Abstract: A bone fixation device according to an exemplary aspect of the present disclosure includes a nail extending along a longitudinal axis. The nail is provided with a transverse bore arranged along a transverse axis that intersects the longitudinal axis. The bone fixation device further includes a screw assembly received in the transverse bore, and a locking device. The locking device is configured to clasp the screw assembly to lock the screw assembly against movement along the transverse axis and against rotation about the transverse axis.
before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))
BONE FIXATION DEVICE FOR TREATMENT OF FEMORAL FRACTURES

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/279,161, filed January 15, 2016, the entirety of which is herein incorporated by reference.

BACKGROUND

[0002] This disclosure is related to a bone fixation device for treatment of a fracture, such as a femoral fracture.

[0003] Femoral nails are used to treat fractures of the femur by using one or more transverse screws to lock and stabilize a fractured portion of the femur, such as the femoral head or trochanter. The fracture may be caused by a traumatic injury or as the result of other medical conditions such as bone defects or tumors. Typically, a nail (sometimes called a "rod") is inserted into the medullary cavity of the femur. Once inserted, a screw is directed through a transverse bore and engages the femoral head. The screw is then locked relative to the nail, which in turn supports the femoral head relative to the remainder of the femur to promote healing of the bone.

SUMMARY

[0004] This disclosure relates to a bone fixation device including a nail and a transverse screw assembly. The transverse screw assembly is configured to maintain a position of a fractured bone fragment relative to the remainder of a bone. In one example, the fixation device is used to promote healing of a femoral fracture by stabilizing a femoral head.

[0005] A bone fixation device according to an exemplary aspect of the present disclosure includes a nail extending along a longitudinal axis. The nail is provided with a transverse bore arranged along a transverse axis that intersects the longitudinal axis. The bone
fixation device further includes a screw assembly received in the transverse bore, and a locking device. The locking device is configured to clasp the screw assembly to lock the screw assembly against movement along the transverse axis and against rotation about the transverse axis.

[0006] In a further non-limiting embodiment of the foregoing bone fixation device, the screw assembly includes a sleeve provided with a first pattern. Further, a distal end of the locking device is provided with a second pattern configured to mate with the first pattern to lock the sleeve against movement along the transverse axis and against rotation about the transverse axis.

[0007] In a further non-limiting embodiment of any of the foregoing bone fixation devices, the first and second patterns are provided by one of (1) a wave-like knurled surface, (2) a diamond knurled surface, (3) a plurality of splines, (4) a recessed flat, and (5) a recessed ellipse-shape.

[0008] In a further non-limiting embodiment of any of the foregoing bone fixation devices, a lateral edge of the transverse bore is chamfered about its entire circumference.

[0009] In a further non-limiting embodiment of any of the foregoing bone fixation devices, a lateral edge of the transverse bore is rounded with tangential transitions about its entire circumference.

[0010] In a further non-limiting embodiment of any of the foregoing bone fixation devices, the screw assembly includes a sleeve and a screw, the screw is received in a bore of the sleeve, and the sleeve is configured to limit axial movement and restrict rotation of the screw about the transverse axis.

[0011] In a further non-limiting embodiment of any of the foregoing bone fixation devices, the screw includes an exterior surface with a channel, and a pin projects into the channel to restrict relative rotation of the screw about the transverse axis.
In a further non-limiting embodiment of any of the foregoing bone fixation devices, the sleeve includes a face configured to abut an outward projection of the screw.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, the sleeve includes a face configured to abut a latch of the screw.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, the screw assembly includes a screw having a distal end with threads and a rounded nose.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, the distal end includes reverse threads.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, the locking device is received in a bore in a proximal end of the nail, and the locking device is moveable along the longitudinal axis of the nail without rotating.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, a set screw is received in the bore in the proximal end of the nail. Further, rotation of the set screw results in movement of the locking device along the longitudinal axis of the nail.

In a further non-limiting embodiment of any of the foregoing bone fixation devices, the bone fixation device is a proximal femoral nail.

A bone fixation device according to another exemplary aspect of the present disclosure includes, among other things, a nail extending along a longitudinal axis. The nail is provided with a transverse bore arranged along a transverse axis that intersects the longitudinal axis. The bone fixation device further includes a screw assembly received in the transverse bore. The screw assembly includes a sleeve provided with a first pattern. Additionally, the bone fixation device includes a locking device configured to clasp the screw assembly to lock the screw assembly against movement along the transverse axis and against rotation about the transverse axis. A distal end of the locking device is provided with a second pattern configured
to mate with the first pattern to lock the sleeve against movement along the transverse axis and against rotation about the transverse axis.

[0020] In a further non-limiting embodiment of the foregoing bone fixation device, the sleeve is configured to limit axial movement and restrict rotation of the screw about the transverse axis.

[0021] In a further non-limiting embodiment of any of the foregoing bone fixation devices, the screw includes an exterior surface with a channel, and a pin projects into the channel.

[0022] A method of fixing fractured bone fragments relative to one another to promote healing according to an exemplary aspect of the present disclosure includes, among other things, inserting a nail into a medullary cavity of a bone. The nail extends along a longitudinal axis and a transverse bore arranged along a transverse axis that intersects the longitudinal axis. The method further includes engaging a fractured fragment of the bone with a screw received through the transverse bore, and positioning a sleeve provided outside the screw within the transverse bore. The sleeve is configured to limit movement of the screw along the transverse axis, and to prevent rotation of the screw about the transverse axis. Further still, the method includes clasping an exterior surface of the sleeve with a locking device. The locking device is configured to prevent movement of the sleeve along the transverse axis, and to prevent rotation of the sleeve about the transverse axis.

[0023] In a further non-limiting embodiment of the foregoing method, a pin projecting into a channel formed in an exterior surface of the screw. The pin limits the axial movement of the screw relative to the transverse axis and prevents rotation of the screw about the transverse axis.
In a further non-limiting embodiment of any of the foregoing methods, the step of positioning the sleeve includes positioning a femoral head to promote healing of the fractured fragment.

The embodiments, examples and alternatives of the preceding paragraphs, the claims, or the following description and drawings, including any of their various aspects or respective individual features, may be taken independently or in any combination. Features described in connection with one embodiment are applicable to all embodiments, unless such features are incompatible.

**BRIEF DESCRIPTION OF THE DRAWINGS**

The drawings can be briefly described as follows:

- Figure 1 illustrates an example bone fixation device relative to a fractured bone.
- Figure 1A illustrates an example cannulated awl with a first example rasper.
- Figure 1B illustrates a second example rasper.
- Figure 1C illustrates a third example rasper.
- Figure 1D illustrates a fourth example rasper.
- Figure 1E illustrates a reamer relative to a fractured bone.
- Figure 1F illustrates an aiming jig, nail, and another reamer relative to a fractured bone.
- Figure 1G is a partial view of an example aiming jig.
- Figure 1H is a cross-sectional view illustrating a first aiming jig orientation.
- Figure 1I is a cross-sectional view illustrating a second aiming jig orientation.
Figure 2 is a cross-sectional view of a first example screw assembly.

Figure 3 is a cross-sectional view of a second example screw assembly.

Figure 4 is a cross-sectional view of a third example screw assembly.

Figure 5 is a cross-sectional view of a fourth example screw assembly.

Figure 6 is a perspective view illustrating an example engagement between a screw and a sleeve.

Figure 6A is an illustration representative of a first example orientation of the interior of the sleeve.

Figure 6B is an illustration representative of a second example orientation of the interior of the sleeve.

Figure 6C is an illustration representative of a third example orientation of the interior of the sleeve.

Figure 7 is a cross-sectional view of the bone fixation device. In Figure 7, the screw assembly is received in a transverse bore of a nail, and is connected to the nail by way of a locking device.

Figure 8 is a close-up view of an exterior surface of the sleeve having an example wave-like knurled pattern.

Figure 9 is a close-up view of a distal surface of the locking device having a pattern corresponding to the pattern of Figure 8.

Figure 10 is a close-up view of an exterior surface of the sleeve having an example diamond knurled pattern.

Figure 11 is a close-up view of a distal surface of the locking device having a pattern corresponding to the pattern of Figure 10.

Figure 12 is a close-up view of an exterior surface of the sleeve having yet another example pattern including splines and a smooth surface.
[0052] Figure 13 is a close-up view of a distal surface of the locking device having a pattern corresponding to the pattern of Figure 12.

[0053] Figure 14 is a close-up view of an exterior surface of the sleeve having an example pattern including a recessed flat.

[0054] Figure 15 is a close-up view of an exterior surface of the sleeve having an example pattern including a recessed elliptical-shape.

[0055] Figure 16 illustrates a rounded lateral edge of the transverse bore.

[0056] Figure 17 is a view taken along line 17-17 and illustrates the rounded lateral edge in detail.

[0057] Figure 18 illustrates a chamfered lateral edge of the transverse bore.

[0058] Figure 19 is a view taken along line 19-19 and illustrates the chamfered lateral edge in detail.

[0059] Figure 20 illustrates a tip of the screw with standard threads.

[0060] Figure 21 illustrates a tip of the screw with reverse threads.
DETAILED DESCRIPTION

[0061] This disclosure relates to a bone fixation device including a nail and a transverse screw assembly. The transverse screw assembly is configured to maintain a position of a fractured bone fragment relative to the remainder of a bone. In one example, the fixation device is used to promote healing of a femoral fracture by stabilizing a femoral head.

[0062] Figure 1 illustrates an example bone fixation device 20. In this example, the bone fixation device 20 is an intramedullary nail. More specifically, the bone fixation device 20 is a proximal femoral nail. The bone fixation device 20 includes a nail 22 received within the medullary cavity 24 of a femur 26. The illustrated femur 26 is a left femur. The nail 22 extends along a longitudinal axis 28 from a proximal end 30 to a distal end 32. The "proximal" and "distal" directions are labeled in the figures. The nail 22 may be inserted into the medullary cavity 24 using known techniques, including making use of tools such as a cannulated reamer, guiding wire, and an aiming jig, among others.

[0063] The fixation device 20 further includes a screw assembly 34 received within a transverse bore (discussed below) in the nail 22. The screw assembly 34 extends along a transverse axis 36. The transverse axis 36 extends generally in the "lateral" and "medial" directions, and intersects the longitudinal axis 28. In this disclosure, "transverse" means the transverse axis 36 intersects the longitudinal axis 28.

[0064] In this example, the screw assembly 34 engages a fractured bone fragment 38, which in this example includes a femoral head, and supports the fractured bone fragment 38 relative to the remainder of the femur 26 to promote healing. While a femoral neck fracture is illustrated, this disclosure applies to other types of fractures including intertrochanteric fractures, subtrochanteric fractures, etc. Further, the fixation device 20 could be used with other bones, and is not limited to use with a femur.
Figure 1A illustrates an example cannulated awl 33. The awl 33 includes a pointed distal end 35 and a handle 37 at a proximal end 39. A shaft 41 extends between the distal and proximal ends 35, 39. The awl 33 is fully cannulated so as to allow a guide wire to be inserted in the medullary cavity 24. The shaft 41 is curved along its length, in this example, to assist in maneuvering the awl 33 into the medullary cavity 24.

The awl 33 further includes a rasper 43 adjacent the distal end 35, which also assists in maneuvering the awl 33 within the medullary cavity 24. The rasper 43 is spaced-apart from the distal end 35 and includes a plurality of rows of staggered teeth 45. Further, the rasper 43 is tapered, and the outer dimension of the rasper 43 increases proximally.

In addition to the staggered teeth 45, the rasper 43 could include a plurality of longitudinal channels 47 (Figure 1B) along its length to allow transportation of bone and/or bone marrow away from the distal end 35. Alternatively, in place of staggered teeth, the rasper 43 in some examples includes ribs 49 (Figure 1C). When the rasper 43 includes ribs 49, the rasper 43 may also include channels 47 (Figure 1D).

After a guide wire is fed into the medullary cavity 24 by way of the awl 33, a reamer 51 (Figure 1E) follows the guide wire and is used to ream a passageway for the nail 22. Next, the nail 22 is connected to an aiming jig 53 (Figure 1F), which is used to insert the nail 22 into the medullary cavity 24. In this example, the aiming jig 53 includes an adjustable nail-jig interface 55 (Figure 1G).

With reference to Figure 1G, the nail-jig interface 55 is provided by a screw 57 having a curved guide 59 configured to slide within a slot 61. The slot 61 includes a lateral end 63 and a medial end 65 (Figure 1H), and is sized to accommodate several sizes and shapes of the nail 22. In Figure 1H, for example, the nail 22 is sized such that, when the screw 57 engages the nail 22, the curved guide 59 abuts the lateral end 63 of the slot 61. Figure 1I shows a different nail size, and in that example the curved guide 59 settles between the lateral and
medial ends 63, 65. Finally, Figure 1J shows yet another nail size, which causes the curved
guide 59 to abut the medial end 65.

[0070] Again, the jig 53 is used to insert the nail 22 into the medullar cavity 24. Once inserted, the jig 53 is also used to align another reamer 67 along the transverse axis 36 (Figure 1F). Once reamed, the aiming jig 53 is used to guide the screw assembly 34 along the transverse axis 36 and into the position of Figure 1.

[0071] Figure 2 is a cross-sectional view of one example screw assembly 34. In this example, the screw assembly 34 includes a sleeve 40 and a screw 42 received within a bore 44 of the sleeve 40. In an alternate example, the screw assembly 34 could be provided by a single piece. The one-piece example may be particularly beneficial when performing surgery on children or persons with relatively small anatomical features.

[0072] The screw 42 is cannulated and includes a shank 46 and a tip 48. The shank 46 is sized to be received within the bore 44, and the tip 48 includes threads 50. At a medial end, the tip 48 includes a rounded nose 52. At a lateral end, the shank 46 includes a drive socket 54 configured to mate with a driver, which rotates the screw 42 and facilitates engagement of the threads 50 with the fractured bone fragment 38.

[0073] When the screw 42 is initially inserted into the fractured bone fragment 38, the screw 42 is allowed to rotate relative to transverse axis 36. Once the screw 42 has been appropriately positioned in the fractured bone fragment 38, the screw 42 is prevented from rotating about the transverse axis 36.

[0074] In the illustrated example, the exterior surface 56 of the sleeve 40 receives a pin 58 in a threaded opening 60. The pin 58 welded into the threaded opening in this example and is configured to project inwardly, toward the transverse axis 36. The exterior surface 62 of the shank 46 includes a channel 64 configured to receive the pin 58. In the illustrated example, the pin 58 has a rounded tip abutting the channel 64. It should be understood that the pin 58
could be cylindrical and have a flat end face. In that example, the channel 64 may be replaced by, or include, a flat surface to correspond to the contour of the end of the pin 58. Further, it should be understood that there may be multiple channels 64 provided circumferentially about the shank 46.

[0075] The channel 64 has a width substantially equal to a width of the pin 58 such that, when the pin 58 is received in the channel 64, the pin 58 prevents relative rotation between the screw 42 and the sleeve 40. The channel 64 has a length substantially greater than the diameter of the pin 58, which allows the screw 42 to move along the transverse axis 36 relative to the sleeve 40 until the pin 58 abuts an end of the channel 64.

[0076] While a pin 58 and a channel 64 are illustrated in Figure 2, this disclosure is not limited to such an arrangement. For instance, in the example of Figure 3, the exterior surface 62 of the shank 46 includes a radially outward projection 66 configured to abut a face 68 of the sleeve 40 projecting radially inwardly from a medial end of the sleeve 40. The projection 66 and face 68, however, could be provided adjacent a lateral end of the screw 42, as shown in Figure 4. In another example, shown in Figure 5, the sleeve 40 is arranged similarly to the Figure 3 embodiment, but the screw 42 includes deflectable latches 74 configured to abut the face 68.

[0077] The embodiments of Figures 3-5 prevent axial movement of the screw 42 medially beyond a certain point, which in this example corresponds to the point where the projections 66 or latches 74 abut the face 68. In order to restrict relative rotation about the transverse axis 36, these embodiments can be arranged as shown in Figure 6. In Figure 6, the exterior surface 62 of the shank 46 includes a planar face 76 corresponding to a planar face 78 (Figure 6A) of the interior of the sleeve 40. The planar faces 76, 78 extend in a direction substantially parallel to the transverse axis 36. This disclosure is not limited to the arrangements
of Figures 3-6, and extends to other arrangements that restrict rotation and limit axial movement.

[0078] While Figures 6 and 6A show one orientation that restricts rotation between the sleeve 40 and screw 42, Figures 6B and 6C illustrate other orientations. In Figure 6B, the inner surface of the sleeve 40 resembles, in cross-section, a generally triangular shape with rounded corners 79. The exterior surface 62 of the shank 46 would be arranged similarly to correspond to the orientation of the sleeve 40. In Figure 6C, the inner surface of the sleeve 40 resembles, in cross-section, a generally square shape with chamfered corners 81. While three orientations are illustrated, this disclosure extends to other orientations that restrict rotation while allowing axial movement.

[0079] Once the screw 42 has been appropriately placed into the fractured bone fragment 38, the entire screw assembly 34 is then positioned and locked relative to the nail 22. With reference to Figure 7, the nail 22 includes a longitudinal bore 80 extending along the longitudinal axis 28 from a proximal end 30 of the nail 22 to a transverse bore 82, which receives the screw assembly 34.

[0080] In this example, a locking device 84 is received in the longitudinal bore 80. The locking device 84 includes a proximal end 86 and a distal end 88. The proximal end 86 is connected to a set screw 90, and the distal end 88 is configured to engage the exterior surface 56 of the sleeve 40. The distal end 88 is curved and generally corresponds to the curvature of the exterior surface 56.

[0081] The locking device 84 is moveable along the longitudinal axis 28 without rotating. In this example, the locking device 84 includes a channel 92 (perhaps best seen in Figure 9) provided in its exterior surface 94. The longitudinal bore 80 includes a channel 96 corresponding to the channel 92. An insert 98 is provided in the two channels 94, 96. The insert 98 is sized such that, when inserted in the two channels 94, 96, the locking device 84 does not
rotate relative to the nail 22. The insert 98, however, does not prevent movement of the locking device 84 along the longitudinal axis 28.

[0082] A distal end 100 of the set screw 90 is provided with a tab 102, which is received in a corresponding recess 104 in the proximal end 86 of the locking device 84. The set screw 90 is threadably engaged at its exterior 106 with the longitudinal bore 80, and includes a drive socket 108 at is proximal end 110 configured to mate with a driver. Rotation of the set screw 90 results in movement of the locking device 84 along the longitudinal axis 28. The set screw 90 can be adjusted to an appropriate level, such that the locking device 84 imparts a sufficient level of force to the screw assembly 34.

[0083] The locking device 84 is configured to clasp the screw assembly 34, specifically the exterior surface 56 of the sleeve 40, and to lock the screw assembly 34 against movement along the transverse axis 36 and against rotation about the transverse axis 36. The locking device 84 of this disclosure thus eliminates the need for separate locking devices dedicated to preventing axial movement and rotation.

[0084] With reference to Figures 8-9, the exterior surface 56 of the sleeve 40 is provided with a first pattern 112, and the distal end 88 of the locking device 84 is provided with a second pattern 114 configured to mate with the first pattern 112. In the example of Figures 8-9, the second pattern 114 includes a plurality of first faces 116 arranged substantially normal to the transverse axis 36 and a plurality of second faces 118 arranged substantially parallel to the transverse axis 36.

[0085] The first pattern 112 of the sleeve 40 in this example is provided by a knurled surface. In particular, this example includes a wave-like knurled surface. The wave-like knurled surface includes a plurality of depressions 120 formed between curved faces 122. When viewed from above, the curved faces 122 provide the depressions with a substantially elliptical shape. In particular, the shape is substantially a prolate spheroid, which is similar to
the cross-sectional shape of an American football. Further, a plurality of smooth sections 124 are provided circumferentially between adjacent depressions 120. Near the midpoint of the projections, pointed peaks 126 are provided between adjacent curved faces 122.

[0086] The first faces 116 of the locking device 84 are configured to engage the faces 122 adjacent the pointed peaks 126, and the second faces 118 are configured to engage the faces 122 adjacent the smooth sections 124. In doing so, the contact between the first and second faces 116, 118 and the depressions 120 prevents axial movement of the sleeve 40 relative to the nail 22 along the transverse axis 36 and also prevents rotation of the sleeve 40 about the transverse axis 36.

[0087] While a wave-like knurled surface is illustrated in Figure 8, the first and second patterns 112, 114 could be different patterns that restrict axial and rotational movement. In Figures 10-11, the first pattern 112 of the sleeve 40 is provided by a diamond knurled surface. In this example, a plurality of pyramid-shaped projections 128 are provided, and are arranged such that the first pattern provides a plurality of longitudinal and circumferential grooves 130, 132, respectively. The second pattern 114 of the locking device 84 includes a plurality of longitudinal projections 134 configured to engage the longitudinal grooves 130 and a plurality of circumferential projections 136 configured to engage the circumferential grooves 132. When engaged, the first and second patterns 112, 114 restrict both axial and rotational movement of the sleeve 40 relative to the nail 22.

[0088] Figures 12 and 13 show another embodiment. In this embodiment, the first pattern 112 includes a plurality of ellipse-shaped splines 137. The ellipse-shaped splines 137 are shaped similar to the depressions 120 of Figure 8, but are oriented parallel to the transverse axis 36. The ellipse-shaped splines 137 are formed as a single ring extending circumferentially about the transverse axis 36. The sleeve 40 includes a smooth surface 138 lateral of the ellipse-shaped splines 137, and further includes a radially outward projection 140 lateral to the smooth
surface 138. The splines 137 are configured to engage corresponding projections 142 provided in the second pattern 114, and a smooth surface 144 of the second pattern 114 is configured to abut the smooth surface 138 and be provided between the splines 137 and the radially outward projection 140 to restrict axial movement of the sleeve 40 relative to the nail 22.

[0089] In other embodiments, the first pattern 112 could be provided by a recessed flat 146 (Figure 14) or a recessed ellipse-shape 148 (Figure 15). These patterns would mate with a locking device 84 provided with a corresponding second pattern 114 to restrict axial and rotational movement of the sleeve 40 relative to the nail 22. While several patterns 112, 114 have been discussed herein, this disclosure is not limited to any particular patterns. This disclosure extends to all patterns capable of restricting both axial and rotational movement.

[0090] Another aspect of this disclosure relates to reducing stress concentrations between the sleeve 40 and the nail 22 adjacent the transverse bore 82. In one example, illustrated in Figures 16-17, a lateral edge 150 of the transverse bore 82 is rounded with tangential transitions about its entire circumference. In other words, the lateral edge 150 is provided by a rounded surface 152 about its entire circumference without including any chamfered or flat sections. Further, the rounded surface 152 is smooth and uninterrupted about the transverse axis 36.

[0091] In another example, illustrated in Figures 18-19, the lateral edge 150 is chamfered about its entire circumference. The lateral edge 150 in this example is provided by a planar, chamfered surface 154. The angle of the chamfered surface 154 may change about the circumference of the lateral edge 150, but the chamfered surface 154 is not interrupted by any flat or rounded sections.

[0092] With reference to Figure 20, the rounded nose 52 of the screw 42 is rounded between a location 156 where the threads 50 end and the medial-most end 158 of the screw 42. In this example, the contour of the rounded nose 52 is provided by a constant radius 160 having
an origin 162 spaced laterally from the medial-most end 158. The rounding of the nose 52 of the screw 42 increases the ease of transporting bone debris.

Further, in the example of Figure 20, the threads 50 are standard threads. Specifically, the threads 50 have leading flanks 164 that are inclined in a lateral direction. The trailing flanks 166 project in a direction substantially normal to the transverse axis 36. In the example of Figure 21, however, the screw includes reverse threads. In that case, the threads 50 have trailing flanks 166 that are inclined in a medial direction, and leading flanks 164 that project in a direction substantially normal to the transverse axis 36. While both types of threads can be used, reverse threads may have a benefit of an increased resistance to acetabular penetration.

It should be understood that terms such as "proximal," "distal," "medial," and "lateral" are used consistent with their art-accepted meanings, and are used for purposes of explanation only. Terms such as "longitudinal," "axial," "radial," and "circumferential" are used above with reference to the respective axis and are also used only for purposes of explanation, and should not be considered otherwise limiting. Terms such as "generally," "subsequently," and "about" are not intended to be boundaryless terms, and should be interpreted consistent with the way one skilled in the art would interpret those terms.

Although the different examples have the specific components shown in the illustrations, embodiments of this disclosure are not limited to those particular combinations. It is possible to use some of the components or features from one of the examples in combination with features or components from another one of the examples.

One of ordinary skill in this art would understand that the above-described embodiments are exemplary and non-limiting. That is, modifications of this disclosure would come within the scope of the claims. Accordingly, the following claims should be studied to determine their true scope and content.
CLAIMS

1. A bone fixation device, comprising:
   a nail extending along a longitudinal axis, the nail provided with a transverse bore arranged along a transverse axis that intersects the longitudinal axis;
   a screw assembly received in the transverse bore; and
   a locking device configured to clasp the screw assembly to lock the screw assembly against movement along the transverse axis and against rotation about the transverse axis.

2. The bone fixation device as recited in claim 1, wherein:
   the screw assembly includes a sleeve provided with a first pattern, and
   a distal end of the locking device is provided with a second pattern configured to mate with the first pattern to lock the sleeve against movement along the transverse axis and against rotation about the transverse axis.

3. The bone fixation device as recited in claim 2, wherein the first and second patterns are provided by one of (1) a wave-like knurled surface, (2) a diamond knurled surface, (3) a plurality of splines, (4) a recessed flat, and (5) a recessed ellipse-shape.

4. The bone fixation device as recited in claim 1, wherein a lateral edge of the transverse bore is chamfered about its entire circumference.

5. The bone fixation device as recited in claim 1, wherein a lateral edge of the transverse bore is rounded with tangential transitions about its entire circumference.

6. The bone fixation device as recited in claim 1, wherein:
the screw assembly includes a sleeve and a screw,
the screw is received in a bore of the sleeve, and
the sleeve is configured to limit axial movement and restrict rotation of the screw about the transverse axis.

7. The bone fixation device as recited in claim 6, wherein the screw includes an exterior surface with a channel, and wherein a pin projects into the channel to restrict relative rotation of the screw about the transverse axis.

8. The bone fixation device as recited in claim 6, wherein the sleeve includes a face configured to abut an outward projection of the screw.

9. The bone fixation device as recited in claim 6, wherein the sleeve includes a face configured to abut a latch of the screw.

10. The bone fixation device as recited in claim 1, wherein the screw assembly includes a screw having a distal end with threads and a rounded nose.

11. The bone fixation device as recited in claim 10, wherein the distal end includes reverse threads.

12. The bone fixation device as recited in claim 1, wherein the locking device is received in a bore in a proximal end of the nail, the locking device being moveable along the longitudinal axis of the nail without rotating.
13. The bone fixation device as recited in claim 12, wherein a set screw is received in the bore in the proximal end of the nail, and wherein rotation of the set screw results in movement of the locking device along the longitudinal axis of the nail.

14. The bone fixation device as recited in claim 1, wherein the bone fixation device is a proximal femoral nail.
15. A bone fixation device, comprising:

a nail extending along a longitudinal axis, the nail provided with a transverse bore arranged along a transverse axis that intersects the longitudinal axis;

a screw assembly received in the transverse bore, the screw assembly including a sleeve provided with a first pattern; and

a locking device configured to clasp the screw assembly to lock the screw assembly against movement along the transverse axis and against rotation about the transverse axis, wherein a distal end of the locking device is provided with a second pattern configured to mate with the first pattern to lock the sleeve against movement along the transverse axis and against rotation about the transverse axis.

16. The bone fixation device as recited in claim 15, wherein the sleeve is configured to limit axial movement and restrict rotation of the screw about the transverse axis.

17. The bone fixation device as recited in claim 16, wherein the screw includes an exterior surface with a channel, and a pin projects into the channel.
18. A method of fixing fractured bone fragments relative to one another to promote healing, comprising:

inserting a nail into a medullary cavity of a bone, the nail extending along a longitudinal axis and a transverse bore arranged along a transverse axis that intersects the longitudinal axis;

engaging a fractured fragment of the bone with a screw received through the transverse bore;

positioning a sleeve provided outside the screw within the transverse bore, the sleeve configured to limit movement of the screw along the transverse axis, and to prevent rotation of the screw about the transverse axis; and

clasping an exterior surface of the sleeve with a locking device, the locking device configured to prevent movement of the sleeve along the transverse axis, and to prevent rotation of the sleeve about the transverse axis.

19. The method as recited in claim 18, further comprising:

a pin projecting into a channel formed in an exterior surface of the screw, the pin limiting the axial movement of the screw relative to the transverse axis and preventing rotation of the screw about the transverse axis.

20. The method as recited in claim 18, wherein the step of positioning the sleeve includes positioning a femoral head to promote healing of the fractured fragment.
**INTERNATIONAL SEARCH REPORT**

**International application No**

PCT/US2016/068355

---

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B17/74

ADD.

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)

A61B

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

---

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 2009/326534 AI (YAMAZAKI KEN [JP] ET AL) 31 December 2009 (2009-12-31) figures 1-3</td>
<td>1, 14</td>
</tr>
<tr>
<td>X</td>
<td>Wo 2013/090859 AI (ANTHEM ORTHOPAEDICS VAN LLC [US] ; MATITAYAHU AMI R M [US] ; CLAWS0N BENJA) 20 June 2013 (2013-06-20) figure 3</td>
<td>1</td>
</tr>
<tr>
<td>X</td>
<td>Wo 2012/107056 AI (STRYKER TRAUMA GMBH [DE] ; MUECKTER HELMUT [DE] ; STOLTENBERG INGO [DE]) 16 August 2012 (2012-08-16) figure 4</td>
<td>1</td>
</tr>
</tbody>
</table>

---

[X] Further documents are listed in the continuation of Box C.  
[X] 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 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
- "A" document member of the same patent family

---

Date of the actual completion of the international search: 8 March 2017

Date of mailing of the international search report: 12/05/2017

Name and mailing address of the ISA:

European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

Authorized officer: Fernandez Ari illo, J
<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>wo 02/098330 A2 (HOFMANN S R L [IT] ; HOFMANN ROBERTO MARIA [IT] ) 12 December 2002 (2002-12-12) figure 2</td>
<td>1-3, 15-17</td>
</tr>
</tbody>
</table>
INTERNATIONAL SEARCH REPORT

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. [X] Claims Nos.: 18-20
   because they relate to subject matter not required to be searched by this Authority, namely:
   Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 18-20 has not been searched, since it is directed to a method for treatment of the human body by surgery (they all contain the step of "inserting a nail into a medullary cavity of a bone" as defined in claim 18).

2. □ Claims Nos.: 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:

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:

see additional sheet

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 an additional fees, this Authority did not invite payment of 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. [X] 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.:

   1-3, 14-17

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.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-3, 14-17

   The bone fixation device of claim 1, wherein the screw assembly includes a sleeve provided with a first pattern, and a distal end of the locking device is provided with a second mating pattern (claims 2, 15), for solving the problem of more effectively locking the screw assembly within the nail.

---

2. claims: 4, 5

   The bone fixation device of claim 1, wherein a lateral edge of the transverse bore is chamfered or rounded, for solving the problem of reducing stress concentrations between the screw assembly and the nail adjacent the transverse bore.

---

3. claims: 6-9

   The bone fixation device of claim 1, further including a sleeve and a screw, the sleeve limiting axial movement and restricting rotation of the screw, thereby solving the problem of better reducing a fracture of the femoral head.

---

4. claims: 10, 11

   The bone fixation device of claim 1, wherein the screw assembly includes a screw having a distal end with threads and a rounded nose, thereby solving the problem of increasing the ease of transporting bone debris.

---

5. claims: 12, 13

   The bone fixation device of claim 1, wherein the locking device is received in a bore in a proximal end of the nail, the locking device being moveable along the longitudinal axis of the nail without rotating, for solving the problem of more easily achieving the locking of the screw assembly in the nail.

---
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td>US 2009326534 Al</td>
<td>31-12-2009</td>
<td>US 2009326534 Al</td>
<td>31-12-2009</td>
</tr>
<tr>
<td>WO 2010002588 Al</td>
<td>07-01-2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2463856 Al</td>
<td>24-04-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1443865 A2</td>
<td>11-08-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 4405261 B2</td>
<td>27-01-2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2005537035 A</td>
<td>08-12-2005</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2002156473 Al</td>
<td>24-10-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 03032852 A2</td>
<td>24-04-2003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2015507487 A</td>
<td>12-03-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2014012259 Al</td>
<td>09-01-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2013090859 Al</td>
<td>20-06-2013</td>
</tr>
<tr>
<td>WO 2012107056 Al</td>
<td>16-08-2012</td>
<td>AU 2011358373 Al</td>
<td>22-08-2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AU 2012216160 Al</td>
<td>22-08-2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2824802 Al</td>
<td>16-08-2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2825444 Al</td>
<td>16-08-2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 103402447 A</td>
<td>20-11-2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 103415264 A</td>
<td>27-11-2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2672909 Al</td>
<td>18-12-2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ES 2551874 T3</td>
<td>24-11-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ES 2592962 T3</td>
<td>02-12-2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 5932842 B2</td>
<td>08-06-2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2014512853 A</td>
<td>29-05-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2014512857 A</td>
<td>29-05-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2016172013 A</td>
<td>29-09-2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2014058392 Al</td>
<td>27-02-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2014088595 Al</td>
<td>27-03-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2012107056 Al</td>
<td>16-08-2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2012107226 Al</td>
<td>16-08-2012</td>
</tr>
<tr>
<td>WO 2010053628 Al</td>
<td>14-05-2010</td>
<td>BR PI0920111 A2</td>
<td>22-12-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CA 2742215 Al</td>
<td>14-05-2010</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CN 102209500 A</td>
<td>05-10-2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 2355729 Al</td>
<td>17-08-2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 5681111 B2</td>
<td>04-03-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2012507355 A</td>
<td>29-03-2012</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2015027469 A</td>
<td>12-02-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>JP 2016190164 A</td>
<td>10-11-2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>KR 20110095247 A</td>
<td>24-08-2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2011196370 Al</td>
<td>11-08-2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>US 2015272634 Al</td>
<td>01-10-2015</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 2010053628 Al</td>
<td>14-05-2010</td>
</tr>
<tr>
<td>WO 02098330 A2</td>
<td>12-12-2002</td>
<td>AU 2002314058 Al</td>
<td>16-12-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>EP 1401344 A2</td>
<td>31-03-2004</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IT MI20011175 Al</td>
<td>04-12-2002</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WO 02098330 A2</td>
<td>12-12-2002</td>
</tr>
</tbody>
</table>