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(54) FLEXIBLE SPINE STABILIZATION SYSTEMS

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(60) Provisional application No. 60/272,102, filed on Feb. 28, 2001.

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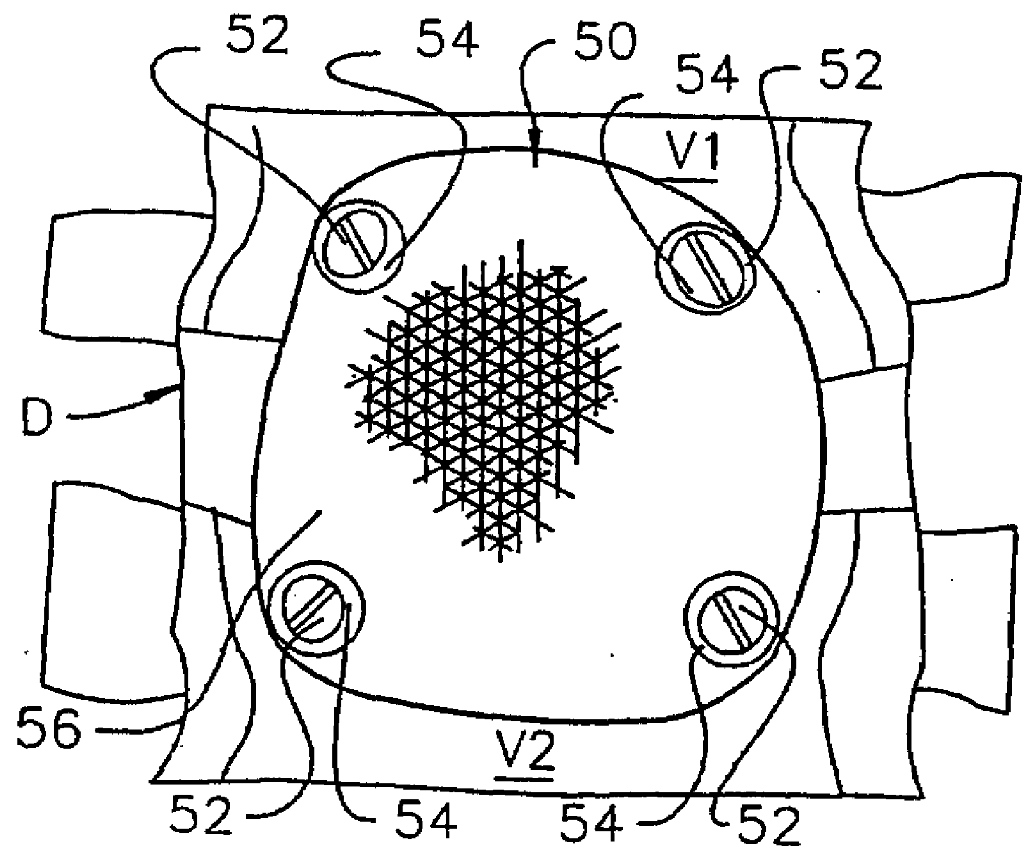
(57) **ABSTRACT**

A spine stabilization system includes a flexible member attachable to a portion of the spinal column. The use of components resist loading applied by extension and rotation of the spine, while the flexibility of the member does not subject it to the compressive loading of the spinal column segment to which it is attached.



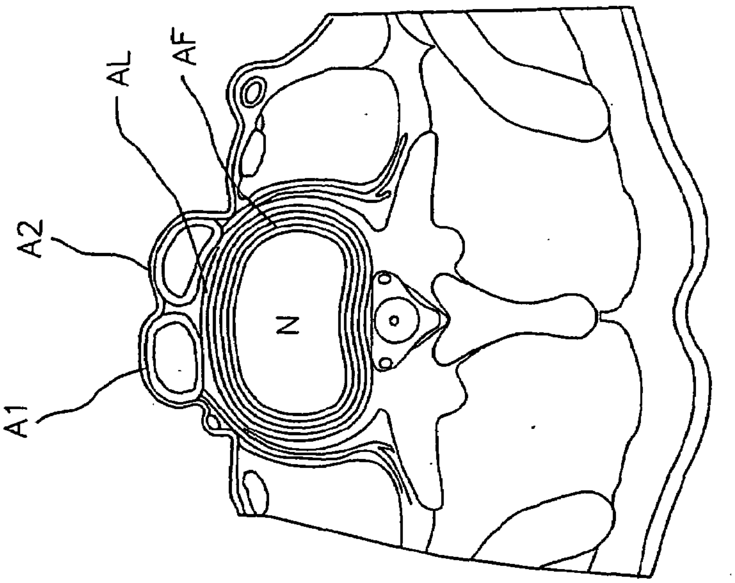


Fig. 2

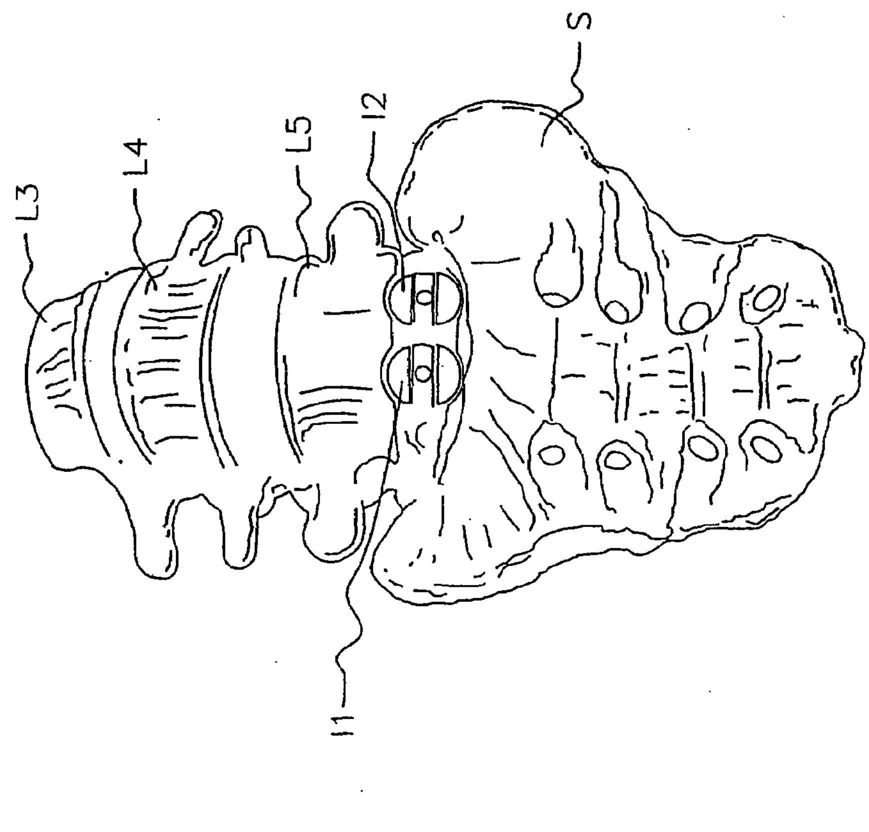


Fig. 1

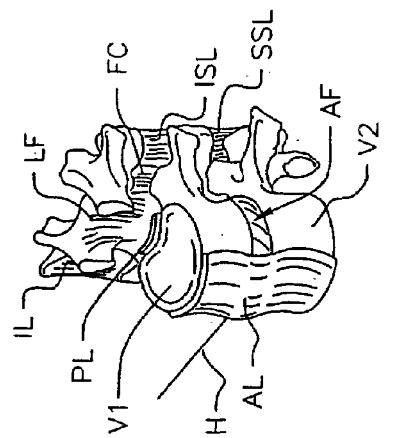


Fig. 3

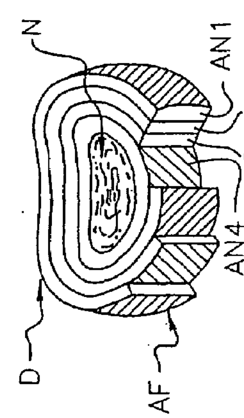


Fig. 4 (a)

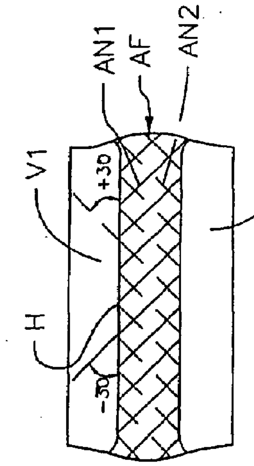


Fig. 4 (b)

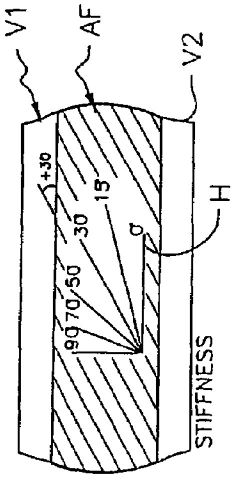


Fig. 5 (a)

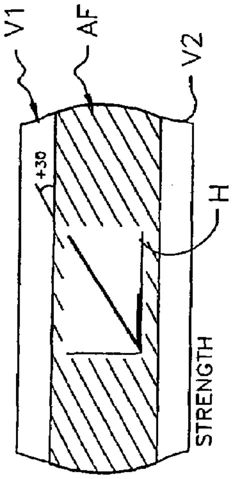


Fig. 5 (b)

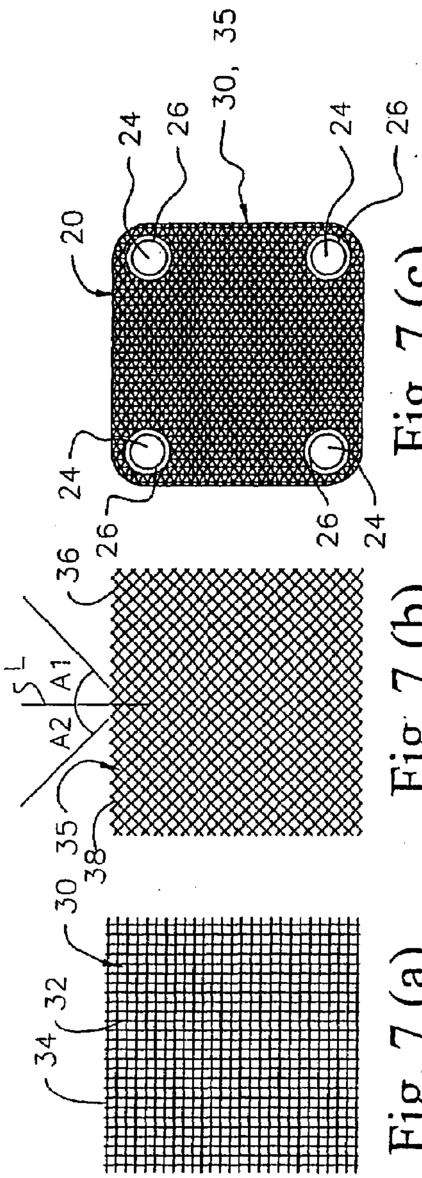


Fig. 7 (a)

Fig. 7 (b)

Fig. 7 (c)

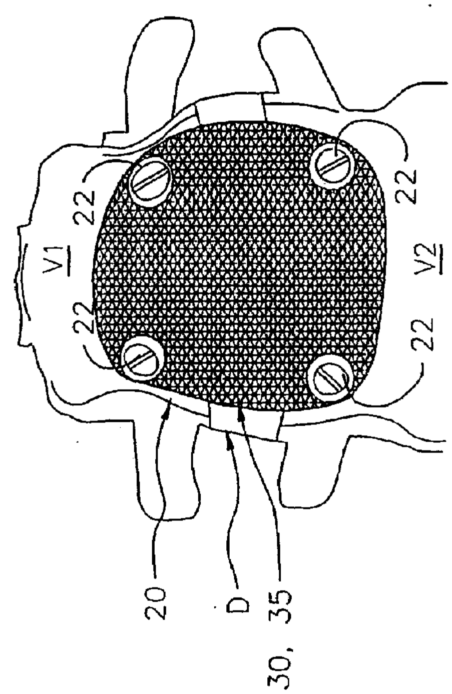


Fig. 6

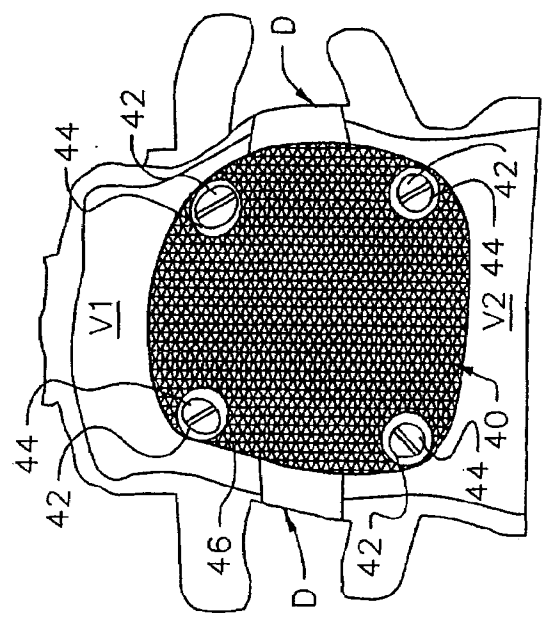


Fig. 8

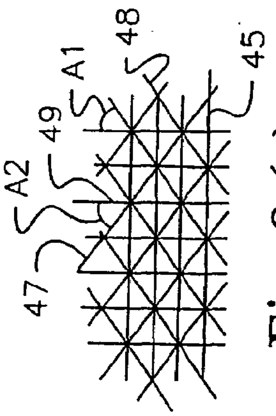


Fig. 8 (a)

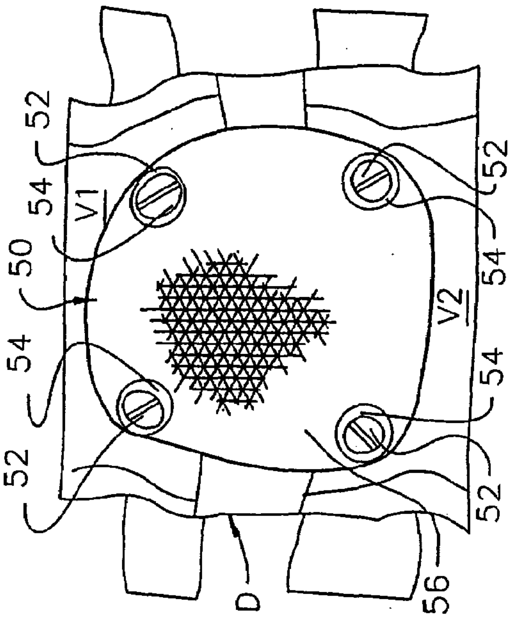


Fig. 9

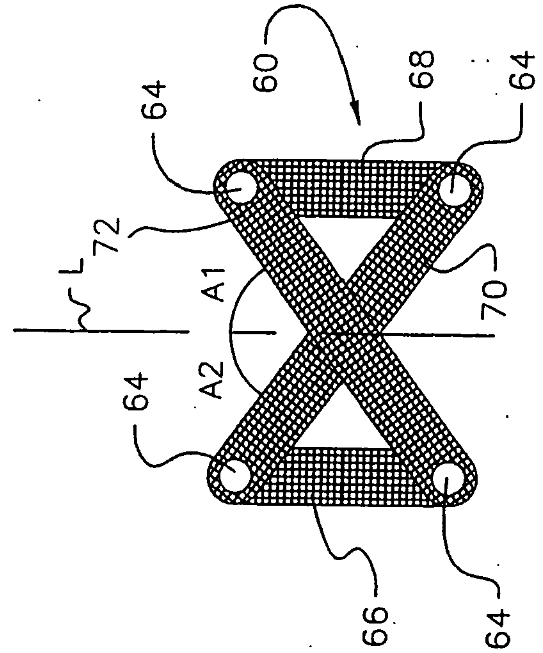


Fig. 10 (a)

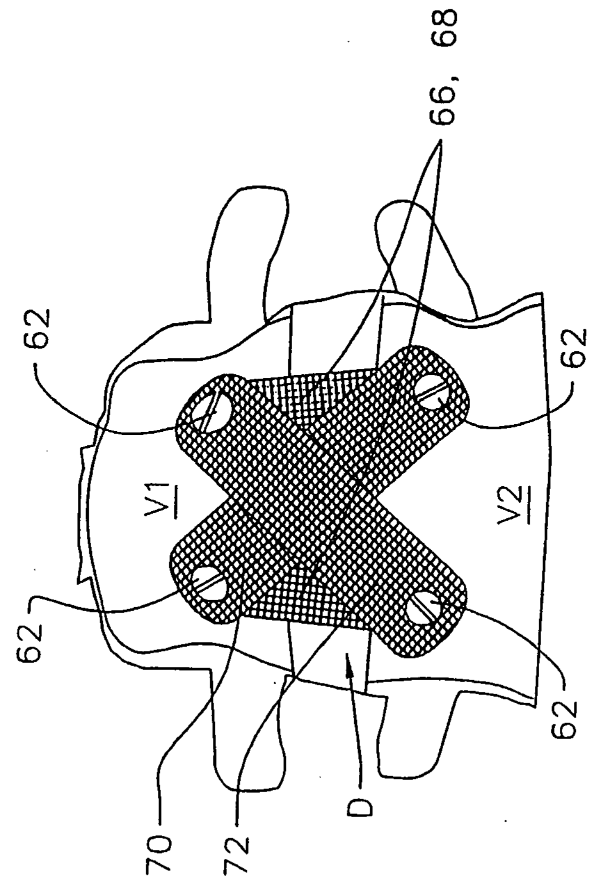


Fig. 10 (b)

FLEXIBLE SPINE STABILIZATION SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is a continuation of U.S. patent application Ser. No. 11/411,452, issuing as U.S. Pat. No. 7,326,249, which is a continuation of U.S. patent application Ser. No. 11/030,550 filed on Jan. 5, 2005, issued as U.S. Pat. No. 7,041,138; which is a continuation of U.S. patent application Ser. No. 10/682,695 filed Oct. 9, 2003, and issued as U.S. Pat. No. 6,852,128; which is a continuation of U.S. patent application Ser. No. 10/078,522 filed on Feb. 19, 2002, and issued as U.S. Pat. No. 6,652,585; which claims the benefit of the filing date of Provisional Patent Application Ser. No. 60/272,102 filed on Feb. 28, 2001. Each of the referenced applications is incorporated herein by reference in its entirety.

BACKGROUND

[0002] The present invention relates to orthopedic implants, and more particularly, to flexible spinal stabilization systems.

[0003] Interbody fusion device, artificial discs, interbody spacers and other devices have been inserted in a spinal disc space or engaged to a vertebral body. For example, as shown in FIG. **1**, a pair of interbody fusion devices I**1** and I**2** are inserted into an intradiscal space between the L5 and S1 levels of the spinal column. Aorta A**1** and vena cava A**2** along with other tissue and vasculature also extend along the anterior aspect of the spinal column. As shown in FIG. **2**, the anterior longitudinal ligament AL extends along the anterior portion of the disc space. The disc space is surrounded by annulus fibrosus or annulus fibers AF. Insertion of implants I**1** and I**2** into the disc space can be facilitated by the removal of all or a portion of the anterior longitudinal ligament AL and the annulus fibers AF.

[0004] In order to stabilize the spinal column, it is known to secure a rigid metal construct to each of the vertebral bodies on either side of the spinal disc space after inserting devices or performing surgical procedures in the disc space or on the vertebral bodies. For example, a rigid metal plate can be placed along the anterior aspect of the vertebrae and secured to the L5 and S1 levels after insertion of implants I**1** and I**2** into the disc space therebetween. In another example, a rigid rod or plate can be secured to the posterior portions of vertebrae V**1** and V**2** after anterior insertion of implants I**1** and I**2**.

[0005] While rigid metal constructs provide adequate load resistance, there can be drawbacks, such as the intrusion of the construct into the adjacent tissue and vasculature, stress shielding, multiple surgeries for installation, and fatigue. What are needed are systems that do not require posterior hardware to support the spinal column or rigid anterior, antero-lateral, or lateral plates and constructs. The systems should be resistant to fatigue, stress shielding and tensile and rotational loads that are typically applied to the spinal column. The present invention is directed toward meeting these needs, among others.

SUMMARY

[0006] The present invention is directed to spine stabilization systems that are flexible and resist loading applied by extension and rotation of the spine, while the flexibility of the components does not subject them to the compressive loading of the spinal column segment to which it is secured.

DESCRIPTION OF THE FIGURES

[0007] FIG. **1** is an elevational view of a spinal column segment having a pair of interbody fusion devices inserted into a disc space.

[0008] FIG. **2** is a plan view of a disc space of a spinal column segment and the surrounding tissue and vasculature.

[0009] FIG. **3** is a perspective view a spinal column segment with its associated ligaments.

[0010] FIGS. **4**(*a*) and **4**(*b*) illustrate various features of a spinal disc space.

[0011] FIGS. **5**(*a*) and **5**(*b*) illustrate various structural properties of the annulus fibrosous.

[0012] FIG. **6** is a flexible spine stabilization system according to one embodiment secured to a spinal column segment.

[0013] FIGS. **7**(*a*) through **7**(*c*) show various components of the system of FIG. **6**.

[0014] FIG. **8** is an elevational view of another embodiment flexible spine stabilization system secured to a spinal column segment.

[0015] FIG. **8*a*** is an enlarged detail view of a portion of the system of FIG. **8**.

[0016] FIG. **9** is elevational view of yet another embodiment flexible spine stabilization system secured to a spinal column segment.

[0017] FIG. **10**(*a*) is an elevational view of a further embodiment flexible spine stabilization system.

[0018] FIG. **10**(*b*) is the system of FIG. **10**(*a*) secured to a spinal column segment.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

[0019] For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the illustrated embodiments and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any such alterations and further modifications of the invention, and any such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

[0020] The present invention is directed to flexible spine stabilization systems for placement on the anterior aspect of the vertebrae of a spinal column segment. It is contemplated the systems may also be placed on the antero-lateral aspect or the lateral aspect of the vertebrae. It is also contemplates that the systems can extend across one or more vertebral levels. The systems are configured to replicate, substitute and/or augment the structure and function of the natural occurring fibers that protect the intervertebral disc space. It is further contemplated that the systems can be used in lieu of the placement of a rigid anterior plate across one or more disc spaces after insertion of an interbody fusion device into the disc space. It is also contemplated that the systems can be used in non-interbody fusion procedures.

[0021] The spine stabilization systems include a member having a first set of one or more components oriented generally in the direction of the annulus fibers, and a second set of components oriented generally in the direction of the fibers of the anterior longitudinal ligament. The use of components having such orientations provides resistance to loading applied by extension, lateral bending, and rotation of the spine. The flexibility of the member does not subject it to stress shielding caused by the compressive loading of the spinal column segment to which it is secured. Thus, the spine stabilization systems of the present invention replicate, augment and/or substitute the load resistant properties capabilities of the annulus fibers and anterior longitudinal ligament.

[0022] Further description of flexible spinal stabilization systems is provided after the following discussion of the anatomical features of the annulus and anterior longitudinal ligament. Referring now to FIG. **3**, a spinal column segment including an upper vertebra V**1** and lower vertebra V**2** is illustrated. The spinal column segment includes anterior longitudinal ligament AL extending along the anterior aspects of vertebra V**1** and vertebra V**2** and across the intervertebral disc space between vertebrae V**1** and V**2**. The nucleus of the disc space is protected by annulus fibers AF. The spinal column segment further includes posterior longitudinal ligament PL, intertransverse ligament IL, facet capsular ligament FC, interspinous ligament ISL, superspinous ligament SSL, and ligamentum flavum LF. The spine is designed in such a way that when the functional spinal unit is subjected to different complex force and torque vectors, the individual ligaments provide tensile resistance to external loads by developing tension. When a surgical procedure interrupts or removes a portion of these ligaments, the ability of the spinal unit to resist these complex force and torque vectors is compromised.

[0023] The anterior longitudinal ligament AL is an uniaxial structure, and is most effective in carrying loads along the direction in which the fibers run. The anterior longitudinal ligament AL has a fibrous tissue structure that arises from the anterior aspect of the basioccipital and is attached to the atlas and the anterior surfaces of all vertebrae, down to and including a part of the sacrum. It is firmly attached to the edges of the vertebral bodies, but is less firmly affixed to the annulus fibers AF. The width of the anterior longitudinal ligament AL diminishes at the level of disc and is narrower and thicker in the thoracic region of the spine. The fibers of the anterior longitudinal ligament run along the length of the spinal column in the direction of the central spinal column axis and transverse to axial plane H. The fibers of the anterior longitudinal ligament AL are much like rubber bands in that they readily resist tensile forces, but buckle when subjected to compressive forces.

[0024] Referring now to FIGS. **4**(*a*) and **4**(*b*), further properties of the spinal disc space D will be discussed. The nucleus pulposus N of the disc space is surrounded by the annulus fibrosus AF. The annulus fibrosus AF includes a number of concentric laminated bands, designated as annulus laminates AN**1**, AN**2**, AN**3**, and AN**4** as shown in FIG. **4**(*a*). As shown further in FIG. **4**(*b*), these annulus laminates AN have fibers oriented either +30 degrees or −30 degrees with respect to axial plane H of the spinal column. Stated another way, the AN fibers are oriented about +60 degrees or about −60 degrees with respect to the fibers of the anterior longitudinal ligament AL. The fibers of the adjacent annulus laminates AN are non-orthogonal with respect to axial plane H and to one another, forming a criss-cross pattern as shown by AN**1** and AN**2** of FIG. **2**(*b*). When interbody fusion devices or other implants are inserted between the vertebrae, or when the disc space is access for surgical procedures, the resection, removal and other cutting required of the annulus laminates AN and anterior longitudinal ligament AL disrupts fiber orientation and continuity.

[0025] Referring now to FIGS. **5**(*a*) and **5**(*b*), the tensile properties and strength properties of the annulus fibrosis will now be discussed. The annulus fibers AF resist tensile forces and torque or rotational forces applied to the spinal column segment. In FIG. **5**(*a*), the tensile stiffness of the annulus AF in different directions is shown. The stiffness of annulus fibrosus AF is highest along a direction oriented 15 degrees with respect to axial plane H. In FIG. **5**(*b*), the strength of the annulus AF has been found to be greatest along a direction oriented 30 degree with respect to horizontal axis H extending through the disc space. It has further been found that the strength of the annulus AF is three times greater along this 30 degree axis as compared to the strength along axial plane H.

[0026] Referring now to FIG. **6**, a spine stabilization system **20** is illustrated. System **20** is secured to vertebra V**1** and vertebra V**2** and extends across the disc space D. It is contemplated that one or more interbody fusion devices, interbody spacers, artificial discs or other implant can be inserted into disc space D in a procedure prior to attachment of system **20** to vertebrae V**1** and V**2**. It is also contemplated that a surgical procedure can be performed in or on disc space D such as, for example, removal of discal material to repair a herniated disc. In such procedures, the excision or disruption to the annulus fibrosus AF and the anterior longitudinal ligament AL compromises the ability of these spinal structures to resist extension, torsion, and lateral bending of the spinal column. System **20** can restore this ability and can cover the entry made through the annulus fibrosis AF and anterior longitudinal ligament AL, preventing devices inserted into the disc space from backing out or protruding through the created opening.

[0027] System **20** includes diagonal components and vertical components. The diagonal components can be oriented in the range of 15 degrees to 60 degrees with respect to axial plane H when the devices are secured to the vertebrae. The vertical components extend generally perpendicular to axial plane H. Stated another way, a first set of diagonal components extends at an angle A**1** in the range of +30 degrees to +75 degrees relative to the vertical components, and a second set of diagonal components extends transverse to the first set and at an angle A**2** in the range of −30 degrees to −75 degrees relative to the vertical components. In another form, the first set of diagonal components extends at an angle A**1** in the range of +45 degrees to +60 degrees relative to the vertical components, and the second set of diagonal components extends transverse to the first set and at an angle A**2** in the range of −45 degrees to 60 degrees relative to the vertical components. In a further form, the first set of diagonal components extends at an angle A**1** of about +60 degrees relative to the vertical components, and the second set of diagonal components extends transverse to the first set and at an angle A**2** of about −60 degrees relative to the vertical components.

[0028] Referring now to FIGS. **7**(*a*) through **7**(*c*), there are shown various components of system **20**. System **20** includes a member extending between the first and second vertebrae V**1** and V**2**. The member includes a first layer **30** which has a number of vertically oriented components **34** and a number of horizontally oriented components **32**. Components **32**, **34** are interwoven or otherwise attached to form a grid-like or mesh pattern having a number of square apertures therethrough. The member further includes a second layer **35** as shown in

FIG. **7**(*b*) having a number of first diagonal components **36** and a number of second diagonal components **38**. Diagonal components **36** and **38** are interwoven or otherwise attached to form a grid-like or mesh pattern having a number of diamond-shaped apertures. Each layer **30**, **35** is flexible in compression yet inelastic or substantially inelastic to resist tensile loading.

[0029] The individual components **32**, **34**, **36**, **38** of each layer can be made from a small diameter or cross-section wire, fiber, rod, strand or other elongated component. As shown in FIG. **7**(*c*), first layer **30** is placed on top of second layer **35** and secured thereto via grommets **26**. Other securement devices and techniques are also contemplated, including, for example, other fasteners such as rivets, clamps, cables, sutures, staples, and hooks; and chemical/thermal bonding, such as welding or adhesives. Other embodiments contemplate that layers **30**, **35** are not engaged to one another, but rather simply placed on top of one another when secured to the spinal column.

[0030] A number of openings **24** are formed through the layers to accommodate fasteners **22**. In the illustrated embodiment, four such openings are formed, with one opening positioned adjacent each corner. Eyelets or grommets **26** extend around each hole **24**. As shown in FIG. **6**, bone engaging fasteners **22** can be placed through corresponding ones of the holes **24** to secure layers **30**, **35** to vertebrae V**1** and V**2**. The corners of layers **30**, **35** can be rounded to provide gradual transitions between the vertical and horizontal edges thereof. Other embodiments contemplate one opening **24** at each vertebra, and further embodiments contemplate more than two openings **24** at each vertebra. Other embodiments also contemplate that no openings are provided, but rather the fasteners extend directly through the layers of material.

[0031] The vertically extending components **34** of first layer **30** are oriented and function in a manner similar to the longitudinal fibers of the anterior longitudinal ligament AL. Diagonal components **36**, **38** of second layer **35** are non-orthogonally oriented with respect to the vertical components **34**, and are oriented and function similar to annulus fibers AF. Thus, system **20** replaces, substitutes, and/or augments the function of the naturally occurring fibers of the anterior longitudinal ligament AL and the annulus fibrosis AF. The orientation of the components of system **20** are such that forces caused by extension, rotation, and lateral bending of the spinal column are resisted in a manner the same as or similar to the natural occurring anatomical structures provided to resist such forces.

[0032] Referring to FIGS. **8** and **8***a*, there is provided a spine stabilization system **40** having a layer **46**. Layer **46** includes a number of interwoven components that include at least longitudinally and diagonally oriented components. In the illustrated embodiment, there are provided first diagonal components **47**, second diagonal components **48**, vertical components **49**, and horizontal components **45**. The first and second diagonal components **47**, **48** are oriented and function similar to the fibers of the annulus fibrosis AF, and the vertical components **49** are oriented and function similar to the anterior longitudinal ligament AL. Small apertures are provided through layer **46** between its components. Eyelets or grommets **44** each surround a corresponding one of the holes provided through layer **46**. Bone engaging fasteners **42** extend through these holes to attach system **40** to vertebra V**1** and vertebra V**2**.

[0033] Referring now to FIG. **9**, there is shown another embodiment spine stabilization system **50**. The components of system **50** are diagonally and vertically oriented to replicate the orientation of the fibers of the anterior longitudinal ligament AL and annulus fibers AF. System **50** includes a member formed by a layer **56** made from components interwoven such that there are no apertures through layer **56**, providing a substantially solid wall across disc space D. Layer **56** includes a number of holes formed therethrough surrounded by grommets or eyelets **54**. Fasteners **52** extend through the holes in order to secure the flexible system **50** to vertebra V**1** and V**2** across the annulus fibrosis AF.

[0034] Referring now to FIG. **10**(*a*), another embodiment spine stabilization system **60** is illustrated. System **60** includes member having a first vertical component **66** and a second vertical component **68**. Vertical components **66** and **68** are interconnected by a first diagonal component **70** and a second diagonal component **72**. As shown in FIG. **10**(*b*), first diagonal component **70** extends from a right lateral side of vertebral body V**2** across the sagittal plane L to a left lateral side of vertebral body V**1**. Second diagonal component **72** extends from the left lateral side of vertebral body V**2** across the sagittal plane L to the right lateral side of vertebral body V**1**. The first vertical component **66** extends from a left lateral side of vertebral body V**2** to the left lateral side of vertebral body V**1** offset to one side of sagittal plane L. Second vertical component **68** extends from the right lateral side of vertebral body V**2** to the right lateral side of vertebral body V**1** offset to the other side of sagittal plane L. In each corner of system **60** there is formed a hole **64** for receiving a fastener **62** to attach system **60** to vertebrae V**1** and V**2**.

[0035] The vertically oriented components **66**, **68** are oriented to replace, substitute and/or augment the structure function of the anterior longitudinal ligament AL and resist at least extension forces applied to the spinal column segment. The diagonal components **70**, **72** are non-orthogonally oriented with respect to the vertically oriented components **66**, **68** and resist at least rotational and torque forces on the spinal column segment. Thus, diagonal components **70**, **72** are oriented and function similar to the fibers of the annulus fibrosis AF.

[0036] The components of the flexible spinal stabilization systems can be made from one or a combination of metal material, polymeric material, ceramic material, shape memory material, and composites thereof. The components of the systems can also be coated or impregnated with anti-adhesive material that will prevent tissue and vasculature from attaching thereto. The components of the systems can be provided in multiple layers each including one or more components with the desired orientation and placed one on top of the other, or the components can be provided in a single interwoven layer that includes the desired component orientation.

[0037] In one specific embodiment, the components are made from metal wire mesh of suitable tensile strength and which is not subject to substantial creep deformation or in vitro degradation. It is contemplated that the wire can be made from stainless steel, cobalt-chrome alloy, titanium, titanium alloy, or nickel-titanium, among others.

[0038] In another specific embodiment, the components are made from a soft fiber material. Soft fiber material can include polymeric material, such as SPECTRA fiber, nylon, carbon fiber and polyethylene, among others. Examples of suitable metal polymers include DACRON and GORE-TEX. One advantage provided by a soft fiber design is that the risk of tissue and vascular injury is further mitigated by reducing the abrasive qualities of the component material. A further advantage is that the components fibers can be radiolucent, allowing radiographic imaging for assessment and monitoring of the disc space and any implant, fusion devices, or artificial disc inserted therein. Another advantage is that some polymeric materials, such as spectra fiber, can be stronger than metals and less susceptible to fatigue or creep.

[0039] While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that the preferred embodiments have been shown and described, and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A spinal stabilization device, comprising:

a flexible member having opposite ends spaced from one another along an axis with a length along said axis sized for attachment between at least a first and a second vertebrae, said flexible member including a plurality of interwoven components, said flexible member further including at least one grommet positioned adjacent each of said opposite ends, said at least one grommet defining a hole for receiving a fastener to secure said flexible member to an underlying one of the first and second vertebrae.

2. The device of claim **1**, wherein said number of interwoven components are arranged so that no apertures are formed between said components.

3. The device of claim **2**, wherein said number of interwoven components of said flexible member include:

a number of vertically oriented components generally paralleling said axis; and

a number of horizontally oriented components extending transversely to said vertically oriented components.

4. The device of claim **3**, wherein said number of interwoven components of said flexible member include:

a number of first and second diagonal components extending transversely to one another, said first and second diagonal components extending in an oblique orientation to said axis and in an oblique orientation to said number of vertically oriented components and in an oblique orientation to said number of horizontally oriented components.

5. The device of claim **4**, wherein said vertically and horizontally oriented components are interwoven with one another and said diagonally oriented components are interwoven with one another.

6. The device of claim **4**, wherein said vertically, horizontally and diagonally oriented components are interwoven with one another.

7. The device of claim **1**, wherein said flexible member comprises at least one layer including a number of square shaped apertures, said square shaped apertures extending through said first layer with a first pair of sides generally paralleling said axis and a second pair of side generally orthogonally oriented to said axis.

8. The device of claim **7**, wherein said flexible member further comprises a second layer including a number of diamond shaped apertures extending through said second layer with sides of said diamond shaped apertures obliquely oriented to said axis.

9. The device of claim **8**, wherein said at least one grommet adjacent each of said opposite ends secure said layers to one another.

10. The device of claim **1**, wherein said components of said flexible member are comprised of a soft fiber material.

11. The device of claim **1**, wherein said opposite ends define horizontal edges of said flexible member and said flexible member further includes opposite vertical edges extending between said horizontal edges, said flexible member including a corner where each of said vertical edges joins a respective one of said horizontal edges, said flexible member including at least one grommet adjacent each of said corners, each of said at least one grommets defining a hole to receive a fastener through said flexible member to secure said flexible member to an underlying one of the first and second vertebrae.

12. A spinal stabilization device, comprising:

a flexible member including opposite ends spaced from one another along an axis with a length along said axis sized for attachment between at least a first and a second vertebrae, said flexible member comprising at least one layer of interwoven components, wherein said interwoven components are arranged to provide a substantially solid wall between said opposite ends.

13. The device of claim **12**, wherein said flexible member comprises a plurality of vertical components extending along said axis and a plurality of horizontal components that are generally orthogonally oriented to said axis and said vertical components.

14. The device of claim **13**, wherein said flexible member further comprises a plurality of diagonal components obliquely oriented to said axis and transversely oriented to each of said vertically and horizontally oriented components.

15. The device of claim **12**, further comprising at least one grommet positioned adjacent each of said opposite ends, said grommets each defining a hole through said at least one layer for receiving a fastener to secure said flexible member to an underlying one of the first and second vertebrae.

16. The device of claim **12**, wherein said flexible member is comprised of a soft fiber material.

17. The device of claim **12**, wherein said opposite ends define horizontal edges of said flexible member and said flexible member further includes opposite vertical edges extending between said horizontal edges, said flexible member including a corner where each of said vertical edges joins a respective one of said horizontal edges, said flexible member including at least one grommet adjacent each of said corners, each of said at least one grommets defining a hole to receive a fastener through said flexible member to secure said flexible member to an underlying one of the first and second vertebrae.

18. A spinal stabilization device, comprising:

a flexible member having opposite ends spaced from one another along an axis with a length along said axis sized for attachment between at least a first and a second vertebrae, said flexible member including a number of interwoven components that form a substantially solid wall between said opposite ends, said flexible member further including at least one grommet positioned adjacent each of said opposite ends, said a least one grommet defining a hole for receiving a fastener to secure said flexible member to an underlying one of the first and second vertebrae.

19. The device of claim **18**, wherein said interwoven components are arranged so that said interwoven components form no apertures through said flexible member.

20. The device of claim **18**, wherein said flexible member comprises a plurality of vertical components extending along said axis and a plurality of horizontal components that are generally orthogonally oriented to said axis and to said vertical components.

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