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(54) Title: POLYAXIAL FASTENER SYSTEMS AND METHODS

(57) Abstract: Embodiments of the present invention provide a bone fixation assembly that can provide polyaxial fixation. The polyaxial is fixation may be provided by differing materials interfacing with one another to provide a secure lock.

POLYAXIAL FASTENER SYSTEMS AND METHODS

This application claims the benefit of U.S. Provisional Application Serial No. 60/702,231, filed July 25, 2005 titled "Locking Screw" and U.S. Provisional Application Serial No. 60/800,355, filed May 15, 2006 titled "Polyaxial Screw System," the entire contents of each of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates generally to orthopedic fixation devices and bone plating systems for fracture fixation, and particularly to systems and methods for polyaxial fixation of fasteners within bone plates.

Bone fractures are often repaired by securing a bone plate across the fracture. Depending upon which bone is to be treated, the bone plate may be straight or curved to match the contour of the bone for which it is designed. Bone plates may also be provided in many shapes and sizes. In cases where a bone is severely comminuted or if bone segments are missing, the use of bone plate and screw systems promotes healing of the fracture by providing a rigid fixation or support structure between the bone and the plate.

Bone plates may be secured to the bone in a number of ways. An existing solution is a plate and screw system where the screws are locked in the plate. A bone screw is threaded through an opening in the plate and into the bone. The screw is then secured to the bone plate via threads in the screw head that cooperate with threaded openings in the bone plate. This secures the plate with respect to the bone and provides rigid fixation because the relationship between the plate and screw(s) is fixed. Because the head of the locking screw interdigitates with threads in the plate, the plate and screws(s) form one stable system, and the stability of the fracture can be dependent upon the stiffness of the construct. Locking a screw into the plate can achieve angular and axial stability and eliminate the possibility for the screw to toggle, slide, or be dislodged, reducing the risk of postoperative loss of reduction.

However, although locking screws may reduce the incidence of loosening, they provide only one fixed angle relationship between the plate and the screw(s).

They have a limited insertion angle because the threads of the head mate with the threads of the hole in one way only. The longitudinal axis of the screw lines up with the central axis of the hole, and no angular variation is allowed. In short, locking screws are unidirectional, limiting their use in some instances.

For example, when treating a comminuted fracture, multiple fragments may be in irregular positions or otherwise displaced. Although a surgeon may wish to obtain the benefits of a locking screw and bone plate used together, the pre-determined angle at which the locking screw extends from the plate may not be the angle that would allow the surgeon to "grab" (or seize, or otherwise secure) the desired bone fragment. In this case, the surgeon may need to secure the plate to the bone somewhere else, or use a non-locking screw (because although non-locking screws do not lock into the plate, they can be inserted at various angles).

Specifically, non-locking screws are secured into bone in the same way that locking screws are, but they are not secured to the plate. Their heads are typically rounded where they contact the bone plate. Thus, one advantage of non-locking screws is that they can be inserted at various angles because they are not limited by the threaded engagement of locking screws with the bone plate. Thus, the use of a non-locking screw to obtain the desired angular orientation is not optimal if the surgeon desires the rigid stable construct of a locking screw and plate.

There have been bone plating systems developed that provide the surgeon with the option of choosing a non-locking or a locking screw. In some embodiments, these systems provide plates with some threaded holes (that may receive either locking screws or non-locking screws) and some non-threaded holes (for non-locking screws). There are also systems that provide partially threaded slots to allow either non-locking or locking screws to be used interchangeably in the same slot. Such combination slots provide surgeons with the intraoperative choice about whether to use the plate with locking screws, non-locking screws, or with a combination of both. These combination slots typically have a partially threaded opening that can receive either a compression screw or a locking screw. However, because these combination slots are only partially threaded, the locking screw(s) may not be able to maintain the fixed angular relationship between the screw(s) and plate under physiological loads. Specifically, the locking screws within the plate are only partially captured and thus only partially surrounded by threads. Under high stress and

loading conditions, the slot may distort and allow the fixed angular relationship between the locking screw and plate to change. This can result in loss of fixation or loss of established intraoperative plate orientation. Moreover, the locking screw can still only be inserted at a single angle -- the predetermined angle defined by the manufacturer.

Additionally, current bone plate and screw systems still limit a surgeon's ability to both (a) lock a fastener with respect to the bone plate, but still (b) allow the fastener to extend from the bone plate at various angles. Locking screws lock into the plate, but only in a single angular configuration, and non-locking screws allow various angle configurations, but they do not provide a stable construct with the plate. Accordingly, none of these options allow a surgeon to capture bone fragments that do not fall in line with the axis of the opening provided on the plate in a rigid fashion. As example of this problem is shown in FIG. 5. Thus, currently available options can still lead to malalignment and poor clinical results.

There have, however, been some attempts to provide polyaxial locking systems. For example, one effort includes providing holes that accept fixed angle locking pegs and multidirectional locking pegs, with a threaded cap inserted over the multidirectional peg to hold it into place. Such a system can be cumbersome to use because although the multidirectional peg can be inserted at any angle, the surgeon then needs to thread a small cap onto the top of the peg head and into the plate, requiring an extra step, extra time, and extra instrumentation. Such systems also fail to allow the use of non-locking members in conjunction with the locking and multidirectional pegs.

Other systems that have attempted to offer polyaxial fixation include providing a bone plate with inserts at the hole peripheries made out of a deformable material, with the remaining part of the plate made of titanium. The plate is manufactured and the inserts are then pushed into the hole peripheries and engaged in place by deformation and pressure. When screws are inserted, the inserts deform and are compressed between the edges of the holes of the plate, which holds the screws and inserts in place. Challenges with such systems are that they cannot be used with non-locking screws, the inserts do not have the strength to receive and hold a regular locking screws, (i.e., they do not provide the surgeon with options), and

plates with deformable inserts are more expensive to manufacture than regular bone plates. Other attempts have failed to provide adequate locking mechanisms.

Accordingly, there exists a need for an improved bone plating system that overcomes the deficiencies of the prior art. There is a need for a system that provides a stable connection between a bone and a bone plate using a fastener that permits different angles to be obtained between the bone plate and the fastener, while the fastener also locks into the bone plate. This would allow surgeons to capture random bone fragments that are in irregular positions, for example, in cases of severe fractures with highly fragmented bone fragments. In these and other cases, it would be advantageous to provide a fastener and plate system that allows the surgeon to choose the angle at which the screw is inserted through, and rigidly affixed in, an opening of the plate.

Such an improvement would allow a surgeon to direct the fastener toward bone fragments that are not necessarily located directly beneath the opening in the plate. It would also provide flexibility in the placement of the plate in relation to the bone fracture. Allowing surgeons to choose the angle at which the fastener is inserted into the plate would lead to better tailoring of the system to the specific nature of the bone fracture to be treated. It would also allow surgeons to adjust their strategy as necessary after the surgical site has been accessed, but prior to insertion of the fastener into bone material. Additionally, in situations where it is desirable to insert a fastener into a plate in a coaxial or polyaxial direction, the embodiments described herein would provide such a secure fit.

BRIEF SUMMARY OF THE INVENTION

Embodiments of the present invention relate to a bone fixation assembly that can provide polyaxial fixation. The polyaxial is fixation may be provided by differing materials interfacing with one another to provide a secure lock. For example, according to one aspect of the invention, there may be provided a polyaxial bone fixation assembly, comprising:

(a) a fastener having a shaft and a head, the head having an outer portion that is at least partially comprised of a first material;

(b) a bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to

the upper surface, wherein a seating surface is formed within the opening, the seating surface being comprised of a second material and wherein the first material is deformable when pressurably engaged with the second material.

According to some embodiments, the first material is polyetheretherketone.

According to other embodiments, the outer portion of the head has a smooth, contoured lower portion.

According to further embodiments, the opening has a central axis and wherein the fastener has a longitudinal axis and wherein when the fastener is inserted into the opening, the axes are not parallel.

According to other embodiments, the fastener head comprises (i) a first portion that is integral with the shaft and (ii) an outer portion that is disposed around the first portion.

According to other embodiments, the outer portion is a ring that is molded or adhered onto the first portion.

According to further embodiments, the outer portion is injection molded onto the first portion.

Other embodiments provide, the fastener shaft comprised one type of material and the fastener head comprised of another type of material that is more deformable than the material of the shaft.

According to other embodiments, the shaft comprises titanium and wherein the head comprises polyethetherketone.

According to other embodiments, the seating surface is an inner surface with an at least partial thread, and wherein when the fastener is inserted into the opening, the first material of the head deforms and locks against the at least partial thread.

Further embodiments provide the fastener head with a curved contour that is non-threaded and wherein the fastener shaft has a feature for engaging bone.

According to other embodiments, the fastener is completely comprised of the first material.

According to a further embodiment, the fastener shaft is comprised of a material that is different from the first material.

According to other embodiments, the bone plate is adapted to contact a femur, a distal tibia, a proximal tibia, a proximal humerus, a distal humerus, a clavicle, a fibula, an ulna, a radius, bones of the foot, or bones of the hand.

Further embodiments provide a kit having a second fastener having a threaded head or (ii) a third fastener having a non-threaded head or (iii) both, wherein the opening in the bone plate is adapted to receive one or more of the fastener of any preceding claim, the second fastener, and/or the third fastener.

Another aspect of the invention provides a polyaxial fastener, comprising a head and a shaft, characterized in that the head comprises a first material and the shaft comprises a second material, wherein the first material of the head is more deformable than the second material of the shaft.

According to another embodiment, the fastener is also provided with a bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, wherein a seating surface is formed within the opening, the seating surface being comprised of a third material, and wherein the first material of the head is deformable when pressurably engaged with the third material of the seating surface.

Other embodiments provide the fastener wherein the first material is polyetheretherketone.

According to other embodiments, the fastener head has an outer lower portion that is a smooth, contoured portion.

According to other embodiments, the fastener head comprises (i) a first portion that is integral with the shaft and (ii) an outer portion that is disposed around the first portion.

According to other embodiments, the outer portion is a ring that is molded or adhered onto the first portion.

Further embodiments provide the outer portion injection molded onto the first portion.

According to other embodiments, the shaft comprises titanium and wherein the head comprises polyethetherketone.

According to further embodiments, the fastener is provided in a kit along with one or more of any combination of

(i) a second fastener having a threaded head;

(ii) a third fastener having a non-threaded head; and

(iii) a bone plate adapted to receive one or more of the polyaxial fastener, the second fastener, and/or the third fastener.

A further aspect of the invention provides a method for implanting one or more of the above-described fasteners. For example, there is provided a method for securing a bone plate to a bone using polyaxial fixation, comprising:

(a) providing a fastener having a shaft and a head, the head having an outer portion that is at least partially comprised of a first material;

(b) providing a bone plate comprised of a second material, the bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, the opening having a seating surface feature;

(c) providing the first material of the fastener head such that the first material is deformable when pressurably engaged with seating surface feature comprised of the second material;

(d) inserting the fastener into the opening of the bone plate; and

(e) securing the bone plate to bone.

Further embodiments include using polyaxial fixation to draw a bone fragment into alignment.

According to other embodiments, a locking screw or a non-locking screw may be inserted into the bone plate.

"Embodiment" as used herein can be considered to mean an aspect or object of the invention, and vice versa.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

FIG. 1 shows a side plan view of a bone fixation assembly according to one embodiment of the invention.

FIG. 2 shows a side plan view of one embodiment of a bone plate opening.

FIG. 3 shows a top perspective view of a bone plate opening according to alternate embodiment.

FIG. 4 shows a further embodiment of a bone plate for use with various fasteners .

FIG. 5 shows an example of a fracture that may be treated with various embodiments of the invention.

FIG. 6 shows examples of alternate bone plate shapes that may incorporate various embodiments of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention provide polyaxial locking systems and methods that offer polyaxial fixation of fasteners within bone fixation systems. The polyaxial fasteners are adapted to be inserted into a bone plate at any angle and achieve a rigid construct with the plate (or otherwise "lock" into the plate). They may be used with any type of bone plate having any shape and size. For example, embodiments of this invention may be used with bone plates that are adapted to contact a femur, a distal tibia, a proximal tibia, a proximal humerus, a distal humerus, a clavicle, a fibula, an ulna, a radius, bones of the foot, or bones of the hand. The bone plate may be curved, contoured, straight, or flat. It may be a periarticular plate or a straight plate. It may have a head portion that is contoured to match a particular bone surface, such as a metaphysis or diaphysis, flares out from the shaft portion, that forms an L-shape, T-shape, Y-shape, with the shaft portion, or that forms any other appropriate shape to fit the bone to be treated. Non-limiting examples of potential bone plates for use with the embodiments of the invention described herein are shown in FIG. 6. An example of only one type of bone plate is shown in FIG. 4, and described more below, although it should be understood that the embodiments described herein are intended for use on all potential bone plates, including those shown in FIG. 6.

FIG. 1 shows a bone fixation assembly 100 comprising a bone plate 102 and a fastener 10. Fastener 10 is adapted to be inserted into one of openings 110 in bone plate in polyaxial fashion, meaning that can be inserted at multiple, variable angles. (Although FIG. 1 shows only one opening 110 in bone plate 102, it is understood that any number of openings may be provided, as shown in FIGS. 4-6.) Openings 110 of bone plate 102 extend from a bone contacting surface 106 to an upper surface 108 and have a seating surface 120 that is shown as formed of a thread 114. Seating surface 120 may be a thread 114 that is a continuous ridge or a non-continuous ridge. It may comprise a portion of a revolution, one complete

revolution, multiple revolutions, a single lead, or multiple leads, or any other threads known in the art. Additionally or alternatively, seating surface 120 may be a series of dimples, ridges, bumps, textured areas, or any other surface that can grasp and secure fastener 10 as described herein. For the sake of reference, opening 110 is shown having a central axis 118.

Fastener 10 has a shaft 12 and a head 30. The shaft 12 may be threaded or otherwise configured to engage bone. It may be fully threaded, partially threaded, comprise a helical blade, and/or may comprise one or more tacks, deployable talons, expanding elements, or so forth. Any feature that allows shaft 12 to engage bone is considered within the scope of this invention and may be referred to generally as a "threaded shaft" for the sake of convenience. For the sake of reference, shaft 12 is also shown having a longitudinal axis 16 that extends from tip 18 of fastener 10 to the head 30. The tip 18 of shaft 12 may be a self-tapping or self-drilling tip.

Additionally, in an alternative embodiment, shaft 12 is not threaded, and fastener 10 takes the form of a peg or a pin. This alternative embodiment may be useful in certain procedures where, for instance, the main goal is to prevent tilting of a bone segment, or in procedures where there is no concern of fastener 10 pulling out from the bone and hence no need for shaft 12 to be threaded or otherwise configured to engage bone.

Head 30 of fastener has a receiving bore 32 that allows it to receive a driver or other instrument that can be used to position fastener 10. Bore 32 may be any size and shape. For example, it may have a hexagonal configuration to receive a corresponding hexagonal driver. Other options include a Phillips screw head, a flat-head, a star configuration, Torx, or any other appropriate configuration that can cooperate with a driver to place fastener 10.

Additionally, at least a portion of the head 30 of fastener 10 is comprised of a material that is more deformable than the material of bone plate 102. For example, bone plate 102 may be comprised of titanium, stainless steel, cobalt chrome, combinations or alloys thereof, or any other appropriate material that has sufficient strength to be secured to and hold bone, while also having sufficient biocompatibility to be implanted into a body. Although the above list of materials includes the typical materials out of which bone plates are made, it should be understood that the plate 102 may also be comprised of plastics -- such as polyetheretherketone (PEEK),

polyethylene, ultra high molecular weight polyethylene (UHMWPE), or a carbon composite -- resorbable polylactic acid (PLA), polyglycolic acid (PGA), combinations or alloys of such materials or any other appropriate material.

By contrast, at least a portion of head 30 is comprised of a material that is deformable when pressurably engaged with bone plate 102, and specifically, when engaged with the seating surface 120 of bone plate. Although bone plate is typically comprised of the same material or material alloy throughout, it is possible that it may be comprised of more than one material. In such a case, it is understood that the portion of the bone plate material being referred to here is the material of the seating surface 120, the portion of the plate 102 that mates with head 30 of fastener 10 in use.

Potential materials for the at least a portion of the head 30 that is comprised of a deformable material may be plastic -- such as polyetheretherketone (PEEK), polyethylene, ultra high molecular weight polyethylene (UHMWPE), or a carbon composite -- resorbable polylactic acid (PLA), polyglycolic acid (PGA), combinations or alloys of such materials or any other appropriate material that has sufficient strength to secure fastener 10 into place in bone plate 102, but that also has sufficient deformability upon the application of pressure that it will deform and seat into seating surface 120. Although the above list of materials includes certain materials out of which fastener may be made, in other embodiments, fastener 10 may be comprised of titanium, stainless steel, cobalt chrome, or combinations or alloys thereof.

As described, the material of the fastener head 30 (or at least a portion of the head 30) is comprised of material that is more deformable than the material of seating surface 120. For example, if head 30 and plate 102 are both comprised of stainless steel, the steel used to manufacture head 30 should be more deformable (or softer or otherwise more apt to be at least partially deformed upon pressure) than the steel used to manufacture plate 102. Various types steel (and the other materials described above) having the desired characteristics are known in the art.

In a specific embodiment, fastener head 30 is comprised of a first portion 38 and an outer portion 40. These two portions may be comprised of the same or different materials. For example, if they are comprised of different materials, first portion may be an extension of or integral with shaft 12, as shown in FIG. 1. Shaft

12 may be comprised of any appropriate material described above. If shaft 12 and head 30 are comprised of different materials, at least the outer portion 40 of head should be of a material that is deformable when pressed against seating surface 120 of plate 102. For example, the shaft 12 may be comprised of titanium or stainless steel, and the outer portion 40 may be comprised of PEEK or some other more deformable material. This allows the shaft 12 of fastener 10 to have a high strength, while also providing a ring or other outer portion 40 on head 30 that allows fastener 10 to be inserted into a plate in polyaxial fashion.

In certain embodiments, outer portion 40 of head 30 is disposed around first portion 38 and may be formed by injection molding, by adhering a ring 42 onto first portion 38, or by any other appropriate manufacturing method. This outer portion 40 (which, in some embodiments is ring 42) is comprised of a material that is deformable when it is pressed against the material of plate, and specifically, against the material of seating surface 120. In another embodiment, the entire fastener 10 (including the shaft 12 and the head 30) is comprised out of the deformable material.

Although shown as a ring 42, outer portion 40 may comprise a washer, a spherical or non-spherical (e.g., hemi-spherical) head, a cap, a conical portion, a tapered ring, or any other appropriate configuration.

Also, as shown, outer portion 40 may have a lower portion 44 with a smooth, curved contour 34. However, outer portion 40 may have any desired configuration or shape or texture. For example, outer portion 40 may be curved, conical, or jagged or any other shape. It may have horizontal ridges, dimples, bumps, a textured surface, a rough surface, or a blasted finish. In short, it may curved and smooth, or smooth but not curved, or curved but not smooth.

If smooth and/or curved, the surface can help to allow fastener 10 to be inserted into opening 110 at any angle. In a certain embodiments with a curved contour, the curved contour 34 can be moved or rotated in seating surface 120 to any desired angle, as shown by α in FIG. 1. This helps to provide ease of angular positioning and the benefits of a non-locking screw. In other words, when the fastener 10 is inserted into the opening 110, the central axis 118 of the opening and the longitudinal axis 16 of the fastener may form axes that are not parallel to one another, as shown. Once the surgeon has fastener 10 positioned at the desired angle, pressure against head 30 causes the outer portion 40 of head 30 to deform so

that outer portion 40 seats itself against seating surface 120. This allows the longitudinal axis 16 of shaft to be angled at any number of configurations or angles (α) with respect to the central axis 118 of opening 110. This provides the benefits of a locking screw, because fastener 10 and bone plate 102 are provided as a single, rigid construct.

As shown in FIG. 2, opening 110 of bone plate 102 may have multiple threads 114. Opening 110 may also have a slight taper so that its circumference is smaller toward the bone contacting surface 106 than it is at the upper surface 108.

In an alternate embodiment shown in FIG. 3, bone plate 102 may have a seating surface 120 that has cutting flutes 122. Flutes 122 are shown as provided as four small indents 124 (although they may be provided in any number) in threads 114. Flutes 122 give a sharp edge 126 to the threads 114 so that threads can engage head 30 more easily as it is being inserted into opening 110. Flutes may have rounded backs 128 where they meet with plate 102 (as shown) or they may be any other appropriate shape or size. Flutes may also be provided in an odd or even number, as few as one or two, or as many as desired to provide the cutting and securing function desired.

As shown in FIG. 4, in addition to openings 110, there may also be provided openings 130 and 132. Openings 130 are non-threaded and are adapted to receive non-locking screws (although, as discussed above, some non-locking screws may be received by a threaded or partially threaded opening 110). As shown, openings 110 and 130 are intended to receive any type of fastener, whether locking screws 50, non-locking screws 52, or fasteners 10. Openings 132 are adapted to receive provisional fixation pins, pegs, or K-wires. Provisional fixation of a bone plate to the bone allows the surgeon to temporarily fix the plate to the bone without the use of clamps or similar tools. In this way, the surgeon may place the bone plate in the proper position before inserting all of the fasteners into the bone plate and bone, while at the same time keeping excess instruments, such as clamps, out of the field of view of the surgeon. This makes placement of the plate easier and faster. It also allows for higher quality x-rays of the bone and bone plate construct during surgery.

One of the benefits of various embodiments of the invention is that they allow the bone plate to be used with a plurality of fasteners. For example, in addition to the polyaxial fasteners 10 described, the bone plate may also be used with regular

locking and/or non-locking fasteners, in order to give the surgeon enhanced options. For example, the embodiments can be provided as a kit, having one or more various bone plates, one or more polyaxial fasteners 10, and/or one or more locking fasteners (with a threaded head), and/or one or more non-locking fasteners (with a non-threaded head), wherein one or more openings in the bone plate are adapted to receive one or more of the polyaxial fastener 10, a locking fastener or a non-locking fastener.

Turning now to the methods of implantation, the surgeon accesses the surgical site of interest, which can be an internal site at which a bone fracture is located that requires stabilization to ensure proper healing. The fracture may be reduced with conventional forceps and guides (which are known to those in the art), and a bone plate of appropriate size and shape is placed over the fracture site. In some instances, the bone plate may be temporarily secured to the bone using provisional fixation pins. In the bone plates shown in FIGS. 4 and 6, provisional fixation pins may be used through either the pinholes 132 or the openings 110 or any other opening (threaded or non-threaded) in the plate. Provisional fixation provides for temporarily securing the bone plate to the bone before placing fixation screws through the bone plate, so that one can be certain the bone plate is properly positioned before placing bone screws for permanent fixation of the bone plate to the bone. Moreover, with provisional fixation, x-rays can be taken of the bone plate/construct without excess instruments in the field of view.

Once the plate 102 is secured at a desired location in relation to the fracture (typically using one or more provisional fixation pins, although any other appropriate method may be used), the surgeon then identifies an insertion angle, or the direction along which fastener 10 is to be inserted through a selected opening 110 and driven into bone material. If bone plate 102 includes more than one opening, as shown in FIGS. 4 and 6, the surgeon also selects the specific opening to be used. After selecting the desired insertion angle and opening, the surgeon inserts shaft 12 of fastener 10 through opening 110 until the tip 18 contacts bone material. In some cases, a hole may need to be drilled or tapped into the bone along the insertion angle to facilitate the initial tapping or insertion of fastener 10. The surgeon then uses an appropriate driving tool in the receiving bore 32 of head 30 to manipulate the fastener 10 into place, and to apply pressure against seating surface 120.

Because fastener 10 may be inserted at angles other than the aligned with the central axis 118 of the opening 110, fastener 10 may be used to grab or secure bone fragments that are out of line with the traditional angle at which a locking screw would normally be inserted. The surgeon may need to toggle or maneuver the fastener in order to secure and draw in displaced bone fragments.

Once the bone fragment is secured, the fastener 10 is ready to be secured to the plate 102. As fastener 10 is driven further into bone so that shaft 12 engages bone (if appropriate), fastener 10 is drawn further into plate and the material of the outer portion 40 of head 30 deforms and anchors into place in the seating surface 120. This rigidly affixes fastener 10 to the bone plate 102 at the desired insertion angle. In some embodiments, the surgeon may then use traditional locking and/or non-locking screws in other openings on plate. This can help further secure the bone plate to the bone fracture if needed. One advantage of opening 110 is that it is adapted to receive any one of a polyaxial fastener 10, a locking screw, or a non-locking screw.

In some instances, once all fasteners and/or screws are placed, the surgeon may place covers over the unused openings, particularly if there are any unused openings that cross the fracture in order to strengthen the plate 102. Additionally or alternatively, the surgeon may use bone graft material, bone cement, bone void filler, and/or any other material to help heal the bone.

Specifically, the method may include

(a) providing a fastener having a shaft and a head, the head having an outer portion that is at least partially comprised of a first material;

(b) providing a bone plate comprised of a second material, the bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, the opening having a seating surface feature;

(c) providing the first material of the fastener head such that the first material is deformable when pressurably engaged with seating surface feature comprised of the second material;

(d) inserting the fastener into the opening of the bone plate; and

(e) securing the bone plate to bone.

The foregoing description of exemplary embodiments of the invention has been presented only for the purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations to the structures and methods recited above and shown in the drawings are possible without departing from the scope or spirit of the above disclosure and the following claims. The embodiments were chosen and described in order to explain the principles of the invention and their practical application so as to enable others skilled in the art to make and utilize the invention and various embodiments and with various modifications as are suited to the particular use contemplated. Alternative embodiments will become apparent to those skilled in the art to which the present invention pertains without departing from its spirit and scope.

What is claimed is:

1. A polyaxial bone fixation assembly, comprising:

(a) a fastener having a shaft and a head, the head having an outer portion that is at least partially comprised of a first material;

(b) a bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, wherein a seating surface is formed within the opening, the seating surface being comprised of a second material and wherein the first material is deformable when pressurably engaged with the second material.

2. The polyaxial bone fixation assembly of claim 1, wherein the first material is polyetheretherketone.

3. The polyaxial bone fixation assembly of claim 1 or 2, wherein the outer portion of the head has a smooth, contoured lower portion.

4. The polyaxial bone fixation assembly of any preceding claim, wherein the opening has a central axis and wherein the fastener has a longitudinal axis and wherein when the fastener is inserted into the opening, the axes are not parallel.

5. The polyaxial bone fixation assembly of any preceding claim, wherein the fastener head comprises (i) a first portion that is integral with the shaft and (ii) an outer portion that is disposed around the first portion.

6. The polyaxial bone fixation assembly of claim 5, wherein the outer portion is a ring that is molded or adhered onto the first portion.

7. The polyaxial bone fixation assembly of claim 6, wherein the outer portion is injection molded onto the first portion.

8. The polyaxial fixation assembly of any preceding claim, wherein the fastener shaft comprises one type of material and the fastener head comprises another type of material that is more deformable than the material of the shaft.

9. The polyaxial fixation assembly of claim 8, wherein the shaft comprises titanium and wherein the head comprises polyetheretherketone.

10. The polyaxial bone fixation assembly of any preceding claim, wherein the seating surface is an inner surface with an at least partial thread, and wherein when the fastener is inserted into the opening, the first material of the head deforms and locks against the at least partial thread.

11 The polyaxial bone fixation assembly of any preceding claim, wherein the fastener head has a curved contour that is non-threaded and wherein the fastener shaft has a feature for engaging bone.

12. The polyaxial bone fixation assembly of any preceding claim, wherein the fastener is completely comprised of the first material.

13. The polyaxial bone fixation assembly of any preceding claim, wherein the fastener shaft is comprised of a material that is different from the first material.

14. The polyaxial bone fixation assembly of any preceding claim, wherein the bone plate is adapted to contact a femur, a distal tibia, a proximal tibia, a proximal humerus, a distal humerus, a clavicle, a fibula, an ulna, a radius, bones of the foot, or bones of the hand.

15. The polyaxial bone fixation assembly of any preceding claim, wherein the bone plate has one or more of the following features:

(a) contoured or flat;

(b) straight or periarticular;

(c) a head that flares out to form an L-shape, T-shape, or Y-shape; or

(d) any combination thereof.

16. The polyaxial bone fixation assembly of any preceding claim, further comprising a kit with (i) a second fastener having a threaded head or (ii) a third fastener having a non-threaded head or (iii) both, wherein the opening in the bone plate is adapted to receive one or more of the fastener of any preceding claim, the second fastener, and/or the third fastener.

17. A polyaxial fastener, comprising a head and a shaft, characterized in that the head comprises a first material and the shaft comprises a second material, wherein the first material of the head is more deformable than the second material of the shaft.

18. The polyaxial fastener of claim 17, further comprising a bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, wherein a seating surface is formed within the opening, the seating surface being comprised of a third material, and wherein the first material of the head is deformable when pressurably engaged with the third material of the seating surface.

19. The polyaxial fastener of claims 17 or 18, wherein the first material is polyetheretherketone.

20. The polyaxial fastener of any of claims 17-19, wherein the fastener head has an outer lower portion that is a smooth, contoured portion.

21. The polyaxial fastener of any of claims 17-20, wherein the fastener head comprises (i) a first portion that is integral with the shaft and (ii) an outer portion that is disposed around the first portion.

22. The polyaxial fastener of claim 21, wherein the outer portion is a ring that is molded or adhered onto the first portion.

23. The polyaxial fastener of claim 21, wherein the outer portion is injection molded onto the first portion.

24. The polyaxial fastener of any of claims 17-23, wherein the shaft comprises titanium and wherein the head comprises polyetheretherketone.

25. The polyaxial fastener of any of claims 17-24, wherein the fastener is provided in a kit along with one or more of any combination of

(i) a second fastener having a threaded head;

(ii) a third fastener having a non-threaded head; and

(iii) a bone plate adapted to receive one or more of the polyaxial fastener, the second fastener, and/or the third fastener.

26. A method for securing a bone plate to a bone using polyaxial fixation, comprising:

(a) providing a fastener having a shaft and a head, the head having an outer portion that is at least partially comprised of a first material;

(b) providing a bone plate comprised of a second material, the bone plate comprising a bone contacting surface, an upper surface, and at least one opening extending from the bone contacting surface to the upper surface, the opening having a seating surface feature;

(c) providing the first material of the fastener head such that the first material is deformable when pressurably engaged with seating surface feature comprised of the second material;

(d) inserting the fastener into the opening of the bone plate; and

(e) securing the bone plate to bone.

27. The method of claim 26, wherein the inserting the fastener into the opening in the bone plate step (d) further comprises using polyaxial fixation to draw a bone fragment into alignment.

28. The method of claims 26 or 27, further comprising inserting a locking screw or a non-locking screw into the bone plate.

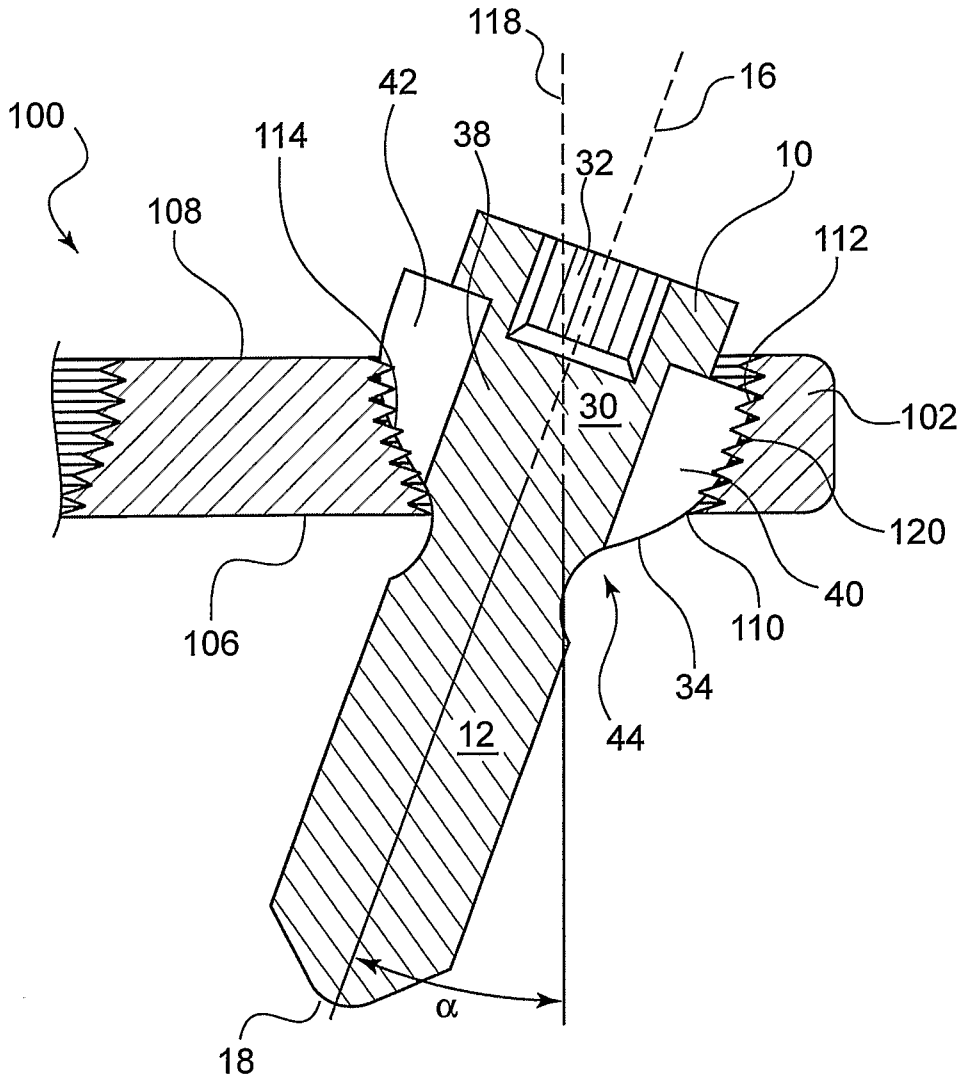

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FIG. 1

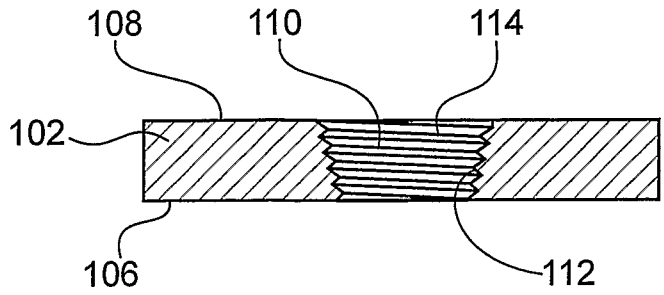


FIG. 2

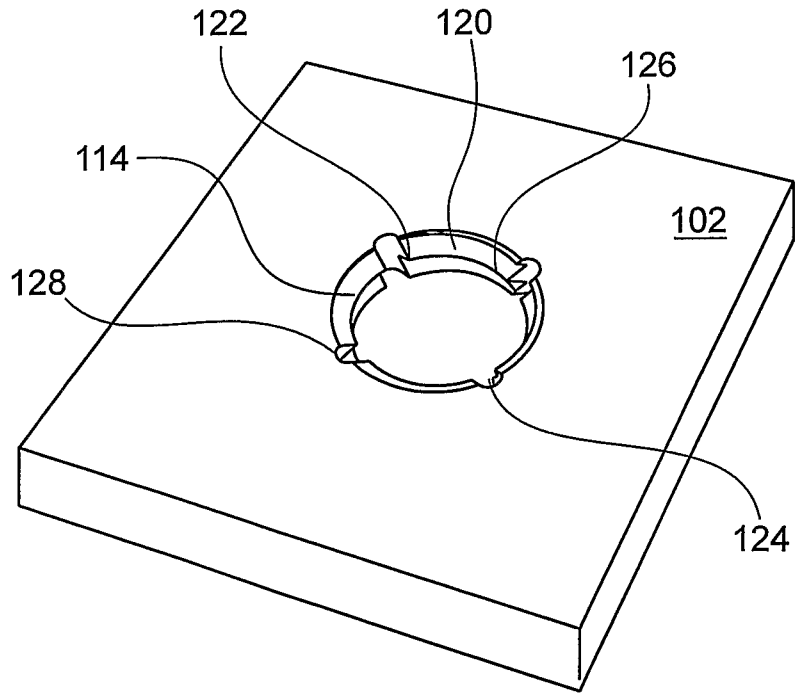


FIG. 3

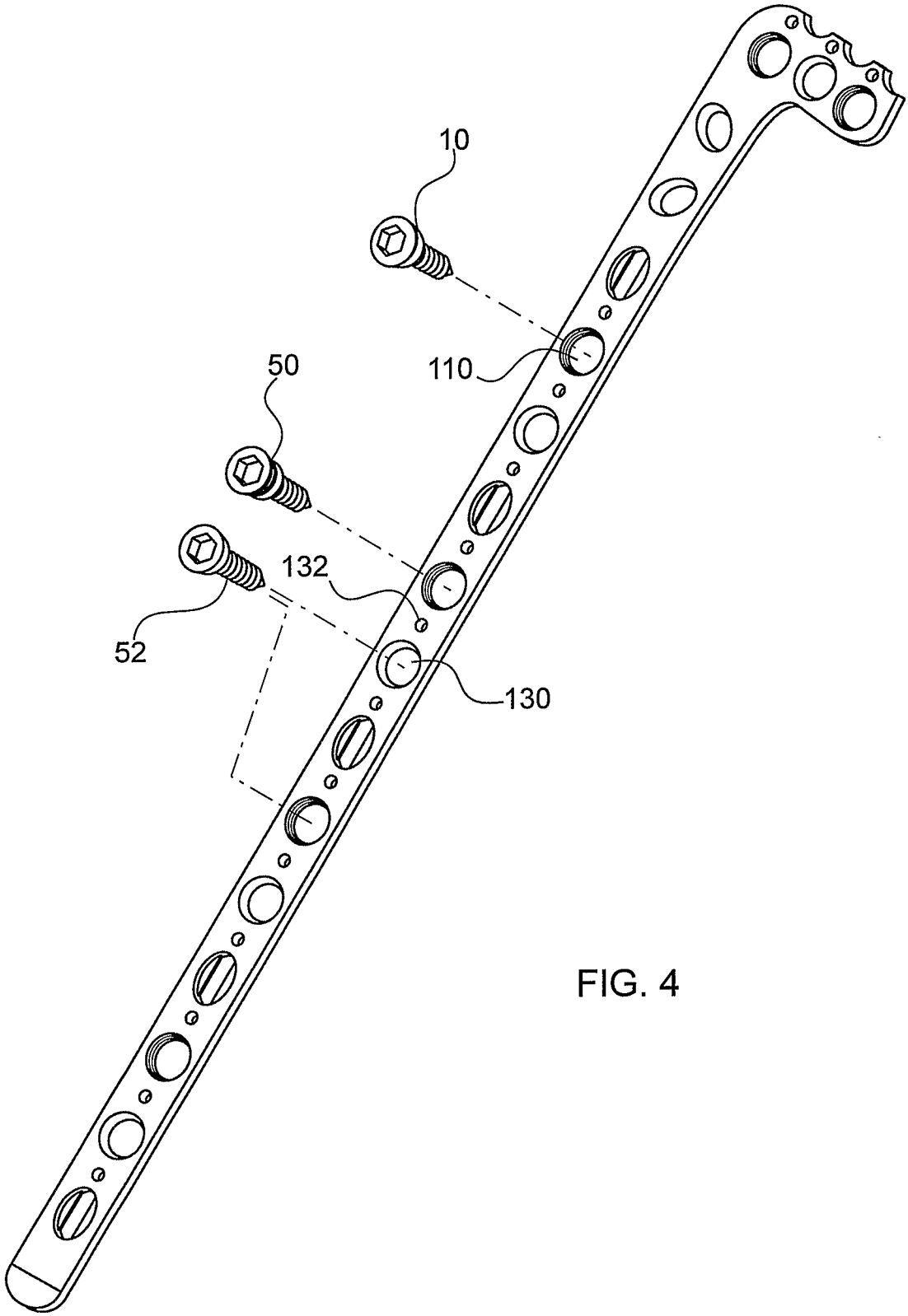


FIG. 4

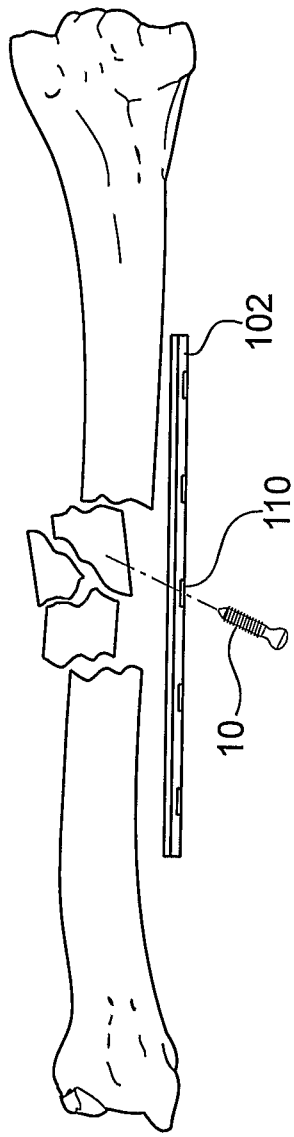


FIG. 5

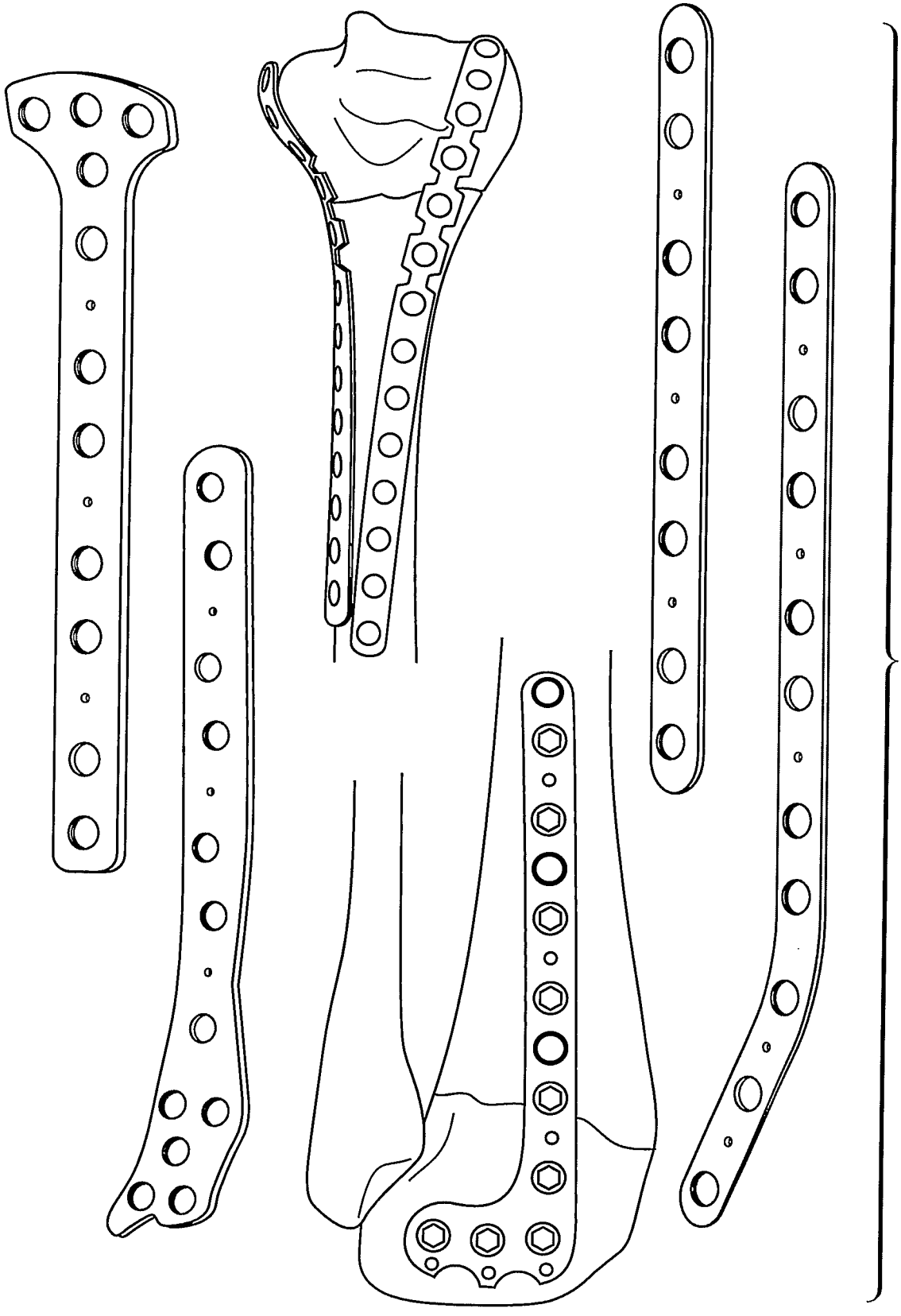


FIG. 6