulating surfaces for the disc of the invention.

[0092] As shown in Figures 22 to 24, the convex portion 402 is preferably wider than the
stem 400. In the embodiment shown in Figures 22 to 24, the convex portion 402 is disc
shaped and has a diameter that is greater than the diameter or width of the stem 400. In
turn, the superior shell 312 is provided with a downwardly depending wall 410 and an
inwardly extending radial flange 412 that preferably envelopes at least a portion of the
convex portion 402. As shown in Figures 22 and 23, the wall 410 and flange 412 serve to
positively engage the convex portion 402. That is, as shown in Figures 22 and 23, the wall
410 and flange 412 combine to form a socket 414 for engaging the convex portion 402
provided on the stem 400. In this way, the socket 414 forms the "female" portion, adapted to
receive the "male" convex portion 402. The stem 400 may also be considered as part of the
"male" portion. Thus, once the superior and inferior shells, 312 and 314, are combined, the
engagement between convex portion 402 and the socket 414 serves to prevent separation
of the shells beyond a pre-set limit. It will be understood that in order for the convex portion
402 to be engaged within the socket 414, the superior shell 312 may need to be provided
first in two sections and assembled or joined together to form the socket 414 within which the
convex portion 402 is contained. Various other embodiments may be possible for providing
the same result. For example, the flange 412 may be made of a resilient material that
permits flexing thereby allowing the convex portion 402 to be "snap-fit" within the socket 414.
Alternatively, the socket 414 may not necessarily engage the entire perimeter of the convex
portion 402, thereby allowing the shells 312 and 314 to be assembled together to form the
disc.

[0093] As shown in Figures 22 and 23, the socket 414 is preferably sized so as to allow
relative movement between the socket 414 and the convex portion 402. That is, the
diameter of the socket 414 is greater than the diameter of the convex portion 402. As will be
understood, this arrangement allows articulation between the superior and inferior shells 312
and 314. However, by sizing the socket 414 as desired, such articulation can be limited in
one or more directions. As will also be understood, the respective movement between the
shells occurs when the outer edge of the convex portion 402 contacts the wall 410. It will
also be understood that articulation may be adjusted in only one direction. For example, the
socket 414 may be designed with a generally oval shape, thereby allowing a greater degree
of relative motion in one direction than another. Such an arrangement may be used, for
example, to allow a greater degree of flexion and extension motion as opposed to lateral
motion. Similarly, the sizing of the socket 414 may be adjusted to allow more relative
movement is, for example, an extension motion as opposed to a flexion motion or vice versa.
As will also be understood the motion restriction afforded by the socket 414 and convex
portion 402 arrangement will generally be in addition to the other means of motion restriction
discussed above.

[0094] In another aspect of the invention, the inferior surface 416 of the convex portion
402 may also be provided with a curved, in this case concave, shape. The superior surface
418 of the flange 412 may also be provided with a cooperating convex shape. As illustrated
in Figures 22 and 23, this arrangement allows the surfaces 416 and 418 to also engage
each other thereby providing another pair of articulating surfaces during relative movement
of the superior and inferior shells 312 and 314. Thus, in one embodiment, the disc shown in
Figures 22 to 24 is provided with six pairs of articulating surfaces. In addition, with the
socket 414 and convex portion 402 arrangement, the shells 312 and 314 are positively
engaged thereby preventing axial separation of thereof.

[0095] In Figure 22 (as well as other discussed below) the curvature of surfaces 408 and
404 are shown as being of generally the same radius. Such an arrangement will be
understood to be preferable but not limiting. Further, the curvature of the surfaces 404, 408
is also shown to be the same as the curvature of the surfaces 406 and 324. It will be
understood that each pair of surfaces may be provided with a different radius of curvature.
However, since relative movement of the superior and inferior shells is generally of a
pivoting nature, it would be preferable for each pair of abutting surfaces to have a common
radius of curvature.

[0096] Figures 25 to 27 illustrate further embodiments of the socket and convex portion
arrangement (414 and 402) discussed with respect to Figures 22 to 24. In Figures 25 to 27,
elements that are identical to those shown in Figures 22 to 24 will be identified with the same
reference numerals. Those elements shown in Figures 25 to 27 that are similar but different
in shape or function will be identified with the same reference numeral but with the letters
"a", "b" and "c" added, respectively, for clarity.
As shown in Figure 25, the convex portion 402a is shown as a "ball" that is engaged within the socket 414a formed by combination of the concave surface 408a, the wall 410a and the flange 412a. As with the previously described embodiment, the socket 414a may be sized in any desired manner to allow the required amount of relative movement between the superior and inferior shells 312 and 314.

Figure 26 illustrates an embodiment wherein the convex portion 402b includes a convex surface 404b that is similar to that shown in Figures 22 to 24. However, the convex portion 402b in this case includes an inferior surface 416b that is generally convex in shape. In turn, the superior surface 418b of the flange 412b comprises a cooperating concave shape.

Figure 27 illustrates a further embodiment, which comprises a combination of the disc shown in Figures 22 and 26. Specifically, as shown, the superior surface 404c of the convex portion 402c and the inferior concave surface 408c of the superior shell are essentially the same as those shown in Figures 22 and 23. However, the inferior surface 416c of the convex portion 402c is provided with a combination of convex and concave portions. Specifically, in the embodiment shown in Figure 27, the posterior (318) portion of the inferior surface 416c is provided with a convex shape while the anterior (316) portion of the inferior surface 416c is provided with a concave shape. Similarly, the superior surface 418c is adapted at the posterior and anterior ends to accommodate such different curvatures. As will be understood, any other combination of curvatures between cooperating surfaces may be used depending on the need and/or desired motion requirements and restrictions.

In the above descriptions with respect to Figures 22 to 27, the various articulating surfaces have been described as having some form of curvature. However, it will be understood that one or more of the surfaces of such figures, and other figures and descriptions provided herein, may also be provided with a flat or undulating shape. Further, the adjacent surfaces may be provided with any degree of relative friction so as to facilitate or restrict relative movement there-between.

Figure 28 provides another variation on the embodiments illustrated in Figures 22 and 23. Elements shown in Figure 28 that are common with those of Figures 22 and 23 are identified with the same reference numerals. Elements that are similar but including some variation are identified with common reference numerals but with the letter "e" added for clarity. As shown, the arrangement depicted in Figure 28 is similar to that of Figure 23 but
the convex portion 402e and the rail 400e are divided into two sections to form two rail-like
structures. In turn, the superior shell 312 is provided with a cooperating rail comprising an
interiorly extending stem 420 terminating with a widened base 422. As shown in Figure 28,
the stem 420 and corresponding base 422 combine to form a pair of sockets or recesses
414e for receiving the pair of convex portions 402e. Although Figure 28 is shown with a pair
of convex portions 402e, it will be understood that the disc may be designed with any
number of such portion. In such case, the number of inferiorly extending stems 420 and
associated bases 422 will also be adjusted. Further, although the convex portions 402e
have been shown with convex inferior surfaces, it will be understood that, as described
above, such surfaces may be concave or a combination thereof.

[00102] Figure 29 illustrates another variation of Figure 28 wherein elements that are
common with those of Figures 28 are identified with the same reference numerals and
elements that are similar but including some variation are identified with common reference
numerals but with the letter "f" added for clarity. In this case, it will be noted that the convex
portions 402f are provided as a pair and that such portions extend only over external lateral
edges of the respective stems 400f. This embodiment also shows an inferiorly extending
stem 420f that does not have an outwardly flared base portion but is essentially monolithic.
That is, in Figure 29, the stem 420 and base 422 of Figure 28 are combined together. The
inferior surface of the stem 420f is provided with a concave curvature to allow articulation
with the superior convex surface 406 of convex portion 322 provided on the inferior shell
314.

[00103] Figure 30 illustrates a further variation of the embodiment of Figure 22 wherein
elements that are common with those of Figures 28 are identified with the same reference
numerals and elements that are similar but including some variation are identified with
common reference numerals but with the letter "g" added for clarity. In Figure 30, the
convex portion 402g is not integrally formed with the stem 400 but is secured thereto. In the
embodiment shown, such securing is achieved by means of a screw 424. As shown, on
means of achieving this involves inserting the screw through the inferior surface of the
inferior shell 314 and extending the screw through the stem 400. As will be understood, this
means of securing would preferably be conducted prior to implantation of the disc. It will
also be understood that any type of securing means can be used to anchor the convex
portion 402g to the stem 400.

[00104] Figure 31 illustrates yet another embodiment wherein the convex portion
discussed above is secured to the superior shell 312. As shown in Figure 31, the inferior
shell 314 includes the convex portion 322, with a superior convex surface 406, as described
previously and the superior shell 312 includes an inferior concave articulating surface 324
adapted to engage the aforementioned convex surface 406. However, the embodiment of
Figure 31 differs from the embodiment of Figure 22 in that the additional "ball" portion
extends inferiorly from the superior as opposed to the opposite orientation as shown above.
That is, the posterior (318) socket portion of the superior shell includes an inferiorly
extending stem 430 having a flared portion 432 at the inferior end thereof. The flared portion
432 includes a concave inferior surface, which forms the concave surface 324 that engages
the superior convex surface 406 of the ball portion 322 of the inferior shell 314. As also
shown in Figure 31, the ball portion 322 of the inferior shell includes a slot 436 adapted to
receive the flared portion 432. The slot 436 is defined by the concave surface 324, a
superiorly extending wall 438, and an inwardly extending flange 440 provided at the superior
end of the wall 438. The slot 436 is adapted to receive the flared portion 432 in the same
manner as described above with respect to Figure 22. Similarly, the flange 440 are received
within a respective recess 442 defined by the superior surface of the flared portion 432 and
the inferior portion of the superior shell. Thus, the combination of the flared portion 432
being positively received within the slot 436 and the flange 440 being received within the
recess 442 serves to prevent separation of the shells 312 and 314 while allowing any
desired amount of articulation there-between.

[00105] In the descriptions above with respect to Figures 22 to 31, various other aspects
of the disc of the invention were not discussed since such elements would be the same or
similar as those described previously. For example, the discs shown in Figures 22 to 31
would preferably include the various force absorption and motion restricting means as
described with respect to prior embodiments. It will be understood that such other elements
have not been depicted in the figures simply for ease of illustration. Similarly, as described
above, the external or bone engaging surfaces of the shells of the invention may be provided
with any manner of bone engaging or anchoring devices, coatings or surface treatments.
For example, the external surfaces may be provided with a plurality of spikes or keels etc. as
known in the art.

[00106] Although the invention has been described with reference to certain specific
embodiments, various modifications thereof will be apparent to those skilled in the art
without departing from the purpose and scope of the invention as outlined herein. The entire
disclosures of all references recited above are incorporated herein by reference.
WE CLAIM:

1. An artificial intervertebral disc for implantation between adjacent superior and inferior vertebrae of a spine, the disc comprising:
   - a superior shell, an inferior shell, and a means of biasing the superior and inferior shells apart;
   - the superior and inferior shells being moveable with respect to each other over two or more articulating surfaces;
   - the inferior shell having a superior surface comprising a posteriorly positioned convex portion;
   - the superior shell having an inferior surface opposing the superior surface of said inferior shell, and comprising a posteriorly positioned concave portion, opposite said convex portion;
   - the convex and concave portions being in articulating cooperation to form a ball and socket joint;
   - at least one of the convex or concave portions having at least one male portion and the other of the convex or concave portions having a corresponding number of cooperating female portions adapted to receive and positively engage said at least one male portion.

2. The disc according to claim 1 wherein said male and female portions have corresponding curved surfaces to form a further articulation surface there-between.

3. The disc according to claim 1 or 2 wherein said male and female portions are engaged in a lock and key arrangement thereby preventing separation of the superior and inferior shells.

4. The disc according to any one of claims 1 to 3 wherein said female portion is sized larger than the male portion to allow relative movement of the superior and inferior shells.

5. The disc according to any one of claims 1 to 4 wherein a plurality of male and corresponding female portions are provided.

6. The disc according to any one of claims 1 to 5 wherein said male portion comprises a generally disc shaped structure.
7. The disc according to any one of claims 1 to 5 wherein said male portion comprises a ball shaped structure.

8. The disc according to any one of claims 1 to 5 wherein said male portion comprises a rail shaped structure.

9. The disc according to any one of claims 1 to 8 wherein said male and female portions are provided with a plurality of articulating surfaces.
INTERNATIONAL SEARCH REPORT

International application No
PCT/CA2009/001603

A CLASSIFICATION OF SUBJECT MATTER

IPC A61F 2/44 (2006 01)

According to International Patent Classification (IPC) or to both national classification and IPC

B FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
P C A61F 2/44 (2006 01)
US CI 623/17

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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, implant, shells, ball/socket, interlocking, locking, male/female, separation

C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US67709095 (GRMBERG ET AL ) 03-Aug-2004 (03-08-2004) Entire document, Figures 1-5</td>
<td>1-4, 6-9</td>
</tr>
<tr>
<td>A</td>
<td>US6679915 (CAUTHEN) 20-January-2004 (20-01-2004) Entire document, Figure 1B &amp; 9</td>
<td>1</td>
</tr>
</tbody>
</table>

[X] See patent family annex

* Special categories of cited documents:
A document defining the general state of the art which is not considered to be of particular relevance
E earlier application or patent but published on or after the international filing date
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)
O document referring to an oral disclosure use exhibition or other means
P document published prior to the international filing date but later than the priority date claimed
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
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
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
& document member of the same patent family

Date of the actual completion of the international search
05 February 2010 (05-02-2010)

Date of mailing of the international search report
16 February 2010 (16-02-2010)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, Cl 14 - 1st Floor, Box PCT
50 Victona Street
Gatmeau, Quebec K1A 0C9
Facsimile No 001-819-953-2476

Authorized officer
Hoan Huynh (819) 934-3467
<table>
<thead>
<tr>
<th>Patent Document</th>
<th>Publication Date</th>
<th>Patent Family Member(s)</th>
<th>Publication Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>US 6770095B2</td>
<td>03-08-2004</td>
<td>AU 2003204770A1</td>
<td>15-01-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BR 0305189A1</td>
<td>17-08-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2432627A1</td>
<td>18-12-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1374807A1</td>
<td>02-01-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2004154549A</td>
<td>03-06-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MX PA00055522A</td>
<td>06-09-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2003233146A1</td>
<td>18-12-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 7493358B2</td>
<td>27-06-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 777480B2</td>
<td>21-10-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 778600B2</td>
<td>09-12-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 3758799A</td>
<td>08-1-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 4178801A</td>
<td>12-09-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 6922400A</td>
<td>26-03-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 20022301243B2</td>
<td>07-10-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2329363A1</td>
<td>28-10-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2329363C</td>
<td>11-12-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2382572A1</td>
<td>08-03-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2394663A1</td>
<td>07-09-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 1262253C</td>
<td>05-07-2006</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 1387423A</td>
<td>25-12-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 60034893D1</td>
<td>28-06-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 60034893T2</td>
<td>24-01-2008</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1075236A1</td>
<td>14-02-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1259197A1</td>
<td>27-1-1-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ES 2284520T3</td>
<td>16-1-1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2002512079T</td>
<td>23-04-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2003512090T</td>
<td>02-04-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2003524505T</td>
<td>19-08-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6440188B1</td>
<td>27-08-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 6846328B2</td>
<td>25-01-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 7270681B</td>
<td>18-09-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 7270681B</td>
<td>18-09-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2004049280A</td>
<td>11-03-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2004153159A1</td>
<td>05-08-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 0115638A1</td>
<td>08-03-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 0164142A1</td>
<td>07-09-2001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 9953871A1</td>
<td>28-10-1999</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 1283501C</td>
<td>30-04-1991</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 3873566D1</td>
<td>17-09-1992</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DE 3873566T2</td>
<td>21-01-1993</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 0282161A1</td>
<td>14-09-1988</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 0282161B1</td>
<td>12-08-1992</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 1308557A</td>
<td>13-12-1989</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 1862420C</td>
<td>08-08-1994</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 5070470B</td>
<td>05-10-1993</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2300613C</td>
<td>23-09-2003</td>
</tr>
</tbody>
</table>