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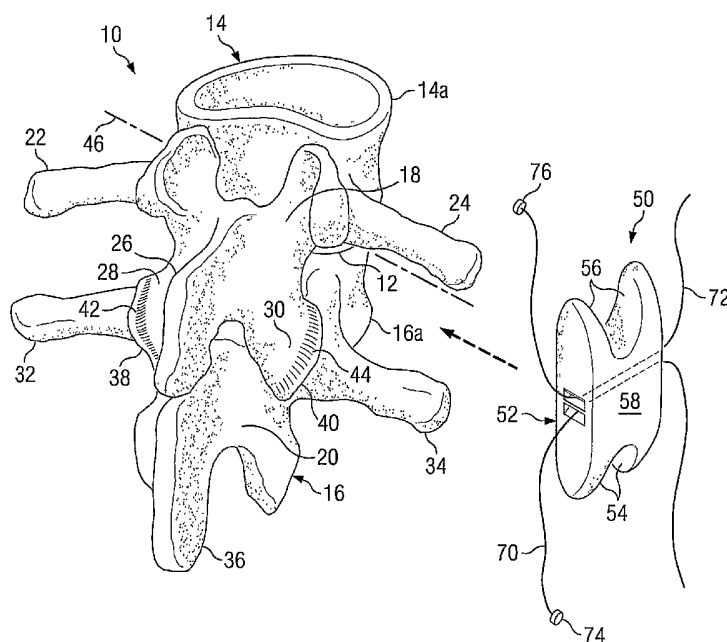
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(54) Title: TRANSVERSE PROCESS AND LAMINAR SPACERS



(57) Abstract: An inter-transverse process spacer system comprises a first spacer device. The first spacer device comprises opposing end portions. The first spacer device is adapted for insertion between a first pair of adjacent transverse processes, and the opposing end portions of the first spacer device are adapted to engage the first pair of adjacent transverse processes. The inter-transverse process spacer system further comprises a first connection device connected to the first spacer device and adapted to engage at least one of the first pair of adjacent transverse processes.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TRANSVERSE PROCESS AND LAMINAR SPACERS

BACKGROUND

5 Severe back pain and nerve damage may be caused by injured, degraded, or diseased spinal joints and particularly, spinal discs. Current methods of treating these damaged spinal discs may include vertebral fusion, nucleus replacements, or motion preservation disc prostheses. Disc deterioration and other spinal deterioration may cause spinal stenosis, a narrowing of the spinal canal and/or the intervertebral foramen, that
10 causes pinching of the spinal cord and associated nerves. Current methods of treating spinal stenosis include laminectomy or facet resection. Alternative and potentially less invasive options are needed to provide spinal pain relief.

SUMMARY

15 In one embodiment of the present disclosure, an inter-transverse process spacer system comprises a first spacer device. The first spacer device comprises opposing end portions. The first spacer device is adapted for insertion between a first pair of adjacent transverse processes, and the opposing end portions of the first spacer device are adapted to engage the first pair of adjacent transverse processes. The inter-transverse process spacer
20 system further comprises a first connection device connected to the first spacer device and adapted to engage at least one of the first pair of adjacent transverse processes. In another embodiment, an inter-laminar spacer system comprises a first connection device adapted to engage a lamina of a first vertebra and a second connection device adapted to engage a lamina of a second vertebra. The inter-laminar spacer system further comprises a
25 first lamina spacer extending between the first and second connection devices.

 In another embodiment, a method of spinal decompression comprises accessing a pair of transverse processes and inserting a spacer device between the pair of transverse processes. The method further comprises engaging a connection device with the spacer device and at least one of the pair of transverse processes.

30 In another embodiment of the present disclosure, a method of decompressing a spinal joint comprises accessing an interlaminar space between first and second lamina and inserting a

spacer system into the interlaminar space. The method further comprises connecting the spacer system to inner and outer faces of the first lamina.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a vertebral column with an inter-transverse process spacer system according to one embodiment of the present disclosure.

FIG. 2 is an assembled perspective view of the spacer system of FIG. 1.

FIG. 3 is a perspective view of a component of the spacer system of FIG. 1.

FIG. 4 is a sectional view of the component of FIG. 3.

FIG. 5 is a perspective view of a vertebral column with an inter-laminar spacer system according to one embodiment of the present disclosure.

FIG. 6 is an assembled perspective view of the spacer system of FIG. 5.

DETAILED DESCRIPTION

The present disclosure relates generally to the field of orthopedic surgery, and more particularly to systems and methods for decompressing a spinal joint. For the purposes of promoting an understanding of the principles of the invention, reference will now be made to embodiments or examples illustrated in the drawings, 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 alteration and further modifications in the described embodiments, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the disclosure relates.

Referring first to FIG. 1, the numeral 10 refers to a vertebral joint which includes an intervertebral disc 12 extending between vertebrae 14, 16. The vertebra 14 includes a lamina 18, and the vertebra 16 includes a lamina 20. The vertebrae 14, 16 also include vertebral bodies 14a, 16a, respectively. The vertebra 14 further includes transverse processes 22, 24; a spinous process 26; and caudal articular processes 28, 30. The vertebra 16 further includes transverse processes 32, 34; a spinous process 36; and rostral articular processes 38, 40. Although the illustration of FIG. 1 generally depicts the vertebral joint 10 as a lumbar vertebral joint, it is understood that the devices, systems, and methods of this disclosure may also be applied to all regions of the vertebral column, including the cervical

and thoracic regions. Furthermore, the devices, systems, and methods of this disclosure may be used in non-spinal orthopedic applications.

A facet joint 42 is formed, in part, by the adjacent articular processes 28, 38. A facet joint 44 is formed, in part, by the adjacent articular processes 30, 40. Facet joints may also be termed zygapophyseal joints. A healthy facet joint includes a facet capsule extending between the adjacent articular processes. The facet capsule comprises cartilage and synovial fluid to permit the articulating surfaces of the articular processes to remain lubricated and glide over one another. The type of motion permitted by the facet joints is dependent on the region of the vertebral column. For example, in a healthy lumbar region, the facet joints limit rotational motion but permit greater freedom for flexion, extension, and lateral bending motions. By contrast, in a healthy cervical region of the vertebral column, the facet joints permit rotational motion as well as flexion, extension, and lateral bending motions. As the facet joint deteriorates, the facet capsule may become compressed and worn, losing its ability to provide a smooth, lubricated interface between the articular surfaces of the articular processes. This may cause pain and limit motion at the affected joint. Facet joint deterioration may also cause inflammation and enlargement of the facet joint which may, in turn, contribute to spinal stenosis. Removal of an afflicted articular process may result in abnormal motions and loading on the remaining components of the joint. The embodiments described below may be used to decompress a deteriorated facet joint and/or restore more natural motion constraint to a resected joint.

Injury, disease, and deterioration of the intervertebral disc 12 may also cause pain and limit motion. In a healthy intervertebral joint, the intervertebral disc permits rotation, lateral bending, flexion, and extension motions. An axis of flexion 46 may extend between the vertebral bodies 14a, 16a and through the intervertebral disc 12. As the intervertebral joint deteriorates, the intervertebral disc may become compressed, displaced, or herniated, resulting in excess pressure in other areas of the spine, particularly the posterior bony elements of the afflicted vertebrae. This deterioration may lead to spinal stenosis. The embodiments described below may restore more natural spacing to the posterior bony elements of the vertebrae, decompress an intervertebral disc, and/or may relieve spinal stenosis.

Referring still to FIG. 1, in one embodiment, a spacer system 50 may be used to support the transverse processes 24, 34; decompress the disc 12 and the facet joint 44;

and/or relieve stenosis. The spacer system 50 includes a spacer device 52 which may be monolithically formed of an elastic, multi-directionally flexible material such as silicone, polyurethane, or hydrogel. The spacer device 52 may include two pairs of legs 54, 56 integrally formed with and extending from a cross member 58. As shown in greater detail in FIGS. 3 and 4, the cross member 58 may comprise transverse conduits 60, 62. The openings of the conduits 60, 62 may be widened and curved to minimize sharp edges that could present a point of wear. The internal faces of the legs 54 are angled to converge toward a recessed area 66, and the internal faces of the legs 56 are angled to converge toward a recessed area 68. The cross member 58 has a thickness 64 which may be slightly greater than the inter-transverse process space between the processes 24, 34 when the vertebra 14, 16 are in a natural position. For example, the cervical and lumbar regions of the vertebral column may be in lordosis when in a natural position.

Referring now to FIGS. 1 and 2, in this embodiment, the spacer system 50 further includes connection devices such as cables 70, 72 which extend through the transverse conduits 62, 64, respectively, of the cross member 58. At least one end of each of the cables 70, 72 may be attached to stopper devices 74, 76, respectively. The connection devices may be either elastic or inelastic and able to carry tensile forces. They may be formed, for example, of biocompatible reinforcing materials such as wire, cable, cord, bands, tape, or sheets. They may have a braided, knitted, or woven construction.

A surgical procedure to implant the spacer system 50 may be ultra minimally invasive. Using a posterior, posterolateral, lateral, anterolateral or anterior approach, a small incision may be created in the patient's skin. The transverse processes 24, 34 may be visualized directly or with radiographic assistance. The spacer device 52 may be compressed and inserted between the transverse processes 24, 34. The spacer device 52 may then expand slightly so that the recess 68 comes into firm contact with the transverse process 24 and the recess 66 comes into firm contact with the transverse process 34. The cross member 58 may remain slightly compressed after implantation so that the recesses 66, 68 may continue to exert pressure on the transverse processes 34, 24, respectively, minimizing the opportunity for the spacer device 52 to be come dislodged. The compression of the cross member 58 may bias the legs 56 to compress together, creating a firm grip on the transverse process 24. This holding action, together with the flexibility of

the device 52, minimizes friction and the associated material and bone wear. The legs 54 may, likewise, grip transverse process 34.

The connection device 72, led for example by a needle, may be inserted through the conduit 60 and around the transverse process 24. The connection device 72 may then be inserted through the stopper 76. The location of the spacer device 52 may still be adjusted while the connection device 72 is relatively loose. For example, the spacer device 52 may be placed close to the base of the transverse processes 24, 34, near the vertebral bodies 14a, 16a, to reduce the torsional forces placed on the spacer device by the transverse processes. With the spacer device 52 in the desired position, the connection device 72 may be tightened, and anchored to the stopper device 76. The stopper device 76 may thus anchor both ends of the connection device 72. The connection device 70 may similarly anchor the spacer device to the transverse process 34.

In certain anatomies, the spacer system 50 may be used alone to provide decompression to a single targeted facet joint or to relieve pressure on a particular side of the intervertebral disc, such as a herniation area. But, as shown in FIG. 2, a second spacer system 80 may be installed on the opposite lateral side from the spacer system 50, between transverse processes 22, 32. The spacer system 80, when used in conjunction with the spacer system 50, may provide more balanced support and equalized decompression. The spacer system 80 may be substantially similar to system 50 and therefore will not be described in detail.

The spacer system 50, as installed, may axially separate the vertebrae 14, 16, relieving pressure on the intervertebral disc 12 and the facet joint 44 and reducing wear and further degeneration. The spacer device 52 may also dampen the forces on the intervertebral disc 12 and facet joint 44 during motion such as flexion and extension. Because the spacer device 52 may be positioned relatively close to the natural axis of flexion 46, the spacer system 50 may be less likely to induce kyphosis as compared to systems that rely upon inter-spinous process devices to provide decompression.

Additionally, the system 50 may be installed minimally invasively with less dissection than the inter-spinous process devices of the prior art. Furthermore, an inter-transverse process system can be used on each lateral side of the vertebrae 14, 16, and may provide greater and more balanced decompression than the single inter-spinous process devices of the prior art.

In an alternative embodiment, the conduits through the spacer device may be omitted and the connection devices attached to other connection points on the spacer device such as side handles. The connection device may extend through or into one or both of the transverse processes. In still another alternative, the connection device may be eliminated and the spacer device held in place by the compressive forces of the transverse processes.

The connection device may also take the form of a clamp, spike, threaded connection or any other type of mechanical or adhesive connection for attaching devices to bone.

In another alternative embodiment, the spacer device may be shaped to address various patient anatomies and afflictions. In one embodiment, the legs of the spacer device may be angled such that the spacer device provides not only cephalad-caudal axial decompression but also anterior or posterior decompression. For example, in a patient recovering from disc surgery, the spacer device may be angled toward lordosis to take pressure off the intervertebral disc temporarily. Likewise the spacer device may be angled toward kyphosis to temporarily reduce pressure on a recovering facet joint.

In another alternative embodiment, the material of the spacer device may be completely or partially rigid. A sheath may be also surround the spacer device to limit direct contact between the spacer device and the surrounding tissue. The sheath may also serve to contain wear debris and limit over stretching of the spacer device.

Referring now to FIGS. 5 and 6, in one embodiment, a spacer system 100 may be used to support the laminae 18, 20; decompress the disc 12 and the facet joint 44; and/or relieve stenosis. The spacer system 100 includes a spacer device 102 which may be monolithically formed of an elastic, multi-directionally flexible material such as silicone, polyurethane, or hydrogel. The spacer device 102 may have a wider midsection and may taper slightly toward the ends. The spacer device may have a height 108 which may be slightly greater than the inter-laminar space between the processes 18, 20 when the vertebra 14, 16 are in a natural position. For example, the cervical and lumbar regions of the vertebral column may be in lordosis when in a natural position.

The spacer system 100 further includes connection devices 104, 106 such as laminar hooks which are attached to the opposite ends of the spacer device 102. The laminar hook 104 may comprise an outer arm 110 and an inner arm 112. The laminar hooks 104, 106 may be formed of any suitable biocompatible material including metals such as cobalt-

chromium alloys, titanium alloys, nickel titanium alloys, and/or stainless steel alloys.

Ceramic materials such as aluminum oxide or alumina, zirconium oxide or zirconia, compact of particulate diamond, and/or pyrolytic carbon may be suitable. Polymer materials may also be used, including any member of the polyaryletherketone (PAEK) family such as polyetheretherketone (PEEK), carbon-reinforced PEEK, or polyetherketoneketone (PEKK); polysulfone; polyetherimide; polyimide; ultra-high molecular weight polyethylene (UHMWPE); and/or cross-linked UHMWPE.

A surgical procedure to implant the spacer system 100 may be relatively minimally invasive. Using a posterior, posterolateral, lateral, or other suitable approach, a small incision may be created in the patient's skin. The ligamentum flavum or other soft tissues may be mobilized and the laminae 18, 20 may be visualized directly or with radiographic assistance. The spacer device 102 may be compressed and the laminar hooks 104, 106 may be inserted between the laminae 18, 20. The spacer device 102 may then expand slightly so that hooks 104, 106 come into firm contact with the laminae 20, 18, respectively. The spacer device 102 may remain slightly compressed after implantation so that the hooks 104, 106 may continue to exert pressure on the laminae 20, 18, respectively, minimizing the opportunity for the spacer device 102 to be come dislodged. With the system 100 installed, the arms 110, 112 of the hook 104 may firmly contact the outer and inner faces, respectively, of the lamina 20. The hook 106 may similarly engage the lamina 18.

In certain anatomies, the spacer system 100 may be used alone to provide decompression to a single targeted facet joint or to relieve pressure on a particular side of the intervertebral disc, such as a herniation area. However, a second spacer system may also be installed on the opposite lateral side from the spacer system 100. The spacer system 100, when used in conjunction with a second spacer system, may provide more balanced support and equalized decompression.

The spacer system 100, as installed, may axially separate the vertebrae 14, 16, relieving pressure on the intervertebral disc 12 and the facet joint 44 and reducing wear and further degeneration. The spacer device 102 may also dampen the forces on the intervertebral disc 12 and facet joint 44 during motions such as flexion and extension.

Because the spacer device 102 may be positioned relatively close to the natural axis of flexion 46, the spacer system 100 may be less likely to induce kyphosis as compared to systems that rely upon inter-spinous process devices to provide decompression.

Additionally, the system 100 may be installed with less dissection than the inter-spinous process devices of the prior art. Furthermore, an inter-laminar system can be used on each lateral side of the vertebrae 14, 16, and may provide greater and more balanced decompression than the single inter-spinous process devices of the prior art.

5 In an alternative embodiment, the laminar hooks may have a spring action which draws the arms together to engage the lamina, or the hooks may have a vise mechanism which draws the arms together to engage the lamina. This holding action, together with the flexibility of the device 102, may minimize friction and the associated material and bone wear.

10 In still another alternative, the spacer device may be formed of a rigid material such as those listed above for the laminar hooks. A rigid spacer device may be height adjustable such that a decreased height may be set to provide easy access for the laminar hooks, and an increased height may be set to bring the hooks into firm contact with the laminar walls.

15 In still another alternative embodiment, the connection devices may attach to other posterior bones such as the adjacent articular or spinous process. A connection device such as the cabling system 72 described above may also be used to connect the spacer device between the laminae. For example, a cable could extend around the lamina, through the spinal foramen to tether the spacer device to the lamina.

20 Although only a few exemplary embodiments have been described in detail above, those skilled in the art will readily appreciate that many modifications are possible in the exemplary embodiments without materially departing from the novel teachings and advantages of this disclosure. Accordingly, all such modifications and alternatives are intended to be included within the scope of the invention as defined in the following claims.

25 Those skilled in the art should also realize that such modifications and equivalent constructions or methods do not depart from the spirit and scope of the present disclosure, and that they may make various changes, substitutions, and alterations herein without departing from the spirit and scope of the present disclosure. It is understood that all spatial references, such as "horizontal," "vertical," "top," "upper," "lower," "bottom," "left," "right," "cephalad," "caudal," "upper," and "lower," are for illustrative purposes only and
30 can be varied within the scope of the disclosure. In the claims, means-plus-function clauses are intended to cover the elements described herein as performing the recited function and not only structural equivalents, but also equivalent elements.

What is claimed is:

1. An inter-transverse process spacer system comprising:

a first spacer device including opposing end portions, wherein the first spacer device is adapted for insertion between a first pair of adjacent transverse processes and the opposing end portions of the first spacer device are adapted to engage the first pair of adjacent transverse processes, and

a first connection device connected to the first spacer device and adapted to engage at least one of the first pair of adjacent transverse processes.

2. The inter-transverse process spacer system of claim 1 wherein the first spacer device comprises an elastically deformable material.

3. The inter-transverse process spacer system of claim 1 wherein the first spacer device comprises a rigid material.

4. The inter-transverse process spacer system of claim 1 wherein the first spacer device further includes at least one through conduit.

5. The inter-transverse process spacer system of claim 4 wherein the first connection device passes through the conduit.

6. The inter-transverse process spacer system of claim 1 wherein the opposing end portions of the first spacer device comprise recesses adapted to engage portions of the first pair of adjacent transverse processes.

7. The inter-transverse process spacer system of claim 1 further comprising:

a second spacer device including opposing end portions, wherein the second spacer device is adapted for insertion between a second pair of adjacent transverse processes and the opposing end portions of the second spacer device are adapted to engage the second pair of adjacent transverse processes, and

a second connection device connected to the second spacer device and adapted to engage at least one of the second pair of adjacent transverse processes.

8. An inter-laminar spacer system comprising:
a first connection device adapted to engage a lamina of a first vertebra ;
a second connection device adapted to engage a lamina of a second vertebra; and
5 a first lamina spacer extending between the first and second connection devices.
9. The inter-laminar spacer system of claim 8 wherein the first connection device
comprises a first arm adapted to engage an inner wall of the lamina of the first vertebra.
10. The inter-laminar spacer system of claim 9 wherein the first connection device
comprises a second arm adapted to engage an outer wall of the lamina of the first vertebra.
11. The inter-laminar spacer system of claim 8 wherein the first lamina spacer
comprises an elastically deformable material.
12. The inter-laminar spacer system of claim 8 wherein the first lamina spacer is rigid.
13. The inter-laminar spacer system of claim 8 further comprising:
a third connection device adapted to engage the lamina of the first vertebra;
20 a fourth connection device adapted to engage the lamina of the second vertebra; and
a second lamina spacer extending between the first and second connection devices.
14. A method of spinal decompression comprising:
accessing a pair of transverse processes;
25 inserting a spacer device between the pair of transverse processes; and
engaging a connection device with the spacer device and at least one of the pair of
transverse processes.
15. The method of claim 14 wherein the step of inserting includes compressing the
30 spacer device.

16. The method of claim 15 further comprising maintaining the spacer device in a compressed position.

17. The method of claim 14 further comprising distracting the pair of transverse processes.

18. The method of claim 14 wherein the step of connecting further comprises inserting the connection device through a portion of the spacer device.

19. The method of claim 14 wherein the step of connecting further comprises extending the connection device around at least a portion of the at least one of the pair of transverse processes.

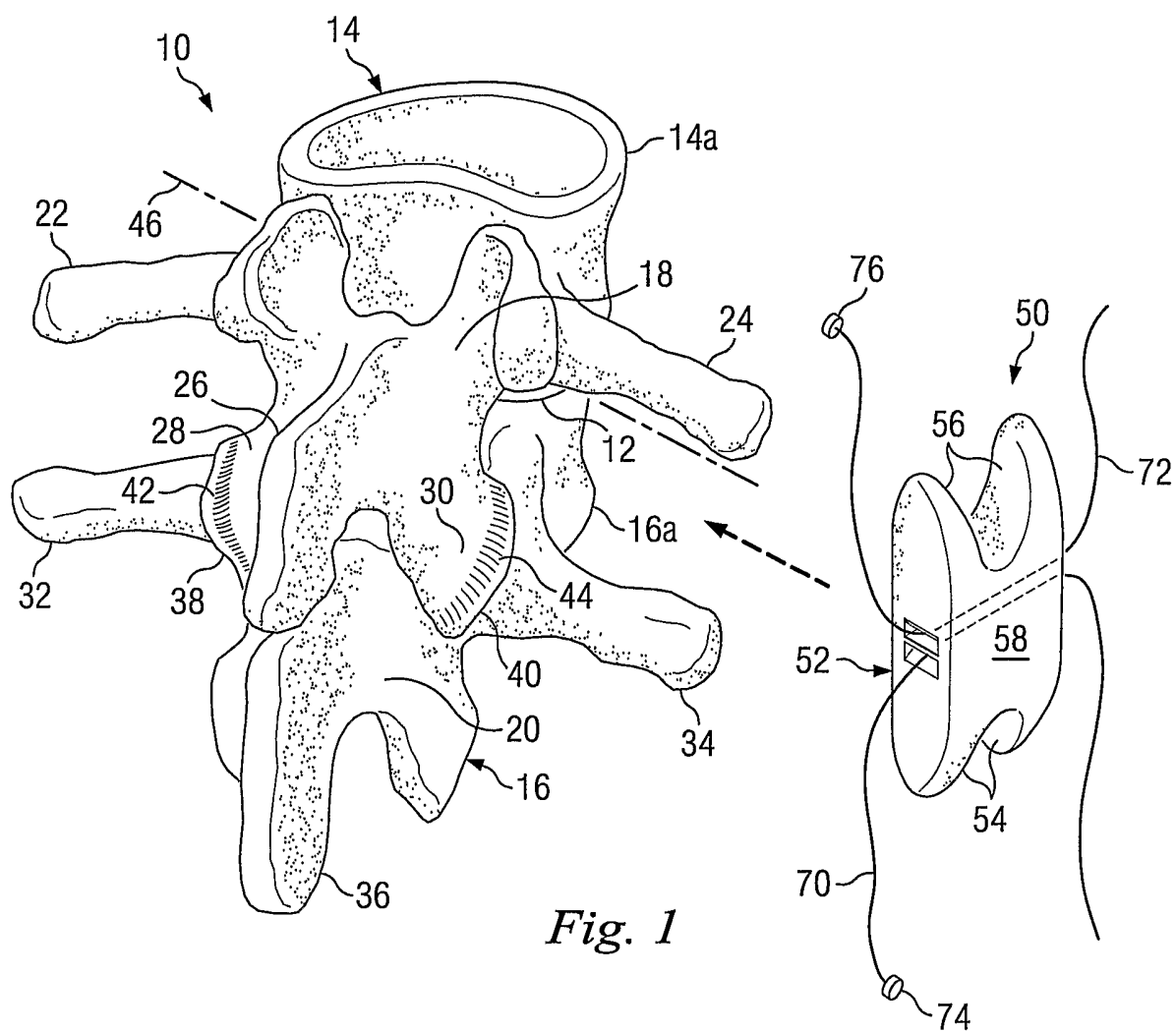
20. The method of claim 14 further comprising positioning the spacer device at a base of the pair of transverse processes.

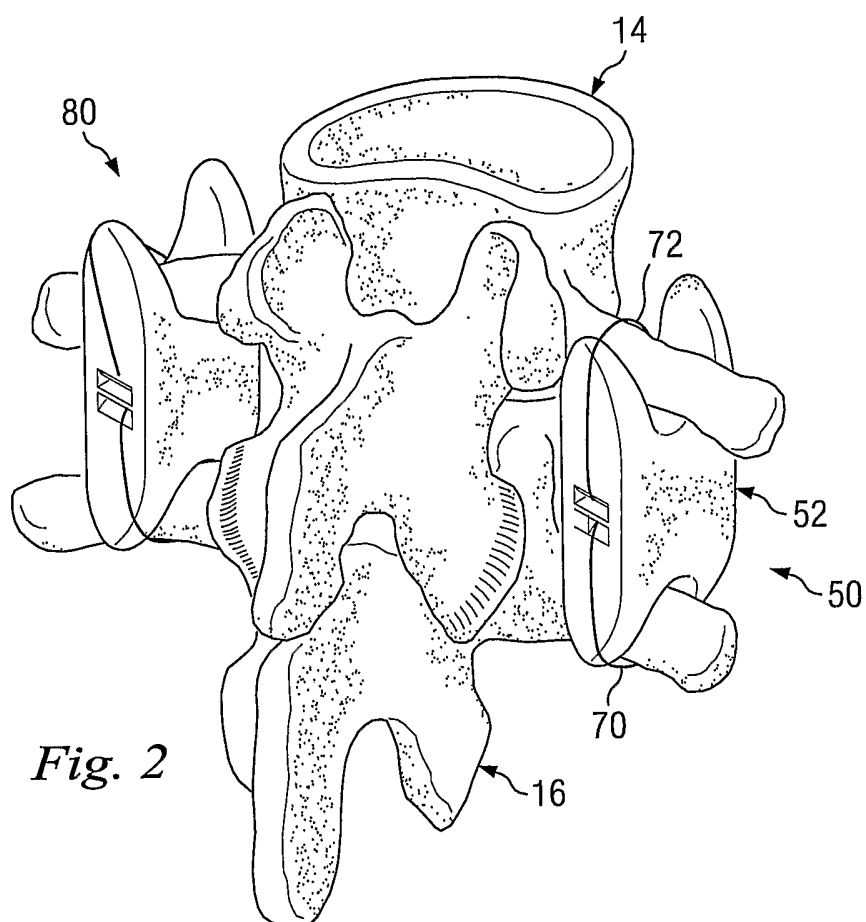
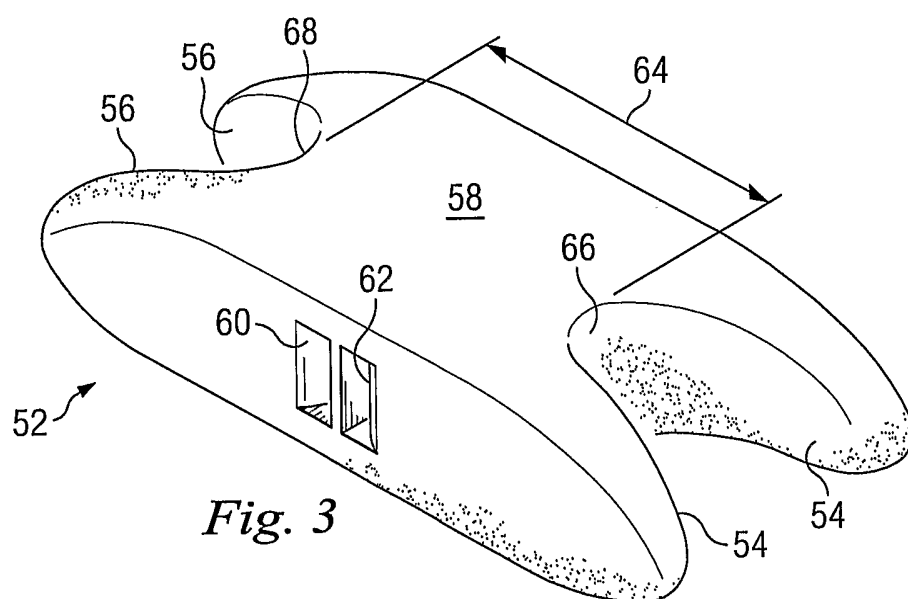
21. A method of decompressing a spinal joint, the method comprising:
accessing an interlaminar space between first and second lamina;
inserting a spacer system into the interlaminar space; and
connecting the spacer system to inner and outer faces of the first lamina.

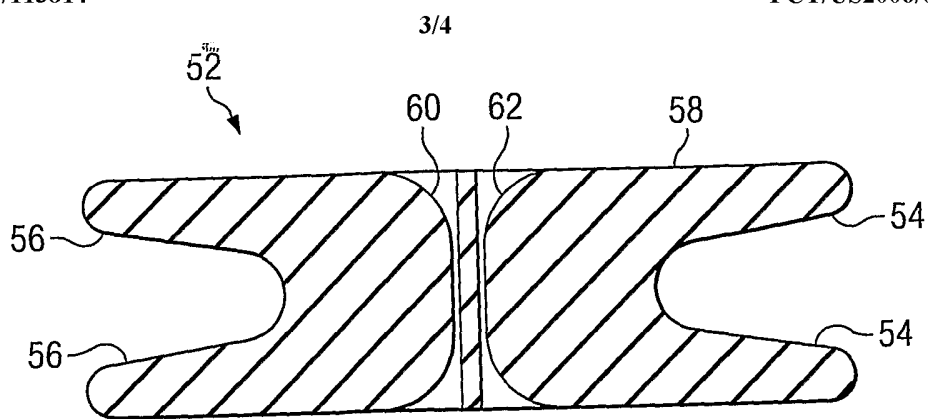
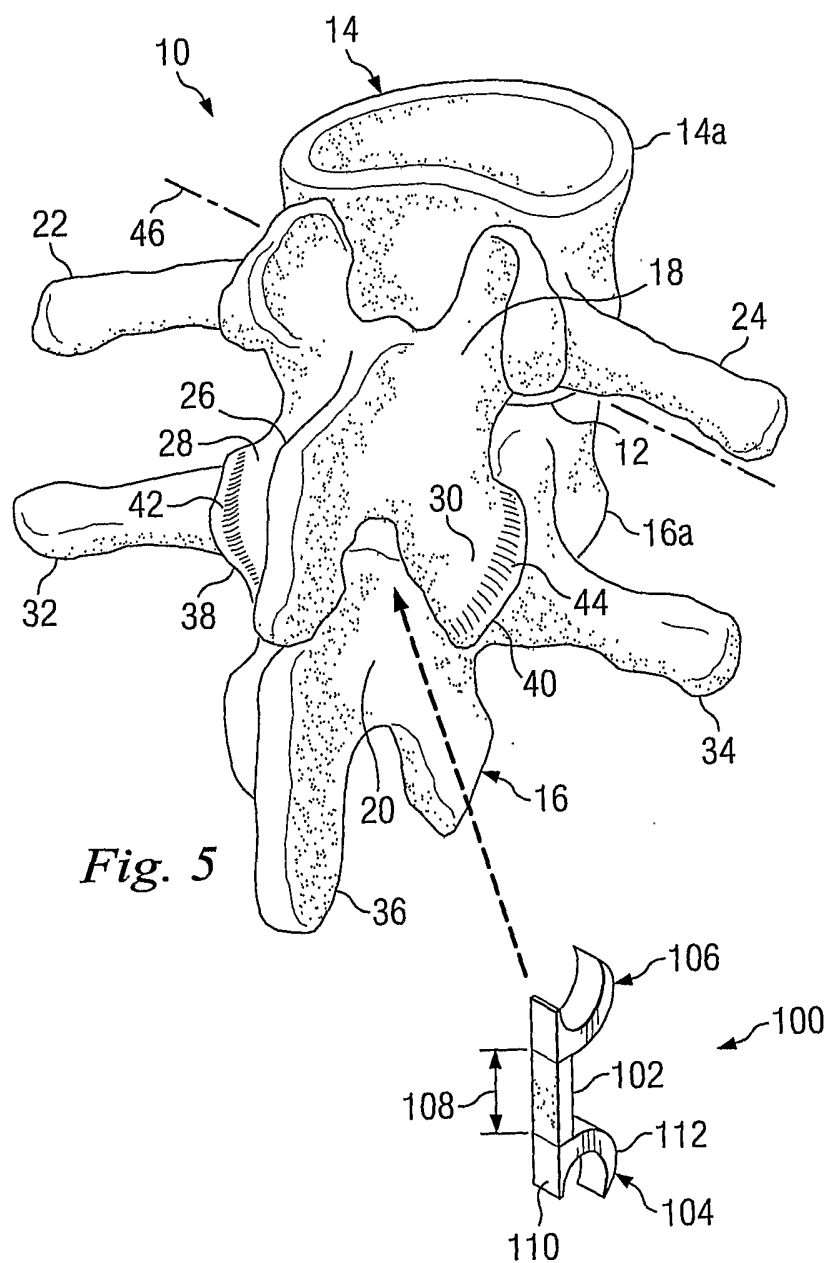
22. The method of claim 21 wherein the step of connecting further comprises clamping a hook component of the spacer system to the inner and outer faces of the first lamina.

23. The method of claim 21 wherein the step of inserting comprises compressing a spacer component of the spacer system.

24. The method of claim 23 further comprising maintaining the spacer component in a compressed position while the spinal joint is in a natural position.



*Fig. 2**Fig. 3*

*Fig. 4**Fig. 5*

