ABSTRACT

Systems and methods for reducing pressure within a spinal disc are described. In accordance with one implementation, a spinal disc system comprises an aperture within a spinal disc body, and the aperture is configured to permit nucleus pulposus to flow from the disc body through the aperture. In accordance with another implementation, a method of reducing pressure within a spinal disc comprises forming an aperture within a spinal disc body, and permitting at least a portion of the nucleus pulposus to flow from the disc body through the aperture.
SYSTEMS AND METHODS FOR REDUCING PRESSURE WITHIN A SPINAL DISC

TECHNICAL FIELD

[0001] This application relates generally to spinal disc systems and methods for reducing pressure within a spinal disc.

BACKGROUND

[0002] A human spinal column includes vertebral bodies alternating with intervertebral discs extending from the neck to the pelvis. The discs generally form strong joints, separate, cushion and allow flexure and torsion between the vertebrae.

[0003] When functioning properly, the vertebrae and discs allow a person to bend forward, backward, sideways and to twist. To accomplish this, the discs typically permit adjacent vertebrae six degrees of motion: vertical (compressing to absorb shock and tension), bending forward and backward, bending to the sides and twisting. The cervical and lumbar discs also can be thicker anteriorly to contribute to lordosis. Thoracic discs usually are more uniform. Unfortunately, disc disease may limit spinal motion or cushioning or permit the motion with pain.

[0004] Each intervertebral disc usually has a central area composed of a colloidal gel, called the nucleus pulposus, on a surrounding collagen-fiber composite structure, the annulus fibrosus. The nucleus pulposus typically occupies 25-40% of the disc’s total cross-sectional area. The nucleus pulposus usually contains 70-90% water by weight and may mechanically function like an incompressible hydrostatic material. The annulus fibrosus surrounds the nucleus pulposus and typically resists torsional and bending forces applied to the disc. The annulus fibrosis thus often serves as the disc’s main stabilizing structure. The annulus fibrosus usually resists hoop stresses due to compressive loads and the bending and torsional stresses produced by a person bending and twisting. The fibers of the annulus form lamellae, individual layers of parallel collagen fibers, that attach to the superior and inferior end plates of adjacent vertebrae. Vertebral end-plates separate the disc from the vertebral bodies on either side of the disc.

[0005] The anterior longitudinal ligament, which is anterior to the vertebral bodies, and the posterior longitudinal ligament, which is posterior to the vertebral bodies and anterior to the spinal cord function to hold the spinal structure together. The muscles of the trunk provide additional support.

[0006] Trauma or disease may displace or damage spinal discs. A disc herniation occurs when annulus fibers weaken, and the inner tissue of the nucleus (nucleus pulposus) bulges out of the annulus. The herniated nucleus may compress a spinal nerve, which could result in pain, lack of sensation, loss of muscle control or even paralysis. Alternatively, disc degeneration may result when the nucleus degenerates. Subsequently, the height of the nucleus decreases often causing the annulus to buckle in areas where the laminated plies are loosely bonded. This also may cause chronic and severe back pain. Further, the disc may rupture, resulting in a portion of the nucleus pulposus flowing through the fractured annulus, outside the disc to compress nerves and/or the spinal cord. This material may irritate the spinal nerve or spinal cord when it flows into a posterior region of the disc.

[0007] Whenever the nuclear tissue is herniated or the disc degenerates, the vertical disc space typically narrows and the adjacent vertebrae may lose much of their normal stability. In many cases, to alleviate pain from degenerated or herniated discs, a surgeon removes the nucleus by performing a discectomy, which requires surgical dissection. The healing from such surgery usually causes scar tissue which may compress the same or nearby nerves and/or spinal cord (which were being affected by the now-removed nucleus) and cause chronic pain and nervous system dysfunction. Other times, if the disc is compressed, the surgeon may perform a surgical fusion of two or multiple adjacent vertebrae together. While this treatment may or may not alleviate the pain and nervous dysfunction, the patient often loses all disc motion in the fused segment. Ultimately, this procedure places greater stress on the discs adjacent to the fused segment as the adjacent discs compensate for lack of motion.

SUMMARY

[0008] In the case of severe disc degeneration, the height of the disc often is flattened to such an extent that the adjacent vertebral body bones touch and eventually grow together. This may stop pain by stopping the movement of the disc between the vertebral bones, and is known as an auto-fusion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] In accordance with one implementation, a spinal disc system comprises an aperture within a spinal disc body, and the aperture is configured to permit nucleus pulposus to flow from the disc body through the aperture.

[0010] In accordance with another implementation, a method of reducing pressure within a spinal disc comprises forming an aperture within a spinal disc body, and permitting at least a portion of the nucleus pulposus to pass from the disc body through the aperture.

[0011] In the drawings, which are discussed below, one or more implementations are illustrated. The drawings are not necessarily to scale and certain features may be removed, exaggerated, moved, or partially sectioned for clearer illustration. It is understood that the spinal disc stent is not limited to the implementations depicted in the drawings herein, but rather it is defined by the claims appended hereto and equivalent structures.

[0012] FIG. 1 is side view of a human spinal column.

[0013] FIG. 2 is an enlarged view of a portion of the column of FIG. 1, illustrating vertebrae alternating with vertebrae and a stent implanted within the wall of one disc.

[0014] FIG. 3 is a perspective, partially sectioned view of FIG. 2, taken generally along the view of line 3-3 of FIG. 2, with the stent removed for clarity.

[0015] FIG. 4 is a sectional view taken generally along line 4-4 of FIG. 3.

[0016] FIG. 5 is a partially sectioned side view of selected vertebra and a disc of FIG. 2, illustrating the disc in a first configuration.

[0017] FIG. 6 is a partially sectioned side view of selected vertebra and a disc of FIG. 2, illustrating the disc in a second configuration.

[0018] FIG. 7 is the view of FIG. 4, illustrating an aperture formed within the wall of a disc, and showing an optional stent, according to an implementation.

[0019] FIG. 8 is the view of FIG. 4, illustrating a cannula for implanting a stent within the wall of a disc, according to an implementation.

[0020] FIG. 9 is an enlarged sectional view of FIG. 8, illustrating the stent of FIG. 2, according to an implementation.
FIG. 1 illustrates a human spinal column 20. The spinal column 20 includes vertebral bodies 22 alternating with intervertebral discs 24 extending from the neck region to the pelvis (not shown). The vertebral bodies 22 typically include seven cervical vertebrae 30 in the neck, 12 thoracic vertebrae 32 below the neck, five lumbar vertebrae 34 of the lower back, one sacrum 36 below the lumbar region and one coccyx 38.

FIGS. 2-8 illustrate a portion of the vertebral bodies 22 as adjacent vertebral bodies 40, 42 and 44 with alternating discs 46 and 48, which are a portion of the discs 24. As seen in FIGS. 3-8, each disc 24 has a nucleus pulposus 60 surrounded by a disc body, or annulus fibrosus, 62. As seen in FIG. 4, the column 20 also includes posterior longitudinal ligaments 64 and anterior longitudinal ligaments 68, which generally maintain the positions of the vertebral bodies 22 relative to discs 24. Other ligaments, which are not discussed, are also typically present. The disc body 62 includes a generally circular lower portion 70, a generally circular upper portion 72, and a generally annular disc wall 74 (FIG. 4). The disc wall, as illustrated in FIGS. 3, 7 and 8, is composed of fibrous tissue, or annulus fibrosus, and includes an inner surface 76 and an outer surface 78. The disc 24 inner surface 76 defines a chamber 80 where the nucleus pulposus 60 is positioned. Further, the disc 24 includes a disc annulus central portion 82 which includes at least a portion of the chamber 80.

As seen in FIG. 2, the spinal column 20 includes a posterior region and an anterior region. In an implementation, a stent 100 may permit the nucleus pulposus 60 to flow into the anterior region of the column 20. In some implementations, a stent is not needed and the nucleus pulposus 60 may flow into the anterior region of the column 20 through the aperture.
permits at least a portion of the nucleus pulposus 60 to flow through the aperture 140 from the chamber 80 to the anterior or lateral region (FIG. 2).

[0035] It may be desired to permit the nucleus pulposus 60 to flow through the aperture 140 from the chamber 80 to the anterior/lateral region for a limited amount of time. Accordingly, in some implementations, the aperture 140 may be desirably restricted. In some implementations, the stent 100 may be removed from the annulus fibrosus 74 and the aperture 90 may be permitted to close. In some implementations, the stent 100 may be collapsed or deformed such that the aperture 140 may restrict the flow of the nucleus pulposus 60. In some implementations, all or substantially all of the nucleus pulposus 60 may be permitted to flow through the aperture 140.

[0036] In some implementations, the aperture 140 may be restricted by engaging a plugging portion with the stent 100. A non-limiting example of a plugging portion is a threaded portion that is proportioned to threadably engage within a helical stent by rotating the plugging portion as the plugging portion is advanced into the stent 100. Another non-limiting example of a plugging portion is illustrated in FIG. 14, where an elongated biocompatible material 160 is wadded or folded prior to insertion within the aperture 140. In some implementations, the material 160 may desirably embed within the aperture 140 and may restrict the flow of the nucleus pulposus 60. In some implementations, the stent 100 may be constructed of a biodegradable material that will degrade sufficiently within a desirable timeframe that permits the aperture 90 to close, thus restricting the flow of the nucleus pulposus 60. That is, the aperture 90 may heal to restrict the flow of the nucleus pulposus 60. In some implementations, the outer surface 92 of the aperture 90 may be treated, such as by heating, freezing, or other suitable method to provide an opening to permit the flow of nucleus pulposus 60 therethrough, where the inner surface 92 of the aperture 90 until about a desired amount of time has been expended.

[0037] A non-limiting example of deforming the stent 100 is to melt or fuse the end 106 of the stent 100 with a device that may heat the end 106. Many biocompatible and/or biodegradable materials are constructed of a material such as polyethylene terephthalate (PET) that will deform when subjected to a temperature above the softening point. A device such as a radiofrequency probe, laser or other suitable device may be advanced toward the stent 100 and used to briefly apply heat to the stent 100, thereby deforming the stent 100 and closing or restricting the aperture 140. If the device is inserted in the lumbar region, the device may be advanced either 1.) from a posterior-lateral region diagonally through the disc annulus central portion 82 to access the end 104; 2.) from a posterior-lateral region and toward the outer surface 78 of the disc wall 74 while not advancing the device through the disc annulus central portion 82 to access the end 106; or 3.) through the anterior region toward the stent 100 to access the end 106. Although, in the lumbar region, it is possible to go through the spinal canal and the spinal fluid, it may be preferable to go around such structures. In the cervical region, the device may be inserted from the anterior portion of the neck for entry. Thus it may be inserted posteriorly through the anterior annulus into the nucleus pulposus.

[0038] Another non-limiting example of deforming the stent 100 is to engage the stent 100 with a tool that mechanically deforms either the end 104 or end 106 by crushing or collapsing at least a portion of the stent 100 to restrict the aperture 140.

[0039] In some situations, the stent 100 may need to be dislodged. In some implementations, the stent 100 may be dislodged mechanically. In some implementations, the stent 100 may be pushed past the disc annulus and thus out of the disc anteriorly to stop or slow flow of nucleus pulposus 60 out of the disc. In some implementations, a hook or like device may be used to pull the stent 100 entirely into the nucleus pulposus 60 area to stop the flow of nucleus pulposus out of the disc.

[0040] In some implementations, the stent 100 may be removed with an additional surgical procedure to access the stent and remove, or by attaching a wire 170 (FIG. 13) to the stent 100 at either the end 104 or the end 106. In some implementations, the wire 170 may have a gripping portion 172 coupled to the end that opposes the end connected to the stent 100. The gripping portion 172 may extend outside the patient, or may be left within the patient in a desired location. In some implementations, the gripping portion may be constructed of a MRI visible or other material to aid in locating the gripping portion 172 when the stent 100 is to be removed. In some implementations, when the stent 100 is to be removed, the gripping portion 172 may be coupled to a device to grasp the wire 170 and pull the stent 100 from the aperture 90. In some implementations, all portions of the stent 100 may not be removed in this procedure, and the portions removed may permit the remainder of the stent 100 to collapse within the aperture 90, thus restricting the aperture 140. In some implementations, after the stent 100 (or portions thereof) are removed from the aperture 90, the stent 100 and wire 90 may be removed from the patient or left inside the patient. In some implementations, the stent 100 may not cause any difficulty if the stent 100 were to be desirably left in the anterior region of the column 20.

[0041] In the implementation illustrated, the stent 100 may be implanted by advancing a device through the disc annulus central portion 82, although the stent 100 may be implanted into the wall 74 by accessing the annular wall 74 from the anterior region. One possible reason for advancing the device 120 through the disc annulus central portion 82 prior to forming the aperture 90 is that the disc 46 may be located in the lower portion of the column 20 such that the disc 46 is more easily accessed from a posterior (FIG. 2) region. However, in upper regions of the column 20, the disc wall 74 may be desirably and/or more easily accessed from the anterior region. When the disc 74 is accessed from the anterior region, then the cannula 102 may not be advanced through the disc annulus central portion 82.

[0042] In the implementation illustrated, the stent 100 is helical. However, any other geometries or shapes, such as a woven cylindrical structure, a square or oval structure or other suitable structure may be used. Some other geometries are illustrated in FIGS. 11-13, although other suitable geometries are contemplated. Further, the stent 100 may be constructed of a metal helical core surrounded by a bioabsorbable helical sheathing to permit the stent 100 to bioabsorb, if desired.

[0043] In some implementations, the stent 100 does not reinforce the disc or support the vertebrae, but rather is about as deformable as the disc 46 in order to remain within the disc wall 75 as the column 20 is articulated.

[0044] Therefore, in some implementations, the diameter of the aperture 140 may be desirably varied based upon the
expected viscosity or water content of the nucleus pulposus. That is, generally, a patient in the age range of mid 40's may have a nucleus pulposus that is relatively more liquid and an aperture of a desired diameter may be formed to accommodate a stent with a selected stent effective flow area. Additionally, a patient in the age range of mid 70's may have a nucleus pulposus that is relatively less liquid and an aperture of a larger diameter may be formed to accommodate a larger stent with a larger stent effective flow area. In this manner, the stent diameter and stent effective flow area may be varied to accommodate an expected viscosity or liquidity of the nucleus pulposus of the particular patient. Furthermore, the stent may be supplied in a configuration that provides an aperture with a larger stent effective flow area and the stent (at either end, or a central portion) may be deformed to adjust the stent effective flow area as the stent is implanted into the disc wall, thereby providing a desired flow rate of the nucleus pulposus for the particular patient.

Although the steps of the method of implanting the stent and restricting the aperture may be listed in an order, the steps may be performed in differing orders or combined such that one operation may perform multiple steps. Furthermore, a step or steps may be initiated before another step or steps are completed, or a step or steps may be initiated and completed after initiation and before completion of (during the performance of) other steps.

A number of implementations have been described. Nevertheless, it will be understood that various modifications may be made without departing from the spirit and scope of the disclosures in this application. As a non-limiting example, in some implementations, the stent may be coated with a chemotherapy material that may prevent or substantially prevent inflammation that may be caused when the nucleus pulposus is extruded from the annulus. As another non-limiting example, the stent may be inserted. What is claimed is:

1. A spinal disc system comprising: an aperture within a spinal disc body, wherein the aperture is configured to permit nucleus pulposus to flow from the disc body through the aperture.
2. The spinal disc system of claim 1, further comprising a stent body at least partially interposed within the aperture.
3. The spinal disc system of claim 2, further comprising a removal portion attached to the stent body for removing the stent from the aperture.
4. The spinal disc system of claim 3, wherein the removal portion is a wire.
5. The spinal disc system of claim 4, wherein the wire is attached to the stent body at a first end and is of a length configured to extend outside a patient's body at the other end.
6. The spinal disc system of claim 2, further comprising a cannula for implanting the stent within the aperture.
7. The spinal disc system of claim 2, wherein the stent body is generally helical prior to insertion.

8. The spinal disc system of claim 2, wherein the stent body is made of a biodegradable material.
9. The spinal disc system of claim 2, wherein the stent body is coated with a chemotherapy material.
10. A method of reducing pressure within a spinal disc comprising: forming an aperture within a spinal disc body; and permitting at least a portion of the nucleus pulposus to flow from the disc body through the aperture.
11. The method of claim 10, further comprising positioning a stent at least partially within the aperture.
12. The method of claim 10, wherein forming the aperture comprises forming the aperture on an anterior or lateral portion of the disc body.
13. The method of claim 10, wherein forming the aperture comprises advancing a device through a disc annulus central portion.
14. The method of claim 10, wherein forming the aperture comprises using at least one of a burn hole, drill hole, balloon dilation, incision and puncture.
15. The method of claim 11, further comprising removing the stent.
16. The method of claim 11, further comprising estimating a desired amount of time for the aperture to permit the flow of the nucleus pulposus.
17. The method of claim 10, further comprising at least partially blocking the aperture to limit flow of the nucleus pulposus therethrough.
18. The method of claim 17, wherein at least partially blocking the aperture is performed in a time frame of about 2 weeks to about 8 weeks after forming the aperture.
19. The method of claim 10, wherein at least partially blocking the aperture includes inserting a plug into the aperture.
20. The method of claim 18, wherein at least partially blocking the aperture includes deforming at least a portion of the aperture.
21. The method of claim 11, further comprising at least partially blocking the aperture by accessing the stent from inside a disc annulus central portion.
22. The method of claim 11, further comprising at least partially blocking the aperture to limit flow of the nucleus pulposus therethrough.
23. The method of claim 22, wherein at least partially blocking the aperture includes deforming at least a portion of the stent.
24. The method of claim 22, wherein at least partially blocking the aperture includes collapsing at least a portion of the stent.
25. The method of claim 23, wherein deforming at least a portion of the stent includes applying heat to at least a portion of the stent.
26. The method of claim 11, further comprising dislodging the stent.