Abstract:

A constrained spinal implant is inserted between adjacent vertebrae to function as an disk prosthesis. The prosthesis has two plates fastened to adjacent vertebrae facing each other. The facing sides of the plates each have a depending skirt formed as concentric arcs of about 90 degrees. The skirts are either bowed or tapered in the axial direction. Depressions are centrally located between the arcs of the plates and a ball is universally movable in the depressions.
CONCENTRIC INTERIOR INSERT BALL AND DUAL SOCKET JOINT

Field of the invention

This invention relates to orthopedic surgery and, in particular, constrained spinal implants for replacement of ruptured or excised spinal disks.

BACKGROUND OF THE INVENTION

Several attempts have been made to design a spinal prosthesis for replacement of missing or excised disk material that replicates the functions of the missing tissue. U. S. Patent No. 4,759,769 to Hedman et al discloses an artificial disk device in which two plates are attached to the adjacent vertebrae by bone screws inserted through flanges on the plates. A spring biasing mechanism is captured between the plates to simulate the actions of the natural disk material. U. S. Patent No. 5,246,458 to Graham and U. S. Patent No. 6,228,118 to Gordon disclose other intervertebral implants with spherical flanges used to connect the device to adjacent vertebra. Graham also teaches a resilient structure.

The patents to Marnay, U. S. Patent No. 5,314,477, Buttner-Janz et al, D. S. Patent No. 5,401,269, Yuan et al, U. S. Patent No. 5,676,701, and Shelokov, U. S. Patent No. 6,039,763, all are directed to the design of the opposing faces of the adjacent plates of an implant to provide a limited universal joint to simulate the natural movement of the spine.

U. S. Patent No. 5,683,465 to Shinn et al teaches two plates with bow shaped skirts which are interlocked.

SUMMARY OF THE PRESENT INVENTION

The invention is directed to a constrained spinal implant for insertion between adjacent vertebrae to function as a disk prosthesis. The prosthesis is formed from two plates fastened to adjacent vertebrae facing each other. The facing sides of the plates have an interacting, depending skirt. The skirts are range limiting wherein the skirt on a superior endplate can be shaped to limit lateral, flexion and extension motion. A depression is centrally located between the arcs of both plates. A sphere or ball is placed in the central depression of one of the plates. The plates are oriented to each other at 90 degrees and the ball is engaged in the depression of the other plate. The plates are then rotated about 90 degrees and the skirt of
one plate interlocks with an opposed arcs of the other plate
to prevent separation in the axial direction.

Therefore, it is an objective of this invention to
provide a constrained spinal implant for axial support of
the spinal column which replicates the dimensions and
function of an intervertebral disk.

It is another objective of this invention to provide a
kit including all the components for assembly and surgical
placement of an artificial spinal disk.

It is a further objective of this invention to provide
a method of assembly of the components of the kit which
results in an axially interlocked constrained spinal
implant. Specifically, one plate forms a receptacle for a
dynamic socket to be inserted and fixed in place internally.

It is yet another objective of this invention to
provide a ball and socket joint between two plates attached
to adjacent vertebrae permitting axial rotation, lateral
bending, vertical tilting and axial compression.

It is a still further objective of this invention to
provide shaped interrupted skirts on two plates which act as
stop limits for tilting and bending.

It is another objective of this invention is to provide
an axially resilient ball and socket joint, compressive load
bearing poly-axial motion joint.

It is another objective of this invention is to provide
use of a true roller-ball bearing which reduces radial
friction forces and the entire spherical ball surface area
can be utilized for low wear characteristics.

Still another objective of this invention is to provide
the use of an endplate that can be shaped to limit lateral,
flexion and extension motion.

Still another objective of this invention is to provide
a constrained construct implant.

Still another objective of this invention is to provide
an inserter instrument.

Other objectives and advantages of this invention will
become apparent from the following description taken in
conjunction with the accompanying drawings wherein are set
forth, by way of illustration and example, certain
embodiments of this invention. The drawings constitute a
part of this specification and include exemplary embodiments
of the present invention and illustrate various objects and
features thereof.
BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the concentric spinal disc of this invention;
Fig. 2 is a front plane view of the embodiment shown in Fig. 1;
Fig. 3 is a front plane view illustrating a 10 degree lateral movement;
Fig. 4 is a side view illustrating a 10 degree flexion;
Fig. 5 is a side view illustrating a 15 degree extension;
Fig. 5A is a side view illustrating a 75% component lateral/extension position with 5 degrees of axial rotation;
Fig. 6 is a partial exploded view depicting the superior endplate separated from the inferior endplate;
Fig. 7 is a fully exploded view depicting the superior endplate separated from the inferior endplate and a ball seat and retainer ring separated from the endplates;
Fig. 8 is a cross sectional side view of the concentric spinal disc;
Fig. 9A is a perspective view of the inner surface of the superior endplate;
Fig. 9B is a perspective view of the inner surface of the inferior endplate;
Fig. 9C is a top view illustrating the inferior endplate and superior endplate in a pre-coupled orientation;
Fig. 9D is a front plant view illustrating the endplates coupled together;
Fig. 10 is a perspective view of the inner surface of the superior endplate depicting the range limiting surface;
Fig. 11 is a cross sectional side view of the concentric spinal disc having an embodiment with a axial compression o-rings;
Fig. 12 is a side view having an embodiment with tapered endplates;
Fig. 13 is a perspective view of the inserter instrument;
Fig. 14 is an enlarged view of the tip of the inserter instrument depicted in Figure 13.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the Figures, the constrained spinal implant 10, shown in Fig. 1, has an upper plate 11, a lower plate 12 pivotable on a universally rotatable sphere or ball
The upper plate 11 and the lower plate 12 form a cage when assembled with the ball 50 captured for universal movement within the interior of the cage to define an inner ball and socket 86. Of course, the position of the plates can be reversed, in use. Both upper plate 11 and lower plate 12 have a plan form substantially the size and shape of the end wall of the vertebra between which the implant will be placed to produce the maximum area of contact between the implant and the vertebra for stability and support. Obviously, different sized plates are necessary because of the difference in size of vertebra within regions of the spinal column and the different sizes or ages of patients. The concentric spinal disc can be sized as a cervical disc, a thoracic disc, or a lumbar disc.

The upper plate 11 has a planar surface 14 for contact with the end wall of a vertebra and an opposite disk surface 15. Depending from the disk surface is a continuous skirt 16 with opposed internal spherical bearing surfaces 17 and 18. The spherical bearing surfaces are approximately 180 degrees apart at their centers and extend about 90 degrees around the continuous skirt. However, it should be noted that smaller or larger spherical bearing surfaces spaced to provide axial guidance and load bearing may be utilized without departing from the scope of the invention. In the preferred embodiment, the diameter of the arcs is less than the periphery of the plate 11 leaving a horizontal flange 19. Centrally located within the spherical bearing surfaces formed within the continuous skirt is a receptacle 13. A sleeve 51 is inserted in the receptacle 13 and telescopes in the plate 11. The sleeve 51 has a spherical depression 52.

The lower plate 12 has a planar surface 20 for contact with the end wall of a vertebra and an opposite disk surface 21. Upstanding from the disk surface is an continuous skirt 22 with opposed external spherical bearing surfaces 23 and 24. The spherical bearing surfaces are approximately 180 degrees apart at their centers and extend about 90 degrees around the skirt. However, it should be noted that smaller or larger spherical bearing surfaces spaced to provide axial guidance and load bearing may be utilized without departing from the scope of the invention. The diameter of the arcs is less than the periphery of the plate 12 leaving a horizontal flange 25. Centrally located within the semi-circular arcs is a receptacle 26. A sleeve 53 is inserted
in the receptacle and reciprocates in the plate 12. The sleeve 53 has a depression 54 that is rounded and shaped to closely mirror the contours of the depression 52. The depressions 52 and 54, as well as the diameter of the ball 50, are of such dimensions construction to provide bearing surfaces suitable to support the weight of the spinal column.

As shown, though the relationship could be reversed, the opposed spherical bearing surfaces 17 and 18 of the depending skirt 16 are concentric with the opposed spherical bearing surfaces 23 and 24 of the upstanding skirt and of larger diameter allowing rotation of the plates relative to each other with surface contact between the outer spherical bearing surface(s) of the upstanding skirt and the inner bearing surface(s) 29 of the depending skirt to define an outer ball and socket 85.

The constrained spinal implant provides support and range of motion similar to the natural joint in that the plates 11 and 12 may rotate axially limited by natural anatomical structures, such as tendons, ligaments and muscles. To simulate the compression of the natural disk during normal activities, such as walking, an alternative embodiment as shown in Figure 11 may include a spring mechanism o-ring 60, 61 placed in the vertical axis of the plates 11 and 12. The springs are resiliently compressible.

In the manufacturing step, the o-ring 61 is inserted and covered by the sleeve 53. A retainer ring 58 is placed between the upper circumference of the sleeve 53 and is preferably laser welded to the plate. Other suitable permanent attachment methods well known in the art may also be used without departing from the scope of the invention. Similarly, an o-ring 60 may be used in the upper plate 11 with the sleeve 51 inserted and held in position by a retainer ring 55, the retainer ring can then be laser welded to the plate or other permanent attachment methods may be used. By absorbing some of the longitudinal loads, the prosthesis lessens the stresses on the adjacent natural disks. Further, during placement of the prosthesis, the springs may be compressed to lessen the overall height of the prosthesis.

The spine may bend laterally and tilt medially in flexion/extension in a range comparable to the normal range of motion. The implant of the instant invention provides
limitation of these movements through interaction of the
depending skirt and the upstanding skirt. As shown in
Figures 9a-9d, the components of the implant are connected
together by orienting the spherical bearing surfaces 17-18
and 23-24 at about 90 degrees relative to each other. This
action allows the skirts to be vertically overlapped. In a
pre-couple orientation, the ball 50 is placed in the
inferior endplate 12 and the superior endplate 11 is placed
over the ball and then the plates 11 & 12 are rotated
through 90 degrees relative to each other. This rotation
aligns the depending opposed spherical bearing surface (s)
with the upstanding opposed spherical bearing surface (s) and
interlocks the plates in a movable joint that cannot be
separated axially. The inner surface 28 of the continuous
skirt 16 slidably contacts the outer surface 29 of the skirt
22. The contacting bearing surfaces are spherical or bowed,
from the plate at least to the height of the diameter of the
ball 50, forming another ball and socket joint with the
bottom edge of the depending arc 23 of a larger diameter
than the top edge of the upstanding arc 17 by which the
plates are interlocked. Of course, the remainder of the
inner and outer surfaces of the skirts may be straight or
tapered and spaced apart to allow for bending and tilting.
As shown in Fig. 2 the inferior endplate 12 and the superior
endplate 11 are interlocked and Fig. 3 depicting the lateral
movement of the superior endplate 11 in a range of ±10°.
Fig. 4 depicts the inferior endplate in a flexion of about
10° and Fig. 5 depicts the inferior endplate in an extension
position of about 15°. These ranges are only to be
considered as illustrative, the skirts can be ground to a
particular geometry to meet a particular patient needs.
Fig. 10 illustrates the range limiting surface 17 that can
be contoured to limit the lateral, flexion and extension
motion for the superior endplate 11.

In the preferred embodiment, fastening to the vertebra
can be enhanced by the use of spikes 34 attached or formed
on flanges 19 and 25 which are to be driven into the end
walls of the adjacent vertebra.

Alternatively, or in conjunction with spikes, each of
flanges 19 and 25 of the constrained spinal implant may
include a vertical extension, not shown, which cooperate
with bone screws to mount the constrained spinal implant on
the vertebra. The vertical extension is illustrated in the
inventors prior application(s) which are incorporated by
reference. The vertical extensions can be on opposite
lateral sides of the flanges 19 and 25 permitting fastening
of each plate on the opposite side of adjacent vertebrae.
The fasteners may be used together, e.g., the spikes may be
on one plate and the vertical extensions on the other plate
of the same constrained spinal implant.

The components are made from materials that are
suitable for implantation in the living body and have the
requisite strength to perform the described functions
without deformation, e.g., the opposed bearing surfaces of
the depressions and ball may be made of metal or ceramic or
a suitable combination thereof, respectively, the ceramic
material is implant grade alumina ceramic or a silicon
nitride or carbide and the metal may be a nitrogen alloyed
chromium stainless steel or cobalt chrome alloy, or
titanium, and alloys of each, coated metals, ceramics,
ceramic coatings, and polymer coatings.

The plates may be made entirely of cobalt chrome alloy
or only the inserts. In the high wear areas, such as the
depressions, coatings or inserts may be used to prevent
galling and permit repair. In this modular concept, the end
plates may be titanium, titanium alloy, or stainless steel
among other materials as discussed above.

The prosthetic ball 50 is preferably made from an
implant grade alumina ceramic or a silicon nitride or
silicon carbide material. The ball 50 may be formed
entirely of the ceramic material or a ceramic coating on
another matrix. The alumina ceramic or silicon nitride or
silicon carbide material can be manufactured by isostatic
pressing or any other suitable method well known in the art.
The ball 50 is then machined to shape and the surface
polished to a mirror-like finish. The ceramic ball is
completely corrosion resistant and is non-abrasive. The
solid matrix eliminates the wear particles, such as those
liberated from metal, other coated metals and polyethylene
implants. The ball 50 has excellent thermal conductivity
thereby reducing patient discomfort associated with exposure
to cold weather. Further, the alumina ceramic or silicon
nitride implant will react well with x-ray and MRI (magnetic
resonance imaging) diagnostic procedures.

The kit contains plates with protrusions and skirts of
varying lengths to allow selection of components for an
implant with the axial dimension substantially the same as
the thickness of the disk the implant will replace. The kit
may also contain upper and lower plate components of varying
sizes. Figure 12 illustrates the implant 10 having tapered
endplates 11 and 12 that can be used for ease of insertion.
Further, the implant can be assembled by a surgeon in the
operating room allowing for modular endplate selection to
make-up for custom disc construct. Modular endplates would
allow control over disc-space height and enable a better
match of the kyphotic/lordotic endplate angles.

Referring now to Fig. 13, the use of the instant
implant provides for a constrained construct when the plates
are coupled together. In addition to coupling the plates
together, the outer ball and socket construction prevents
migration of the plates in relation to each other. The face
of each endplate may include a radial surface positioned in
relation to the ball bearing centerline. Insertion of the
instant invention may be aided by a drive tool 80 having a
handle 82 and an implant holder 84 formed from a rigid shank.
The implant holder 84 allows for impacting forces to be on
the endplate faces 19 and 25, thereby eliminating an impact
on the outer skirt 16. In this manner, both endplates are
manipulated as a single unit. In use, the implant holder
84 is positioned along the first end and conforms to the
superior endplate of a constrained spinal implant by use of
a C-shaped end with an upper surface 21 and a lower surface
23 sized to fit between the upper plate and lower plate of
the spinal implant. The second end forming a handle 82 with
an impact tip 83. The spinal implant is positioned within
the first end 84 with the handle available to align the
spinal implant. The impact tip available for receipt of
mallet impact to allow a forced placement of the implant
between the vertebrae.

A number of embodiments of the present invention have
been described. Nevertheless, it will be understood that
various modifications may be made without departing from the
spirit and scope of the invention. Accordingly, it is to be
understood that the invention is not to be limited by the
specific illustrated embodiment but only by the scope of the
appended claims.
We Claim:

1. A constrained spinal implant for placement between adjacent vertebrae to replace disk material comprising a first plate and a second plate adapted to interlock about a central axis, said first plate having a substantially planar vertebrae engaging side and a disk side, a first skirt on said disk side extending approximately normal to said plate, said first skirt formed to include opposing spherical bearing surfaces on an inner surface thereof, a first depression along said central axis of said disk side of said plate centrally located between said opposing spherical bearing surfaces, said second plate having a second planar vertebrae engaging side and a second disk side, a second skirt on said second disk side extending approximately normal to said second plate, said second skirt formed to include opposing spherical bearing surfaces on an outer surface thereof, a second depression along said central axis of said second disk side of said second plate centrally located between said opposing spherical bearing surfaces and a universally rotatable ball captured in said depressions; whereby said substantially planar vertebrae engaging side of said first plate is adapted to contact a vertebrae and said substantially planar vertebrae engaging side of said second plate is adapted to contact an adjacent vertebrae with said depressions each adapted to form a bearing surface for said ball along said central axis and whereby said first and second skirts are interlocked forming a universal joint and shaped to limit lateral, flexion and extension motion.

2. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said first skirt and said second skirt are concentric in a plane substantially parallel with said first and second plates.

3. The constrained spinal implant for placement between adjacent vertebrae of claim 2 wherein said spherical bearing surfaces on said first and said second plates are constructed and arranged to couple said first plate to said second plate for universal movement therebetween.
4. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said opposed spherical bearing surfaces of said first skirt are adapted to contact said opposed spherical bearing surfaces of said second skirt.

5. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said opposed spherical bearing surfaces of said first skirt and said second skirt each extend approximately 90 degrees along the perimeter of said first and said second skirts respectively.

6. The constrained spinal implant for placement between adjacent vertebrae of claim 2 wherein said first skirt and said second skirt are concentric in a plane parallel with said first and second plates, said opposed spherical bearing surfaces of said first interrupted skirt adapted to contact said opposed spherical bearing surfaces of said second interrupted skirt to form an interlocked universally movable outer ball and socket.

7. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said first plate includes a central bore, a sleeve slidably secured in said bore, said first depression formed in said sleeve.

8. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said opposed spherical bearing surfaces of said first interrupted skirt and said opposed spherical bearing surfaces of said second interrupted skirt are concentric segments of a sphere whereby said concentric bearing segments of said first skirt are adapted to contact said concentric segments of said second skirt to form an interlocked universal joint.

9. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said first plate includes a cavity between said depression and said vertebrae side, an O-ring spring secured in said cavity, said ball adapted to flex said O-ring spring- resulting in resilient compression.
10. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein said second plate includes a cavity between said second depression and said vertebrae side, an O-ring spring secured in said cavity, said ball adapted to flex said O-ring spring resulting in resilient compression.

11. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein a plurality of first plates of different sizes, a plurality of balls of different sizes and a plurality of second plates of different sizes comprise a kit whereby a proper sized constrained spinal implant can be selected from said kit.

12. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein an elastic membrane extends between said first plate and said second plate about the periphery of said first plate and said second plate.

13. The constrained spinal implant for placement between adjacent vertebrae of claim 12 wherein said elastic membrane is continuous and a viscous polymeric composition is located within said membrane.

14. The constrained spinal implant for placement between adjacent vertebrae of claim 1 wherein at least one of said vertebrae engaging side or said second vertebrae engaging side includes a plurality of spikes for engaging vertebrae.

15. A drive tool for positioning a constrained spinal implant between adjacent vertebrae comprising an elongated shaft having a first end conforming to a superior endplate of a constrained spinal implant and a second end forming a handle with an impact tip, whereby said spinal implant is positioned within said first end with said handle available to align said implant with said impact tip available for receipt of mallet impact to allow a forced placement of the implant between the vertebrae.
16. The drive tool for positioning a constrained spinal implant according to Claim 15 wherein said first end is C-shaped having an upper surface and a lower surface sized to fit between an upper plate and a lower plate of said spinal implant with said C-shape engaging said endplate.

17. A method of assembling a constrained spinal implant comprising the steps of:
   a) providing a first plate, said first plate having a planar vertebrae engaging side and a disk side, a first shaped skirt on said disk side extending approximately normal to said plate, said skirt formed to include opposing spherical bearing surfaces, a depression in said disk side of said plate centrally located between said opposing spherical bearing surfaces,
   b) providing a second plate having a second planar vertebrae engaging side and a second disk side, a second shaped skirt on said second disk side extending approximately normal to said second plate, said second skirt formed to include opposing separated spherical bearing surfaces, a second depression in said second disk side of said second plate centrally located between said opposing arcs,
   c) providing a ball and placing said ball in said depression,
   d) orienting said first plate and said second plate parallel with each other and rotated about ninety degrees with respect to said second plate,
   e) moving said first plate closer to said second plate to engage said ball into said depression and said second depression in axial alignment, and
   f) rotating said first plate with respect to said second plate about a central axis until said spherical bearing surfaces of said first plate interlock with said opposing spherical bearing surfaces of said second plate to form a universally moveable connection therebetween.

18. The method of assembling a constrained spinal implant according to Claim 17 wherein said shaped skirt is contoured to provide a predetermined lateral bending of said first plate with respect to said second plate.
19. The method of assembling a constrained spinal implant according to Claim 17 wherein said shaped skirt is contoured to provide a predetermined flexion bending of said first plate with respect to said second plate.

20. The method of assembling a constrained spinal implant according to Claim 17 wherein said shaped skirt is contoured to provide a predetermined extension bending of said first plate with respect to said second plate.

21. A constrained spinal implant for placement between adjacent vertebrae to replace disk material comprising:

   a first plate having a first substantially planar vertebrae engaging side and a disk side, a first continuous skirt on said disk side extending approximately normal to said plate, said first skirt formed to include substantially opposing spherical bearing surfaces on an inner surface thereof, a spherical depression formed along said central axis of said disk side of said plate centrally located between said opposing spherical bearing surfaces;

   a second plate having a second substantially planar vertebrae engaging side and a second disk side, a second skirt on said second disk side extending approximately normal to said second plate, said second skirt formed to include opposing spherical bearing surfaces on an outer surface thereof, a second spherical depression along said central axis of said second disk side of said second plate centrally located between said opposing spherical bearing surfaces, and

   a universally rotatable ball captured in said depressions, said ball and said spherical depressions defining an inner universally moveable ball and socket, said spherical bearing surfaces of said first and said second skirt interlocking to define a universally movable outer ball and socket.

22. The constrained spinal implant for placement between adjacent vertebrae of claim 21 wherein at least one of said first or second skirts is shaped to limit lateral, flexion and extension motion.
23. The constrained spinal implant for placement between adjacent vertebrae of claim 21 wherein said inner ball and socket and said outer ball and socket both pivot about the same central point.

24. The constrained spinal implant for placement between adjacent vertebrae of claim 21 wherein said inner ball and socket is constructed and arranged to be compressible.

25. The constrained spinal implant for placement between adjacent vertebrae of claim 21 wherein said outer ball and socket is constructed and arranged to prevent axial separation of said first and said second plates.
**Fig. 9A**

**Fig. 9B**

**Fig. 9C**

**Coupling clearance zone**

**Fig. 9D**

**Coupled Joint**