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(54) **Title:** SPINAL STABILIZATION SYSTEM

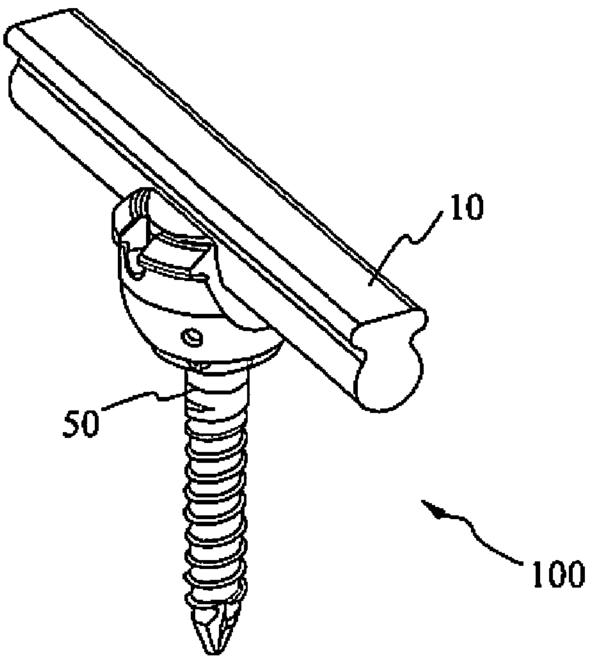

FIG. 1

(57) **Abstract:** A spinal stabilization system includes a connecting rod, a rod bending device, and a plurality of bone screws. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The rod bending device includes an elongate body defining an aperture configured and dimensioned to receive the connecting rod therethrough in a single orientation. The bone screws include a housing portion and a screw shaft distally extending from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein. The outer housing is movable relative to the inner housing between an unlock state and a locked state.

WO 2012/006064 A1

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SPINAL STABILIZATION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to, and the benefit of, U.S. Provisional Patent Application No. 61/359,028, filed on June 28, 2010, the entire contents of which is hereby incorporated by reference herein.

BACKGROUND

Technical Field

[0002] The present disclosure relates to orthopedic surgical devices, and more particularly, to a spinal stabilization system and a method of use therefor.

Background of Related Art

[0003] The spinal column is a complex system of bones and connective tissues that provide support for the human body and protection for the spinal cord and nerves. The adult spine is comprised of an upper and lower portion. The upper portion contains twenty-four discrete bones, which are subdivided into three areas including seven cervical vertebrae, twelve thoracic vertebrae and five lumbar vertebrae. The lower portion is comprised of the sacral and coccygeal bones. The cylindrical shaped bones, called vertebral bodies, progressively increase in size from the upper portion downwards to the lower portion.

[0004] An intervertebral disc along with two posterior facet joints cushion and dampen the various translational and rotational forces exerted upon the spinal column. The intervertebral disc is a spacer located between two vertebral bodies. The facets provide stability to the posterior portion of adjacent vertebrae. The spinal cord is housed in the canal of the vertebral bodies. It is protected posteriorly by the lamina. The lamina is a curved surface with three main protrusions. Two transverse processes extend laterally from the lamina, while the spinous process extends caudally and posteriorly. The vertebral bodies and lamina are connected by a bone bridge called the pedicle.

[0005] The spine is a flexible structure capable of a large range of motion. There are various disorders, diseases and types of injury, which restrict the range of motion of the spine or interfere with important elements of the nervous system. The problems include, but are not limited to, scoliosis, kyphosis, excessive lordosis, spondylolisthesis, slipped or ruptured discs, degenerative disc disease, vertebral body fracture, and tumors. Persons suffering from any of the above conditions typically experience extreme or debilitating pain and often times diminished nerve function. These conditions and their treatments can be further complicated if the patient is suffering from osteoporosis, or bone tissue thinning and loss of bone density.

[0006] Spinal fixation apparatuses are widely employed in surgical processes for correcting spinal injuries and diseases. When the disc has degenerated to the point of requiring removal, there are a variety of interbody implants that are utilized to take the place of the disc. These include interbody spacers, metal cages and cadaver and human bone implants. In order to facilitate stabilizing the spine and keeping the interbody in position, other implants are commonly employed, such as bone screws and rods. Depending on the pathology and treatment, a surgeon will select the appropriate spinal rod material and size, specifically, the cross-sectional diameter.

[0007| To meet the problem of providing a rigid pedicle screw and rod construct, especially for addressing the demands of stiff deformity corrections, larger rod constructs have been made to improve the strength of the screw and rod construct. Spinal rods are typically made of a titanium alloy. However when large deformity corrections need to be made, these rods are not always strong enough. Larger diameter stainless steel rods have been made for these applications, but a larger rod requires a larger mating screw head to contain the rod which in turn increases the profile of the construct. In addition, in order to reduce the likelihood of material incompatibility in vivo, the screw assembly also needs to be made of stainless steel to match the rod material, which is not a cost effective alternative.

|0008] Therefore, a need exists for a cost effective, rigid screw and rod construct that can still maintain a low profile, while maintaining the surgical correction.

SUMMARY

[00091 In accordance with an embodiment of the present disclosure, there is provided a spinal stabilization system including a connecting rod and a bone screw. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot.

|0010| The elongate head portion of the connecting rod may have a non-circular cross-section. In particular, the elongate head portion of the connecting rod may have a substantially rectangular cross-section. The neck portion of the connecting rod may have an arcuate profile. The neck portion and the elongate head portion of the connecting rod may be disposed proximal of the inner housing when the elongate round portion of the connecting rod is disposed in the slot defined in the inner housing. The connecting rod may be monolithically formed. The screw shaft may be fixed relative to the rod receiving portion, or may be coupled with the housing portion to permit uniaxial, monoaxial or polyaxial motion of the screw relative to the housing portion.

|001 1] In accordance with another embodiment of the present disclosure, there is provided a spinal stabilization system including a connecting rod, a rod bending device, and a

bone screw. The connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The rod bending device includes an elongate body defining an aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot.

[0012) The rod bending device may further include a second aperture configured and dimensioned to receive the rod oriented orthogonal to the direction in which the first aperture receives the rod. Side walls defining the apertures may have an arcuate profile. The apertures may include a rounded portion and a non-circular portion. The non-circular portion of the apertures may have a substantially rectangular shape. The rod bending device may further include a third aperture configured and dimensioned to receive the rod oriented oppositely to the orientation in which the first aperture receives the rod.

|00131 In accordance with another aspect of the present disclosure, there is provided a method of stabilizing a spine. The method includes providing a spinal stabilization system including a connecting rod, a pair of rod bending devices, and a bone screw. In particular, the connecting rod includes an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion. The pair of rod bending devices each includes an elongate body defining at least one aperture therethrough,

each aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation. The bone screw includes a housing portion and a screw shaft extending distally from the housing portion. The housing portion includes an inner housing and an outer housing slidably surrounding at least a portion of the inner housing. The inner housing defines a slot configured and dimensioned to rcleasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured in the slot. The method further includes implanting a plurality of bone screws into a plurality of vertebral bodies, bending the connecting rod using the rod benders, inserting the connecting rod into the connecting rod slots in the plurality of bone screws, and locking the connecting rod in the connecting rod slots in the plurality of bone screws.

[0014] Bending the connecting rod may include inserting the connecting rod through an aperture in each of the pair of rod bending devices and applying leveraged force to the connecting rod through the handle members of the rod bending devices. Bending the connecting rod may include bending the connecting rod in an anterior-posterior orientation. Bending the connecting rod may include bending the connecting rod in a medial-lateral orientation. Providing multiple apertures in the rod bending devices facilities bending the rod by permitting the rod to be oriented in various positions relative to the handles.

[0015] The pair of rod bending devices may each include a plurality of apertures configured and dimensioned to receive therethrough the connecting rod. The plurality of apertures may be defined to receive the rod in different orientations. Bending the connecting rod may include inserting the connecting rod through the apertures of the pair of rod bending devices having different orientations and applying twisting force. In addition, inserting the connecting rod into the connecting rod slots in the bone screws may include positioning the elongate round portion of the connecting rod in the connecting rod slots in the plurality of bone screws. Bending the connecting rod may include bending the connecting rod to conform to a desired contour of the spine.

|0016| The method may further include orienting the plurality of bone screws to the contour of the connecting rod prior to locking the connecting rod in the connecting rod slots in the plurality of bone screws. In addition, locking the connecting rod in the connecting rod slots in the plurality of bone screws includes partially locking the connecting rod in the connecting rod slots.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The foregoing and other features of the present disclosure will become apparent to one skilled in the art to which the present disclosure relates upon consideration of the following description of the disclosure with reference to the accompanying drawings, wherein:

[0018) FIG. 1 is a perspective view of a spinal stabilization system in accordance with an embodiment of the present disclosure;

[00191 FIG. 2 is a front view of the spinal stabilization system of FIG. 1;

[0020] FIG. 3 is a top view of the spinal stabilization system of FIG. 1;

[002 11 FIG. 4 is a side view of the spinal stabilization system of FIG. 1;

[0022] FIG. 5 is a partial cross-sectional view of a taper lock screw of the spinal stabilization system of FIG. 1 shown in an unlocked position to receive a rod;

[0023) FIG. 6 is a perspective view of a connecting rod of the spinal stabilization system of FIG. 1;

[00241 FIG. 7 is a front view of the connecting rod of FIG. 6;

|0025J FIG. 8 is a top view of the connecting rod of FIG. 6;

[0026] FIG. 9 is a side view of the connecting rod of FIG. 6;

[0027] FIG. 10 is a graph illustrating deflection of the connecting rod of FIG. 6;

[0028] FIG. 11 is a graph illustrating flexural rigidity of the connecting rod of FIG. 6;

[0029] FIG. 12A is a side view of a rod bender device for use with the spinal stabilization system of FIG. 1;

[0030] FIG. 12B is a side cross-sectional view of the area of detail indicated in FIG. 12A;

[0031] FIG. 13 is a perspective view of a pair of rod bender devices of FIG. 12A having the connecting rod of FIG. 6 inserted therethrough;

[0032] FIG. 14 is a perspective view of the pair of rod bender devices of FIG. 13 having the connecting rod of FIG. 6 inserted therethrough in a different orientation;

[0033] FIG. 15 is a perspective view of a spinal correction procedure on a deformed spine utilizing the spine stabilization system of FIG. 1; and

[0034] FIGS. 16A and 16B are flow charts illustrating an overview of a method of stabilizing a spine.

DETAILED DESCRIPTION OF EMBODIMENTS

[0035] Embodiments of the present disclosure will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein, the term "distal," as is conventional, will refer to that portion of the instrument, apparatus, device or component thereof which is farther from the user while, the term "proximal," will refer to that portion of the instrument, apparatus, device or component thereof which is closer to the user. In addition, the term "cephalad" is used in this application to indicate a direction toward a patient's head, while the term "caudad" indicates a direction toward the patient's feet. Further still, for the purposes of this application, the term "medial" indicates a direction toward the middle of the body of the patient, while the term "lateral" indicates a direction toward a side of the body of the patient, i.e., away from the middle of the body of the patient. The term "posterior" indicates a direction toward the patient's back, while the term "anterior" indicates a direction toward the patient's front. In the following description, well-known functions or constructions arc not described in detail to avoid obscuring the present disclosure in unnecessary detail.

[0036] With reference to FIGS. 1-4, an embodiment of the present disclosure is shown generally as a spinal stabilization system 100. Spinal stabilization system 100 includes at least one bone screw 50 and a connecting rod 10 releasably secured to bone screw 50. Bone screw 50 is a multi-planar taper lock screw that enables manipulation of a screw shaft 52 about multiple axes, whereby bone screw 50 is capable of securing connecting rod 10 with bone screws 50 on multiple vertebral bodies that are aligned in the spinal column on different planes due to the natural curvature of the spine. However, it is also envisioned that bone screws 50 may be, for example, fixed angle screw, uniplanar screws or monoaxial taper lock screws.

[0037] With reference now to FIGS. 4 and 5, a suitable multi-planar taper lock bone screw 50 includes a dual layered housing 60 and screw shaft 52 having a spherically configured screw head 54 rotatably coupled with housing 60. In particular, dual layered housing 60 includes an outer housing 62 and an inner housing 64. Outer housing 62 can be selectively positioned relative to inner housing 64 to fully lock screw head 54 and connecting rod 10 in position within inner housing 64 (see Fig. 4) or alternatively to selectively partially lock screw head 54 and/or connecting rod 10 in position while permitting a sliding and/or rotating motion of the connecting rod 10 relative to screw head 54, and the screw head 54 relative to bone screw 50, respectively. Specifically, outer housing 62 is configured such that at least a portion of an inner surface of outer housing 62 is capable of sliding over a portion of an outer surface of inner housing 64 in upward and downward directions along the longitudinal axis of bone screw 50. When outer housing 62 is slid upward in relation to inner housing 64 an inner surface of outer housing 62 causes inner housing 64 to impart compressive force radially inward to secure connecting rod 10 at least partially disposed therein.

[0038] With continued reference to FIG. 5, inner housing 64 defines a connecting rod slot 70 that is configured and dimensioned to accommodate the connecting rod geometry contemplated by the present disclosure, and to retain connecting rod 10 in inner housing 64 without impairing the locking ability of bone screw 50. Specifically, an elongate round section 12 of connecting rod 10 is releasably secured in connecting rod slot 70 of inner housing 64, as will be discussed in detail below. The term "round" in elongate round section 12 refers to a portion of connecting rod 10 having a generally circular/arcuate cross-section that is received in bone screw 50. In particular, inner walls that define connecting rod slot 70 imparts compressive force to connecting rod 10 disposed in connecting rod slot 70, whereby the inner walls serve to securely lock and hold connecting rod 10 in its relative position to inner housing 64. This required forced is provided by the operational engagement of a locking device (not shown) with bone screw 50 that results in an upward sliding motion of outer housing 62 relative to inner housing 64.

[0039] Inner housing 64 further defines a screw head articulation recess 66 in a lower portion of inner housing 64. The interior surface of screw head articulation recess 66 has a complementary surface configuration to the generally spherical shape of screw head 54 to facilitate multi-planar rotational articulation of screw head 54 within articulation recess 66. The lower-most portion of inner housing 64 defines a screw shaft exit portal 68 that is sized small enough to retain the spherical screw head 54 within screw head articulation recess 66, but that is large enough to allow multi-directional movement of screw shaft 52 that extends exterior to inner housing 64.

[0040] Outer housing 62 includes a receiving element configured to facilitate grasping of bone screw 50 by a locking and/or unlocking instrument (not shown) that can insert and lock connecting rod 10 securely into place in bone screw 50 or selectively unlock connecting rod 10 from bone screw 50 using complementarily designed unlocking instruments. The receiving clement is a proximally located annular flange 74 radially extending from the upper portion of the outer surface of outer housing 62.

[0041] One suitable taper lock screw is commercially available from K2M, Inc. (Leesburg, VA) under the trade name MESA™. In addition, suitable multi-planar taper lock screws are shown and described in U.S. Patent Application Publication 2008/0027432 and in U.S. Patent Application Publication 2007/0093817, both of which arc herein incorporated by reference in their entireties. It is contemplated that other types of screws such as, e.g., a fixed screw in which the head of the screw has no movement relative to the screw shaft, a mono-axial screw such as that disclosed in U.S. Patent Application Publication 2009/0105716, and a uni-axial screw such as that disclosed in U.S. Patent Application Publication 2009/0105769 may be utilized. Suitable mono-axial and uni-axial screws arc also commercially available under the trade name MESA™.

[0042] With reference back to FIGS. 1-4, connecting rod 10 is configured and dimensioned to be selectively and releasably secured to bone screw 50. Connecting rod 10 is defined by an elongate body of a particular length. The elongate body is made of a biocompatible material such as Titanium (Ti-CP) and its alloys (e.g., Ti-6Al-4V), Cobalt-Chrome Alloy (CoCr) or Stainless Steel (SS).

[0043] With reference to FIGS. 6 and 7, the elongate body of connecting rod 10 includes an elongate rounded section 12 having a substantially circular cross-section (see Fig. 7), an elongate head portion 14, and a neck portion 16 that connects and transitions elongate round section 12 into elongate head portion 14, thereby providing reduced stress concentration along the elongate body of connecting rod 10. The neck portion may define a pair of concave sides joining the elongate head portion to the elongate round portion, so that the concave sides provide clearance for the taper lock screw housings. The elongate body of connecting rod 10 may be monolithically formed as a unitary construct. For example, connecting rod 10 may be machined from a single piece of bar stock.

[0044] With reference now to FIGS. 6 to 9, elongate head portion 14 may have a non-circular cross-section. As shown, elongate head portion 14 has a substantially rectangular cross-section having suitable dimensions of, for example, about 6 mm x about 1 mm (0.246 in. x 0.039 in.). However, it is envisioned that elongate head portion 14 may have a cross-section that is substantially square, elliptical or any other shape to add rigidity to round section 12 of connecting rod 10.

[0045] With particular reference back to FIGS. 5 and 6, elongate round section 12 of connecting rod 10 is configured and dimensioned to be received in connecting rod slot 70 of inner housing 64 (see Fig. 2). For example, round section 12 of connecting rod 10 may have a standard diameter of, for example, 5.5 mm, suitable to mate with connecting rod slot 70. Bone screw 50 may be positioned at any desired point along the elongate body of connecting rod 10. When connecting rod 10 is secured to bone screw 50, neck portion 16 of connecting rod 10 is disposed at the top of bone screw 50 (FIG. 2) and does not interfere with the interaction between connecting rod 10 and bone screw 50. Furthennore, elongate head portion 14 of connecting rod 10 is disposed above the top of taper lock screw 50. While elongate head portion 14 is disposed above elongate round section 12, head portion 14 does not appreciably increase the height profile of the screw-rod combination.

[0046] Connecting rod 10 affords greater strength and rigidity in comparison with ordinary circular rods with comparable dimensions. With reference now to FIG. 10, connecting rods 10 made of different materials were placed under cantilever loading and were analyzed under Finite Element Analysis (FEA), wherein each rod sample was 100 mm in length. The distal end was fixed while the proximal end was subject to 200 N of force. Connecting rod 10 lacks radial symmetry. Accordingly, the graph differentiates deflection of connecting rod 10 between cantilever loading in flexion/extension and lateral bending.

[0047] For example, placing a circular rod formed from a titanium alloy (e.g. Ti-6A1-4V) under the same loading conditions as connecting rod 10 in Figure 10 results in a deflection of about 13.4 mm for a rod diameter of 5.5 mm and a deflection of about 5.00 mm for a rod with a diameter of 7.00 mm. A stainless steel rod placed under the same loading conditions results in a deflection of about 8.00 mm for a rod diameter of 5.5 mm and a deflection of about 3.00 mm for a rod diameter of 7.00 mm. A rod formed from a cobalt chrome alloy under the same loading conditions has a deflection of about 6.8 mm for a rod diameter of 5.5 mm and a deflection of about 2.8 mm for a rod diameter of 7.00 mm.

(0048) Flexural rigidity of connecting rod 10 is shown in FIG. 11. For example, circular rods made of a titanium alloy (e.g. Ti-6A1-4V) placed under the same loading conditions as connecting rod 10 in FIG. 11 have flexural rigidity of about 5.01 N-m^2 for a rod diameter of 5.5 mm and 23.5 N-m^2 for a rod diameter of 8.00 mm. Circular rods made of stainless steel placed under the same loading conditions have flexural rigidity of about 9.0 N-m^2 for a diameter of 5.5 mm and 40.01 N-m^2 for a rod diameter of 8.00 mm. Circular rods made of cobalt chrome alloy placed under the same loading conditions have flexural rigidity of about 10.1 N-m^2 for a rod diameter of 5.5 mm and 47.0 N-m^2 for a rod diameter of 8.00 mm.

[0049) Connecting rod 10 provides a greater stiffness and rigidity than circular rods having comparable dimensions in various materials. As such, connecting rod 10 and bone screw 50 construct affords greater rigidity and strength without increased bulk and profile. In addition, such construct, as shown, does not require any design changes to taper lock screw 50, and thus advantageously provides efficiency of manufacture and inventory.

[0050] With reference now to FIGS. 12 to 14, spinal stabilization system 100 may further include rod bender devices 80. Each rod bender devices 80 define matching apertures 88 configured to receive and hold at least a portion of connecting rod 10 therein. Rod bender device 80 includes a handle member 82, an elongate body 84 extending distally from handle portion 82, and an engaging portion 86 coupled to elongate body 84. Elongate body 84 is coupled or formed with handle member 82 and engaging portion 86 so as to reduce stress concentration. Handle member 82 may contain scalloped sections to facilitate gripping by the user. Elongate body 84 may have a rectangular cross-section and may define a cavity along the length thereof to reduce the weight of device. Engaging portion 86 defines at least one aperture 88 adapted and dimensioned to receive therethrough connecting rod 10. In particular, inner walls that define aperture 88 are arcuate to facilitate insertion of connecting rod 10 through aperture 88 in a single orientation with respect to such aperture.

[0051] Each aperture 88 defines a round section 88a corresponding to elongate round section 12 of connecting rod 10 and a rectangular shaped section 88b corresponding to rectangular portion 14 of connecting rod 10. In this manner, connecting rod 10 is inserted into each aperture 88 in a single orientation. Thus, in order to accommodate insertion of connecting rod in aperture 88 in various orientations, a plurality of apertures 88 is defined in engaging portion 86 in different orientations, as shown in FIG. 12A-12B. For example, the pair of apertures 88 defined in engaging portion 86 is oriented at a 90-degree angle, whereby the rectangular portions of apertures 88 are orthogonal to each other. In this manner, the user can bend connecting rod 10 in both an anterior-posterior orientation and a medial-lateral orientation. It is also contemplated that connecting rod 10 may be inserted in non-corresponding apertures 88 in rod bender devices 80 to facilitate twisting of connecting rod 10, if necessary or desired.

[0052] The length of elongate body 84 is, for example, 18 inches. However, the length of elongate body 84 may be tailored to meet the needs of the surgical application to provide a suitable long moment arm necessary to provide the user a mechanical advantage to bend connecting rod 10.

In addition, it is also envisioned that elongate body 84 may be a hollow tubular member and/or define lightening holes to reduce the weight of device 80.

[0053] With reference now to FIGS. 16A and 16B, a method of performing spinal stabilization utilizing spinal stabilization system 100 is illustrated. Initially, the user implants a plurality of bone screws 50 in vertebral bodies of patient in step 500. Preliminary to the operation of bone screw 50, outer housing 62 is positioned in the open/unlocked position, that is, outer housing 62 is moved downward relative to inner housing 64. Screw shaft 52 can then be driven into the desired vertebral body by providing torsional force via a driving tool (not shown) configured to mate with and grip bone screw 50. After screw shaft 52 is positioned within the vertebral body and the driving tool removed from the screw, elongate round section 12 of connecting rod 10 can be positioned transversely within connecting rod slot 70 defined in inner housing 64.

[0054] However, prior to securing connecting rod 10 with bone screw 50, the surgeon can manipulate and correct the curve of the spinal column, i.e., to manually manipulate and reduce the "rib hump" in step 502. After placing the spine in proper position in step 504, the surgeon can bend connecting rod 10 in step 506 prior to securing connecting rod 10 to the first two points of the spinal column where the construct is to be attached.

[0055] The surgeon can bend connecting rod 10 by utilizing the pair of rod bender devices 80 in step 508. In use, connecting rod 10 is inserted through apertures 88 of rod bender devices 80 and force is applied at handle members 82 of rod bender devices 80 to appropriately contour and shape connecting rod 10 to a desired curve in step 514.

[0056] In particular, spinal stabilization system 10 can be utilized to correct spinal deformity (see FIG. 15) in step 510 to appropriately contour and shape connecting rod 10 to a desired curvature of the spine, e.g., the sagittal curve, in step 512. For example, a rod reduction device or plurality of rod reduction devices 150 including a screw jack mechanism and a manipulation device or plurality of manipulation deviesl70 adapted and configured for attachment to heads of taper lock bone screws 50, and which provides leverage (i.e., long moment arm) to facilitate the manipulation of the spine may be utilized to orient the spine and place connecting rod 10 in bone screw 50. In particular, rod reduction device 150 includes a housing with two arms that are pivotaliy attached to the housing, an anvil movably mounted on the two arms, and a screw threadably coupled with the housing and the anvil. The distal ends of arms provide positive and secure attachment of rod reduction device 150 with bone screw 50. When the anvil is adjacent the housing the two arms are pivoted outwards, such that the distal ends of the arms can receive bone screw 50 therebetween. Rotating the screw of rod reduction device 150 in a first direction advances the screw through the housing and causes corresponding movement of the anvil toward bone screw 50, which in turn causes the arms to move toward each other and provides positive engagement with bone screw 50. The anvil defines an arcuately defined recess that is configured and dimensioned for positively engaging connecting rod 10. The recess cooperates with connecting rod slot 70 and defines an opening adapted for receiving connecting rod 10. With connecting rod 10 positioned in or near connecting rod slot 70, the surgeon continues to advance the screw capturing connecting rod 10 between the recess of the anvil and connecting rod slot 70. When the anvil is sufficiently advanced, the recess presses upon the outer surface of connecting rod 10 and pushes it into connecting rod slot 70. A suitable rod reduction device 150 is disclosed in a commonly assigned U.S. Patent Application Publication No. 2009/0018593, the complete disclosures of which are fully incorporated herein by reference.

[0057] With reference to FIG. 15, rod reduction device 150 is attached to the heads of bone screws 50 on the concave side of the spinal deformity. Manipulation device 170 is placed on bone screws 50 on the convex side of the spinal deformity. Depending on the nature of the deformity, however, rod reduction device 150 may be used on both sides of the deformity.

[0058] At this time, connecting rod 10 is positioned in slots 70 of bone screws 50 implanted in vertebral bodies in step 516. With screw shaft 52 and screw head 54 being fixed in position relative to the vertebral body, bone screws 50 may be partially locked in step 518. In particular, inner housing 64 and the circumfcrentially disposed outer housing 62 can be articulated relative to screw head 54 as necessary to manipulate the disposition of connecting rod 10 within bone screw 50 to make necessary adjustments in step 520. For example, bone screw 50 may be partially locked to connecting rod 10 for compression, distraction and rotation without torsional stress being applied to the spine.

|0059] Upon completion of the necessary positional adjustments of inner housing recess 66 relative to screw head 54 and the adjustments of connecting rod 10 relative to connecting rod slot 70, outer housing 62 can be grasped by the operator using the complementarily configured locking device. Activation of the locking device slides the outer housing upward circumferentially over the outer surface of inner housing 64 while the push rod holds down connecting rod 10 and inner housing 64 so that bone screw 50 is reconfigured from the open or unlocked position to closed or locked position in step 522. Similarly, the operator can use the complementarily configured unlocking device to grasp inner housing 64 and slidably move outer housing 62 downward along the outer surface of inner housing 64 from a closed or locked position to an open or unlocked position. The rod and bone screw combination of the present disclosure may provide particular advantages in scoliosis or other spinal deformity surgery in which high stress levels arc exerted upon such constructs at particular levels in the construct or over the entire length of such a construct.

(0060] Although the illustrative embodiments of the present disclosure have been described herein with reference to the accompanying drawings, the above description, disclosure, and figures should not be construed as limiting, but merely as exemplifications of particular embodiments. For example, it is contemplated that elongate head portion 14 of connecting rod 10 need not extend over substantially the entire the elongate body of connecting rod 10, but instead may only be provided in a portion of connecting rod 10 where it is desired to enhance the rigidity of that portion of the rod. One skilled in the art will recognize that the present disclosure is not limited to use in spine surgery, and that the instrument and methods can be adapted for use with any suitable surgical device. It is to be understood, therefore, that the disclosure is not limited to those precise embodiments, and that various other changes and modifications may be effected therein by one skilled in the art without departing from the scope or spirit of the disclosure.

What is claimed is:

1. A spinal stabilization system comprising:

a connecting rod including an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion; and

a bone screw including a housing portion and a screw shaft extending distally from the housing portion, the housing portion including an inner housing and an outer housing slidably surrounding at least a portion of the inner housing, the inner housing defining a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured to the slot.

2. The spinal stabilization system according to claim 1, wherein the elongate head portion of the connecting rod has a non-circular cross-section.

3. The spinal stabilization system according to either claim 1 or 2, wherein the elongate head portion of the connecting rod has a substantially rectangular cross-section.

4. The spinal stabilization system according to claim 1, wherein the neck portion of the connecting rod has an arcuate profile.

5. The spinal stabilization system according to claim 4, wherein the neck portion is narrower than the elongate round portion.

6. The spinal stabilization system according to claim 1, wherein the neck portion and the elongate head portion of the connecting rod are disposed proximal of the inner housing when the elongate round portion of the connecting rod is disposed in the slot defined in the inner housing.

7. The spinal stabilization system according to claim 1, wherein the connecting rod is monolithically formed.

8. The spinal stabilization system according to claim 1, wherein the screw shaft is polyaxially coupled to the housing portion.

9. The spinal stabilization system according to claim 1, wherein the outer housing includes a circumferentially disposed flange.

10. The spinal stabilization system of claim 1, further comprising a plurality of bone screws,

11. A spinal stabilization system comprising:

a connecting rod including an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion;

at least one rod bending device including an elongate body defining an aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation; and

a bone screw including a housing portion and a screw shaft rotatably extending distally from the housing portion, the housing portion including an inner housing and an outer housing slidably surrounding at least a portion of the inner housing, the inner housing defining a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured to the slot.

12. The spinal stabilization system according to claim 11, wherein the at least one rod bending device further includes a second aperture oriented orthogonal to the aperture.

13. The spinal stabilization system according to claim 11, wherein side walls defining the aperture have an arcuate profile.

14. The spinal stabilization system according to claim 11, wherein the aperture includes a round portion and a non-circular portion.

15. The spinal stabilization system according to claim 14, wherein the non-circular portion of the aperture has a substantially rectangular shape.

16. A method of stabilizing a spine, the method comprising:

providing a spinal stabilization system including:

a connecting rod including an elongate round portion, an elongate head portion and a neck portion connecting the elongate round portion with the elongate head portion;

a pair of rod bending devices each including an elongate body defining an aperture configured and dimensioned to receive therethrough the connecting rod in a single orientation; and

a bone screw including a housing portion and a screw shaft extending distally from the housing portion, the housing portion including an inner housing and an outer housing slidably surrounding at least a portion of the inner housing, the inner housing defining a slot configured and dimensioned to releasably secure the elongate round portion of the connecting rod therein, wherein the outer housing is movable relative to the inner housing between an unlock state in which the elongate round portion of the connecting rod is releasable from the slot defined in the inner housing and a locked state in which the connecting rod is secured to the slot;

implanting a plurality of bone screws into a plurality of vertebral bodies;

bending the connecting rod using the rod bending devices;

inserting the elongated round portion of the connecting rod into the connecting rod slots in the plurality of bone screws with the head portion disposed above the screws; and

locking the connecting rod in the connecting rod slots in the plurality of bone screws.

17. The method according to claim 16, wherein the elongate head portion of the connecting rod has a non-circular cross-section.

18. The method according to either claim 16 or 17, wherein the elongate head portion of the connecting rod has a substantially rectangular cross-section.

19. The method according to claim 16, wherein bending the connecting rod includes inserting the connecting rod through the apertures of the pair of rod bending devices and applying force to the connecting rod through the handle members of the rod bending devices.

20. The method according to claim 19, wherein bending the connecting rod includes bending the connecting rod in an anterior-posterior orientation.

21. The method according to claim 19, wherein bending the connecting rod includes bending the connecting rod in a medial-lateral orientation.

22. The method according to claim 16, wherein the pair of rod bending devices each includes a plurality of apertures configured and dimensioned to receive therethrough the connecting rod, the plurality of apertures defined in different orientations.

23. The method according to claim 22, wherein bending the connecting rod includes inserting the connecting rod through the apertures of the pair of rod bending devices having different orientations and applying twisting force.

24. The method according to claim 16, wherein inserting the connecting rod into the connecting rod slots in the bone screws includes positioning the elongate round portion of the connecting rod in the connecting rod slots in the plurality of bone screws.

25. The method according to either claim 16 or 22, wherein bending the connecting rod includes bending the connecting rod to conform to a desire contour of the spine.

26. The method according to claim 16, wherein the housing portion of the bone screw is rotatably coupled with the screw shaft.

27. The method according to either claim 16 or 22, further comprising orienting the plurality of bone screws to the contour of the connecting rod prior to locking the connecting rod in the connecting rod slots in the plurality of bone screws.

28. The method according to either claim 16 or 22, wherein locking the connecting rod in the connecting rod slots in the plurality of bone screws includes partially locking the connecting rod in the connecting rod slots.

29. A connecting rod bending device comprising:

a handle member; and

an elongate body extending from the handle member, the elongate body defining a non-circular aperture configured and dimensioned to receive a non-circular rod in a particular orientation.

30. The connecting rod bending device according to claim 27, wherein the elongate body further defines a plurality of non-circular apertures, the plurality of non-circular apertures being defined in various orientations, whereby a connecting rod can be received in variety of orientations with respect to the elongate body.

31. The connecting rod bending device according to claim 28, wherein the plurality of non-circular apertures are orthogonal to each other.

32. The connecting rod bending device according to claim 27, wherein the non-circular aperture includes an arcuate portion and a substantially rectangular portion.

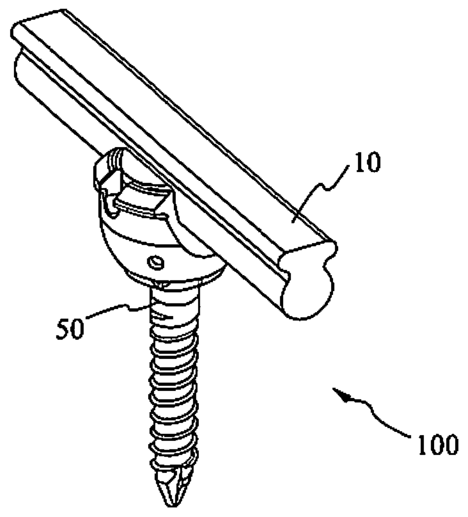

FIG. 1

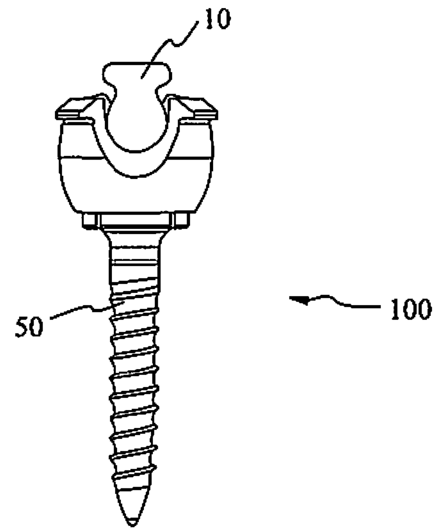

FIG. 2

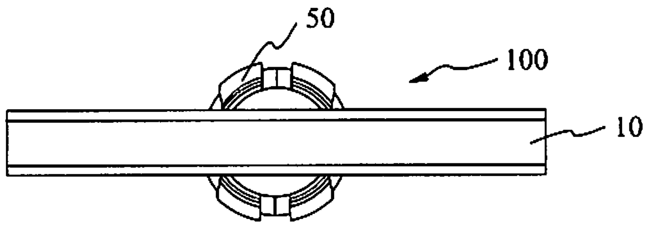

FIG. 3

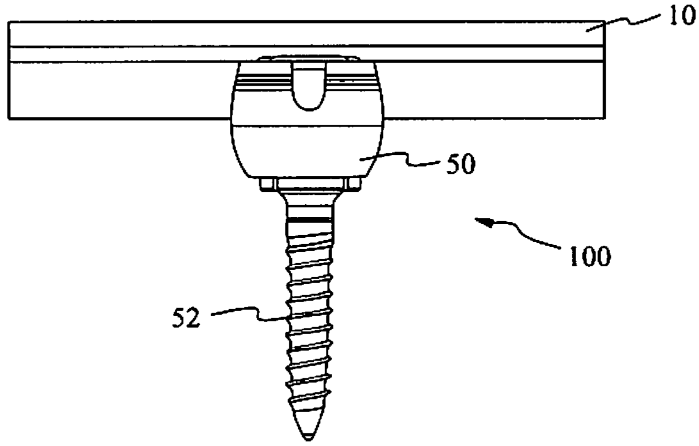

FIG. 4

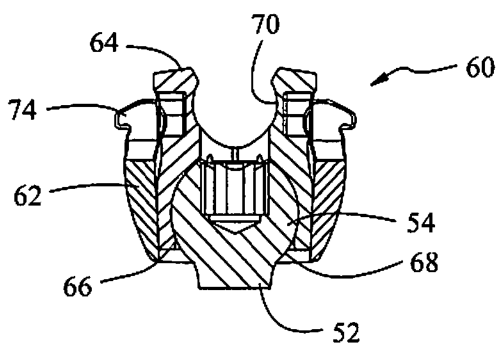

FIG. 5

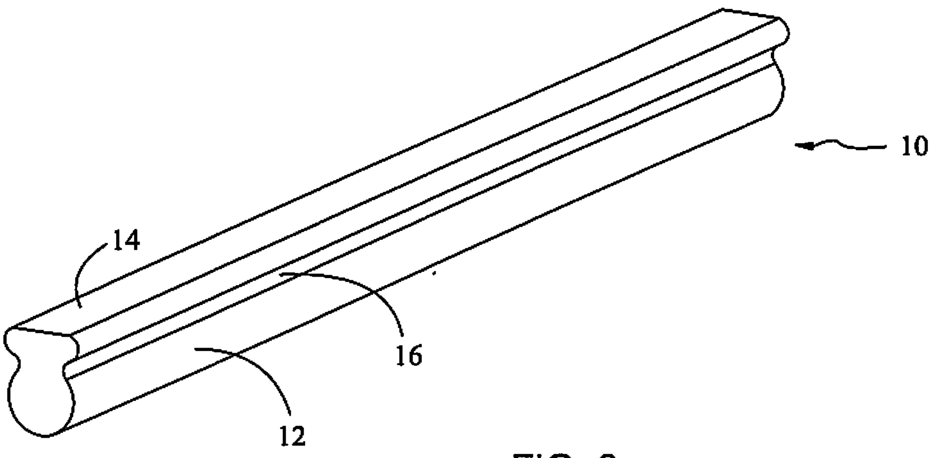

FIG. 6

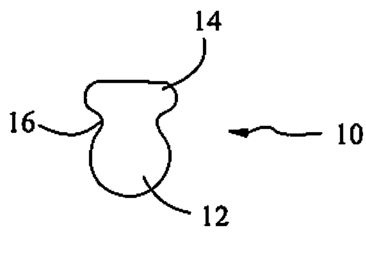

FIG. 7

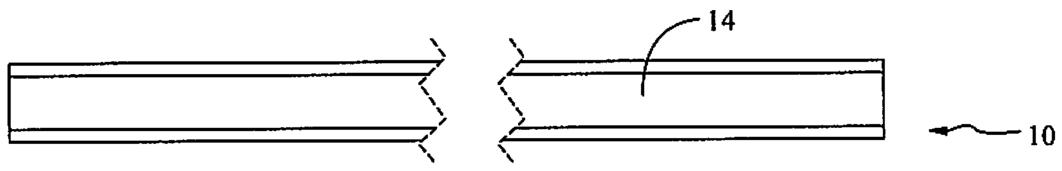

FIG. 8

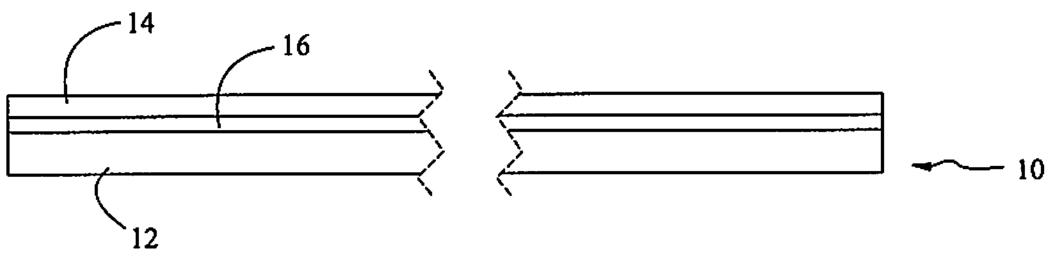

FIG. 9

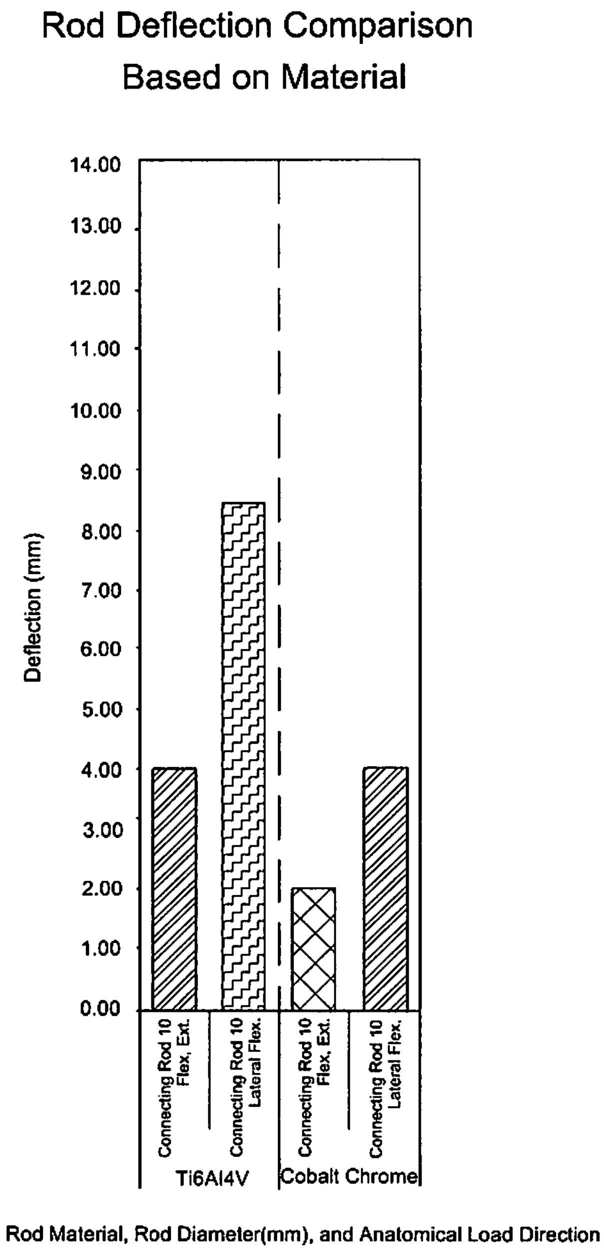
Rod Deflection Comparison
Based on Material
14.00
13.00
12.00
11.00
10.00
9.00
8.00
7.00
6.00
5.00
4.00
3.00
2.00
1.00
0.00
Deflection (mm)
Connecting Rod 10 Flex, Ext.
Connecting Rod 10 Lateral Flex.
Connecting Rod 10 Flex, Ext.
Connecting Rod 10 Lateral Flex.
Ti6Al4V
Cobalt Chrome
Rod Material, Rod Diameter(mm), and Anatomical Load Direction

FIG. 10

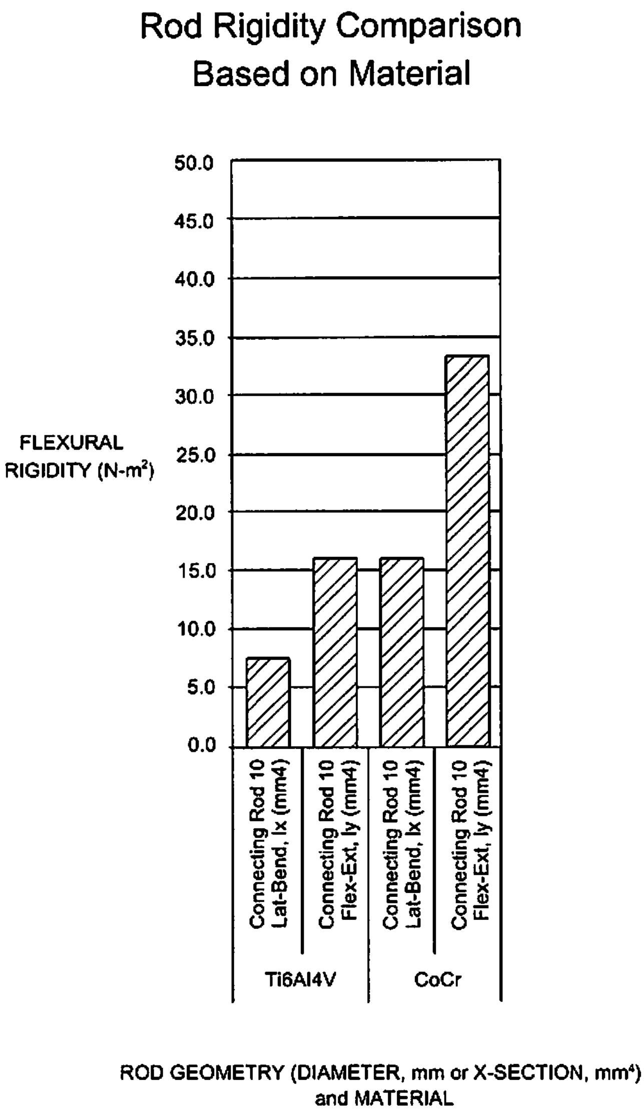
Rod Rigidity Comparison
Based on Material
FLEXURAL RIGIDITY (N-m²)
50.0
45.0
40.0
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
Connecting Rod 10 Lat-Bend, Ix (mm4)
Connecting Rod 10 Flex-Ext, Iy (mm4)
Connecting Rod 10 Lat-Bend, Ix (mm4)
Connecting Rod 10 Flex-Ext, Iy (mm4)
Ti6Al4V
CoCr
ROD GEOMETRY (DIAMETER, mm or X-SECTION, mm⁴) and MATERIAL

FIG. 11

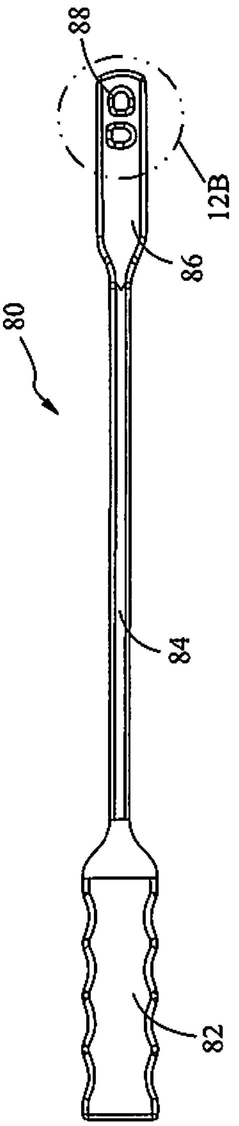

FIG. 12A

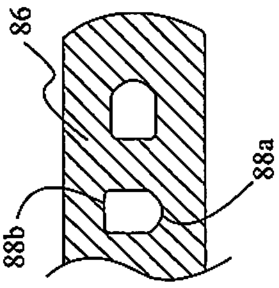

FIG. 12B

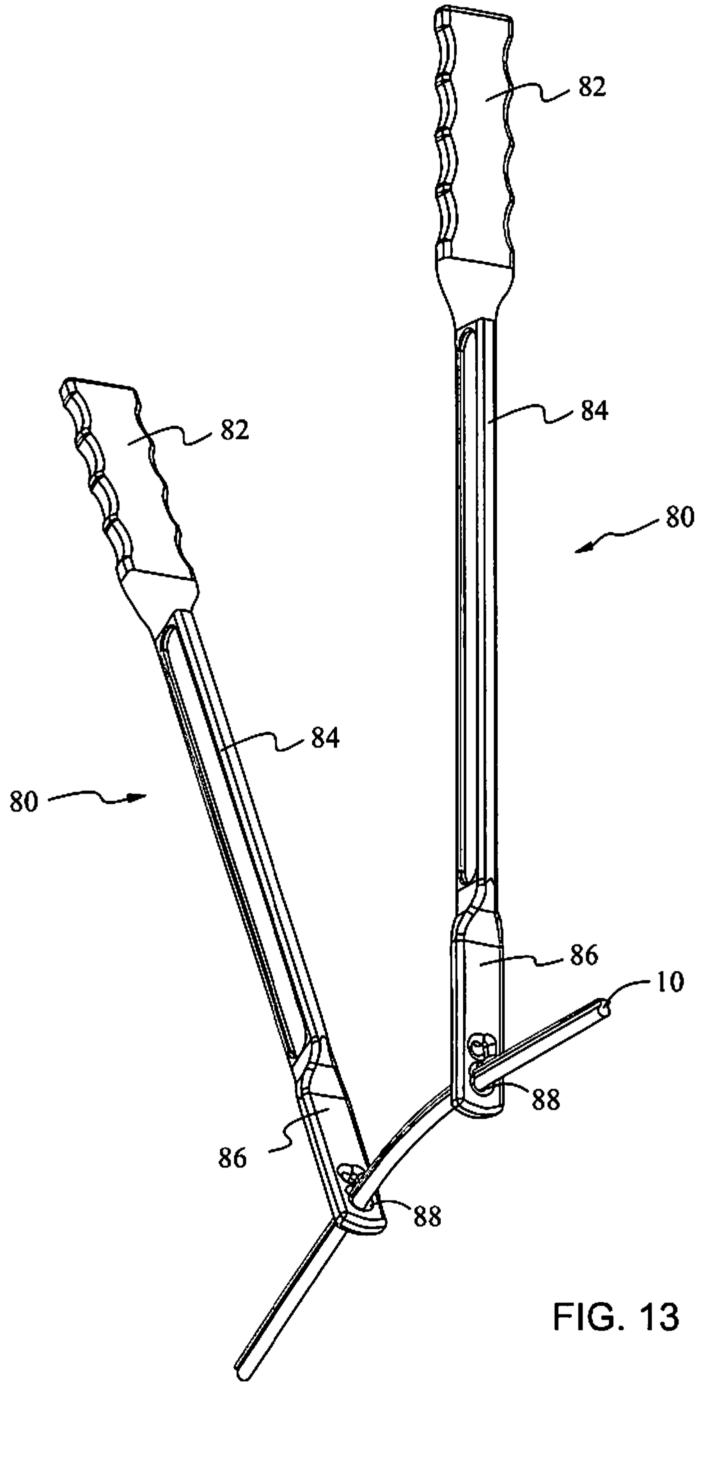

FIG. 13

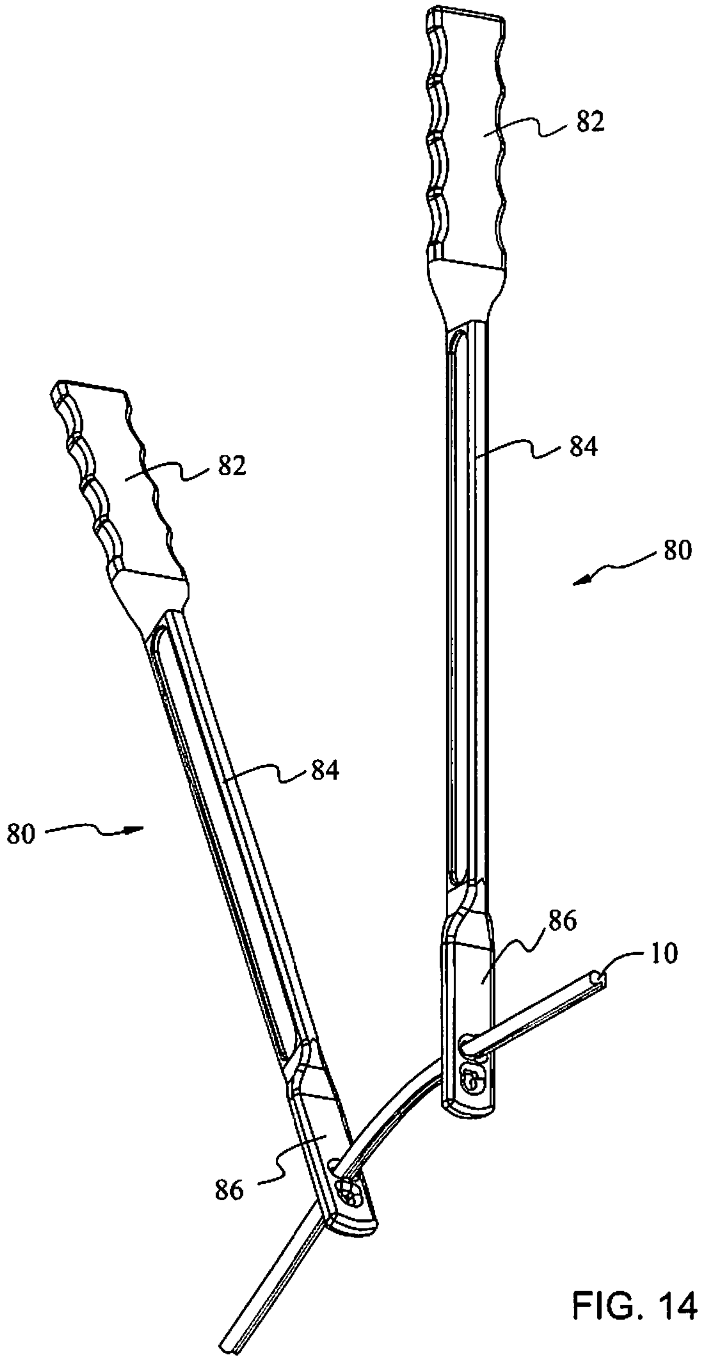

FIG. 14

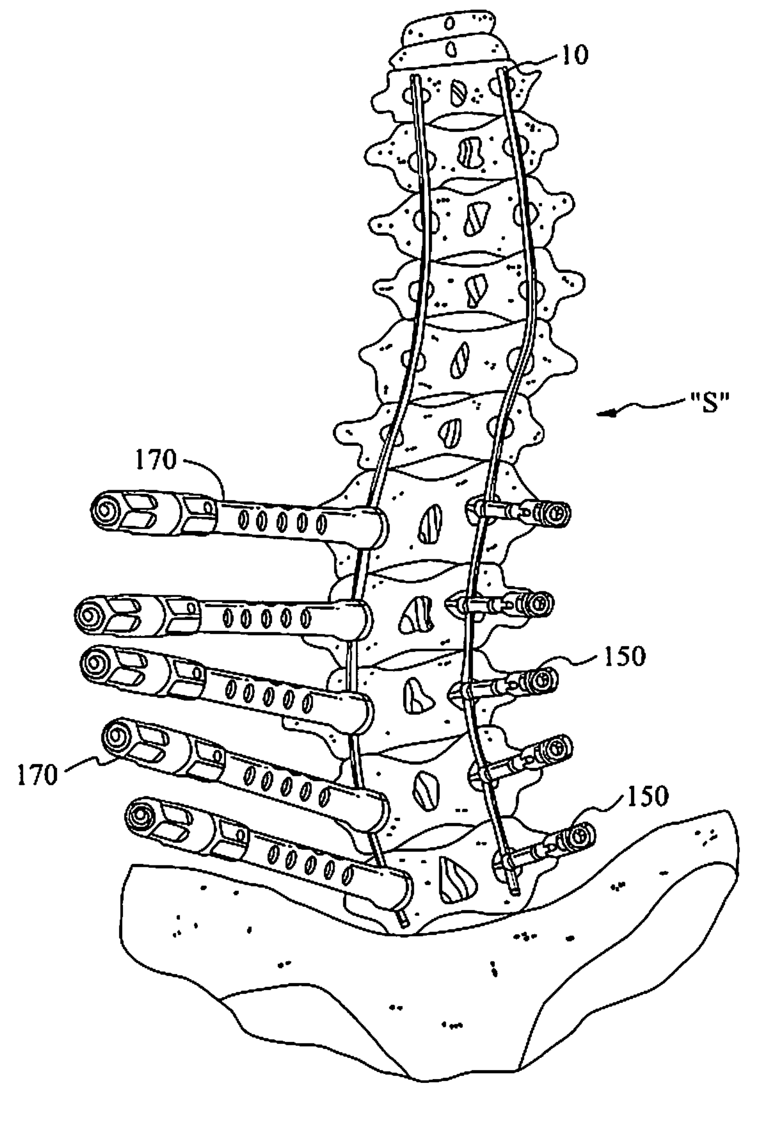

FIG. 15

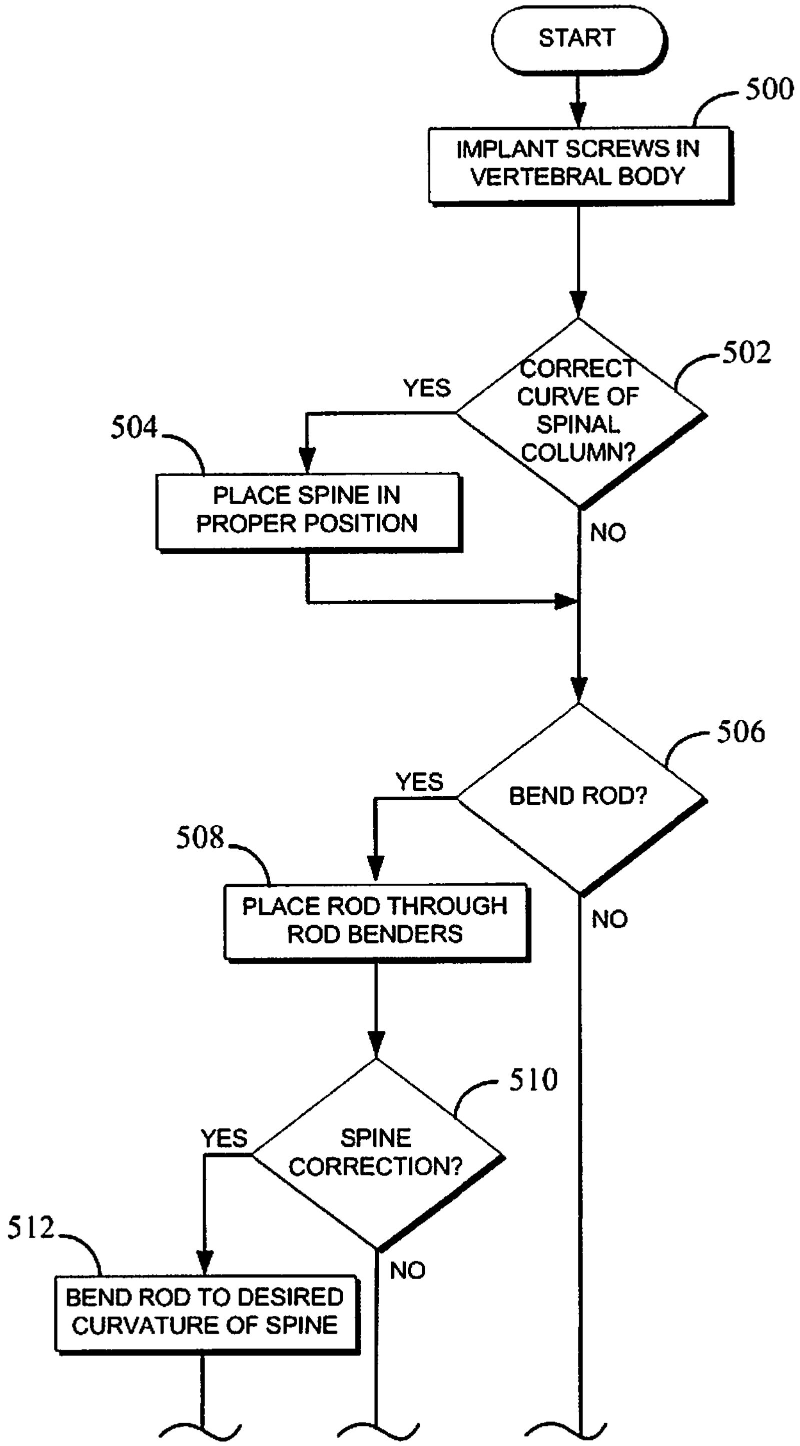
START
500
IMPLANT SCREWS IN VERTEBRAL BODY
502
CORRECT CURVE OF SPINAL COLUMN?
YES
504
PLACE SPINE IN PROPER POSITION
NO
506
BEND ROD?
YES
508
PLACE ROD THROUGH ROD BENDERS
NO
510
SPINE CORRECTION?
YES
512
BEND ROD TO DESIRED CURVATURE OF SPINE
NO

FIG. 16A

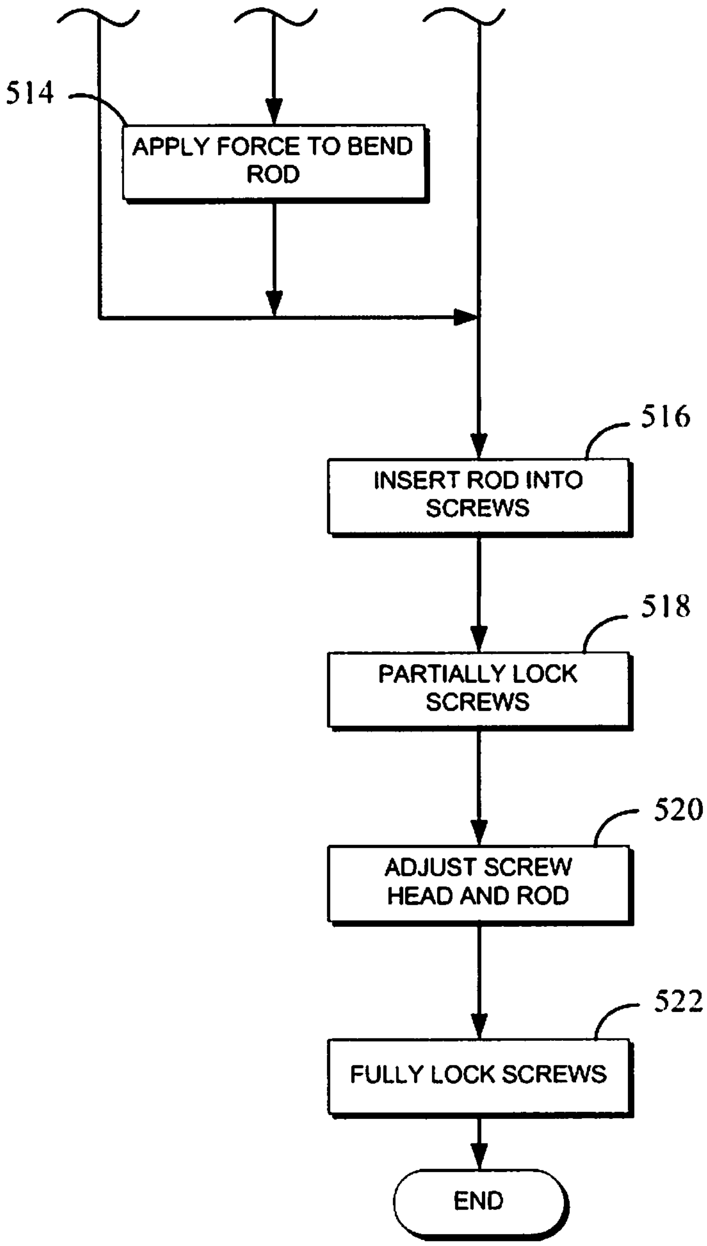
514
APPLY FORCE TO BEND ROD
516
INSERT ROD INTO SCREWS
518
PARTIALLY LOCK SCREWS
520
ADJUST SCREW HEAD AND ROD
522
FULLY LOCK SCREWS
END

FIG. 16B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US201 1/042127

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61 B 17/70 (201 1.01)
USPC - 606/261
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 17/68, 17/70, 17/86, 17/88 (201 1.01)
USPC - 606/258, 261, 264, 279, 305

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 7,488,331 B2 (ABDELGANY) 10 February 2009 (10.02.2009) entire document	29-32 --------- 11-28
Y	US 2010/01 14170 A1 (BARRUS et al) 06 May 2010 (06.05.2010) entire document	1-5, 7-28
Y	US 7,563,274 B2 (JUSTIS et al) 21 July 2009 (21.07.2009) entire document	1-5, 7-28
A	US 2007/0191841 A1 (JUSTIS et al) 16 August 2007 (16.08.2007) entire document	1-32

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 October 201 1	**2 8 OCT 2071**

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Blaine R. Copenheaver **PCT Helpdesk: 571-272-4300** **PCT OSP: 571-272-7774**