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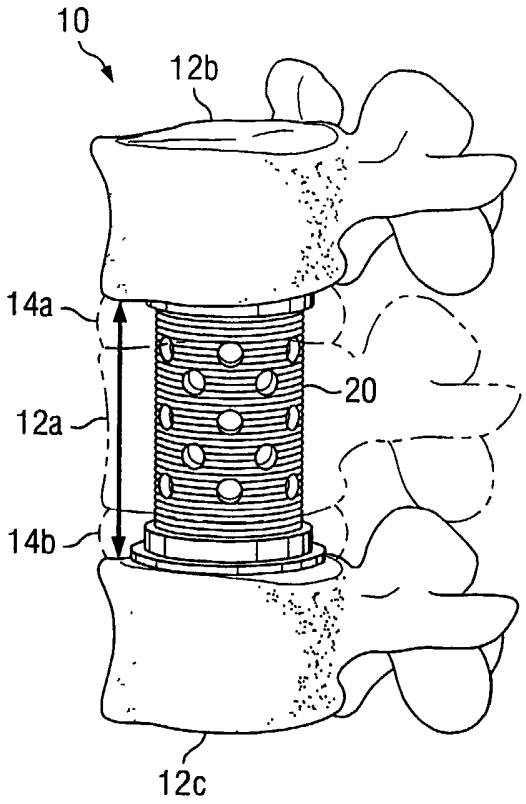
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[Continued on next page]

(54) Title: EXPANSION APPARATUS FOR ADJUSTABLE SPINAL IMPLANT



(57) Abstract: Abstract A vertebral implant assembly having a tubular body and a pair of endplate assemblies is installed between two vertebral endplates using an apparatus comprising an axle having a proximal end and a distal end, a set of gears connected to the proximal end of the axle, and an engager device connected to the set of gears and adapted to rotate the tubular body when the axle is rotated. As the tubular body is rotated, the vertebral implant assembly expands.

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EXPANSION APPARATUS FOR ADJUSTABLE SPINAL IMPLANT

FIELD OF THE INVENTION

The present invention concerns medical procedures and instruments used during surgery. More particularly, a novel apparatus and method is provided for adjusting an adjustable vertebral implant.

CROSS REFERENCE

This application claims the benefit of U.S. Provisional Application No. 60/412,730 filed on September 23, 2002.

BACKGROUND

A variety of spinal injuries and deformities can occur due to trauma, disease or congenital effects. For example, one type of spinal deformity, a kyphosis, involves a prolapse of the vertebral column towards the front of the body, often caused by the destruction of the vertebral body itself. This destruction can be in the form of a trauma type injury, such as a fracture or burst injury to the vertebral body, or a non-traumatic deformity caused by a tumor or a degeneration of the bone in the vertebral body. Treatment of a kyphosis in the thoracic or lumbar spine appears now to be best achieved through an anterior approach, particularly in order to avoid some of the more severe complications associated with support or replacement of a damaged vertebral body. In most treatments of a kyphosis, a high degree of anterior reconstruction of the spine is required, most frequently involving total removal of the damaged vertebral body. In a typical anterior approach, partial or total ablation of the vertebral body and the two adjacent vertebral discs is carried out. Following this vertebrectomy, a vertebral implant assembly may be used to restore the vertebral column to the correct orientation.

One implant that may be used is disclosed in U.S. Patent No. 6,344,057 to Rabbe et al. ("Rabbe patent"), which is hereby incorporated by reference. The implant disclosed in the Rabbe patent is an adjustable vertebral implant assembly configured to span the void created by the removed vertebral body and discs. The assembly includes a thin-walled

tubular body which defines a hollow interior and further includes endplates with end surfaces configured to engage the tubular body between the adjacent vertebrae. In some embodiments, the end surfaces defines a bore through the endplate.

Current surgical spinal reconstruction techniques can use a plurality of wrenches to expand or otherwise manipulate rotationally adjustable implants, such as the assembly disclosed in the Rabbe patent. However, a wrench requires lateral translation which, in the confined area of the wound, can require an enlarged wound and increased labor and time. It must also relocate and reattach to the implant after each turn, which is both difficult and time consuming.

SUMMARY

The present invention provides an apparatus for installing a vertebral implant assembly, having a tubular body and a pair of endplate assemblies, between two vertebral endplates. The apparatus comprises an axle having a proximal end and a distal end, a set of gears connected to the proximal end of the axle, and an engager device connected to the set of gears and adapted to rotate the tubular body when the axle is rotated, wherein the rotation of the tubular body expands the vertebral implant assembly.

In one embodiment, the apparatus further comprises a plurality of gears selectively engaged with the axle.

In another embodiment, the engager device comprises a toothed section configured to engage apertures on the vertebral implant assembly.

In another embodiment, the engager device comprises a positioning mechanism for at least partially surrounding the vertebral implant assembly.

In another embodiment, the apparatus further comprises a holding instrument to resist movement of the vertebral implant assembly during expansion.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an perspective view of a destroyed vertebral body within a vertebral column (in shadow) and a vertebral implant assembly according to one embodiment of the present invention positioned within the vertebral column.

FIG. 2 a perspective view of a vertebral implant assembly coupled with a portion of an expansion apparatus according to one embodiment of the present invention.

FIG. 3 is a perspective view of an expansion apparatus according to an embodiment of the present invention.

FIG. 4 is a cross-sectional view of a portion of the expansion apparatus of FIG. 3.

FIG. 5 is a partial cross-section of a portion of the expansion apparatus of FIG. 3.

FIG. 6a and 6b are perspective views of a holding instrument used with the expansion apparatus of FIG. 3.

DETAILED DESCRIPTION

Referring to Fig. 1, a vertebral column 10 includes a damaged vertebra 12a (shown in phantom) extending between a vertebra 12b and a vertebra 12c. An intervertebral disc 14a (shown in phantom) extends between vertebrae 12a and 12b, and an intervertebral disc 14b (shown in phantom) extends between vertebrae 12a and 12c. In a surgical excision, the vertebra 12a can be removed together with discs 14a and 14b creating a void between the two intact vertebra 12b and 12c. This procedure may be performed using an anterior, anterolateral, or other approach known to one skilled in the art. A vertebral implant assembly 20 as described in the Rabbe patent can then be provided to fill the void between the two intact vertebrae 12b and 12c.

Referring now to Fig. 2, the vertebral implant assembly 20 is shown as a turnbuckle in accordance with one embodiment of the present invention. The implant assembly 20 generally includes a threaded tubular body 22 extending between threaded endplate assemblies 24 and 26. The threaded tubular body 22 is provided with a plurality of apertures 28 that may be used for installation of the assembly 20 and that may also provide an avenue for bone or tissue ingrowth to further enhance the stability of the replacement assembly after implantation. In the present embodiment, the opposite ends of the tubular body 22 are formed into external threads 30. The threads 30 may extend from each opposite end over most or all of the length of the tubular body 22 and may be configured to threadedly engage endplate assemblies 24 and 26.

The endplate assembly 24 may include a flange 32, which may cover a substantial load-bearing area of the endplates of the adjacent intact vertebral bodies. A cylinder 34 may be integrally formed with flange 32 to extend toward the threaded tubularl body 22 when the endplate assembly 24 is placed within the excised vertebral space. The cylinder 34 and flange 32 define a bore 36 there through. The inside surface of the bore 36 is

provided with internal threads 38 which are configured to mate with the external threads 30 of the tubular body 22. In one embodiment, the threads 38 extend along the entire length of the cylinder 34 and into the flange 32. Endplate assembly 26 may be configured similar or identical to endplate assembly 24 and therefore will not be described in detail. The endplate assemblies 24 and 26 may further include one or more apertures 40 configured to engage a holding instrument (as described below for Figs. 6a and 6b).

In one specific embodiment, the external threads 30 on the threaded tubular body 22 may be cut in opposite directions (e.g., right handed and left handed) so that the endplates can be drawn together or apart by rotating only the body. Thus, as the body is rotated in one direction, the threads 30 at each of the ends engage the internal threads 38 of each of the end caps 24 and 26 in the proper direction to draw the end caps together. Alternatively, the handedness of the threads 30 can be the same at each end so that it is necessary to individually thread each end cap in opposite directions onto the tubular body 22. The disadvantage of this arrangement is that it is more difficult to adjust the height of the total assembly 20 while maintaining the proper orientation of each of the endplate assemblies 24 and 26. An advantage is that in situ the assembly is unable to unthread itself. Further details of the assembly 20 and its operation are described in the embodiments shown in the Rabbe patent.

The assembly 20 may be inserted into the vertebral column (as shown in Fig. 1) and then expanded to achieve the desired fit and alignment between the adjacent intact vertebrae. In one embodiment, expansion of the assembly can be achieved by rotating the tubular body 22 using an expander apparatus 50 as shown in Fig. 3.

Referring now to Fig. 3, in accordance with one embodiment of the present invention, the expander apparatus 50 includes a handle section 52, an extension section 54, a main gear box 56 and an engager 58. The expander apparatus 50 may allow the assembly 20 to be adjusted without the use of lateral movement, thereby reducing the size of a patient's wound and decreasing the time and labor involved to complete the procedure.

Referring to both Fig. 3 and Fig. 4, the handle section 52 can receive and enclose a portion of the extension section 54. In the present embodiment, the extension section 54 may comprise an outer casing 60 through which an interior axle 62 may extend. The handle section 52 may include a handle 64 that receives, surrounds and rotationally engages the outer casing 60 of the extension section 54 through one or more bushings 66. It is

understood that in other embodiments, the rotational engagement of the outer casing 60 may be accomplished using ball bearing assemblies and/or the material comprising the handle 64. Although not shown, in some embodiments, the handle 64 may be separated into two independent portions, with one portion being fixed to the outer casing 60 to secure and position the expander apparatus 50 during use, and the other portion being free to rotate for providing the rotational force discussed below.

In the present embodiment, the handle section 52 may further include a distally located selector gear box 70. The selector gear box 70 may include a set or plurality of gears 72a, 72b, 72c configured to selectively engage with the distal end of the interior axle 62 of the extension section 54. Each of the gears 72a, 72b, and 72c may be of a different size so that a user of the expander apparatus 50 may choose from a range of selectable gear ratios, enabling the user to achieve a desired speed or torque for adjusting the vertebral implant assembly 20. The selector gear box 70 may be configured to engage with a cap member 74. The cap member 74 can be both axially and rotationally movable about the handle 64 and can further include a gear selection member 76 which, as the cap member 74 is moved, can engage any of the different gears 72a, 72b, or 72c to create the desired gear ratio.

Although the present embodiment depicts three gears, it is understood that in other embodiments a fewer or a greater number of gears may be used. Further, any of a variety of gear train systems may be employed incorporating a variety of gear components such as a planetary gear systems, a layshaft, a clutch, a worm gear system, a bevel gear system, a rack and pinion system, or other gear based systems. In the present embodiment, the cap member 74 rotates or translates about the handle 64 to select a particular gear, but other gear selection mechanisms can also be used. In some embodiments, the selector gear box may not be located in the handle section 52, but rather, may be included in the extension section 54 or elsewhere in the expander tool 50.

Although not shown, in another embodiment, the selector gear box 70 may be omitted and the distal end of the axle 62 may be fixedly engaged with the gear selection cap 74 and/or a rotating portion of the handle section 52. In this embodiment, the rotation of the axle 62 may be directly driven by rotation of the gear selection cap 74. In still another embodiment, the axle 62 may be driven by a motor coupled to the axle 62 or to the selector gear box 70.

Referring now to Fig. 5, while one end of the extension section 54 engages with the handle section 52, the opposite end may engage with the main gear box 56. The main gear box 56 may include a main gear/tooth assembly 80 and a secondary gear assembly 82. The main gear/tooth assembly 80 can be partially enclosed and secured within a casing 83, and can include a gear section 84 coaxially attached to a toothed section 86. The casing 83 may include a pin 88 about which the main gear/tooth assembly 80 can rotate. In the present embodiment, the rotational axis of the pin 88 and the gear section 84 may be aligned perpendicular to the rotational axis of the axel 62, although different embodiments may have different arrangements.

The secondary gear assembly 82 may be attached to the proximate end of the interior axle 62, opposite from the end engaged with the selector gear box 70, and may rotate about the axis of the axle 62. The secondary gear assembly 82 may engage with the gear section 84 of the main gear/tooth assembly 80 causing any rotational force from the axle 62 to be transferred to the main gear/tooth assembly 80.

Referring to Figs. 2 and 5, the main gear box 56 can be further connected to the engager 58. The casing 83 of the main gear box 56 may be attached to a positioning mechanism 90, which in the embodiment of Fig. 2 is shaped like a semi-circle with opposing arc portions 92a and 92b. The arc portions 92a and 92b can define a cross-section of an engagement area 91 into which the implant assembly 20 may be positioned. The positioning mechanism 90 is shaped to mate with the tubular body 22 of the implant assembly 20, allowing the tubular body 22 to rotate while assisting in maintaining the general position and proximity of the engager 58 to the tubular body 22.

As described above, the casing 83 may cover only a portion of the main gear/tooth assembly 80. The other portion, which can include the tooth section 86, may extend into the engagement area 91 of the engager 58. The tooth section 86 may include a plurality of teeth 93 that are sized, spaced, and shaped to engage the apertures 28 on the tubular body 22 when the tubular body 22 is positioned in the engagement area 91. With the endplate assemblies at least tentatively affixed to the adjacent vertebral endplates, the tubular body 22 can rotate as the tooth section 86 is rotated. Furthermore, the positioning mechanism 90 and the arrangement of the apertures 28 can minimize any translation of the tubular body 22, ensuring that the next tooth 93 easily locates and engages the next aperture 28, to thereby maintain the rotation. In the present embodiment, the teeth 93 are radially

arranged on the tooth section 86 in a gear-like configuration. In other embodiments, a toothed belt or another gripping mechanism can be used to drive the rotation of the tubular body 22.

Referring more specifically to Fig. 5, in some embodiments, the positioning mechanism 90 is shaped more like a "C." In these embodiments, the positioning mechanism 90 also helps to prevent the engager 58 from accidentally disengaging from the replacement assembly 20. In one embodiment, the opposing arc portions 92a, 92b are selectively pivotable about pins 94a and 94b with friction keeping the arc portions 92a, 92b either open or closed. In the open position, the tubular body 22 can be positioned in or removed from the engagement area 91. In the closed position, the arc portions 92a and 92b aid in keeping the positioning mechanism 90 engaged to the tubular body 22 while the body rotates. It is understood, that other embodiments may use a clip, a spring, or some other means of engagement to selectively allow the positioning mechanism 90 to remain engaged.

In some embodiments, the positioning mechanism 90 may be configured to more securely maintain the desired position of implant assembly 20. For example, the positioning mechanism 90 may extend laterally along the tubular body 22 to restrain the assembly 20 from pivoting about its longitudinal axis. Another example (e.g. FIG. 6a and 6b) may include a second positioning mechanism 90 extending from the casing 83 in which case the assembly 20 can be held in position by arc positions both above and below the tooth section 86.

Referring now to Figs 1-5, in operation, once the implant assembly 20 is placed in position between the endplates of the two adjacent vertebrae 12b and 12c (as shown in Fig. 1), the expander apparatus 50 may be positioned within the surgical area proximate to the implant assembly 20. It is understood, however, that in some instances the expander apparatus 50 can be used to facilitate the placement of the assembly 20 inside the vertebral column 10. The expander apparatus 50 is positioned so that the engager 58 is engaged with the tubular body 22 of the implant assembly 20. Specifically, at least one of the teeth 93 may engage one of the apertures 28. The handle 60 can extend away from the vertebral column 10, for example, in an anterior surgical approach, the handle may be positioned in the anterior area of the patient, within easy reach of the surgeon.

After the expander apparatus is in place, the surgeon can rotate or axially translate the cap member 74 to engage the appropriate gear 72a, 72b, 72c to achieve the desired gear ratio, although it is understood that in some embodiments the selector gear box 70 can be omitted. The surgeon can then turn either the handle 64 or the rotatably movable portion of the handle 64 around the axis of the interior axle 62 to expand (or contract, if necessary) the implant assembly 20. Specifically, the rotation of the handle 64 or handle portion is transferred through the gear box 70 to rotate the axle 62. The axle, in turn, rotates the secondary gear assembly 82, which rotates the gear section 84. The rotation of the gear section 84, causes the fixedly attached tooth section 86 to rotate which, in turn moves the teeth 93. With the endplate assemblies 24 and 26 held immovably in place by compression of the vertebral endplates, by structural features of the endplate assemblies 24 and 26, or by mechanical means, the movement of the teeth 93 can cause the tubular body 20 to rotate which may cause the endplate assemblies 24 and 26 to move relative to one another, thereby expanding, contracting, or otherwise adjusting the implant assembly 20. Referring now to Figs. 6a and 6b, in this embodiment, a holding instrument 100 may be coupled to the expander apparatus 50 to hold the implant assembly 20 in position during the expansion, all the while minimizing backlash or lateral movement of the assembly 20. The holding instrument can be attached to the extension section 54 by an attachment device 102 which may include one or more rings 104 configured for fastening to the outer casing 60. The one or more rings 104 may be fixedly attached to the extension section with one or more fastening mechanisms 106 which can be, for example, screws. In one alternative embodiment, to avoid interference with the interior axle 62 running through the extension section 54, the fastening mechanisms 106 may engage a protrusion (not shown) extending from the outer casing 60.

A plurality of expansion members 108 may connect the attachment device 102 to a pair of alignment arms 110 and 112. Each expansion member 108 may be a rigid bar pivotally connected at one end to the attachment device 102 and at the opposite end to one of the alignment arms 110 or 112. In alternative embodiments, the expansion member may be a spring, an elastic member, or another mechanism capable of expanding with the alignment arms 110 and 112 as the implant 20 is expanded. An alignment member 114 may further extend between the alignment arms 110 and 112 and may be adjustable to maintain a relatively parallel alignment of the alignment arms. Each of the alignment

arms 110 and 112 extend toward the engagement area 91 where the ends of each alignment arm 110 and 112 are configured with holding assemblies 116 and 118, respectively. The holding assemblies 116 and 118 may be arc-shaped to accept the assembly 20 and may further include fasteners 120 for engaging the apertures 40 on the endplate assemblies 24 and 26 to maintain the assembly 20 in a generally rigid vertical position while the assembly 20 is expanded. The fasteners may be, for example, pins, screws, or clamps. In some embodiments, the holding assemblies 116 and 118 may fasten to the endplate assemblies 24 and 26 without engaging the apertures 40.

Referring still to Fig 6a and 6b, in operation, once the implant assembly 20 is placed in position between the endplates of the two adjacent vertebrae 12b and 12c (as shown in Fig. 1), the expander apparatus 50 with the attached holding instrument 100 may be positioned within the surgical area proximate to the implant assembly 20. It is understood, however, that in some instances the expander apparatus 50 and holding instrument 100 can be used to facilitate the placement of the assembly 20 inside the vertebral column 10. The expander apparatus 50 is positioned so that the engager 58 is engaged with the tubular body 22 of the implant assembly 20. Specifically, at least one of the teeth 93 may engage one of the apertures 28. To further secure the implant assembly 20, the pins 120 may be engaged with the apertures 40 on the endplate assemblies 24 and 26. The handle 60 can extend away from the vertebral column 10, for example, in an anterior surgical approach, the handle may be positioned in the anterior area of the patient, within easy reach of the surgeon.

After the expander apparatus is in place, the surgeon can rotate or axially translate the cap member 74 to engage the appropriate gear 72a, 72b, 72c to achieve the desired gear ratio. It is understood that in some embodiments the selector gear box 70 can be omitted. The surgeon can then rotate either the handle 64 or the rotatably movable portion of the handle 64 along the axis of the interior axle 62 to expand (or contract, if necessary) the implant assembly 20. Specifically, the rotation of the handle 64 or handle portion is transferred through the gear box 70 to rotate the axle 62. The axle, in turn, rotates the secondary gear assembly 82, which rotates the gear section 84. The rotation of the gear section 84, causes the fixedly attached tooth section 86 to rotate which, in turn moves the teeth 93.

With the endplate assemblies 24 and 26 held immovably in place by the holding instrument 100, the movement of the teeth 93 can cause the tubular body 20 to rotate, which in turn can cause the endplate assemblies 24 and 26 to move relative to one another, thereby expanding (or contracting, if necessary) the implant assembly 20. As the implant assembly 20 expands, the expansion members 108 may pivot to allow the alignment arms 110 and 112 to move apart while remaining in relatively parallel alignment. As the alignment arms 110 and 112 move, the alignment member 114 may adjust to further preserve the parallel alignment of the alignment arms 110 and 112. After the implant assembly 20 has attained the desired height, the pins may be removed from the apertures 40, disconnecting the holding instrument 100 from the implant assembly 20.

Although only a few exemplary embodiments of this invention 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 invention. Accordingly, all such modifications are intended to be included within the scope of this invention.

Claims

What is claimed is:

1. An apparatus for installing a vertebral implant assembly, having a tubular body and a pair of endplate assemblies, between two vertebral endplates, the apparatus comprising:

an axle having a proximal end and a distal end;

a set of gears connected to the proximal end of the axle; and

an engager device connected to the set of gears and adapted to rotate the tubular body when the axle is rotated,

wherein the rotation of the tubular body expands the vertebral implant assembly.

2. The apparatus of claim 1 further comprising

an outer casing and

a handle section connected to the distal end of the axle,

wherein the axle extends through the outer casing and at least partially into the handle.

3. The apparatus of claim 2 wherein the handle section is fixedly connected to the axle.

4. The apparatus of claim 2 wherein the handle section rotationally engages the outer casing.

5. The apparatus of claim 2 wherein the handle section comprises a first portion fixed to the outer casing and a second portion adapted to rotate the axle.

6. The apparatus of claim 2 further comprising a plurality of gears selectively engaged with the axle.

7. The apparatus of claim 6 further comprising a cap member movable about the handle section, wherein the cap member is adapted to select one or more of the plurality of gears to engage the axle.

8. The apparatus of claim 1 wherein the engager device comprises a toothed section configured to engage apertures on the vertebral implant assembly.

9. The apparatus of claim 1 wherein the engager device comprises a positioning mechanism for at least partially surrounding the vertebral implant assembly.

10. The apparatus of claim 9 wherein the positioning mechanism comprises a pair of selectively pivotable arc portions.

11. The apparatus of claim 8 wherein the set of gears comprises
a secondary gear assembly attached to the axle and
a gear section attached to the toothed section,
wherein the secondary gear assembly engages the gear section for translating rotation of the axle into rotation of the toothed section.

12. The apparatus of claim 1 further comprising:
an outer casing through which the axle extends, and
a holding instrument attached to the endplate assemblies of the vertebral implant assembly and further attached to the outer casing.

13. The apparatus of claim 11 wherein the holding instrument further comprises:
a pair of parallel alignment arms for the attachment to the endplate assemblies;
an attachment device for the attachment to the outer casing;
one or more expansion members extending between the attachment device and each alignment arm; and
an alignment member extending between the alignment arms for maintaining the parallel alignment of the alignment arms as the vertebral implant assembly expands.

14. A method for adjusting a vertebral implant assembly having a tubular body and a pair of endplate assemblies, the method comprising:

fixing the endplate assemblies to prevent rotation;

engaging an expander apparatus with the vertebral implant assembly, wherein the expander apparatus includes a set of gears connected between an axle and an implant engager device;

turning the axle; and

rotating the implant engager device, wherein rotating the engager device adjusts the vertebral implant assembly.

15. The method of claim 14 wherein the expander apparatus remains laterally fixed while adjusting the vertebral implant assembly.

16. The method of claim 14 further comprising:

moving the implant into a spinal column with the expander apparatus.

17. The method of claim 14 further comprising:

selecting from a plurality of gears to engage the axle, thereby adjusting the speed and torque of the rotating implant engager device.

18. The method of claim 17 further comprising:

moving a cap member about the handle to select from the plurality of gears.

19. The method of claim 14 wherein the implant engager device comprises a plurality of radially arranged teeth adapted to engage a plurality of radially arranged apertures on the tubular body and wherein the rotation of the implant engager device advances the teeth into the apertures and rotates the tubular body.

20. The method of claim 19 wherein the set of gears includes a first gear coupled to the axle and a second gear coupled to the implant engager and wherein the first gear is positioned perpendicular to and in contact with the second gear so that the rotation of the axle is translated into rotation of the implant engager device through the set of gears.

21. The method of claim 14 wherein fixing the endplate assemblies comprises attaching the endplate assemblies to a holding instrument fixedly attached to the expander apparatus and wherein the holding instrument prevents lateral movement of the vertebral implant assembly during the adjustment of the vertebral implant assembly.

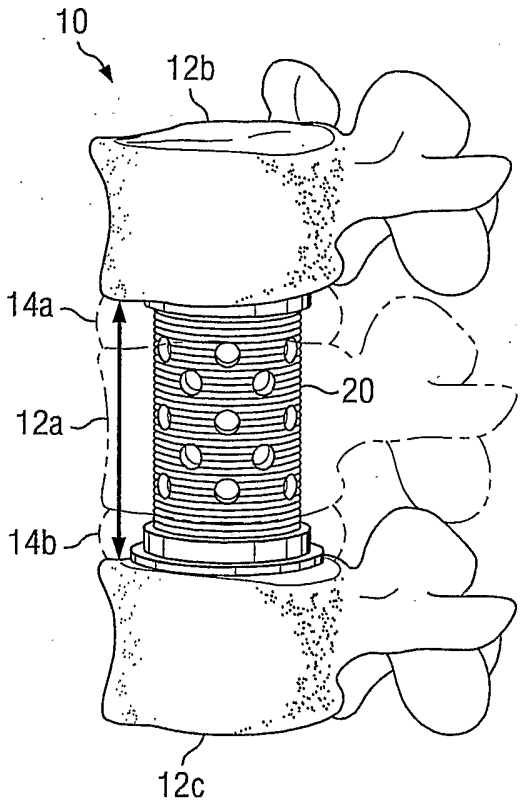

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Fig. 1

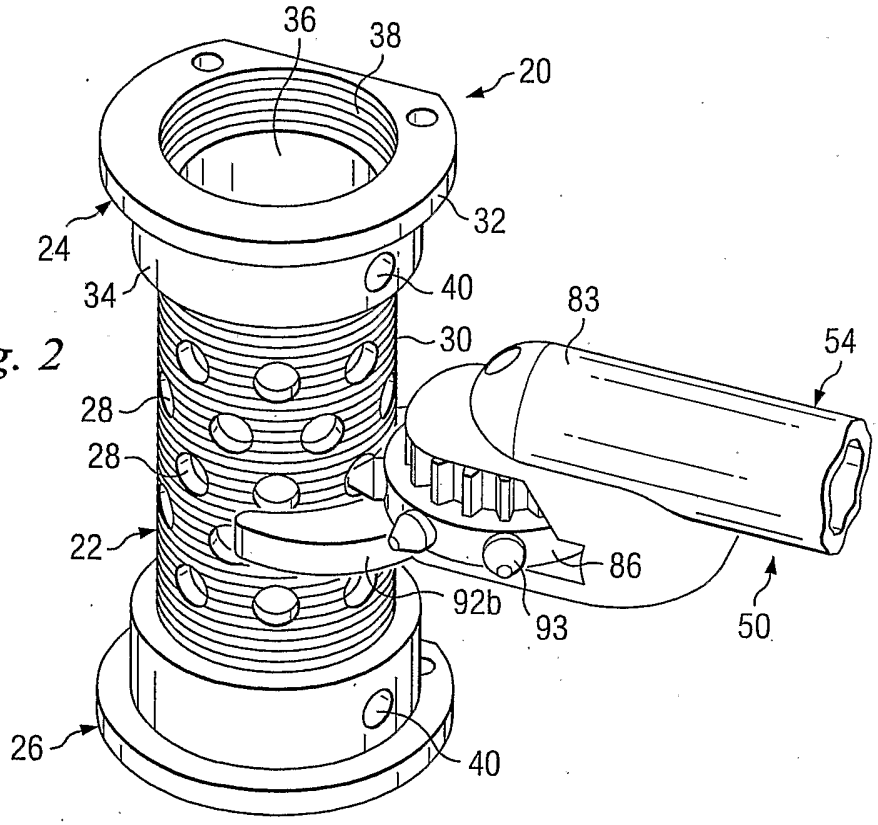

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Fig. 2

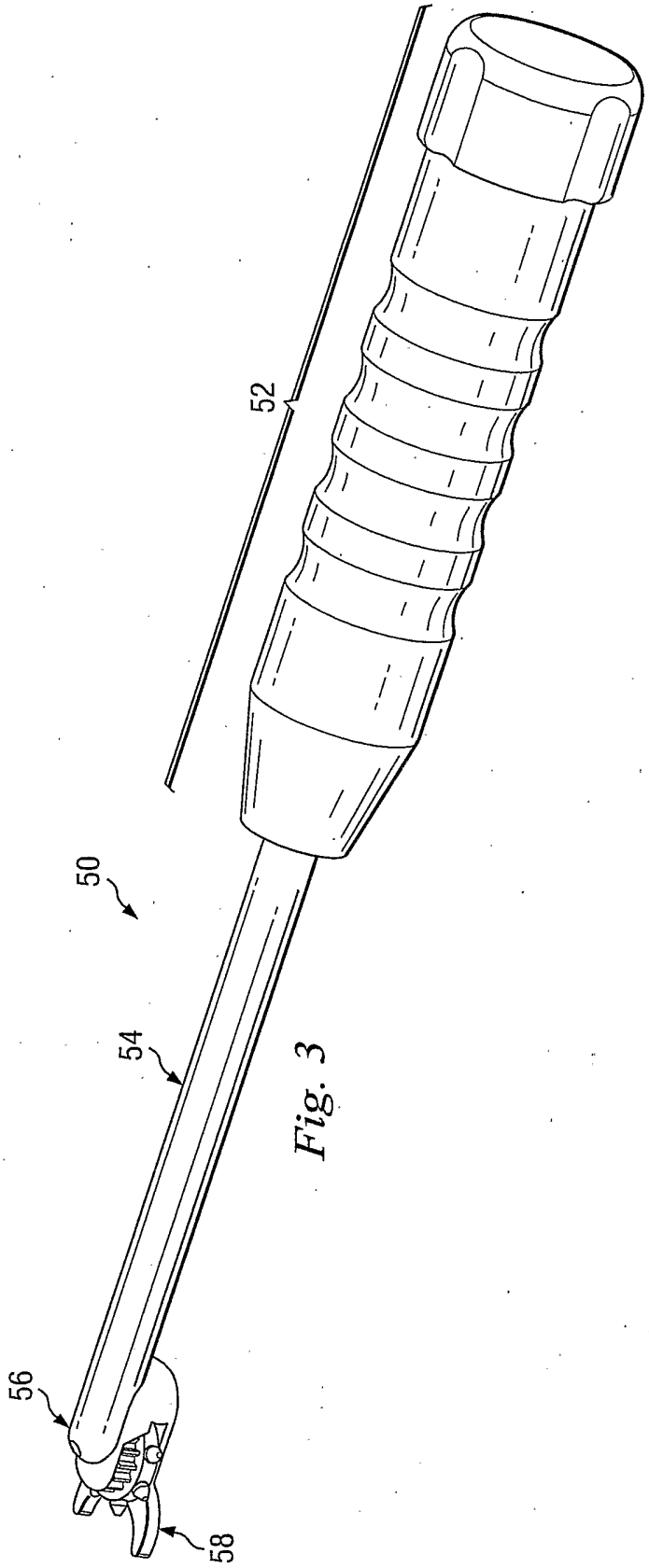


Fig. 3

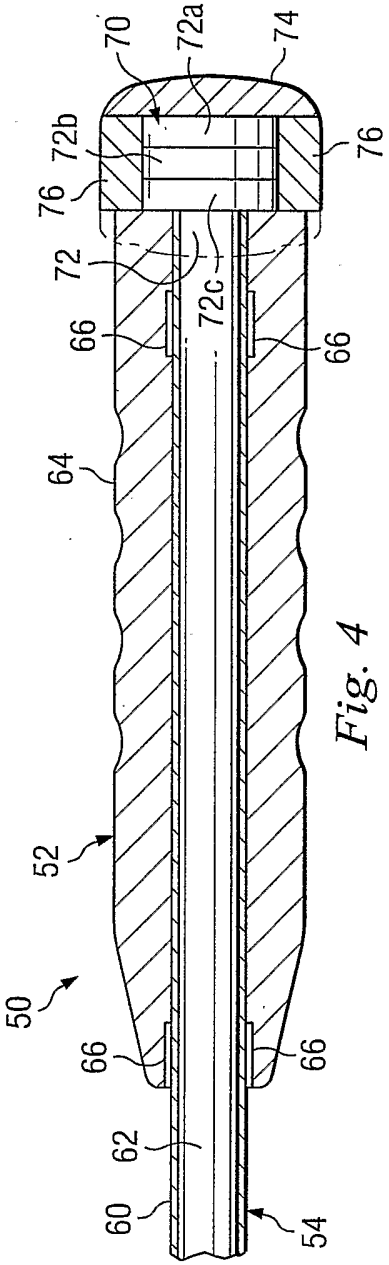


Fig. 4

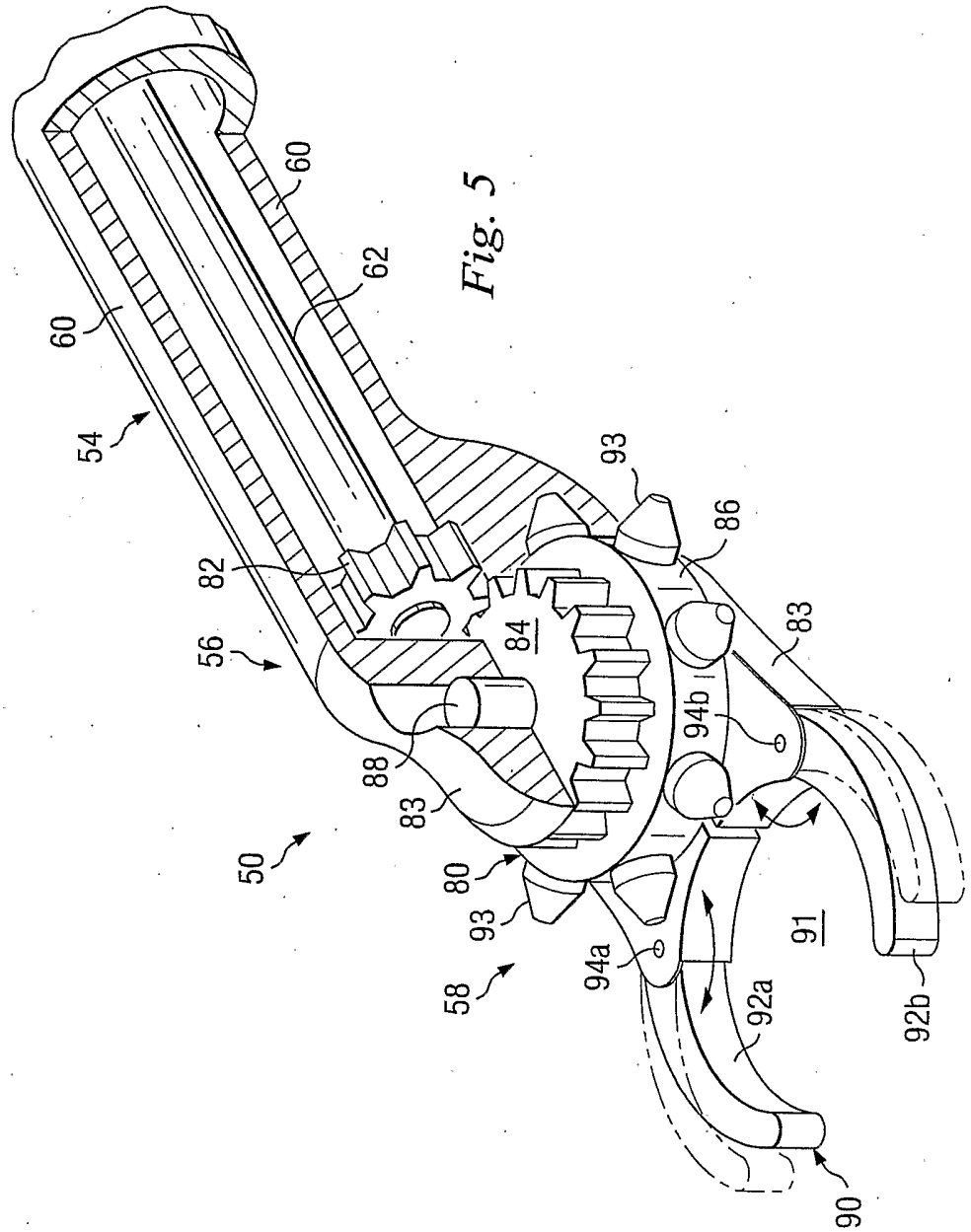


Fig. 5

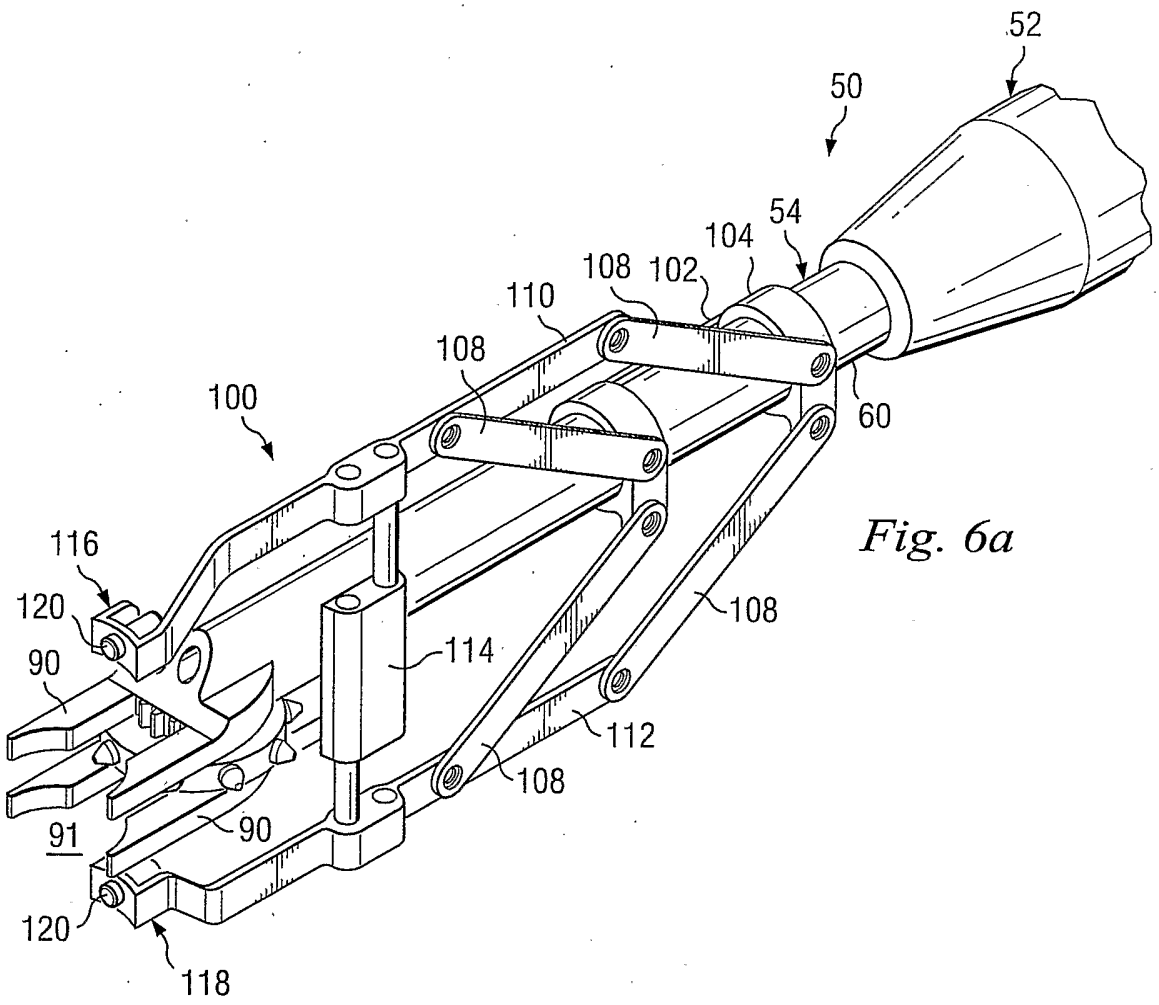

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90
120
118

Fig. 6a

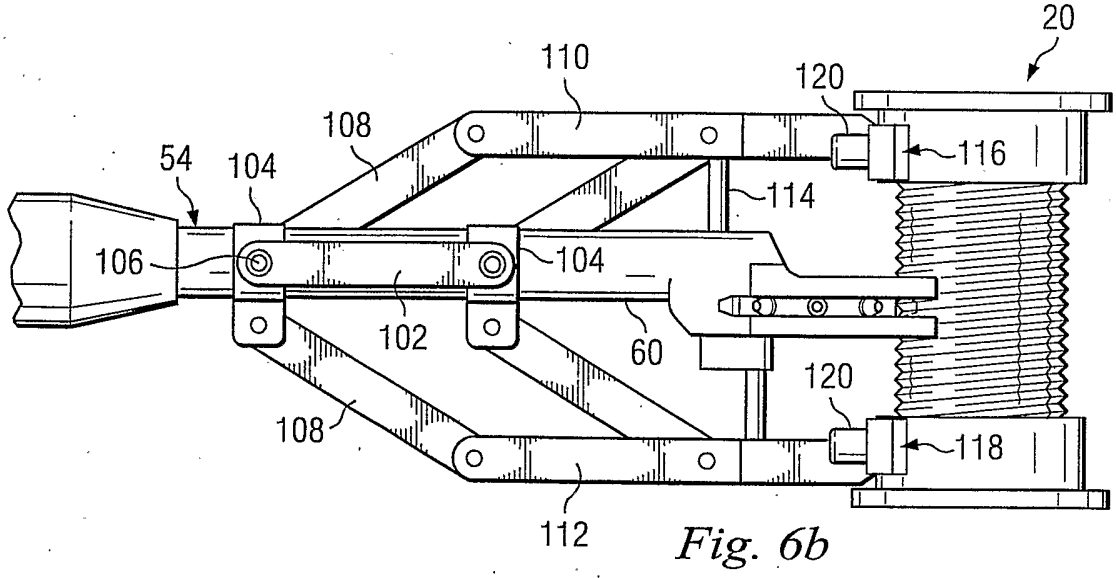

20
110
120
108
54
104
116
114
106
104
102
60
120
108
118
112

Fig. 6b