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Bailey

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(54) **SPINAL FIXATION SYSTEM**

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(76) Inventor: **Kirk J. Bailey**, Blairstown, NJ (US)

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Correspondence Address:

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303 (US)

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(57) **ABSTRACT**

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A clamp assembly for securing a bone anchor to a generally cylindrical rod. The clamp assembly includes a first portion, a second portion and a compressible ball carried by the second portion, the ball having a through hole for receiving the generally cylindrical rod. The first portion includes first and second flanges, each of the first and second flanges defining an aperture for receiving a portion of the bone anchor. The first and second flanges are movable from a first position in which the first and second flanges are separated by a gap to a second position in which the first and second flanges are drawn toward each other. The first and second flanges include first and second opposing surfaces, respectively, the first and second opposing surfaces being angled relative to one another in the first position.

Related U.S. Application Data

(63) Continuation of application No. 10/341,658, filed on Jan. 14, 2003, now Pat. No. 7,104,992.

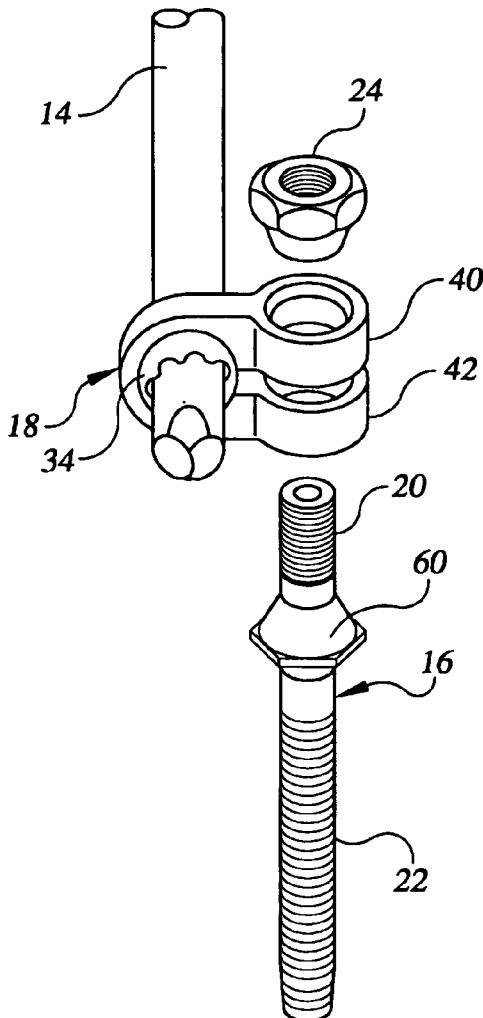


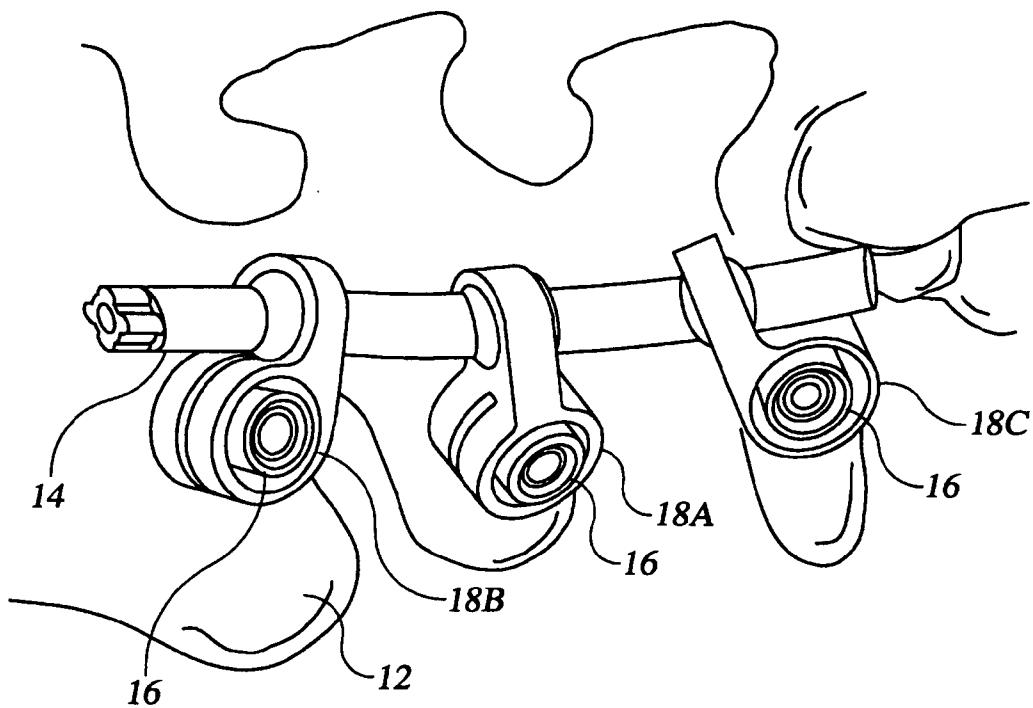
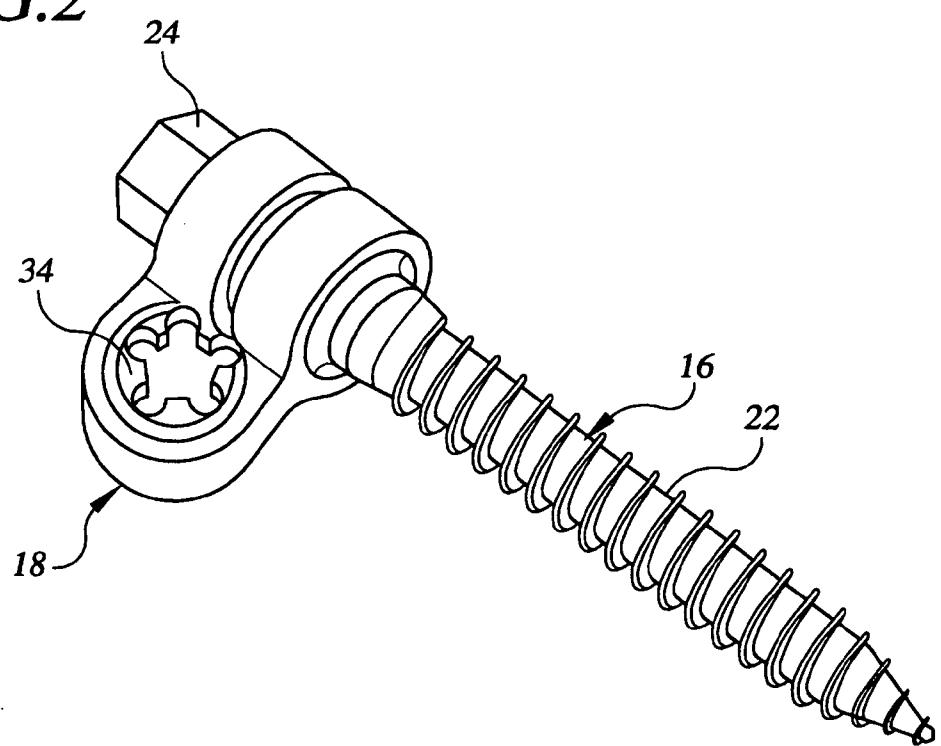
FIG.1**FIG.2**

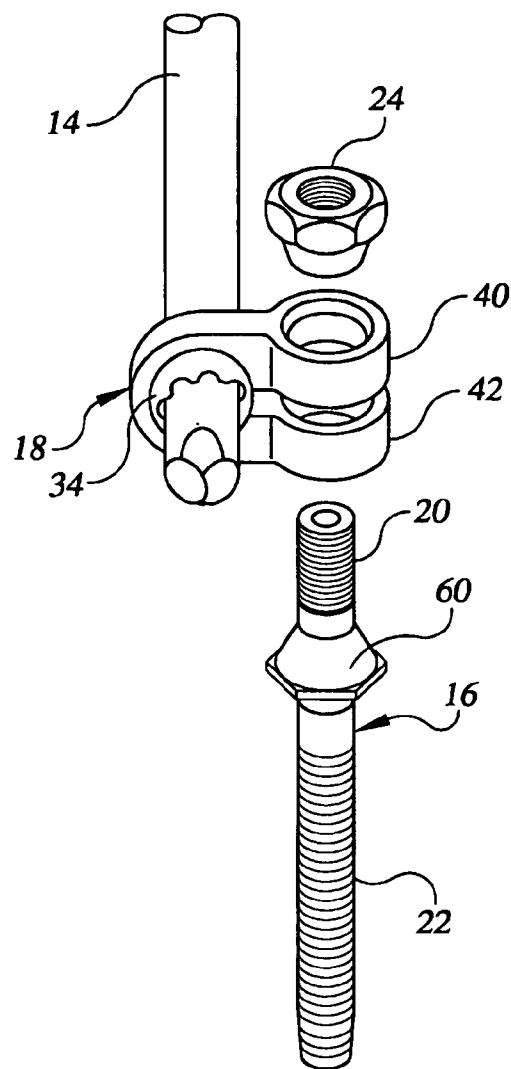
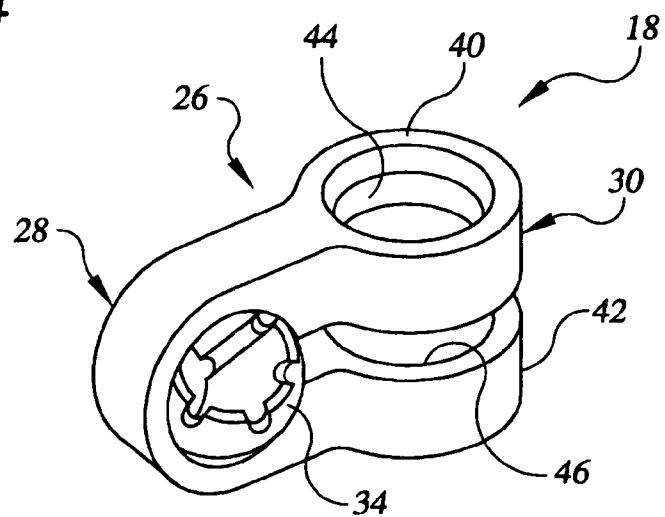
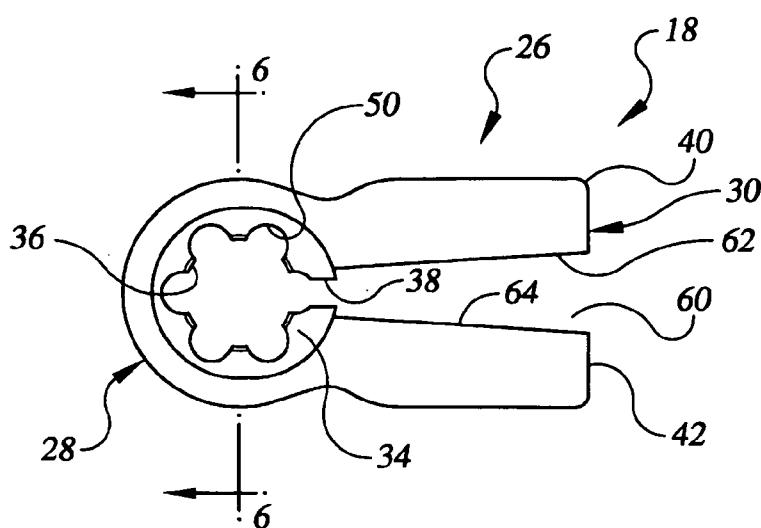
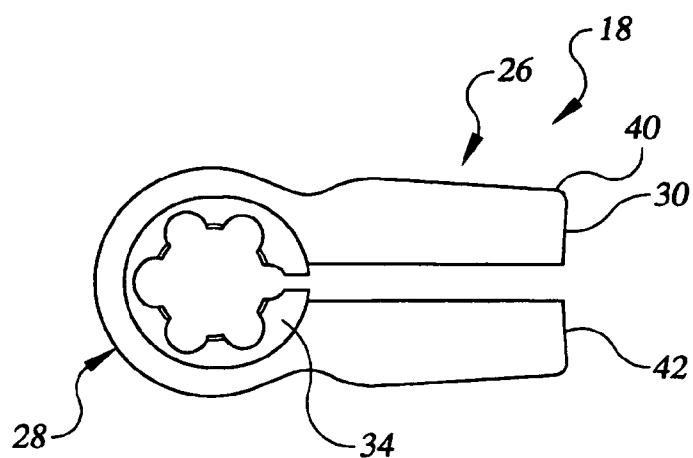
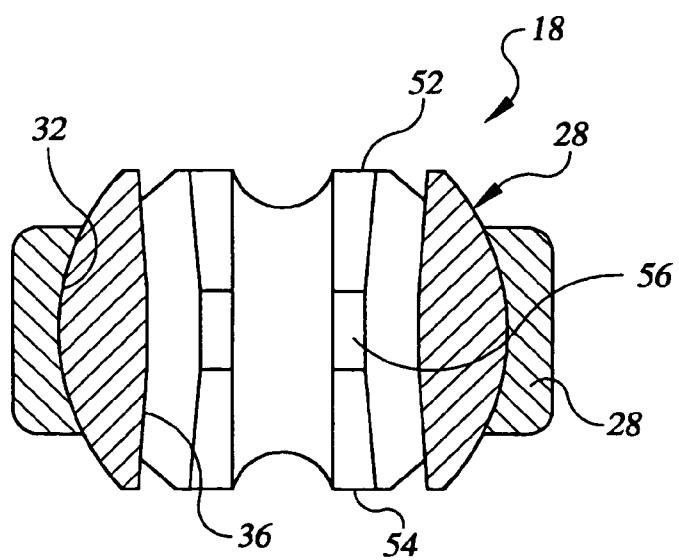
FIG.3**FIG.4**

FIG.5A**FIG.5B****FIG.6**

SPINAL FIXATION SYSTEM

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 10/341,658 filed on Jan. 14, 2003. The disclosure of the above application is incorporated herein by reference.

INTRODUCTION

[0002] The spinal column is a highly complex structure which houses and protects critical elements of the nervous system. In spite of these complexities, the spinal column is a highly flexible structure, capable of a high degree of curvature and twist through a wide range motion. Genetic or developmental irregularities, trauma, chronic stress, tumors, and disease, however, can result in spinal pathologies which either limit this range of motion, or threaten the critical elements of the nervous system housed within the spinal column.

[0003] A variety of systems has been disclosed in the art which achieve immobilization of portions of the spinal column by implanting artificial assemblies in or on the spinal column. These assemblies may be generally classified as anterior, posterior or lateral implants. Posterior implants are attached to the back of the spinal column generally by coupling to the pedicles with screws, or through hooks that attach under the lamina. In either case, the implants generally include elongate support rod elements which are coupled to the screws or hooks to immobilize two or more sequential vertebrae, for example to hold them stable so that adjacent bones may be fused with bone graft.

[0004] During implantation of a spinal fixation system of the type having an elongated support rod and anchors, it is important to provide adjustability between the support rod and the anchors. Adjustability facilitates ideal placement of the bone anchors relative to the spine. Preferably, the adjustability between the support rod and the anchors allows the supports rods to translate relative to the anchors and also allows for pivotal movement of the anchors relative to the support rod. The spinal system must also be able to arrest relative movement between the support rod and the anchors after implantation so that the spinal segments are post-operatively immobilized.

[0005] While known spinal fixation systems have proven to be useful for various applications, they are all associated with drawbacks. In this regard, the fixation screws or hooks of most known systems are difficult or impossible to adequately tighten to arrest relative movement between the anchors and support rod after implantation. Overcoming this limitation typically involves a complex clamping arrangement or an arrangement that requires undue tightening. Use of known systems is often a tedious process, which is inconsistent in result and adds unwanted time to a procedure.

[0006] Accordingly, it remains a need in the art to provide an improved spinal system clamping mechanism for coupling a rod and a bone anchor that overcomes the above discussed and other drawbacks of the prior art.

SUMMARY

[0007] The present teachings provide a clamp assembly for securing a bone anchor to a generally cylindrical rod. In

one aspect, the clamp assembly includes a first portion, a second portion and a compressible ball carried by the second portion, the ball having a through hole for receiving the generally cylindrical rod. The first portion includes first and second flanges, each of the first and second flanges defining an aperture for receiving a portion of the bone anchor. The first and second flanges are movable from a first position in which the first and second flanges are separated by a gap to a second position in which the first and second flanges are drawn toward each other. The first and second flanges include first and second opposing surfaces, respectively, the first and second opposing surfaces being angled relative to one another in the first position.

[0008] Further areas of applicability will become apparent from the description provided herein. It should be understood that the description and specific examples are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The drawings described herein are for illustration purposes only and are not intended to limit the scope of the present disclosure in any way.

[0010] FIG. 1 is a perspective view of a spinal fixation system constructed in accordance with the teachings of a preferred embodiment of the present invention, the spinal fixation system shown arranged in an exemplary construct and operatively attached to a human spinal column;

[0011] FIG. 2 is a perspective view of one of the spinal anchors and an associated clamp assembly of FIG. 1 removed from the construct of FIG. 1 for purposes of illustration;

[0012] FIG. 3 is a partially exploded side view of a portion of the construct of FIG. 1;

[0013] FIG. 4 is a perspective view of the clamp assembly of FIG. 2;

[0014] FIG. 5A is a side view of the clamp assembly of FIG. 4 shown with the first and second flanges normally spaced apart;

[0015] FIG. 5B is a view similar to FIG. 5A illustrating the first and second flanges drawn together; and

[0016] FIG. 6 is a cross-sectional view taken along the line 6-6 of FIG. 5A.

DESCRIPTION

[0017] The following description of the preferred embodiments of the present invention is merely exemplary in nature and is in no way intended to limit the subject invention or its application or uses.

[0018] With general reference to the drawings, a spinal fixation system constructed in accordance with the teachings of the preferred embodiment of the present invention is illustrated and generally identified at reference character 10. As shown in the environmental view of FIG. 1, components of the system 10 have been arranged in an exemplary construct for attachment to a portion of a spinal column 12 of a human patient. The components of the system 10 of the present invention used in the construct of FIG. 10 generally include a linkage in the form of a generally cylindrical

support rod 14, a plurality of spinal anchors 16 for engaging the spinal column 12, and a plurality of clamp assemblies 18 securing the spinal anchors 16 to the cylindrical rod 14.

[0019] The spinal anchors are illustrated throughout the drawings as bone screws 16. Alternatively, it will be understood by those skilled in the art that other types of anchors known in the art may be employed for directly engaging the spine. For example, the anchors may alternatively be hooks that attach under the lamina of the spine.

[0020] With particular reference to **FIGS. 2 and 3**, one of the spinal anchors 16 and an associated one of the clamp assemblies 18 are illustrated in further detail. The spinal anchor 16 includes an upper threaded shaft portion 20 and a lower threaded shaft portion 22. The upper threaded shaft portion 20 threadably engages a nut 24 when the spinal anchor 16 is secured to a linkage or rod 14 in a manner discussed below. The rod is preferably a generally cylindrical rod 14.

[0021] The clamp assemblies 18 each adjustably interconnect one of the spinal anchors 16 that engage the spinal column 12 with the rod 14. In the exemplary construct of **FIG. 1**, the system 10 of the present invention is illustrated to include three clamp assemblies 18A, 18B, 18C. A first of the clamp assemblies 18A is shown in further detail in **FIGS. 2-6** and is illustrated to generally include a body 26 having a first portion 28 for engaging the rod 14 and a second portion 30 for engaging the spinal anchor 16. The body 26 of the clamp assembly 18A is shown to generally have a C-shape with an intermediate portion or arm that defines an opening 32 for receiving the rod 14. In the embodiment illustrated, the opening 32 is partially spherical and is adapted to adjustably receive a compressible locking member or ball 34.

[0022] The compressible locking ball 34 is shown particularly in **FIGS. 5A and 5B** and the cross-sectional views of **FIG. 6**. As shown, the locking ball 34 is generally spherical in shape and includes an aperture or through hole 36 which passes therethrough for receiving the rod 14. As will become more apparent below, the clamp body 26 and the ball 34 cooperate to form a ball and socket joint that allows pivotal movement of the rod 14 relative to the anchor 16. This pivotal movement is about an imaginary center of the ball 34. The locking ball 34 is normally permitted to universally move within the opening 32. A slit 38 is provided in the locking ball 34 to facilitate compression of the ball and resulting clamping on the rod 14.

[0023] The through hole 36 is defined by a generally cylindrical inner surface. The generally cylindrical inner surface preferably includes at least one relieved channel 50. In the embodiment illustrated, the cylindrical inner surface is shown to include five relieved channels 50. The particular number of relieved channels 50 will be understood to be a matter of design choice and may vary from that shown in the drawings. The relieved channels 50 allow for a more uniform collapse of the locking ball 34. In this manner, the locking strength of the clamp assembly 18 is increased independent of the position of the ball 34 within the partially spherical opening defined by the clamp 34.

[0024] As perhaps most particularly shown in the cross-section view of **FIG. 6**, at least a portion of the through hole 36 tapers from a first end 52 of the through hole 36 to a

second end 54 of the through hole 36 toward a center of the locking ball 34. As shown, the through hole 36 preferably tapers from the first end 52 towards the center and also from the second end 54 towards the center. A center portion 56 of the through hole 36 has a constant diameter. This configuration of the through hole 36 allows the locking ball 34 to be loaded and not impinge on a contoured rod.

[0025] In the embodiment illustrated, the through hole 36 passes through the center of the locking ball 34. Alternatively, the through hole 36 may be eccentric to the sphere defined by the locking ball 34. By orienting the through hole 36 eccentric to the sphere, adjustments can be made by rotating the locking ball 34 within the clamp body 26.

[0026] The clamp body 26 further includes a first or upper flange 40 and a second or lower flange 42. In the embodiment illustrated, the upper and lower flanges 40 and 42 are symmetrical about a plane extending therebetween. The upper and lower flanges 40 and 42 are shown to be generally circular in shape. The intermediate portion or arm of the clamp body 26 that extends between the flanges 40 and 42 is disposed radially relative to the upper and lower flanges 40 and 42. The upper and lower flanges 40 and 42 define distinct but aligning apertures 44 and 46 (see **FIG. 4**), respectively. The apertures 44 and 46 are both associated with recesses 48 to receive either a nut 24 or a partially spherical shaped portion 60 of the screw 16, respectively. In this manner, it is impossible to put the clamp assembly 18 on the rod 14 upside down.

[0027] As shown particularly in **FIG. 5A**, the first and second flanges 40 and 42 are normally spaced apart by a gap. The first and second flanges 40 and 42 include first and second opposing surfaces 62 and 64, respectively. As shown in **FIG. 5A**, when the first and second flanges 40 and 42 are normally spaced apart, the opposing surfaces 60 and 64 are angled relative to one another.

[0028] Upon tightening of the nut 24, movement of the clamp body 26 relative to the rod 14 is arrested. Explaining further, tightening of the nut 24 serves to draw the upper and lower flanges 40 and 42 together causing the intermediate portion of the clamp body 26 to compress squeeze the locking ball 34 and correspondingly clamp the rod 14. Relative movement is also arrested between the locking ball 34 and the clamp body 26.

[0029] Importantly, the clamp body 26 is formed to include sufficient spacing between the upper and lower flanges 40 and 42 so that the gap 60 is always maintained throughout the range of tightening. In this manner, clamping forces are more efficiently transferred to the locking ball 34. The clamp body 26 is illustrated in a fully clamped condition in **FIG. 5B**. As shown, the opposing surfaces 62 and 64 are oriented generally parallel to one another.

[0030] With particular reference to **FIG. 1**, the clamp assemblies 18B and 18C will be understood to be identical. The clamp assemblies 18B and 18C differ from the clamp assembly 18A in that the second portion 30 is tangentially oriented relative to the first and second flanges 40 and 42. In other words, the intermediate portion or arm that connects the first and second flanges 40 and 42 is offset to one side from a radial position. This offset allows the rod 14 to be positioned closer to the anchor 16 and reduces the medial lateral profile of the construct. Otherwise, it will be understood that the clamp assemblies 18A-18C are identical.

[0031] The foregoing discussion discloses and describes merely exemplary arrangements of the present invention. One skilled in the art will readily recognize from such discussion, and from the accompanying drawings and claims, that various changes, modifications and variations can be made therein without departing from the spirit and scope of the invention as defined in the following claims.

What is claimed is:

1. A clamp assembly for securing a bone anchor to a generally cylindrical rod, the clamp assembly comprising:

a first portion including first and second spaced apart flanges, the first and second spaced apart flanges both defining apertures for receiving a portion of the bone anchor, wherein the first and second flanges include first and second opposing surfaces, respectively, the first and second opposing surfaces being angled relative to one another before the first and second flanges are drawn toward one another;

a second portion; and

a compressible ball carried by the second portion, the ball having a through hole for receiving the generally cylindrical rod.

2. The clamp assembly of claim 1, wherein the through hole defined by a generally cylindrical inner surface has at least one relieved channel.

3. The clamp assembly of claim 1 in combination with the bone anchor, the bone anchor having an upper threaded portion extendable through the apertures of the first and second flanges and engaging a nut such that tightening of nut draws the first and second flanges toward one another and the second portion compresses the ball.

4. The clamp assembly of claim 3, wherein the first and second opposing surfaces are generally parallel to one another when the nut is tightened.

5. The clamp assembly of claim 4, wherein the second portion circumferentially surrounds the ball substantially completely when the first and second flanges are drawn together.

6. The clamp assembly of claim 1, wherein the generally cylindrical surface includes a plurality of relieved channels.

7. The clamp assembly of claim 6, wherein the plurality of relieved channels extend generally parallel to an elongated axis of the rod.

8. The clamp assembly of claim 1, wherein the compressible ball and the second portion of the clamp assembly define a ball and socket joint such that the rod is permitted to pivot relative to the clamp assembly about a center of the ball.

9. A clamp assembly for securing a bone anchor to a generally cylindrical rod, the clamp assembly comprising:

a first portion including first and second flanges, each of the first and second flanges defining an aperture for receiving a portion of the bone anchor, the first and second flanges movable from a first position in which the first and second flanges are separated by a gap to a second position in which the first and second flanges are drawn toward each other, the first and second flanges including first and second opposing surfaces, respectively, the first and second opposing surfaces being angled relative to one another in the first position;

a second portion; and

a compressible ball carried by the second portion, the ball having a through hole for receiving the generally cylindrical rod.

10. The clamp assembly of claim 9, in which the first and second opposing surfaces are generally parallel to one another in the second position.

11. The clamp assembly of claim 10, wherein the second portion circumferentially surrounds the ball substantially completely when the first and second flanges are in the second position.

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