EUROPEAN PATENT SPECIFICATION

GUIDE ASSEMBLY FOR INTRAMEDULLARY FIXATION
FÜHRUNGSANORDNUNG ZUR INTRAMEDULLÄREN FIXIERUNG
ENSEMBLE DE GUIDAGE POUR FIXATION INTRAMÉDULLAIRE

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Proprietor: Wright Medical Technology, Inc.
Arlington
Tennessee 38002-9501 (US)

Inventors:
• LARSEN, Scott
Devon
PA 19333-1492 (US)

• TAN, Virak
New Providence
NJ 07974-2729 (US)

• WARBURTON, Mark, J.
High Point
NC 27262-3606 (US)

Representative: Hirsch & Associés
58, avenue Marceau
75008 Paris (FR)

References cited:

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Description

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention is related to the use of orthopedic fixation devices and devices for installing the same, and in particular, to intramedullary fixation devices and guides for facilitating installation and fixation of the same within the distal radius.

Description of Related Art

[0002] Long bone fractures are fairly common in the elderly population, often due to the onset of osteoporosis. Long bone fractures may be reduced by the use of assorted conventional bone plates. For example, a bone plate may be attached to the outside surface of two adjacent fragments of a long bone and then secured by inserting bone screws through openings in the bone plate. Problems may arise with such bone plates, however, in that the soft tissues covering the bone plates may become irritated by passage or movement over the bone plates.

[0003] An alternative to bone plates are intramedullary nails or rods that extend through a medullary canal defined within the fractured long bone. The nails or rods are typically fastened to the fractured portions of the long bones with bone screws. The nails or rods are placed into the medullary canal by insertion through a hole which is drilled into one end of the long bone. For instance, to reduce a fractured femur with an intramedullary rod or nail, a hole is drilled through the articular cartilage between the condyles to provide access for the rod. Because the intramedullary nails or rods are contained within the medullary canal, they avoid the problems with soft tissue associated with plates. However, insertion of these rods through holes in the ends of the long bones requires damaging the articular cartilage on the ends of the long bones.

[0004] U.S. Patent No. 6,527,775 to Warburton ("the 775 patent"), describes an intramedullary fixation device used to reduce a distal fracture of the radius. As shown in Figure 3A of the '775 patent, the intramedullary fixation device 25 includes an elongated axially extending rod 26 with a distal portion 27 and a proximal portion 28. The fixation device also includes a distal fixation member 30 and proximal fixation members 35. The distal fixation member extends through the distal portion of the rod and into a distal fracture fragment 18. The proximal fixation members extend through the proximal portion of the rod and the portion of the radius proximal the fracture line.

[0005] Furthermore, the '775 patent discloses an insertion guide device 150 for guiding fixation members 35a, 35b into proximal fixation apertures 25a1, 25a2. The insertion guide device includes visual indicia 153, 155 that function as drill guides that align with the fixation apertures 25a1, 25a2. The insertion guide 150 attaches to a distal end portion 27 of the rod 26 and includes an axially extending arm residing external of the body. In addition, the insertion guide 150 is attached to the rod 26 prior to inserting the rod within the medullary canal.

[0006] Although the '775 patent discloses an insertion guide device for facilitating placement of the rod within the medullary canal, it would be advantageous to provide a guide assembly that facilitates easier placement of a fixation member within a radius. It would also be advantageous to provide a guide assembly that is capable of being easily assembled and disassembled and that provides a surgeon with more effective techniques for implanting a fixation member within a radius of a variety of patients.

[0007] Moreover GB-A-2 290 478 discloses a surgical intramedullary nail for stabilizing fractures of the condyles or supracondylar region of the femur or humerus. GB-A-2 290 478 also describes a jig for facilitating the insertion of such a surgical nail. The jig comprises an extension piece attached to the distal end of the nail, a distal guide and a proximal locking guide arm. The distal locking guide is rigidly attached to the extension piece by a securing bolt.

BRIEF SUMMARY OF THE INVENTION

[0008] Embodiments of the present invention may address the above needs and achieve other advantages by providing a guide assembly for installing a fixation member within the medullary canal of the radius. The guide assembly generally provides an interchangeable guide assembly that allows the physician to more easily manipulate the fixation member, as well as adapt to patients of various sizes. The guide assembly may also comprise lighter and radiolucent material, which may also improve the installation process.

[0009] More specifically the invention refers to a guide assembly according to claim 1.

[0010] The guide fastener may also include an opening configured to receive a drill guide therethrough. The guide member may include a threaded opening for receiving a fastener to secure the proximal guide member to the guide member.

[0011] Additional aspects of the guide assembly include providing a handle that may attach to the guide member. The distal guide member may include a protrusion, and the proximal guide member may include a channel for receiving the protrusion therein. The proximal guide member and distal guide member may be configured for threaded engagement. In addition, the distal guide member may include an alignment pin configured to engage an opening defined in the proximal guide member. The guide assembly may further include a plurality of tissue protectors, wherein each of the plurality of fastener guide openings of the proximal guide member and distal guide member may be configured to receive a respective tissue protector therethrough. The proximal and
distal guide members are spaced outwardly from the radius such that the tissue protectors are configured to extend through the proximal guide member and distal guide member and adjacent to the radius. Moreover, the guide assembly may include a plurality of drill guides, wherein each of the plurality of tissue protectors is configured to receive a respective one of the drill guides therein.

[0012] An additional embodiment of the present invention provides an intramedullary fixation member kit for repairing a radius fracture. The kit includes an intramedullary fixation device configured to be positioned within an intramedullary canal of a radius and defining a plurality of fastener openings for receiving respective fasteners therethrough. The kit also includes a guide member configured to be coupled to the intramedullary fixation device and an interchangeable distal guide member configured to engage and be disengaged from the guide member. The distal guide member defines a plurality of fastener guide openings for guiding respective fasteners through a plurality of fastener openings defined in the intramedullary fixation member. The kit may also include an interchangeable proximal guide member and/or a guide fastener, as described above.

[0013] A method for placing a fixation member within a medullary canal of a radius is also described. The method includes defining a side aperture in the radius that extends into a medullary canal thereof and attaching a guide member to the fixation member with a guide fastener. The method further includes inserting the fixation member through the side aperture until the fixation member is positioned in the medullary canal and side aperture and attaching an interchangeable distal guide member to the guide member, wherein the distal guide member defines a plurality of fastener guide openings. Moreover, the method includes defining a plurality of fastener openings within the radius via the plurality of fastener guide openings defined in the distal guide member that align with a plurality of fastener openings defined in the fixation member. The method also includes advancing a plurality of bone fasteners through the plurality of fastener guide openings defined in the distal guide member and the plurality of fastener openings defined in the fixation member and the radius.

[0014] Variations of the method include attaching an interchangeable proximal guide member to the distal guide member, wherein the proximal guide member defines a plurality of fastener guide openings. The method may further include defining a plurality of fastener openings within the radius via the plurality of fastener guide openings defined in the proximal guide member that align with a plurality of fastener openings defined in the fixation member that are located proximally of the plurality of fastener openings defined via the distal guide member. Furthermore, the method may include detaching the distal guide member from the guide member while the guide member is attached to the fixation member.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0015] Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

Figure 1 is a perspective view of a guide assembly coupled to a fixation member according to one embodiment of the present invention;
Figure 2 is a side elevation view of a fixation member positioned within the medullary canal of a radius according to one embodiment of the present invention;
Figure 3 is a perspective view of the fixation member of Figure 1;
Figures 4-6 are side elevation views of the fixation member of Figure 3;
Figure 7 is a perspective view of a guide member according to one embodiment of the present invention;
Figure 8 is an end view of the guide member of Figure 6;
Figure 9 is a cross-sectional view of the guide member of Figure 6;
Figure 10 is an elevation view of a distal guide member according to one embodiment of the present invention;
Figure 11 is an elevation view of a distal guide member according to an embodiment of the present invention;
Figure 12 is a perspective view of distal guide member of Figure 11;
Figures 14 and 15 are side elevation views of a distal guide member of another embodiment of the present invention;
Figure 16 is a cross-sectional view of the distal guide member of Figure 14;
Figures 17 and 18 are side elevation views of a distal guide member of one embodiment of the present invention;
Figure 19 is a cross-sectional view of the distal guide member of Figure 17;
Figure 20 is perspective view of a guide member coupled to a distal guide member according to one embodiment of the present invention;
Figure 21 is perspective view of a guide member coupled to a distal guide member according to an embodiment of the present invention;
Figure 22 is a side elevation view of a distal guide member coupled to a radius according to one embodiment of the present invention;
Figure 23 is a side elevation view of a guide member coupled to radius, a distal guide member coupled to the guide member, and a proximal guide member prior to engaging the distal guide member, according
DETAILED DESCRIPTION OF THE INVENTION

[0016] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, this invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

[0017] A guide assembly 10 of one embodiment of the present invention is shown coupled to a radius 11 of a patient in Figure 1. The guide assembly 10 is employed to install a fixation member 20 within the radius 11, as explained in further detail below. The fixation member 20 is most suited for repairing fractures of the distal radius 11 wherein the fracture is at one end near an articular cartilage surface 12 and wherein it is desired to leave the articular surface undisrupted during the repair. Although reference is made herein to a guide assembly 10 and fixation member 20 suitable for the radius, it is understood that the guide assembly may be configured to install a fixation member within a variety of long bones, such as a femur, tibia, radius or humerus.

[0018] As shown in Figure 2, the radius 11 generally includes a widened end 13 that supports the articular cartilage surface which tapers to a more narrow shaft 14. Extending within the shaft 14 and a portion of the widened end 13 is a medullary canal 15. In addition, the guide assembly 10 and fixation member 20 could be used to repair a variety of fractures of the long bones, but is shown being used to repair a first bone fragment 16 separated from a second bone fragment 17 by a single fracture line 18. A side aperture 19 is defined in a lateral surface of the widened end 13, subjacent the articular cartilage surface 12, to allow insertion of the fixation member 20.

[0019] Generally, the fixation member 20 is configured to receive a plurality of fasteners 21 therethrough and attach to the radius I 1 above and below the fracture line 18 and thereby reduce the fracture, for example, as shown in Figure 2. The elongate fixation member 20, when positioned within the medullary canal 15 of the radius 11, has a first end 22 positioned adjacent the side aperture 19. Extending from the first end, through the rest of the aperture and into the medullary canal 15 of the first bone fragment 16, is a curved body 24 (shown in broken lines in Figure 2) of the fixation member 20. The curved body 24 extends to a second end 23 which is positioned within the medullary canal 15 of the second bone fragment 17. Advantageously, a radius of curvature of the curved body 24 is selected to promote smooth insertion of the curved body through the side aperture 19 and into the medullary canal 15.

[0020] For example, one embodiment of the fixation member 20 of the present invention is shown in Figures 3-6. The first end 22 of the fixation member 20 has two intersecting flat surfaces, including an exposed first end surface 27 that is accessible through the side aperture 19 and an adjacent first end surface 28 that is at a right angle to the exposed surface, as shown in Figure 4. The second end 23 of the fixation member 20 may have a rounded profile.

[0021] The curved body 24 of the fixation member 20 includes a convex side 29 and a concave side 30 that are on opposite sides of the curved body. The sides have radii of curvature with a similar center, but the center of the convex side changes so that the sides converge in a slight taper as they extend to the second end 23, as shown in Figure 4. For instance, the radius of curvature of the concave side 30 is about 3.12 inches and the radius of curvature of the convex side 29 is about 3.40 inches.
near the first end 22 when measured from a first center 31 positioned about 2.31 inches from the plane of the adjacent first end surface 28 and about 2.35 inches from the plane of the exposed first end surface 27. Notably, this shift produces the taper near the second end 23 of the fixation member 20.

**[0022]** A second pair of opposite, side surfaces 33 extend between the convex side 29 and concave side 30, as shown in Figures 3, 5, and 6. Similar to the convex side 29 and concave side 30, the side surfaces 33 taper slightly toward each other as they extend from the first end 22 to the second end 23 of the curved body 24. However, the side surfaces 33 in the illustrated embodiment are relatively planar, as opposed to the curved shape of the sides 29, 30. Advantageously, the taper of the sides 29, 30, 33, the continuous curve of the curved body 24 between the ends 22, 23 and the rounded profile of the second end 23 help to facilitate insertion through the side aperture 19 and into the medullary canal 15.

**[0023]** To allow passage of the fasteners 21 through the fixation member, a plurality of fastener openings are defined in the fixation member. These fastener openings include a side aperture accessible fastener opening 34, a pair of fastener openings 35 extending between the curved convex side 29 and concave side 30, and fastener openings 36 extending between the side surfaces 33. The fastener opening 34 extends from the exposed first end surface 27 (which is accessible through the side aperture 19 when the fixation member 20 is installed) through a portion of the curved body 24 and to the convex side 29, as shown in Figure 4. The fastener opening 34 includes a guide portion 38 and a fastener portion 39 that is generally narrower than the guide portion. Both of the portions may be threaded to facilitate a secure fit by the fasteners 21 and various installation devices, as will be described in more detail below. Defined around the periphery of the guide portion 38 of the fastener opening 34 are four indentations 40. These indentations 40 are arranged in a cross, or cruciform, shape each radiating out from the fastener opening 34 and spaced 90° from each other. As will be described in more detail below, the concave indentations 40 serve to provide for a secure, properly oriented positive fit with a guide assembly 10.

**[0024]** The pair of fastener openings 35 which extend between the sides 29, 30 extend through the curved body 24 nearer the first end 22 so as to be within the first bone fragment 16, as shown in Figure 2, 5, and 6. Each of the fastener openings 35 may have a threaded fastener portion similar to the fastener opening 34, but a non-threaded fastener head portion which may define a counterbore. These fastener openings 35 extend at different, divergent angles than each other and the orientation of the fastener opening 34 which is relatively orthogonal with respect to the exposed first end surface 27 and the convex side 29, as shown in Figures 3, 5, and 6. As a result, the fastener openings (such as the fastener openings 35) need not all be aligned with the axis of the fixation member.

**[0025]** These different angles improve fixation by allowing angled insertion of the fasteners 21 into different portions of the first bone fragment 16, as shown in Figure 2. In addition, the angles of the fastener openings 34, 35 may be configured so that the fasteners extend subjacent to the articular cartilage for improved fixation. Generally, this will require the fastener openings 34, 35 to extend at some acute angle, such as an angle between about 50° and 85° (depending on the origin of the fastener opening), and preferably about 60° to 70°, with respect to the fixation member 20. Basically, these angles are to match the inclination angle of the articular surface so as to provide a buttress effect for the articular cartilage. For instance, the ulnar inclination angle of the articular cartilage on the radius is about 23° (resulting in a 67° fastener opening angle). The buttress effect is also improved by the sub-chondral placement of the first end surface 28 that is adjacent and at a right angle with respect to the exposed first end surface 27 so as to underlie the articular cartilage.

**[0026]** In the illustrated embodiment shown in Figures 3 and 4, six fastener openings 36 are defined in the curved body 24 at a position nearer the second end 23 of the fixation member 20. The fastener openings 36 having the larger diameter are configured to receive threaded fasteners 21 therethrough, similar to the fastener openings 34, 35, while the fastener openings having a smaller diameter are configured to receive a relatively smaller diameter Kirschner wire/k-wire 41. The larger of the fastener openings 36 may not be threaded to allow a slip fit of the threaded fasteners 21 through the fixation member 20 without damaging the threads. Furthermore, Figure 2 demonstrates that the fixation member 20 may be positioned within the radius 11 such that each of the larger fastener openings 36 may guide respective fasteners 21 in the second bone fragment 17.

**[0027]** Although six fastener openings are shown in the illustrated fixation member 20, it is understood that the fixation member may include any number of desired fastener openings. For example, the fixation member 20 may be configured to be a size 1 or 2 implant such that increasing to a size 3 or 4 implant may include additional fastener openings 35 and/or 36. Moreover, it is understood that the fixation member 20 could be a variety of configurations depending on the type of long bone, the patient, and/or other factors. For additional details regarding a fixation member and bone fasteners according to additional embodiments of the present invention, see U.S. Patent Appl. Publ. No. 2006/0015101, filed July 15, 2004.

**[0028]** Figure 1 illustrates a guide assembly 10 according to one embodiment of the present invention. The guide assembly generally includes a guide member 51, a distal guide member 52, and a proximal guide member 53. As discussed in detail below, the guide member 51 and distal 52 and proximal 53 guide members are capable of being engaged to and disengaged from each other so as to provide an interchangeable guide assembly 10 that may provide for easier installation of the fixation.
Figures 7-9 illustrate a guide member 51 ac
crmed member 20 within the radius 11. Figures 7-9 illustrate a guide member 51 according to one embodiment of the present invention. The guide member 51 is configured to be coupled to the distal end of the fixation member 20 via a guide fastener 54. In particular, the guide member 51 includes a longitudinal opening 56 that is configured to receive the guide fastener 54 therethrough. The guide fastener 54 includes a threaded end 58 that is configured to mate with threads defined in the fastener opening 34 of the fixation member 20. Moreover, the guide member 51 includes a plurality of prongs 60 that are configured to fit into similarly shaped, but somewhat smaller, concave indentations 40 in a positive, or interference, type fit, as shown, for example, in Figure 33.

When the threaded end 58 is advanced into the threads of the guide portion 38, the guide member 51 and its prongs 60, which are also spaced in a cruciform or cross pattern similar to the indentations 40, are advanced into the indentations. The cruciform pattern, combined with the positive fit, firmly locks the guide member 51 to the fixation member 20 before attaching the distal 52 and proximal 53 guide members, as well as during guidance of insertion of the various fasteners 21. The cruciform shape and positive fit may be effective at restricting rotation between the guide assembly 10 and fixation member 20, which can be a problem due to the relative length and cantilevered configuration of the guide assembly and fixation member. It should be noted, however, that the positive fit of the prongs 60 in the concave indentations 40 could be accomplished in other ways, such as by having the indentations on the guide member 51 instead of the exposed first end surface 27 of the fixation member 20.

The guide member 51 also includes a handle mount 62 and a threaded opening 64 extending therethrough that is configured to mate with a handle 114, as shown in Figures 32-34, 36, and 37. The handle 114 is typically used to manipulate the fixation member 20 within the medullary canal 15, as explained in additional detail below. Moreover, the guide member 51 includes a protrusion 66 that also includes a threaded opening 68. As also explained in further detail below, the protrusion is configured to mate with a slot 76 defined in the distal guide member 52. The protrusion 66 is shown as being generally rectangular, but could be various sizes and configurations to mate with the slot 76 of the distal guide member 52, such as tapered to engage a tapered slot in an interference type of fit.

Figures 10-13 illustrate distal guide members 52 according to particular embodiments of the present invention. The distal guide member 52 shown in Figures 10-13 may be used for guiding fasteners 21 within the first end 22 of the fixation member 20 and the first bone fragment 16. In particular, the distal guide member 52 shown in Figures 10 and 13 may be configured to guide fasteners 21 within the patient’s left radius 11, while the distal guide member 52 shown in Figures 11 and 12 may be used to guide fasteners in the right radius.

Each of the distal guide members 52 shown in Figures 10-13 includes a plurality of openings 70. The openings 70 are oriented so as to have an axis collinear and aligned with the axes of the pair of openings 35 defined in the curved body 24 of the fixation member 20. According to one embodiment, the openings 70 are defined so that the fasteners 21 extend at an angle into the first bone fragment 16 below the articular cartilage surface 12, as shown in Figure 2.

Furthermore, the openings 70 are configured to slidably receive respective tissue protectors 72 therethrough, as shown in Figure 34. Each tissue protector 72 includes a head 75 and a longitudinal shaft 77, wherein the shaft is configured to extend through the openings 70 and adjacent to the radius. Thus, the distal end of the tissue protector is capable of being inserted through the skin and abutting the radius. The offset distance between the distal guide member 52 and the patient’s skin may allow the distal guide member 52 to accommodate patients of a variety of sizes, while the tissue protectors 72 may protect the patient’s skin from injury resulting from implanting the fixation member 20, such as from drilling into the tissue. Furthermore, the distal guide members 52 include an opening 74 configured to receive the guide fastener 54 therethrough, as shown in Figures 20 and 21. Figures 1 and 34 show that the tissue protectors 72 and guide fastener 54 include respective longitudinal openings 73 that are configured to receive drill bits, k-wires, drill guides, fasteners, and the like in order to facilitate placement of the fixation member 20 within the radius 11. For example, Figure 1 shows each of the tissue protectors 72 and guide fastener 54 may have a drill guide 78 positioned therein.

Each distal guide member 52 also includes a slot 76 that is configured to mate with the protrusion 66 of the guide member 51. Extending within the slot 76 is a fastener 80 having a threaded end 82 that is configured to engage with the threads 68 of the protrusion 66. The engagement of the protrusion 66 and fastener 80 within the slot 76 provides resistance to rotational movement between the guide member 51 and the distal guide member 52, which may ensure more accurate placement of fasteners 21 within the radius 11. The slot 76 is generally rectangular in configuration but could be modified to a variety of sizes and configurations to mate with the protrusion 66 and resist rotational movement therebetween.

Each distal guide member 52 shown in Figures 10-13 includes a hook-shaped portion 84 that includes a curvature that is configured to extend partially about the circumference of the patient’s wrist and engage a proximal guide member 53. The distal guide members 52 of Figures 10-13 include a fastener 86 and an associated threaded end 87 that is configured to thread an opening 92 defined in the proximal guide member 53, as shown in Figure 23. However, it is understood that the proximal guide member 53 may include a fastener that is configured to engage threads defined in the distal guide mem-
Figures 14-19 illustrate additional embodiments of the present invention, which is configured to be coupled to the distal guide members 52 illustrated in Figures 14-19. As described above, the proximal guide member 53 includes a channel 100 that is configured to receive the protrusion 98, as shown in Figures 32 and 33. Different proximal guides 53 can also be used for different sized fixation members 20. For example, Figure 28 shows a proximal guide member 53 having additional openings 106 for accommodating a longer fixation member 20. In addition, the proximal guide member 53 can be employed in right and left handed configurations depending on the type of long bone being treated and the orientation of the side aperture 19.

The guide assembly 10 further includes a proximal guide member 53 for guiding fasteners 21 within the second end 23 of the fixation member 20 and the second bone fragment 17, as shown in Figures 24-28 according to additional embodiments of the present invention. The proximal guide member 53 is configured to engage a respective distal guide member 52, as shown in Figure 29. In particular, the proximal guide member 53 of Figure 24 is generally configured to be coupled to the distal guide members 52 shown in Figures 10-13.

The proximal guide member 53 is generally L-shaped in configuration and includes a first portion 102 for engaging with the distal guide member 52 and a second portion 104 for guiding respective fasteners 21 into respective openings 36 defined in the fixation member 20. In particular, the second portion 104 includes a plurality of openings 106 that are configured to receive various devices for implanting the fixation member 20, such as a tube protector 72, as shown in Figure 34. In addition, the second portion 104 includes a smaller opening 108 that could be configured to receive a k-wire 41 or similar device therein.

Figures 25-27 illustrate a proximal guide member 53 according to an additional embodiment of the present invention, which is configured to be coupled to the distal guide members 52 illustrated in Figures 14-19. As described above, the proximal guide member 53 includes a channel 100 that is configured to receive the protrusion 98, as shown in Figures 32 and 33. Different proximal guides 53 can also be used for different sized fixation members 20. For example, Figure 28 shows a proximal guide member 53 having additional openings 106 for accommodating a longer fixation member 20. In addition, the proximal guide member 53 can be employed in right and left handed configurations depending on the type of long bone being treated and the orientation of the side aperture 19.

The guide assembly 10 further includes a proximal guide member 53 for guiding fasteners 21 within the second end 23 of the fixation member 20 and the second bone fragment 17, as shown in Figures 24-28 according to additional embodiments of the present invention. The proximal guide member 53 is configured to engage a respective distal guide member 52, as shown in Figure 29. In particular, the proximal guide member 53 of Figure 24 is generally configured to be coupled to the distal guide members 52 shown in Figures 10-13.

The proximal guide member 53 is generally L-shaped in configuration and includes a first portion 102 for engaging with the distal guide member 52 and a second portion 104 for guiding respective fasteners 21 into respective openings 36 defined in the fixation member 20. In particular, the second portion 104 includes a plurality of openings 106 that are configured to receive various devices for implanting the fixation member 20, such as a tube protector 72, as shown in Figure 34. In addition, the second portion 104 includes a smaller opening 108 that could be configured to receive a k-wire 41 or similar device therein.

Figures 25-27 illustrate a proximal guide member 53 according to an additional embodiment of the present invention, which is configured to be coupled to the distal guide members 52 illustrated in Figures 14-19. As described above, the proximal guide member 53 includes a channel 100 that is configured to receive the protrusion 98, as shown in Figures 32 and 33. Different proximal guides 53 can also be used for different sized fixation members 20. For example, Figure 28 shows a proximal guide member 53 having additional openings 106 for accommodating a longer fixation member 20. In addition, the proximal guide member 53 can be employed in right and left handed configurations depending on the type of long bone being treated and the orientation of the side aperture 19.

The guide assembly 10 further includes a proximal guide member 53 for guiding fasteners 21 within the second end 23 of the fixation member 20 and the second bone fragment 17, as shown in Figures 24-28 according to additional embodiments of the present invention. The proximal guide member 53 is configured to engage a respective distal guide member 52, as shown in Figure 29. In particular, the proximal guide member 53 of Figure 24 is generally configured to be coupled to the distal guide members 52 shown in Figures 10-13.

The proximal guide member 53 is generally L-shaped in configuration and includes a first portion 102 for engaging with the distal guide member 52 and a second portion 104 for guiding respective fasteners 21 into respective openings 36 defined in the fixation member 20. In particular, the second portion 104 includes a plurality of openings 106 that are configured to receive various devices for implanting the fixation member 20, such as a tube protector 72, as shown in Figure 34. In addition, the second portion 104 includes a smaller opening 108 that could be configured to receive a k-wire 41 or similar device therein.
The distal 52 and proximal 53 members may be visualized the radius 11 if desired. The wires 41 are inserted within the radius 11 in order to visualize the k-wire 41 therein. Defined within the elongate shaft 124 of the drill guide 78 is a guide shaft opening that tapers from a wider to narrower diameter near its distal end. Thus, a dual diameter drill bit could be used to drill a hole within radius 11, wherein the larger diameter of the drill bit prevents travel of the drill bit beyond the shoulder defined near the distal end of the drill guide 78 so as to prevent drilling past a selected depth. As shown in Figure 1, the depth of the hole drilled in the radius 11 may be determined based on the alignment of a predetermined marking on the k-wire 41 with one of the measurement indicators 122. The k-wire 41 and/or measurement indicators 122 could also employ fluorescent paint or grooved notches to facilitate reading of the measurements. In addition, the drill guides 78 are capable of being removed from respective tissue protectors 72 while k-wires 41 are inserted therein, which may aid the surgeon in viewing the k-wire within the radius 11. The tissue protectors 72 could also be removed from the distal 52 and proximal 53 guide members while the k-wires 41 are inserted within the radius 11 in order to visualize the radius 11 if desired.

The distal 52 and proximal 53 members may be a radiolucent material. Thus, the distal 52 and proximal 53 guide members do not obstruct images taken of the radius during implantation of the fixation member 20, such as images taken using radiographic techniques. For example, the radiolucent material could be a carbon reinforced PEEK material, which is lighter than conventional stainless steel guide assemblies. A guide assembly 10 comprising a lighter material may also be easier to handle by a surgeon and apply less torque on the bone fragments. Moreover, other components of the guide assembly could be a radiolucent material, such as the tissue protectors 72, k-wires 41, and/or handle body 116, in order to reduce weight of the guide assembly 10, as well as provide better visualization of the fixation member 20 within the radius during surgery.

In order to install the fixation member 20, a side aperture 19 is cleared in a lateral side of the radius 11, and a conventional bone awl (not shown) may be used to open the medullary canal 15 of cancellous bone. A trialing broach may be urged through the side aperture 19 and into the medullary canal 15 to approximate the size of the fixation member 20. Other conventional tools could also be employed to clear bone, such as reamers and awls.

Once the side aperture 19 has been formed and the medullary canal 15 cleared and sized, an appropriately sized fixation member 20 may be selected. The handle 114 is attached to the threaded opening 64 defined in the guide member 51, as shown in Figures 32-34. The guide member 51 may then be attached to the fixation member 20 via the guide fastener 54. In particular, the threaded tip 58 of the guide fastener 54 may be advanced into the threaded opening 34 of the fixation member 20, which mates the prongs 60 with the indentations 40, thereby locking out micro-motion and rotation between the guide member 51 and the fixation member 20. The handle 114 may then be used to orient the fixation member 20 through the side aperture 19 and into the medullary canal 15. The handle 114 may then be unscrewed from the guide member 51.

The distal guide member 52 may then be attached to the guide member 51 by inserting the protrusion 66 within the slot 76 and tightening the fastener 80 to the threaded opening 68, as shown in Figures 20 and 21. The proximal guide member 53 may then be attached to the distal guide member 52 by sliding the protrusion 98 within the channel 100 such that the alignment pin 88 aligns with the opening 94. The fastener 86 may then be tightened to secure the threaded end 87 within the threaded opening 92.

The surgeon may then insert tissue protectors 72 within each of the openings 70 of the distal guide member 52 and the openings 106 of the proximal guide member 53. For temporary fixation, a k-wire 41 may be inserted within the smaller guide openings 36, 108 of the distal 52 and proximal 53 guide members, respectively. The drill guides 78 may then be placed into respective tissue protectors 72, as well as within the guide fastener 54. A drill bit (not shown) may be advanced into the drill guides 78 to form pilot holes in the radius 11.

The depth of these holes may then be tested using measurement indicators 122 by inserting a k-wire within the longitudinal slot 126 of the drill guides 78, as shown in Figure 1. The depth measurements facilitate selection of fasteners 21 of the appropriate length. If necessary, the drilled holes are then tapped to prepare them for insertion of threaded fasteners 21. After tapping, the threaded fasteners 21 may be advanced through the aligned openings 34, 35, 36, 106 in the fixture member 20 and the radius 11 so as to connect the bone fragments 16, 17, as shown in Figure 2. The guide assembly 10 can then be removed by unscrewing the guide fastener 54.

It is understood that various techniques could be used to install the fixation member 20 within the radius 11, as the particular order of steps discussed above need not be limiting, as the particular procedure may depend on various factors, such as the surgeon or the patient. For example, the distal guide member 52 could be attached to the guide member 51 prior to inserting the fixation member 20 within the medullary canal 15. For additional and alternative details regarding a guide assem-
The present invention may provide several advantages. For example, the guide member 51 may be coupled to the fixation member 20 without first having to attach the distal guide member 52 and/or proximal guide member 53. Thus, the surgeon may be able to more easily position the fixation member 20 within the radius 11 since the surgeon will have a better view of the radius and will have a lighter device to manipulate. In addition, the distal guide member 52 is interchangeable with the guide member 51 such that the surgeon could remove the distal guide member 52 during surgery, such as for better visualization or to change to a different size. Thus, attachment of the guide member 51 to the fixation member 20 with the guide fastener 54 provides a secure engagement that allows the distal guide member 52 to be attached and removed when desired. Similarly, the proximal guide member 53 is interchangeable with the distal guide member 52 such that the proximal guide member may be selectively engaged to and disengaged from the distal guide member. Therefore, the combination of the guide member 51, distal guide member 52, and proximal guide member 53 provides interchangeable components for a more universal guide assembly 10.

Furthermore, the distal 52 and proximal 53 members may be a radiolucent material, which also enhances visualization during surgery, as well as reduces the weight of the guide assembly, thereby resulting in easier manipulation of the assembly and less torque on the bone fragments. The distal 52 and proximal 53 guide members are also configured to be spaced away from the patient's radius 11 such that the guide assembly 10 is adaptable to various sized patients. In addition, the offset distance between the distal 52 and proximal 53 guide members from the patient's skin allows tissue protectors 72 to be placed within each of the holes 70, 106 in order to provide additional protection from injuring the patient's skin during installation of the fixation member 20.

Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

**Claims**

1. A guide assembly (10) for facilitating placement of a fixation member (20), the fixation member having a plurality of fastener openings (34, 35), within a medullary canal of a radius (11) such that an exposed first end (27) of the fixation member (20) is accessible through a side aperture (19) defined in the radius (11) without disrupting the surface of the articular surface of the distal radius (11), the guide assembly (10) comprising:

   a guide fastener (54) configured to attach to the fixation member (20), the guide fastener (54) configured to engage the exposed distal end (22) of the fixation member (20) that is accessible through the side aperture (19) defined in the radius;

   a guide member (51) configured to receive the guide fastener (54) such that the guide member (51) is secured to the fixation member (20) via the guide fastener (54), the guide member (51) defining an opening (56) configured to allow passage of the guide fastener (54) through the guide member (51) and into the exposed end of the fixation member (20);

   an interchangeable distal guide member (52) configured to engage and be disengaged from the guide member (51), the guide member (52) comprising an opening (74) configured to align with the opening (56) defined in the guide member (51) and to allow passage of the guide fastener (54) therethrough, the distal guide member (52) defining a plurality of fastener guide openings (70) for guiding respective fasteners (21) through the plurality of fastener openings (35) in the fixation member (20); and

   an interchangeable proximal guide member (53) configured to engage and be disengaged from the distal guide member (52) and defining a plurality of fastener guide openings (106) for guiding respective fasteners into a plurality of fastener openings (36) defined in the intramedullary fixation member (20) that are located proximally of the plurality of fastener openings (35) defined via the distal guide member (52); characterized in that,

   the guide member (51) includes a protrusion (66), the distal guide member (52) comprising a slot (76) configured to mate with the protrusion (66) and to resist rotational movement therebetween such that the guide member (51) can be coupled to the fixation member (20) without first having to attach the distal guide member (52) and such that the distal guide member (52) can be removed from the guide member (51) during surgery.

2. The guide assembly of Claim 1, wherein the guide fastener (54) comprises an opening configured to receive a drill guide (78) there through.
3. The guide assembly of Claim 1, wherein the guide member (51) comprises a threaded opening (68) for receiving a fastener (82) to secure the distal guide member (52) to the guide member (51).

4. The guide assembly of Claim 1, further comprising a handle (114), wherein the guide member (51) includes a handle mount (62) for attachment of the handle (114).

5. The guide assembly of Claim 1, wherein the distal guide member (52) comprises a protrusion (98), and wherein the proximal guide member (53) comprises a channel (100) for receiving the protrusion therein.

6. The guide assembly of Claim 1, wherein the proximal guide member (53) and distal guide member (52) are configured for threaded engagement (86, 92).

7. The guide assembly of Claim 1, wherein the distal guide member (52) comprises an alignment pin (88) configured to engage an opening (94) defined in the proximal guide member (53).

8. The guide assembly of Claim 1, further comprising a plurality of tissue protectors (72), wherein each of the plurality of fastener guide openings (70, 106) of the proximal guide member (53) and distal guide member (52) is configured to receive a respective tissue protector (72) there through.

9. The guide assembly of Claim 8, wherein each of the proximal guide member (53) and distal guide member (52) is spaced outwardly from the radius (11) such that the tissue protectors (72) are configured to extend through the proximal guide member and distal guide member and adjacent to the radius.

10. The guide assembly of Claim 8, further comprising a plurality of drill guides (78), wherein each of the plurality of tissue protectors (72) is configured to receive a respective one of the drill guides (78) therein.

11. The guide assembly of Claim 10, further comprising a plurality of k-wires (41), wherein each of the plurality of drill guides (78) is configured to receive a respective k-wire (41) there through in order to determine a depth of drilling into the radius (11) based on a measurement reading on a respective drill guide (78).

12. The guide assembly of Claim 1, wherein the proximal guide member (53) and distal guide member (52) comprise a radiolucent material.

13. An intramedullary fixation device kit for repairing a radius (11) fracture, the intramedullary fixation member comprising:

   an intramedullary fixation member (20) configured to be positioned within an intramedullary canal (15) of a radius (11) and defining a plurality of fastener openings (34, 35, 36) for receiving respective fasteners (21) there through; a guide assembly (10) according to any one of claims 1 to 12.

**Patentansprüche**

1. Führungsaufbau (10) zur Erleichterung der derartigen Anordnung eines Fixierungselements (20), wobei das Fixierungselement mehrere Befestigungs mittelöffnungen (34, 35) aufweist, in einem Markkanal eines Radius (11), dass ein freiliegendes erstes Ende (27) des Fixierungselements (20) durch eine in dem Radius (11) definierte Seitenöffnung (19) zugänglich ist, ohne die Oberfläche der Gelenkfläche des distalen Radius (11) zu sprengen, wobei der Führungsaufbau (10) Folgendes umfasst:

   ein Führungsbefestigungsmittel (54), das zur Anbringung an dem Fixierungselement (20) gestaltet ist, wobei das Führungsbefestigungsmittel (54) dazu gestaltet ist, mit dem freiliegenden distalen Ende (22) des Fixierungselements (20), das durch die in dem Radius definierte Seitenöffnung (19) zugänglich ist, einzugreifen; ein Führungselement (51), das dazu gestaltet ist, das Führungsbefestigungsmittel (54) so aufzunehmen, dass das Führungselement (51) über das Führungsbefestigungsmittel (54) an dem Fixierungselement (20) befestigt wird, wobei das Führungselement (51) eine Öffnung (56) definiert, die dazu gestaltet ist, einen Durchgang des Führungsbefestigungsmittels (54) durch das Führungselement (51) und in das freiliegende Ende des Fixierungselements (20) zu gestatten;

   ein austauschbares distales Führungselement (52), das dazu gestaltet ist, mit dem Führungselement (51) einzugaugen und davon gelöst zu werden, wobei das distale Führungselement (52) eine Öffnung (74) umfasst, die dazu gestaltet ist, sich mit der in dem Führungselement (51) definierten Öffnung (56) auszurichten und einen Durchgang des Führungsbefestigungsmittels (54) zu gestatten, wobei das distale Führungselement (52) mehrere Befestigungsmittelöffnungen (70) definiert, um jeweilige Befestigungsmittel (21) durch die mehreren Befestigungsmittelöffnungen (35) in dem Fixierungselement (20) zu führen; und

   ein austauschbares proximales Führungselement (53), das dazu gestaltet ist, mit dem distalen Führungselement (52) einzugaugen und davon gelöst zu werden, und mehrere Befesti-
gungsmittelführungsoffnungen (106) definiert, um jeweilige Befestigungsmittel in mehrere in dem intramedullären Fixierungselement (20) definierte Befestigungsmittelöffnungen (36), die proximal von den über das distale Führungselement (52) definierten mehreren Befestigungsmitteln (35) liegen, zu führen; dadurch gekennzeichnet, dass das Führungselement (51) einen Vorsprung (66) umfasst, und das distale Führungselement (52) einen Schlitz (76) umfasst, der dazu gestaltet ist, mit dem Vorsprung (66) ineinanderzugreifen und einer Drehbewegung dazwischen zu widerstehen, so dass das Führungsmittel (51) mit dem Fixierungselement (20) gekoppelt werden kann, ohne dass zuerst das distale Führungselement (52) angebracht werden muss, und so dass das distale Führungselement (52) während der Operation aus dem Führungselement (51) entfernt werden kann.

2. Führungsaufbau nach Anspruch 1, wobei das Führungsbefestigungsmittel (54) eine Öffnung umfasst, die dazu gestaltet ist, eine Bohrführung (78) hindurchgehend aufzunehmen.

3. Führungsaufbau nach Anspruch 1, wobei das Führungselement (51) eine Gewindeöffnung (68) zur Aufnahme eines Befestigungsmittels (82) umfasst, um das distale Führungselement (52) an dem Führungselement (51) zu befestigen.

4. Führungsaufbau nach Anspruch 1, ferner umfassend einen Griff (114), wobei das Führungselement (51) eine Griffhalterung (62) zur Anbringung des Griffs (114) umfasst.

5. Führungsaufbau nach Anspruch 1, wobei das distale Führungselement (52) einen Vorsprung (98) umfasst, und wobei das proximale Führungselement (53) einen Kanal (100) umfasst, um darin den Vorsprung aufzunehmen.

6. Führungsaufbau nach Anspruch 1, wobei das proximale Führungselement (53) und das distale Führungselement (52) für einen Gewindeeingriff (86, 92) gestaltet sind.

7. Führungsaufbau nach Anspruch 1, wobei das distale Führungselement (52) einen Ausrichtungsstift (88) umfasst, der dazu gestaltet ist, mit einer Öffnung (94), die in dem proximalen Führungselement (53) definiert ist, eingzugreifen.

8. Führungsaufbau nach Anspruch 1, ferner umfassend mehrere Gewebeschutzeinrichtungen (72), wobei jede der mehreren Befestigungsmittelöffnungen (70, 106) des proximalen Führungselements (53) und des distalen Führungselements (52) dazu gestaltet ist, eine jeweilige Gewebeschutzeinrichtung (72) hindurchgehend aufzunehmen.

9. Führungsaufbau nach Anspruch 8, wobei jedes aus dem proximalen Führungselement (53) und dem distalen Führungselement (52) so von dem Radius (11) nach außen beabstandet ist, dass die Gewebeschutzeinrichtungen (72) darunter gestaltet sind, dass sie sich durch das proximale Führungselement und das distale Führungselement und neben dem Radius erstrecken.

10. Führungsaufbau nach Anspruch 8, ferner umfassend mehrere Bohrführungen (78), wobei jede der mehreren GewebeschutzEinrichtungen (72) gestaltet ist, um darin eine jeweilige der Bohrführungen (78) aufzunehmen.

11. Führungsaufbau nach Anspruch 10, ferner umfassend mehrere K-Drähte (41), wobei jede der mehreren Bohrführungen (78) dazu gestaltet ist, einen jeweiligen K-Draht (41) hindurchgehend aufzunehmen, um auf Basis einer Messablesung an einer jeweiligen Bohrführung (78) eine Tiefe des Bohrens in den Radius (11) zu bestimmen.

12. Führungsaufbau nach Anspruch 1, wobei das proximale Führungselement (53) und das distale Führungselement (53) ein strahlendurchlässiges Material umfassen.

13. Satz einer intramedullären Fixierungsvorrichtung zur Reparatur der Fraktur eines Radius (11), wobei der Satz der intramedullären Fixierungsvorrichtung Folgendes umfasst:

- ein intramedulläres Fixierungselement (20), das dazu gestaltet ist, in einem intramedullären Kanal (15) eines Radius (11) positioniert zu werden, und mehrere Befestigungsmittelöffnungen (34, 35, 36) zur hindurchgehenden Aufnahme jeweiliger Befestigungsmittel (21) definiert; einen Führungsaufbau (10) nach einem der Ansprüche 1 bis 12.

Revendications

1. Ensemble de guidage (10) pour faciliter la mise en place d’un élément de fixation (20), l’élément de fixation ayant une pluralité d’ouvertures d’attache (34, 35), à l’intérieur d’un canal médullaire d’un radius (11) de sorte qu’une première extrémité exposée (27) de l’élément de fixation (20) est accessible à travers un trou latéral (19) défini dans le radius (11) sans perturber la surface de la surface articulaire du radius distal (11), l’ensemble de guidage (10)
Ensemble de guidage selon la revendication 1, dans ouverture configurée pour recevoir un guide-forets lequel l’attache de guidage (54) comprend une ouverture filetée (68) pour recevoir une attache (82) afin de maintenir l’élément de guidage distal (52) sur l’élément de guidage (51).

2. Ensemble de guidage selon la revendication 1, dans lequel l’attache de guidage (54) comprend une ouverture configurée pour recevoir un guide-foret (78) à travers cette dernière.

3. Ensemble de guidage selon la revendication 1, dans lequel l’élément de guidage (51) comprend une ouverture filetée (68) pour recevoir une attache (82) afin de maintenir l’élément de guidage distal (52) sur l’élément de guidage (51).

4. Ensemble de guidage selon la revendication 1, comprenant en outre une poignée (114), dans lequel l’élément de guidage (51) comprend un support de poignée (62) pour la fixation de la poignée (114).

5. Ensemble de guidage selon la revendication 1, dans lequel l’élément de guidage distal (52) comprend une saillie (98), et dans lequel l’élément de guidage proximal (53) comprend un canal (100) pour recevoir la saillie à l’intérieur de ce dernier.

6. Ensemble de guidage selon la revendication 1, dans lequel l’élément de guidage distal (52) comprend une saillie (98), et dans lequel l’élément de guidage proximal (53) comprend un canal (100) pour recevoir la saillie à l’intérieur de ce dernier.

7. Ensemble de guidage selon la revendication 1, dans lequel l’élément de guidage distal (52) comprend une saillie (98), et dans lequel l’élément de guidage proximal (53) comprend un canal (100) pour recevoir la saillie à l’intérieur de ce dernier.

8. Ensemble de guidage selon la revendication 1, comprenant en outre une pluralité de protecteurs de tissu (72), dans lequel chacune de la pluralité d’ouvertures de guidage d’attache (70, 106) de l’élément de guidage proximal (53) et de l’élément de guidage distal (52) est configurée pour recevoir un protecteur de tissu respectif à travers cette dernière.

9. Ensemble de guidage selon la revendication 1, dans lequel chacun parmi l’élément de guidage proximal (53) et l’élément de guidage distal (52) est espacé vers l’extérieur du radius (11) de sorte que les protecteurs de tissu (72) sont configurés pour s’étendre à travers l’élément de guidage proximal et l’élément de guidage distal et de manière adjacente au radius.

10. Ensemble de guidage selon la revendication 8, comprenant en outre une pluralité de guide-forets (78), dans lequel chacun de la pluralité de protecteurs de tissu (72) est configuré pour recevoir un respectif des guide-forets (78) à l’intérieur de ce dernier.

11. Ensemble de guidage selon la revendication 10, comprenant en outre une pluralité de broches de Kirschner (41), dans lequel chacun de la pluralité de guide-forets (78) est configuré pour recevoir une broche de Kirschner (41) respective à travers ce dernier afin de déterminer une profondeur de perçage dans
le radius (11) en fonction d’une lecture de mesure sur un guide-foret (78) respectif.

12. Ensemble de guidage selon la revendication 1, dans lequel l’élément de guidage proximal (53) et l’élément de guidage distal (52) comprennent un matériau radiotransparent.

13. Kit de dispositif de fixation intramédullaire pour réparer une fracture de radius (11), le kit d’élément de fixation intramédullaire comprenant :

   un élément de fixation intramédullaire (20) configuré pour être positionné à l’intérieur d’un canal intramédullaire (15) d’un radius (11) et définissant une pluralité d’ouvertures d’attache (34, 35, 36) pour recevoir des attaches (21) respectives à travers ces dernières ;
   un ensemble de guidage (10) selon l’une quelconque des revendications 1 à 12.
REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description