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(54) **Title:** MULTI-AXIAL, DOUBLE LOCKING BONE SCREW ASSEMBLY

(57) **Abstract:** A Top-Loading Multi-axial, double locking bone anchor apparatus is disclosed. The apparatus includes a receiver member, internal threaded ring member, an internal "saddle" member, a bi-polar member, a bone anchor and a double-locking compression retaining member comprising of two components; one external "nut-like" fastener and, one internal "setscrew-like" fastener; both fasteners comprising one single double- locking compression retaining member. The "nut-like" fastener only interfaces with the internal "saddle" member and the receiver member. The "setscrew-like" fastener only interfaces with the elongated member. When installed, the opposing forces created by both fasteners create a "locking" force within the double-locking compression retaining member thus restricting the involuntary "loosening" of the double-locking compression retainer member. The receiver member defines an upper opening and a lower opening, which may form part of the same opening, a channel, and external threaded portion located at the bottom. The internal "saddle" member, bi-polar member and bone anchor are loaded into the lower opening of the receiver member thru the bottom of the receiver member, and internal threaded ring member fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the internal "saddle" member, bi-polar and the bone anchor member. The bone anchor is capable of multi-axial as well as multi-polar positioning with respect to the receiver member. An elongated member is placed in the channel of the receiver member, contacting the internal "saddle" member, and the double-locking compression retaining member is applied via the upper opening. The external component of the double-locking compression retaining member presses down on the internal "saddle" member and locks the bone anchor member between bi-polar member and the internal "saddle" member: the internal threaded retaining member retains this assembly. The internal component of the double-locking compression retaining member presses down and locks the elongated member between the internal "saddle" member and itself; the two opposing forces create a "locking" that resists the involuntary loosening of the double-locking compression retaining member assembly.

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Description

FIELD OF THE INVENTION

The present invention relates to devices and implants used in osteosynthesis and other orthopedic surgical procedures such as devices for use in spinal surgery, and, in particular, to an posterior pedicle screw, connector/rod assembly which is implantable within a patient for stabilization of the spine. Specifically, the present invention contemplates a top loading bone anchor assembly capable of achieving multiple angular axial orientations with respect to an elongated member extending along bone tissue.

BACKGROUND OF THE INVENTION

Several techniques and systems have been developed for correcting and stabilizing damage or malformation of bones, especially the long bones and the spine. In one type of system, an elongated member such as a bendable rod is disposed longitudinally along a length of the bone(s). In spinal applications, the rod is preferably bent to correspond to the normal curvature of the spine in the particular region being instrumented. For example, the rod can be bent to form a normal kyphotic curvature for the thoracic region of the spine, or a lordotic curvature for the lumbar region. In accordance with such a system, the rod is engaged to various vertebrae along a length of the spinal column by way of a number of fixation elements. A variety of fixation elements can be provided which are configured to engage specific portions of the vertebra and other bones. For instance, one such fixation element is a hook that is configured to engage the laminae of

the vertebra. Another very prevalent fixation element is a screw that can be threaded into various parts of the vertebrae or other bones.

In one typical spinal procedure utilizing a bendable rod, the rod is situated on opposite sides of the spine or spinous processes. A plurality of bone screws are threaded into a portion of several vertebral bodies, very frequently into the pedicles of these vertebrae. The rods are affixed to these plurality of bone screws to apply corrective and stabilizing forces to the spine.

One example of a rod-type spinal fixation system includes elongated rods and a variety of hooks, screws and bolts all configured to create a segmental construct throughout the spine. In one aspect of the system, the spinal rod is connected to the various vertebral fixation elements by way of an eyebolt. In this configuration, the fixation elements are engaged to the spinal rod laterally adjacent to the rod. In another aspect of the system, a variable angle screw is engaged to the spinal rod by way of an eyebolt. The variable angle screw allows pivoting of the bone screw in a single plane parallel to the plane of the spinal rod. Details of this variable angle screw can be found in U.S. Pat. No. 5,261,909 to Sutterlin et al. One goal achieved by the system is that the surgeon can apply vertebral fixation elements, such as a spinal hook or a bone screw, to the spine in appropriate anatomic positions. The system also allows the surgeon to easily engage a bent spinal rod to each of the fixation elements for final tightening.

Another rod-type fixation system provides a variety of fixation elements for engagement

between an elongated rod and the spine. In one aspect of the system, the fixation elements themselves include a body that defines a slot within which the spinal rod is received. The slot includes a threaded bore into which a threaded plug is engaged to clamp the rod within the body of the fixation element. The system includes hooks and bone screws with this "open-back" configuration. Details of this technology can be found in U.S. Pat. No. 5,005,562.

On the other hand, these fixation elements of the system are capable only of pivoting about the spinal rod to achieve variable angular positions relative to the rod. While this limited range of relative angular positioning is acceptable for many spinal pathologies, many other cases require more creative orientation of a bone screw, for instance, relative to a spinal rod. Certain aspects of this problem are addressed by the variable angle screw of the system, as discussed in the '909 Patent. However, there is a need for a bone screw that is capable of angular orientation in multiple planes relative to the spinal rod as well as multiple spherical head orientations. Preferably, the bone screw axis is capable of various three dimensional orientations with respect to the spinal rod. Screws of this type of angular orientation in multiple planes relative to the spinal rod have been referred to as poly-axial or multi-axial bone screws. The use of both angular orientation in multiple planes relative to the spinal rod allows for virtually unlimited axial angulations of the bone engaging screw member within the design parameters as well as an ultra-low profile of the said device utlizating a minimum of components without sacrificing the security of the interfaces of the invention components.

Others have approached the solution to this problem with various poly-axial screw designs. For example, in U.S. Pat. No. 5,466,237 to Byrd et al., a bone screw is described which includes a spherical projection on the top of the bone screw. An externally threaded receiver member supports the bone screw and a spinal rod on top of the spherical projection. An outer nut is tightened onto the receiver member to press the spinal rod against the spherical projection to accommodate various angular orientations of the bone screw relative to the rod. While this particular approach utilizes a minimum of components, the security of the fixation of the bone screw to the rod is lacking. In other words, the engagement or fixation between the small spherical projection on the bone screw and the spinal rod is readily disrupted when the instrumentation is subjected to the high loads of the spine, particularly in the lumbar region.

In another approach shown in U.S. Pat. No. 4,946,458 to Harms et al., a spherical headed bone screw is supported within separate halves of a receiver member. The bottom of the halves are held together by a retaining ring. The top of the receiver halves are compressed about the bone screw by nuts threaded onto a threaded spinal rod. In another approach taken by Harms et al., in U.S. Pat. No., 5,207,678, a receiver member is flexibly connected about a partially spherical head of a bone screw. Conical nuts on opposite sides of the receiver member are threaded onto a threaded rod passing through the receiver. As the conical nuts are threaded toward each other, the receiver member flexibly compresses around the head of the bone screw to clamp the bone screw in its variable angular position. One detriment of the systems in the two Harms et al. patents is that the spinal rod must be threaded in order to accept the compression nuts. It is known

that threading rods can tend to weaken the rods in the face of severe spinal loads. Moreover, the design of the bone screws in the '458 and '678 Patents require a multiplicity of parts and are fairly complicated to achieve complete fixation of the bone screw.

A further approach illustrated in U.S. Pat. No. 5,797,911 to Sherman et al., is to provide a U-shaped holder through the top of which a bone fastener topped with a crown member is loaded. The holder accommodates a rod in a channel above the crown member and a compression member above the rod. The compression member presses on the rod and crown member to lock the fastener against the holder in any of a number of angles in three dimensions with respect to the rod. This approach has proven to be quite effective in addressing the above-identified problems. However, it does not permit bottom-loading of the fastener. Additionally, the holder is somewhat bulky in order to accommodate the other structural components.

Yet a further approach is shown in U.S. Pat. No. 5,733,285 to Errico et al., in which a holder is provided with a tapered and colletted portion at the bottom into which a bone fastener head is inserted. A sleeve is provided that slides down around the colletted portion to crush lock the colletted portion around the head of the bone fastener. This apparatus is believed to be relatively bulky and difficult to manipulate given the external sliding locking mechanism. It is further dependent on the fit of the external sleeve and the relative strength of the collet and its bending and crushing portions for secure locking of the bone fastener head.

There is therefore a need remaining in the industry for a ultra-low profile, multi-axial/double-locking bone anchor that can be readily and securely engaged to an elongated member of any configuration--i.e., smooth, roughened, knurled or even threaded--which achieves greatly improved angulations of the bone anchor, improved strength, and reduced size, including profile and bulk, of the components used to engage the bone anchor to the elongated member in any of a variety of angular orientations.

SUMMARY OF THE INVENTION

In one embodiment of the invention, a Top-Loading Multi-axial, double locking bone anchor apparatus is disclosed. The apparatus includes a receiver member, internal threaded ring member, an internal "saddle" member, a bi-polar member, a bone anchor and a double-locking compression retaining member comprising of two components; one external "nut-like" fastener and, one internal "setscrew-like" fastener; both fasteners comprising one single double-locking compression retaining member. The "nut-like" fastener only interfaces with the internal "saddle" member and the receiver member. The "setscrew-like" fastener only interfaces with the elongated member. When installed, the opposing forces created by both fasteners create a "locking" force within the double-locking compression retaining member thus restricting the involuntary "loosening" of the double-locking compression retainer member. The receiver member defines an upper opening and a lower opening, which may form part of the same opening, a channel, and external threaded portion located at the bottom. The internal "saddle" member, bi-polar member and bone anchor are loaded into the lower opening of the receiver member thru the bottom of the receiver member, and internal threaded ring member fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the internal "saddle" member, bi-polar and the bone anchor member. The bone anchor is capable of multi-axial as well as multi-polar positioning with respect to the receiver member. An elongated member is placed in the channel of the receiver member, contacting the internal "saddle" member, and the double-locking compression retaining member is applied via the upper opening. The external component of the double-locking compression retaining member presses down on the internal "saddle" member and locks

the bone anchor member between bi-polar member and the internal "saddle" member: the internal threaded retaining member retains this assembly. The internal component of the double-locking compression retaining member presses down and locks the elongated member between the internal "saddle" member and itself; the two opposing forces create a "locking" that resists the involuntary loosening of the double-locking compression retaining member assembly.

Additional embodiments, examples, advantages, and objects of the present invention will be apparent to those of ordinary skill in this art from the following specification.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of one embodiment of the multi-axial, double-locking bone screw anchor assembly of the present invention.

FIG. 2 is an exploded view of the embodiment of the invention depicted in FIG. 1.

FIG. 3a is a side elevational view of an embodiment of the receiver member of the embodiment of the invention illustrated in FIG. 2.

FIG. 3b is a front elevational view of the embodiment of the receiver member illustrated in FIG. 3a.

FIG. 3c is a sectional view, taken along the lines 3c--3c in FIG. 3a, and viewed in the direction of the arrows, of the embodiment of the receiver member illustrated in FIG. 3a.

FIG. 3d is a sectional view, taken along the lines 3d--3d of FIG. 3b and viewed in the direction of the arrows, of the embodiment of the receiver member illustrated in FIG. 3a.

FIG. 4a is a side elevational view of an embodiment of a bone anchor used in the embodiment of the invention illustrated in FIG. 2.

FIG. 4b is a sectional view, taken along the lines 4b--4b of FIG. 4a and viewed in the direction of the arrows, of the embodiment of the bone anchor illustrated in FIG. 4a.

FIG. 4c is a magnified view of one embodiment of the head of the embodiment of the bone anchor illustrated in FIG. 4a.

FIG. 5a is a side view of one embodiment of an internal "saddle" member used in the embodiment of the present invention illustrated in FIG. 2.

FIG. 5b is an end view of one embodiment of an internal "saddle" member used in the embodiment of the present invention illustrated in FIG. 2.

FIG. 5c is a sectional view, taken along the lines 5c-5c in FIG. 5a and viewed in the direction of the arrows, of the embodiment of the internal "saddle" member illustrated in FIG. 5a.

FIG. 5d is a sectional view, taken along the lines 5d-5d in FIG. 5b and viewed in the direction of the arrows, of the embodiment of the internal "saddle" member illustrated in FIG. 5a.

FIG. 6a is a top view of one embodiment of an internal threaded ring member that fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the internal "saddle" member and the bone anchor member used in the embodiment of the invention illustrated in FIG. 2.

FIG. 6b is a sectional view, taken along the lines of 6b--6b in FIG. 6a and viewed in the direction of the arrows, of the embodiment of the internal threaded ring member illustrated in FIG. 6a.

FIG. 7a is a top view of the retaining member.

FIG. 7b is a side elevational view of the retaining member.

FIG. 7c is a bottom view of the retaining member.

FIG. 7d is a sectional view, taken along the lines 7d-7d in FIG. 7a and viewed in the direction of the arrows. This view is also an exploded view of the embodiment of the retaining member in FIG. 7a.

FIG. 8a is a top view of one embodiment of a bi-polar member used in the embodiment of the present invention illustrated in FIG. 2.

FIG. 8b is a sectional view, taken along the lines 8b--8b in FIG. 8a and viewed in the direction of the arrows, of the embodiment of the bi-polar member illustrated in FIG. 8a.

FIG. 8c is a sectional view substantially similar to FIG. 8b of another embodiment of a bi-polar member used in the embodiment of the invention illustrated in FIG. 2.

FIG. 9 is an enlarged sectional view of the embodiment of the present invention illustrated in FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein, being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring generally to FIGS. 1 and 2, there is shown one embodiment of a multi-axial/double-locking bone anchor assembly 20 of the present invention. In the illustrated embodiment, assembly 20 includes a receiver member 30, a bone anchor 50, an internal "saddle" member 70, a bi-polar cup member 101, and a internal threaded ring member 90. The assembly 20 of the present invention is designed for use with an elongated member R (FIG. 9) such as a spinal rod, bar or other orthopedic construct, as further described below.

Referring now generally to FIGS. 3a-3d, one embodiment of the receiver member 30 of the present invention is shown. Receiver member 30 defines an upper opening portion 31a and a lower opening portion 31b, which in the illustrated embodiment form a single opening 32 extending through receiver member 30 from an upper aperture 33 in top end 34 to a lower aperture 35 in bottom end 36. Lower opening portion 31b of opening 32, in one specific embodiment, includes a chamber/void 38 defined by a chamber wall 39.

Alternatively, upper and lower opening portions 31a, 31b can have a variety of configurations, such as each having one or more sections of differing diameter.

Opening 32 is partially surrounded by a chamfered or rounded edge 40a at top end 34 of receiver member 30, and is surrounded by chamfered or rounded edge 40b at the bottom end 36 of receiver member 30. Proximate to bottom end 36, receiver member 30 defines threads 41 and associated ledge 41a around axis of 32. In the illustrated embodiment, thread 41 extends around the entire perimeter of lower surface 32, although it will be seen that thread 41 could extend only partially around the perimeter of lower surface 32. Thread 41 has a thread depth A (FIG. 9) and a thread diameter B (FIG. 3a).

Receiver member 30 in the illustrated embodiment includes a pair of upright branches 42, 43 through which opening 32 extends. Branches 42, 43 further define a U-shaped channel 45 transverse to opening 32 that communicates with upper portion 31a and lower portion 31b of opening 32, and that accommodates an elongated member R (FIG. 9). In a specific embodiment, extenal threads 44 are formed in branches 42, 43; internal thread 44 in a specific embodiment is a modified acme buttress thread. Preferably, the top portion 47 of receiver member 30 (which includes branches 42, 43) is narrower than bottom portion 48 of receiver member 30, thereby reducing the bulk and profile of receiver member 30.

Referring now generally to FIGS. 4a-4c, an embodiment of a bone anchor 50 used in the present invention is shown. The illustrated bone anchor 50 is a bone screw. Bone anchor 50 includes an anchorage portion 52 and a head portion 54. Anchorage portion 52

includes at least one thread 56, which may be a cancellous self-tapping thread. Head portion 54 forms part of a sphere in the illustrated embodiment, though alternative curvate and other configurations may be employed. Head 54 in one particular embodiment includes a series of ridges 58 for improving purchase with the lower inside of internal "saddle" member 70 (described below). Head 54 may have alternative friction-increasing surface configuration(s) such as roughening or knurling. Further, head 54 includes a tool-engaging print 60 (not shown), with which a tool (not shown) may be engaged to drive anchorage portion 52 into a bone. Tool-engaging print 60 is an interior print in the illustrated embodiment, although an exterior print could be used, and it may have any of a number of configurations, such as hexagonal, hexalobate, X-shaped, or other known torque-transferring configurations.

Other embodiments of bone anchor 50 are contemplated as being within the scope of the present invention. For example, bone anchor 50 could be a bone-engaging hook rather than a screw. In that embodiment, anchorage portion 52 would be configured with a hook rather than an elongated section with thread 56.

Head 54 of bone anchor 50 is shaped and sized to fit within at least interior portion 78 of internal "saddle" member 70 of (Fig.5a-5d) and chamber 38 of receiver member 30. Specifically, head 54 has a width that is smaller than the width of lower opening portion 70 and chamber 38. As more fully described below, bone anchor 50 is inserted into receiver member 30, with anchorage portion 50 entering thru opening 80 and interfacing with surface 78 of internal "saddle" 70 of (fig. 5a).

Referring now to FIGS. 5a-5d, there is shown one embodiment of internal "saddle" member 70 of the present invention. In that embodiment, internal "saddle" member 70 is in the shape of a cylinder, having an exterior surface 72 with a beveled edge 74 and a interior surface 78. Interior surface 78 is configured to accommodate head 54 of bone anchor 50, and therefore the illustrated embodiment of interior surface 78 has the shape of part of a sphere. Interior surface 78 can be provided with a friction- or purchase-enhancing surface configuration (e.g. roughening or knurling) for cooperation with head 54 of bone anchor 50.

The illustrated embodiment of internal "saddle" member 70 a screw driving tool can access the bone anchor 50, to "drive the bone anchor 50. Internal "saddle" member 70 is sized and shaped to fit within at least lower portion 31b of opening 32 and chamber 38 of receiver member 30. The outer dimension of internal "saddle" member 70 is preferably slightly smaller than the inner dimension of chamber 38 and lower portion 31b of opening 32 so that internal "saddle" member 70 is slidably movable within chamber 38 and opening 32. Further, in the illustrated embodiment the outer dimension of internal "saddle" member 70 is larger than the inner dimension of upper opening portion 31a, so that internal "saddle" member 70 cannot move into upper opening portion 31a.

Referring now to FIGS. 8a-8b, there is shown one embodiment of bi-polar member 101 of the present invention. In that embodiment, bi-polar member 101 is in the shape of a circular disc, having an exterior surface 102 with a beveled edge 104 and a interior surface 108. Interior surface 108 is configured to accommodate head 54 of bone anchor

50, and therefore the illustrated embodiment of interior surface 108 has the shape of part of a sphere. Alternatively or additionally, the exterior surface of bi-polar member 101 can have one or more other spherical type shapes, such as beveled or conical lower surface 108 (FIG. 8c). Interior surface 108 can be provided with a friction- or purchase-enhancing surface configuration (e.g. roughening or knurling) for cooperation with head 54 of bone anchor 50.

The illustrated embodiment of bi-polar member 101 also includes a hole 110. Hole 110 is provided so that bone engaging threads 50, of bone anchor 50 may be accessed through bi-polar member 101. Bi-polar member 101 is sized and shaped to fit within at least lower portion 31b of opening 32 and chamber 38 of receiver member 30. The outer dimension of bi-polar member 101 is preferably slightly smaller than the inner dimension of chamber 38 and lower portion 31b of opening 32 so that bi-polar member 101 is slidably and rotatably movable within chamber 38 and opening 32. Further, in the illustrated embodiment the outer dimension of bi-polar member 101 is larger than the inner dimension of upper opening portion 31a, so that bi-polar member 101 cannot move into upper opening portion 31a.

Referring now to FIGS. 6a-6b, there is shown one embodiment of internal threaded ring member 90 of the present invention. In the illustrated embodiment, internal threaded ring member 90 has the form of a ring-shaped geometry. Internal threaded ring member 90 includes a top surface 92 and a bottom surface 94. In the illustrated embodiment, internal threaded ring member 90 also includes internal surfaces 96, 98, 100 that substantially

surround aperture 102. In one specific embodiment, internal surface 96 forms a portion of a sphere of radius substantially identical to the radius of head 54 of bone anchor 50, internal surface 98 is cylindrical and internal surface 100 is conical and angled outward to allow a greater range of angular positioning of bone anchor 50. In alternative embodiments, there may be single or multiple internal surfaces surrounding aperture 102, which surface(s) may be cylindrical, conical, spherical or of other appropriate configuration. The diameter of aperture 102 is smaller than the diameter of head 54 of bone anchor 50 and the diameter of internal "saddle" member 70.

Generally referring to FIGS. 1, 2 and 9, assembly 20 is assembled as follows: bone anchor 50, bi-polar cup member 101, internal "saddle" member 70 and internal threaded ring member 90 are inserted into receiver member 30 through bottom end 36, either individually or substantially in one step as shown in (Fig. 2).

Internal "saddle" member 70 remains slideably positioned in the interior surface of the bi-polar cup member 101, this assembly is positioned within the lower portion 31b of opening 32 and/or chamber 38 of receiving member 30, and bi-polar cup member 101 and bone anchor 50 remains multi-axially moveable with respect to internal "saddle" member 70 and receiving member 30. Internal threaded ring member 90 is threaded upward into lower portion 31b of opening 32.

When internal threaded ring 90 is installed, bone anchor 50, bi-polar cup member 101 and internal "saddle" member 70 are retained within opening 32 of receiver member 30.

Head 54 of bone anchor 50 is supported between internal "saddle" member 70 and the bi-polar cup member 101, and is supported by internal surface 96 of internal threaded ring member 90. Thus bone anchor 50, bi-polar cup member and internal "saddle" member 70 will not pass through internal threaded ring 90 and out of receiver member 30 when internal threaded ring 90 is installed.

Preferably, assembly 20 is assembled (as described above) prior to use in a surgical procedure. In using the illustrated embodiment of assembly 20, bone anchor 50 of assembly 20 is threaded into an appropriately prepared hole in a bone (not shown). It will be understood that in alternative embodiments of the invention, for example where bone anchor 50 is a bone hook, drilling a hole in bone and threading the anchor therein may not be necessary. Threaded anchoring portion 52 is inserted into the hole, and an appropriate screwing tool is used with tool-engaging print 60 of bone anchor 50, and bone anchor 50 is threaded into the bone. When bone anchor 50 has been threaded into the bone to the desired depth, receiver member 30 is positioned so that opening 32 forms a desired angle with bone anchor 50, as depicted in FIG. 1. In the illustrated embodiment, the angle theta. between bone anchor 50 and opening 32 can be any value up to 57 degrees in any direction (112 degrees total angulation) . It will be seen that the maximum angle of bone anchor 50 relative to opening 32 can be changed, for example by angling bone anchor 50 to its maximum in association to the axis of the internal "saddle" 70 component.

As described above, receiver member 30 may be angled as the surgeon desires with

respect to bone anchor 50. An elongated member R such as a spinal rod, connector, or other orthopedic surgical implant is coupled with assembly 20. Elongated member R is placed in channel 45 of receiver member 30 which surrounds channel 75 of internal "saddle" 70, and contacts interior surface of 75 of internal "saddle" member 70. A compression member 120 assembly, is threaded into/onto threads 44 of receiver member 30 and down onto both the elongated member R as well as the top edge of the internal "saddle" 70. Compression member 120, in one embodiment, is a set screw or plug 121a having external threads and a print 124 for applying torque, and a nut-like cap 121b having internal threads and a print 124 for applying torque. Each different components of compression member separately being tightened; these apposing forces prevent involuntary loosening. In a further embodiment, alternatively, where receiver member 30 is externally threaded, compression member 120 could be an internally-threaded nut.

As component 121b of compression member 120 is tightened, internal "saddle" member 70 is forced downward against bone anchor 50. Head 54 is thereby clamped between the bi-polar cup member 101 and the internal threaded ring member 90 and internal "saddle" member 70. As component 121a of compression member 120 is tightened, elongated member R is forced downward against internal "saddle" member 70, which locks the elongated member independently from the bone anchor 50. These two apposing forces lock the assembly from involuntary loosening. In the embodiment of the invention in which head 54 includes ridges 58, ridges 58 are pressed into internal surface 78 of internal "saddle" member 70. In this way, bone anchor 50 is locked into the desired angular position with respect to elongated member R and the remainder of assembly 20.

Alternatively, assembly 20 can be assembled during the surgical procedure.

Preferred materials for the present invention include stainless steel and titanium. It will be recognized that any sturdy biocompatible material may be used to accomplish the osteosynthesis and other orthopedic surgical goals of the present invention.

While the present invention has been shown and described in terms of preferred embodiments thereof, it will be understood that this invention is not limited to any particular embodiment and that changes and modifications may be made without departing from the true spirit and scope of the invention as defined and desired to be protected.

Claims

What is claimed is:

1. A bone anchor assembly for engagement to an elongated member, comprising a receiver member defining an upper opening portion and a lower opening portion each having respective minimum widths, a channel configured to receive the elongated member (rod) and communicating with said upper opening portion and said lower opening portion, and a threads around a portion of said lower opening portion and a internal "saddle" member having a lower internal portion configured to engage the top of a bone anchor head and a upper internal portion configured to engage the elongated member, and a bi-polar cup having internal geometry configured to engage the bottom of the bone anchor head and a external geometry portion configured to engage the internal geometry of the receiver member, the said internal width of said internal "saddle" member and the bi-polar cup member being larger than the said width of the head of the bone-anchor member and the said external width of said internal "saddle" member and bi-polar member being larger than said minimum width of said lower opening portion of said internal threaded ring member and the said head of the bone-anchor member being movably disposed in said internal opening portion and the saddle member, bi-polar member and the bone anchor are loaded into the lower opening of the receiver member thru the bottom of the receiver member, and internal threaded ring member fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the saddle member, bi-polar member and the bone anchor member and an internal threaded ring member that fits around the bone anchor and over the outer lower threaded

portion in the receiver member to retain the internal "saddle" member, bi-polar member and the bone anchor member and a double-locking compression retaining member defining an internal aperture smaller than said width of said head, and a external aperture larger that said width of said head. The said double-locking compression retaining member at least partially housed in and over said top portion of said receiver member and positioned over said elongated member and tightened during utilization and forces transmitted during tightening are imparted on both the bone anchor member/bi-polar member, internal "saddle" member, the internal threaded ring member and the elongated member to anchor all said components in any angular and/or axial configuration within design parameters.

2. The assembly of the present invention, wherein said upper opening portion and said lower opening portion form at least part of a single opening through said receiver member.

3. The assembly of the present invention, wherein said receiver member includes two branches which define said upper opening portion and said channel.

4. The assembly of the present invention, wherein said branches include external threads.

5. The assembly of the present invention, further includes a double-locking compression retaining member assembly threadedly connected to said external threads.

6. The assembly of the present invention, wherein said receiver member defines a chamber/void that forms at least a part of said lower opening portion, and said internal "saddle" member being movably disposed within said chamber/void.

7. The assembly of the present invention, wherein said anchor is a bone screw with a head to be located and retained within the internal surfaces of the internal "saddle" member and internal surfaces of the bi-polar member and retained by the internally threaded ring member.

8. The assembly of the present invention, wherein said head of said bone screw is at least partially spherical.

9. The assembly of the present invention, wherein said head of said bone screw includes ridges or spherical grooves.

10. The assembly of the present invention,, wherein said lower internal surface of said internal "saddle" member is at least partially spherical and includes ridges or spherical grooves.

11. The assembly of the present invention, wherein said external surface of said internal "saddle" member is at least partially cylindrical.

12. The assembly of the present invention, wherein said upper internal surface of said internal "saddle" member is at least partially cylindrical positioned at a right angle to the axis of the double-locking compression retaining member.

13. The assembly of the present invention, wherein said internal surfaces of said internal "saddle" member includes a roughened portion.

14. The assembly of the present invention, wherein said internal "saddle" member has a width greater than said upper opening portion of said receiver member.

15. The assembly of the present invention, wherein said head of said bone anchor includes a tool-engaging print.

16. The assembly of the present invention, wherein said internal "saddle" member, bi-polar member and bone anchor member are restrained within the receiving member via said internal threaded ring member that fits around the bone anchor and over the outer lower threaded portion in the receiver member.

17. The assembly of the present invention, wherein said double-locking compression retaining member employs both a internal "nut-like" component with internal threads and a cylinder-shaped "setscrew-like" internal member with external threads.

18. The assembly of the present invention, wherein said "nut-like" external double-

locking compression retaining member component has an unloaded inner threaded diameter, said receiver member has a threaded external diameter grooved at 180 degrees apart, and said unloaded inner threaded diameter of said retaining member is greater than said threaded diameter of said receiver member per the requirements for mating thread forms.

19. The assembly of the present invention, wherein said "setscrew-like" internal double-locking compression retaining member component has an outer threaded diameter, and the "nut-like" external double-locking compression retaining member component has a threaded internal diameter about its surface per the requirements for mating thread forms.

20. The assembly of the present invention, wherein said internal "saddle" member has a body width, said internal geometry of said receiving member an internal void width and said internal "saddle" member, bi-polar member and bone anchor member are restrained within said internal void width.

21. The assembly of the present invention, wherein said internal threaded ring member includes an inner concave surface for engaging said external surface of said bi-polar member.

22. The assembly of the present invention, wherein said inner concave surface forms part of a sphere.

23. The assembly of the present invention, wherein said lower internal surface of said internal "saddle" member is concaved

24. The assembly of the present invention, wherein said upper surface of the internal "saddle" is concaved and is at a right angle to the cylindrical axis if the internal "saddle" member.

25. The assembly of the present invention, wherein said external surface of said internal "saddle" member is cylindrical.

26. The assembly of the present invention, wherein said internal "saddle" member has a width greater than said upper opening portion of said receiver member.

27. The assembly of the present invention, wherein said internal "saddle" member defines a hole through and along its axis to allow a "driving tool" to be inserted to "drive" said bone anchor.

28. The assembly of the present invention, wherein said double-locking compression retaining member employs both a internal "nut-like" component with internal threads and a cylinder-shaped "setscrew-like" internal member with external threads.

29. The assembly of the present invention, wherein said "nut-like" external double-locking compression retaining member component has an unloaded inner threaded

diameter, said receiver member has a threaded external diameter grooved at 180 degrees apart, and said unloaded inner threaded diameter of said retaining member is greater than said threaded diameter of said receiver member per the requirements for mating thread forms. Equally, wherein said "setscrew-like" internal double-locking compression retaining member component has an outer threaded diameter, and the "nut-like" external double-locking compression retaining member component has a threaded internal diameter about its surface per the requirements for mating thread forms.

30. The assembly of the present invention, wherein said double-locking compression retaining member has a body width, said groove has a groove depth, and said body width and said elongated member width is not greater than said groove depth.

31. The assembly of the present invention, wherein said retaining member includes an external and internal tool surface for assembly and tightening and a flat lower surfaces for engaging said internal "saddle" member and the elongated member.

32. The assembly of the present invention, wherein said internal tool surfaces does not interfere with the flat geometry.

33. The assembly of the present invention illustrates a bone fixation apparatus comprising of an elongated member configured for placement adjacent and along a length of at least one bone and a bone anchor assembly for engagement to the elongated member, comprising a receiver member defining an upper opening portion and a lower opening

portion each having respective minimum widths, a channel configured to receive the elongated member (rod) and communicating with said upper opening portion and said lower opening portion, and a threads around a portion of said lower opening portion and a internal "saddle" member having a lower internal portion configured to engage the top of a bone anchor head and a upper internal portion configured to engage the elongated member, and a bi-polar cup having internal geometry configured to engage the bottom of the bone anchor head and a external geometry portion configured to engage the internal geometry of the receiver member, the said internal width of said internal "saddle" member and the bi-polar cup member being larger than the said width of the head of the bone-anchor member and the said external width of said internal "saddle" member and bi-polar member being larger than said minimum width of said lower opening portion of said internal threaded ring member and the said head of the bone-anchor member being movably disposed in said internal opening portion and the saddle member, bi-polar member and the bone anchor are loaded into the lower opening of the receiver member thru the bottom of the receiver member, and internal threaded ring member fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the saddle member, bi-polar member and the bone anchor member and an internal threaded ring member that fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the internal "saddle" member, bi-polar member and the bone anchor member and a double-locking compression retaining member defining an internal aperture smaller than said width of said head, and a external aperture larger that said width of said head. The said double-locking compression retaining member at least partially housed in and over said top portion of said receiver member and

positioned over said elongated member and tightened during utilization and forces transmitted during tightening are imparted on both the bone anchor member/bi-polar member, internal "saddle" member, the internal threaded ring member and the elongated member to anchor all said components in any angular and/or axial configuration within design parameters.

34. The assembly of the present invention, wherein said elongated member is a spinal rod.

35. The assembly of the present invention, wherein said double-locking compression retaining member employs both a internal "nut-like" component with internal threads and a cylinder-shaped "setscrew-like" internal member with external threads.

36. The assembly of the present invention, wherein said "nut-like" external double-locking compression retaining member component has an unloaded inner threaded diameter, said receiver member has a threaded external diameter grooved at 180 degrees apart, and said unloaded inner threaded diameter of said retaining member is greater than said threaded diameter of said receiver member per the requirements for mating thread forms.

37. The assembly of the present invention, wherein said "setscrew-like" internal double-locking compression retaining member component has an outer threaded diameter, and

the "nut-like" external double-locking compression retaining member component has a threaded internal diameter about its surface per the requirements for mating thread forms.

38. The assembly of the present invention, wherein said double-locking compression retaining member has a body width, said groove has a groove depth, and said body width and said elongated member width is not greater than said groove depth.

39. The assembly of the present invention, wherein said retaining member includes an external and internal tool surface for assembly and tightening and a flat lower surfaces for engaging said internal "saddle" member and the elongated member.

40. The assembly of the present invention, wherein said internal tool surfaces does not interfere with the flat geometry.

41. The assembly of the present invention, wherein said internal "saddle" member defines a hole through and along its axis to allow a "driving tool" to be inserted to "drive" said bone anchor.

42. The assembly of the present invention, wherein said head of said bone anchor is at least partially spherical.

43. The assembly of the present invention, wherein said lower internal surface of said internal "saddle" member is concaved. Likewise, the upper surface of the internal

"saddle" is concaved and is at a right angle to the cylindrical axis if the internal "saddle" member.

44. The assembly of the present invention illustrates an apparatus for receiving and holding components of a multi-axial bone anchor system, comprising a member defining an upper opening portion and a lower opening portion, a channel transverse to and communicating with said upper opening portion and said lower opening portion, and a threads around at least a portion of said lower opening portion.

45. The assembly of the present invention, wherein said upper opening portion and said lower opening portion form at least part of an opening through said member from a top end to a bottom end.

46. The assembly of the present invention, wherein said threads is proximate said bottom end of said member.

47. The assembly of the present invention, wherein at least a portion of said upper opening portion is externally threaded.

48. The assembly of the present invention, wherein said member includes two branches that define said upper opening portion and at least a portion of said channel.

49. The assembly of the present invention, wherein said internal surface of said bi-polar member is at least partially spherical and includes ridges or spherical grooves. Wherein said external surface of said bi-polar member is at least partially spherical.

50. The assembly of the present invention, wherein said internal and external surfaces of said bi-polar member includes a roughened portion.

51. The assembly of the present invention, wherein said bi-polar member has a width greater than said upper opening portion of said receiver member.

52. The assembly of the present invention, wherein said internal threaded ring member includes an inner concave surface for engaging said external surface of said bi-polar member.

53. The assembly of the present invention, wherein said inner concave surface forms part of a sphere.

54. The assembly of the present invention, wherein said internal surface of said bi-polar member is concaved.

55. The assembly of the present invention, wherein said external surface of said bi-polar member is concave.

56. The assembly of the present invention, wherein said bi-polar member has a width greater than said upper opening portion of said receiver member.

57. The assembly of the present invention, wherein said bi-polar member defines a hole through said lower surface through which said bone engaging threads of said bone anchor can be placed.

58. The assembly of the present invention, wherein said bi-polar member and bone anchor member are restrained within the receiving member via said internal threaded ring member that fits around the bone anchor and over the outer lower threaded portion in the receiver member.

59. The assembly of the present invention illustrates a bi-polar member having a internal portion configured to engage a bone anchor head and an external portion configured to engage the internal geometry of the receiver member, said internal width of said bi-polar member being larger than said width of the head of the bone-anchor member and said external width of said bi-polar member larger than said minimum width of said lower opening portion of said internal threaded ring member , said head of the bone-anchor member being movably disposed in said lower opening portion adjacent to said internal surface of said bi-polar member.

60. The assembly of the present invention illustrates a bone-engaging anchor having a lower portion configured to engage a bone and a head having a width, said width of said

head being smaller than said minimum width of said lower opening portion, said head being movably disposed in said lower opening portion adjacent to said lower surface of said bi-polar member and an internal threaded ring member that fits around the bone anchor and over the outer lower threaded portion in the receiver member to retain the Bi-Polar member and the bone anchor member.

61. The assembly of the present invention illustrates the bone anchor member and bi-polar member is restrained in the lower opening of the receiving member, the bi-polar and the bone anchor member is capable of multi-axial positioning as well as multi-polar positioning with respect to the receiver member.

62. The assembly of the present invention, wherein refers to the system requirements to include ancillary components as listed in claim 1, thus utilizing the technology for required ancillary components of this system.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/26559

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61B 17/56**(2006.01)

USPC: 606/61
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)
U.S. : 606/61

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,896,677 B1 (LIN) 24 May 2005 (24.05.2005), see whole document.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* 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 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
02 October 2006 (02.10.2006)

Date of mailing of the international search report
27 NOV 2006

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/26559

Continuation of Box II Reason 2:
Claims 2-62 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 2-62 are indefinite for the following reason(s): Claims 2-62 are omnibus claims.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US06/26559

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 2-62
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
Please See Continuation Sheet

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of any additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.