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(54) Title: SYSTEMS AND METHODS FOR USING POLYAXIAL PLATES

(57) Abstract: Embodiments of the present invention provide a bone fixation assembly that can provide polyaxial fixation. The polyaxial fixation may be provided by fins that protrude from an opening in a bone plate or fins that protrude from a fastener head.



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SYSTEMS AND METHODS FOR USING POLYAXIAL PLATES

This application claims the benefit of U.S. Provisional Application Serial No. 60/702,231 filed July 25, 2005 titled "Locking Screw," the entire contents of which is
5 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
10 for using bone plates that provide polyaxial fixation of fasteners.

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
15 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
20 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
25 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.

30 However, although 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 severe fracture, fragments may be shattered and in irregular positions. Although a surgeon may wish to obtain the benefits of a locking screw and bone plate used together, the angle at which the locking screw extends from the plate at a certain opening may not be the angle that would allow the surgeon to "grab" (or seize, or otherwise secure) the desired, random bone fragment. In this case, the surgeon may need to secure the plate to the bone somewhere else, or use a non-locking screw. 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 thread-to-thread contact of locking screws with the bone plate. However, if the surgeon desires the rigid stable construct of a locking screw and plate, the use of a non-locking screw to obtain the desired angular orientation is not necessarily optimal.

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 with 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 together. 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. 21. 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.

Another attempt at polyaxial fixation includes a plate with holes that have an internal jacket with recesses that extend away from the axis of the hole or into the internal jacket surface. This attempt is described in International Application WO 2005/018472, titled Bone Plate. The internal jacket surface of the plate described in that application is threaded or has ribs or protuberances. A bone screw is intended to be pulled into the hole of the plate by the internal jacket surface. If the bone screw head is threaded, when the screw is inclined, the threaded head is intended to "jump over" the pitches of the threads in the hole of the plate interrupted by the recesses, without "cutting through" them. The goal of the invention is provide a bone plate that can have bone screws introduced at an angle that is different from the specified axis of the hole and secured into position.

However, some of the problems encountered by this attempted solution are that (1) threaded openings in bone plates typically require the plate to be of a certain thickness and thus, do not lend themselves to use with a thin plate, (2) threaded openings can be difficult and more expensive to manufacture than non-threaded openings in a bone plate, and (3) threaded openings can take more effort in use because the surgeon needs to have the appropriate alignment for use. Moreover, the threads of this application are short because they are interrupted by the recesses so it is likely that a fastener will not actually "grab" the threads to get good engagement.

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 fixation may be provided by fins that protrude from an opening in a bone plate or fins that protrude from a fastener head. For example, according to one aspect of the invention, there may be provided a polyaxial bone fixation assembly comprising

- (a) a bone plate comprising a lower surface, an upper surface and at least one opening extending from the lower surface to the upper surface;
- (b) a fastener that is insertable through the opening; and
- (c) at least one member of co-operation between the opening and the fastener comprising a plurality of protruding fins located within the opening or on the fastener.

In a specific aspect or embodiment, the opening has a non-threaded inner surface and wherein the fins are located on the inner surface.

Further embodiments have fins that are a series of concavely indented, inwardly protruding fins that are adapted to secure a threaded head of a fastener in place at varying angles.

According to a further embodiment, the opening is further defined by a round circumference at the upper surface and a jagged circumference formed by the protruding fins at the lower surface.

According to a further embodiment, the protruding fins form a concave portion of the inner surface.

According to an even further embodiment, the protruding fins have bases that meet the inner surface in substantially the same plane.

According to another embodiment, the fastener has a threaded head adapted to engage with the protruding fins.

Another embodiment provides fins that have a tapered shape, a straight shape, a rectangular shape, or a triangular shape.

5 A further embodiment provide a bone plate with the opening located on the head.

In further specific aspect or embodiment, the fastener has a head with fins, wherein the fins are adapted to cooperate with threads in a bone plate.

10 According to another embodiment, the fins are provided in more than one layer.

Another embodiment provides the opening in the bone plate with one or more rectangular threads.

15 In a further embodiment, the fins are trapezoidally-shaped, rounded, oval, rectangular, curved, rhomboid, diamond-shaped, or triangular. The fins may also have the edges of fins taper inwardly, outwardly, or are about parallel with one another.

According to a further embodiment, 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.

20 Further embodiments have a bone plate with one or more of the following features:

- (a) contoured, straight, or flat;
- (b) a head portion that is contoured to match a particular bone surface;
- (c) a head that flares out to form an L-shape, T-shape, or Y-shape; and
- 25 (d) any combination thereof.

Other embodiments provide the bone plate with one or more of the follow openings:

- (a) a threaded opening;
- (b) a non-threaded opening;
- 30 (c) an opening adapted to receive locking or non-locking fasteners;
- (d) a combination slot; or;
- (e) any combination thereof.

Other aspects of the invention also provide methods for securing a bone plate to a bone using polyaxial fixation. For example, one aspect provides a method for securing a bone plate to a bone using polyaxial fixation, comprising:

- (a) providing a bone plate comprising a lower surface, an upper surface, and at least one opening extending from the lower surface to the upper surface, the opening having a non-threaded inner surface with one or more protruding fins located on the inner surface;
- (b) providing a fastener having a shaft and a head, the head having at least one set of threads adapted to cooperate with the protruding fins;
- (c) inserting the fastener into the opening of the bone plate and allowing the at least one set of threads to engage the fins of the plate; and
- (d) securing the bone plate to bone.

Another aspect provides a method for securing a bone plate to a bone using polyaxial fixation, comprising:

- (a) providing a bone plate comprising a lower surface, an upper surface, and at least one opening extending from the lower surface to the upper surface; the opening having one or more threads;
- (b) providing a fastener having a shaft and a head, the head having at least one set of fins adapted to cooperate with threads of the plate;
- (c) inserting the fastener into the opening of the bone plate and allowing the one or threads to engage the fins of the fastener head; and
- (d) securing the bone plate to bone.

Embodiments of the above aspects include using polyaxial fixation to draw a bone fragment into alignment.

Another embodiment includes inserting a locking screw or a non-locking screw 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 perspective view of a bone plate having fins according to one embodiment of the invention with a fastener inserted therein.

FIG. 2 shows a top perspective view of an opening in a bone plate according to one embodiment of the invention.

FIG. 3 shows a top view of a bone plate having multiple openings, with a fastener inserted therein.

5 FIG. 4 shows an underneath view of the bone plate of FIG. 3.

FIG. 5 shows a side perspective view of a bone plate with fasteners inserted therein to illustrate a few of the multiple angles at which the plate can receive a fastener.

10 FIG. 6 shows an example of a fastener for use with various bone plates described herein.

FIG. 7 shows a top plan view of an alternate embodiment of an opening in a bone plate.

FIG. 8 shows a perspective view of the bone plate of FIG. 7.

15 FIG. 9 shows a top plan view of a further embodiment of an opening in a bone plate.

FIG. 10 shows a perspective view of the bone plate of FIG. 9.

FIGS. 11- 15 show alternate shapes and types of bone plates that may be used with various embodiments of this invention.

20 FIG. 16 shows a cross-section view of an alternate embodiment having a finned fastener in place in a bone plate.

FIG. 17 shows a side perspective view of a fastener having a finned head according to one embodiment of the invention.

FIG. 18 shows a top perspective view of the fastener of FIG. 17.

25 FIG. 19 shows a top perspective view of a bone plate that may be used to receive the fastener of FIGS. 17 and 18.

FIG. 20 shows a cross-section of the threads of the plate of FIG. 19.

FIG. 21 shows an example of a fracture that may be treated with various embodiments of the invention.

30 **DETAILED DESCRIPTION OF THE INVENTION**

Embodiments of the present invention provide a bone fixation assembly that can accept and fix fasteners at a plurality of angles. A specific embodiment of a bone fixation assembly 10 is shown as a bone plate 12 and fastener 80 in FIG. 1. As

shown in more detail in FIGS. 2-4, bone plate 12 has a lower surface 14 and an upper surface 16 and one or more openings 18 that extend from the lower surface 14 to the upper surface 16.

The embodiments described herein may be used in connection with any type of bone plate, non-limiting examples of which are shown in FIGS. 11-15. Plate 12 may be adapted to contact one or more of 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. An example of a straight plate is shown in FIG. 11. Plate 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. An example of a T-shaped plate is shown in FIGS. 12-15, the openings on the plates in those figures are described in more detail below.

Bone plate 12 may be comprised of titanium, stainless steel, cobalt chrome, 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 be secured to and hold bone, while also having sufficient biocompatibility to be implanted into a body. Although the above list of materials includes many typical materials out of which bone plates are made, it should be understood that bone plates comprised of any appropriate material are within the scope of this invention.

Opening 18 of plate 12 is shown having a central axis 20, and it is adapted to receive a fastener. The fastener may be any typical, standard locking fastener or a non-locking fastener, although the embodiments described herein are intended for particular use with locking fasteners that have a series of threads on their heads. FIGS. 5-6 show examples of fastener 80 that may be used in accordance with embodiments of this invention. As shown specifically in FIG. 6, fastener 80 has a shaft 82 and a head 84. Shaft 82 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 82 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. It is also possible, however, that shaft 82 is not threaded, so that fastener 80 takes the form of a peg or a pin. This alternative embodiment may be preferred 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 80 pulling out from the bone and hence no need for shaft 82 to be threaded or otherwise configured to engage bone. For the sake of reference, shaft 82 is also shown having a longitudinal axis 86. The end of shaft 82 may be a self-tapping or self-drilling tip, as shown in more detail in FIG. 5.

The head 84 of fastener 80 preferably has at least one set of threads 88. Threads 88 are typically any standard-type thread. For example, the threads 88 may be 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, head 84 of fastener 80 may include any other surface that will engage with and seat within specific features of plate (described further below). For example, head 84 may have a series of dimples, ridges, bumps, textured areas, or any other surface that can secure fastener 80 as described herein. As will be described in more detail below, threads 88 of head are adapted to engage, associate with, or otherwise cooperate with fins 24 of opening 18. In short, any type of threaded fastener head is intended for use with various embodiments of this invention.

Referring to FIG. 2, it can be seen that the embodiment shown has an opening 18 with an inner surface 22 that is defined by a series of concavely indented, inwardly protruding fins 24. Fins 24 extend into opening 18 toward central axis 20. The bases 26 of fins 24 form a concave portion 28 at or near a round circumference 30 of upper surface 16. (The term "round" circumference is intended to refer to any round shape, such as a circle, an oval, an egg-shaped circumference, or any other opening shaped to receive the head of a fastener 80.) The bases 26 of the fins 24 may all meet in substantially the same plane and then angle downwardly and inwardly at a similar angle or slope.

It bears noting that the concave portion 28 is smooth and non-threaded. In fact, there are not any threads on concave portion 28 or anywhere on inner surface

22 of opening 18. The lack of threads helps ease the manufacturing of plate 12, and allows plate be manufactured as thinly as desired.

For example, the thickness of plate 12 and the dimensions of fins 24 are typically dependent upon the pitch and threads of fastener 80. For example, a larger plate 12 for use with a larger fastener (e.g., for use on a femur bone) will likely be thicker and will have larger and thicker fins than a smaller plate (e.g., for use on a smaller bone). In specific embodiments, the fins 24 are particularly thin so that they can be moved up or down and deformed upon pressure. In some embodiments, the fins may be pressed toward the edges of the plate opening. A non-limiting exemplary range of thicknesses for fins may be from about 0.5 mm to about 5 mm, although larger and smaller sizes are possible. In theory, the fins 24 are intended to fit between crimps on the threadform of fastener 80, as shown in FIG. 1.

Providing a non-threaded inner surface 22 also allows the fastener 80 to be inserted into opening 18 at any desired angle, because there are not any threads to interfere with the desired angle, as illustrated by FIG. 5. The fins 24 are intended to slightly bend or deform in order to secure the fastener 80 in place in opening 18. Fins 24 actually engage threads 88 or other surface of fastener 10.

Referring back to FIG. 2, in the embodiment shown, as fins 24 extend toward central axis 20, they taper to form tapered sides 32. The fins end at rounded tip 34, although tips 34 can be pointed, square, rectangular, or any other appropriate configuration. For example, as shown in FIGS. 7 and 8, fins 24 may have straight edges or sides 42 and straight ends 44. This embodiment shows fins 24 that are partially rectangular-shaped. The openings 46 between fins 24 are slit-shaped.

An alternate embodiment is shown in FIGS. 9 and 10, which illustrate fins 24 with a more triangular shape. In this embodiment, fins 24 are shown having sides 52 that taper inwardly and edges 54 that are flat and small, forming the apex area 56 where sides 52 come to an end. Openings 58 between fins 24 are more elongated than openings 46. Both sets of openings 46, 58 in these alternate embodiments are shown having rounded backs 60, where they meet inner surface 22 of opening 18. It should be understood however, that these are merely examples of fin 24 shapes and openings 46, 58 and that any appropriate shapes are possible and considered within the scope of this invention. Non-limiting examples include trapezoidal, square,

round, circular, triangular (with a pointed tip instead of apex area 56), and any other possible option.

As shown in FIG. 4, a second circumference 36 at the lower or underneath surface 14 of plate 12 may appear to be more jagged than the round circumference 30 at the upper surface 16 due to the fins 24 forming a portion of lower surface 14. The circumference can appear almost "flower-like" – each fin 24 appears to form a petal of the circumference. Alternatively, for the embodiments of FIGS. 7-10, the second circumference will appear similar to the shape created by fins 24.

Although the figures show an opening 18 with about five to eight fins 24, it should be understood that any number of fins 24 is considered within the scope of this invention. For example, there may be two or three fins, or ten or twenty or more fins 24, depending upon the plate for which the opening 18 is intended for use.

The primary purpose of fins 24 is to grasp one or more threads 88 of a threaded head fastener in order to secure the fastener in place in the bone plate 12, but at any angle. For example, as opposed to threaded openings (which engage the threads of the head of the fastener in one way only, limiting the surgeon's ability to angle the fastener as desired), the fins 24 of this embodiment are still intended to secure the threads of the head of fastener in place, but at any angle. As the fastener is inserted, its threads start to engage the fins 24, as shown in FIG. 1. As discussed above, the fins 24 may be very thin so that as the head threads 88 start to grab fins 24, the fins 24 may move up or down as appropriate to engage the threads 88 and secure the fastener 80. In short, the threads 88 engage fins 24 (or fit in between fins 24). In most cases, this movement of fins 24 is a permanent deformation, so that the fins cannot flex back and allow the fastener to work its way out.

As discussed above, finned openings 18 may be provided on all types of bone plates, examples of which are shown in FIGS. 11-15. FIG. 11 shows a specific example of an opening 18 with fins 24 (referred to as a finned opening 18), a smooth opening 60, a threaded opening 62, and a provisional pin opening 64. Other options are holes that can be used with either a threaded or non-threaded fastener, as well as combination slots. It should be understood that these various types of openings may be used on any types of bone plates, in any combination and in any size, examples of which are shown in FIGS. 12-15. FIG. 12 shows a plurality of finned openings 18 in the head 70 of bone plate 12. This may help achieve better fixation

of a fractured bone, because the fastener can be inserted at various angles to capture "renegade" or random bone fragments that have split from the bone during fracture, but still secure the bone fragments to the plate. For example, if a wrist bone is broken, there will be numerous fragments that may shatter in various directions.

5 The plates 12 with finned openings 18 described herein can be used to place a fastener 8- at various angles in order to capture the renegade fragments that would otherwise not be secured to a bone plate using only a locking or a non-locking fastener. It should additionally be understood that other types of openings (in addition to or instead of finned openings 18) may be present in the head 70, as well
10 as elsewhere on plate 12.

As previously mentioned, fastener 80 may be any typical fastener, made out of any appropriate material. It will typically have a bore for receiving a driver in order to secure fastener into bone and into plate 12. The receiving bore may be any size and shape, for example, it may have a hexagonal configuration to receive a
15 corresponding hexagonal driver, 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.

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
20 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. 11 and 12, provisional
25 fixation pins may be used through either the provisional pin openings, or any other opening (threaded or non-threaded or finned) 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
30 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 12 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 80 is to be inserted through a selected opening 18 and driven
5 into bone material. If bone plate 12 includes more than one opening, as shown in the figures, the surgeon also selects the specific opening to be used. After selecting the desired insertion angle and opening, the surgeon inserts shaft fastener 80 through opening 18 until the tip 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
10 initial tapping or insertion of fastener 80. The surgeon then uses an appropriate driving tool in the receiving bore of head 84 to manipulate the fastener 80 into place.

Because fastener 10 may be inserted at angles other than the aligned with the central axis 20 of the opening 18, as shown in FIG. 5, fastener 80 may be used to grab or secure bone fragments that are out of line with the traditional angle at which
15 a locking screw would normally be inserted. The surgeon may need to toggle or maneuver the fastener 80 in order to secure and draw in displaced bone fragments.

Once the bone fragment is secured, the fastener 80 is ready to be secured to the plate 12. As fastener 80 is driven further into bone, it is also drawn further into plate 12. As threads 88 of fastener head 84 begin to contact fins 24, the fins are
20 allowed to engage within the threads to hold the fastener 80 in place in the desired angle, even angles that are other than in line with the central axis 20. The action of engagement between fins 24 and threads 88 rigidly affixes fastener 80 to the bone plate 12 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
25 can help further secure the bone plate to the bone fracture if needed. One advantage of opening 18 is that it is adapted to receive any one of the potential fasteners that may be used with plate 12.

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
30 openings that cross the fracture in order to strengthen the plate 12. Additionally or alternatively, the surgeon may use bone graft material, bone cement, bone void filler, and any other material to help heal the bone.

An alternate embodiment of a fixation assembly is shown in FIGS. 16-18. These figures show a fastener 102 with a finned head 104. Specifically, the finned head 104 comprises a receiving bore 106 at its upper portion 108 and at least one set of extending fins 110 around the main portion 112 of the head 104. Fins 110 are shown as being square or trapezoidally-shaped with tapered edges, although they may be any other shape, such as rounded, oval, rectangular, curved, rhomboid, diamond-shaped, triangular or any other appropriate shape. The edges 111 of fins 110 may taper inwardly, outwardly, or be about parallel with one another. Fins 110 may be provided in a single row around head 104 or layered in multiple rows as shown. If layered in multiple rows, each individual fin 110 may be directly above another fin (so the top of the fastener 100 looks like that shown in FIG. 18). Alternatively, each individual fin 110 in a lower layer may be offset from a fin in a higher layer. The number of fins 24 in a set may also vary from about two or three up to any desired number that can fit on main portion 112 of head 104. As with the fins 24 of opening 18 described above, the fins 110 are preferably quite thin, the thickness varying depending upon the use of fastener and plate. For example, a larger fastener 102 for use with a larger plate (e.g., for use on a femur bone) will likely have larger and thicker fins 110 than a smaller fastener (e.g., for use on a smaller bone). In specific embodiments, the fins 110 are particularly thin so that they can be moved up or down or compressed upon pressure. A non-limiting exemplary range of thicknesses for fins may be from about 0.5 mm to about 5 mm, although larger and smaller sizes are possible. In theory, the fins 110 are intended to fit between the threadform of plate. Fastener may also have a shaft 114 that is threaded or unthreaded, as described above with respect to fastener 80.

Fastener 102 may be used with any bone plate that has a threaded opening. Any of the examples shown in the figures are described above may be used with fastener 102. One option of a specific bone plate that can be used with fastener 110 is shown in FIG. 19. This bone plate 120 has Acme threads 124 that have a more rectangular shape than the pointed, sharp threads that are typically used in bone plates. As shown in FIG. 20, opening 122 has threads 124 that end at their edges 126 in a rectangular shape. Providing a rectangular shape with a flatter edge 126 allows a larger channel for the fins 110 to engage. In an even more specific embodiment, the threads 124 may be angled at about 15-20° off of the central axis

130 of opening 122, and even more specifically, at about 18° off of the central axis 130.

An example of the method of use is similar to that describe above. As fastener 102 is being inserted into bone plate 120 (although it should be understood that any traditional bone plate may used; Acme threads are not a requirement), the fins 110 are intended to engage threads of the plate and, much like the fins of the bone plate described above, fins 110 are very thin so that as the threads of plate start to grab the fins 110, the fins 110 may move up or down as appropriate to engage the threads of plate and secure the fastener 102 in place, as shown in FIG.

16. In most cases, this movement of fins 110 is a permanent deformation, so that the fins cannot flex back and allow the fastener to work its way out.

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;
 - 5 (a) a bone plate comprising a lower surface, an upper surface and at least one opening extending from the lower surface to the upper surface;
 - (b) a fastener that is insertable through the opening; and
 - (c) at least one member of co-operation between the opening and the fastener comprising a plurality of protruding fins located within the opening or
10 on the fastener.
2. The polyaxial bone fixation assembly, wherein the opening has a non-threaded inner surface and wherein the fins are located on the inner surface.
- 15 3. The polyaxial bone fixation assembly of claim 2, wherein the fins are provided as a series of concavely indented, inwardly protruding fins that are adapted to secure a threaded head of a fastener in place at varying angles.
4. The polyaxial bone fixation assembly of claims 2 or 3, wherein the opening is
20 further defined by a round circumference at the upper surface and a jagged circumference formed by the protruding fins at the lower surface.
5. The polyaxial bone fixation assembly of any of claims 2-4, wherein the protruding fins form a concave portion of the inner surface.
25
6. The polyaxial bone fixation assembly of any of claims 2-5, wherein the protruding fins have bases that meet the inner surface in substantially the same plane.
- 30 7. The polyaxial bone fixation assembly of any of claims 2-6, wherein the fastener has a threaded head adapted to engage with the protruding fins.

8. The polyaxial bone fixation assembly of any of claims 2-7, wherein the fins have a tapered shape, a straight shape, a rectangular shape, or a triangular shape.

9. The polyaxial bone fixation assembly of any of claims 2-8, 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.

10. The polyaxial bone fixation assembly of any of claims 2-9, wherein the bone plate has one or more of the following features:

- (a) contoured, straight, or flat;
- (b) a head portion that is contoured to match a particular bone surface;
- (c) a head that flares out to form an L-shape, T-shape, or Y-shape; and
- (d) any combination thereof.

11. The polyaxial bone fixation assembly of any of claims 2-10, wherein the bone plate has a head and the opening is located on the head.

12. The polyaxial bone fixation assembly of any of claims 2-11, wherein the bone plate further comprises one or more of the follow openings:

- (a) a threaded opening;
- (b) a non-threaded opening;
- (c) an opening adapted to receive locking or non-locking fasteners;
- (d) a combination slot; or;
- (e) any combination thereof.

13. The polyaxial bone fixation assembly of claim 1, wherein the fastener has a head with fins, and wherein the fins are adapted to cooperate with threads in a bone plate.

14. The polyaxial bone fixation assembly of claim 13, wherein the fins are provided in more than one layer.

15. The polyaxial bone fixation assembly of claims 13 or 14, wherein the opening in the bone plate comprises one or more rectangular threads.

16. The polyaxial bone fixation assembly of claims 13-15, wherein the fins are trapezoidally-shaped, rounded, oval, rectangular, curved, rhomboid, diamond-shaped, or triangular.

17. The polyaxial bone fixation assembly of claims 13-16, wherein the edges of fins taper inwardly, outwardly, or are about parallel with one another.

18. The polyaxial bone fixation assembly of any of claims 13-17, 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.

19. The polyaxial bone fixation assembly of any of claims 13-18, 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.

20. The polyaxial bone fixation assembly of any of claims 13-19, wherein the bone plate further comprises one or more of the follow openings:

- (a) a threaded opening;
- (b) a non-threaded opening;
- (c) an opening adapted to receive locking or non-locking fasteners;
- (d) a combination slot;
- (e) an opening with fins; or
- (f) any combination thereof.

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

- (a) providing a bone plate comprising a lower surface, an upper surface, and at least one opening extending from the lower surface to the upper surface, the opening having a non-threaded inner surface with one or more protruding fins located on the inner surface;
- (b) providing a fastener having a shaft and a head, the head having at least one set of threads adapted to cooperate with the protruding fins;
- (c) inserting the fastener into the opening of the bone plate and allowing the at least one set of threads to engage the fins of the plate; and
- (d) securing the bone plate to bone.

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

- (a) providing a bone plate comprising a lower surface, an upper surface, and at least one opening extending from the lower surface to the upper surface; the opening having one or more threads;
- (b) providing a fastener having a shaft and a head, the head having at least one set of fins adapted to cooperate with threads of the plate;
- (c) inserting the fastener into the opening of the bone plate and allowing the one or threads to engage the fins of the fastener head; and
- (d) securing the bone plate to bone.

23. The method of claims 21 or 22, wherein the inserting the fastener into the opening in the bone plate step (c) further comprises using polyaxial fixation to draw a bone fragment into alignment.

24. The method of any of claims 21 -23, further comprising inserting a locking screw or a non-locking screw into the bone plate.

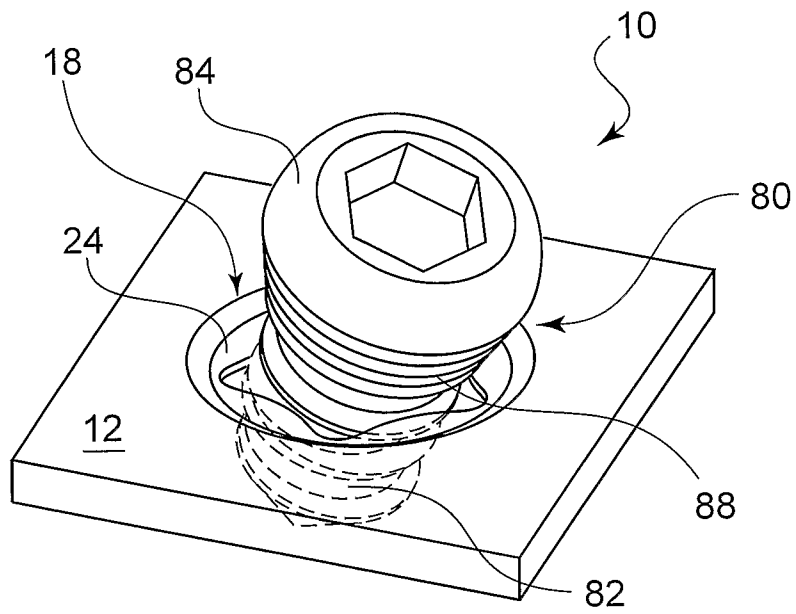


FIG. 1

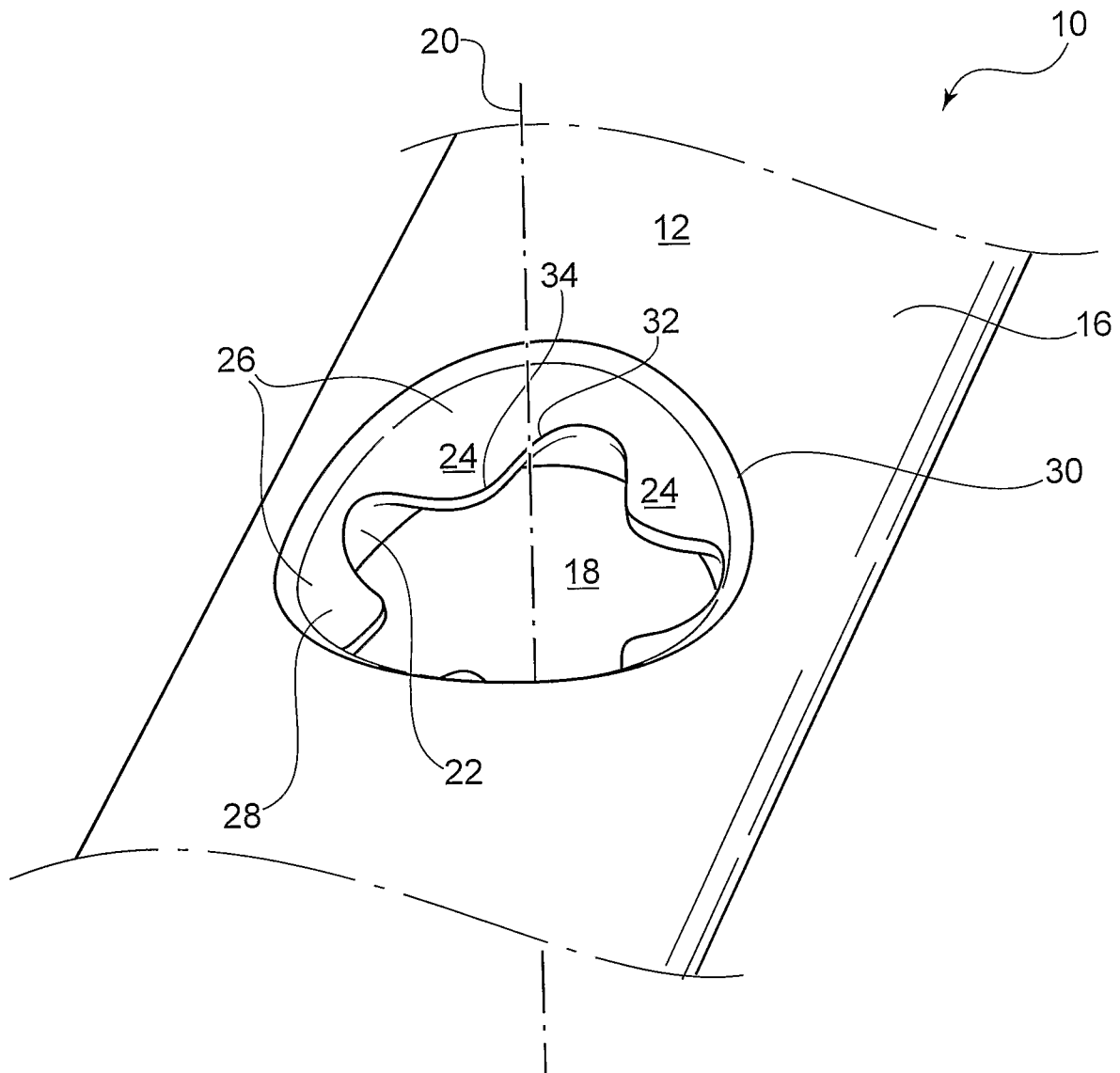
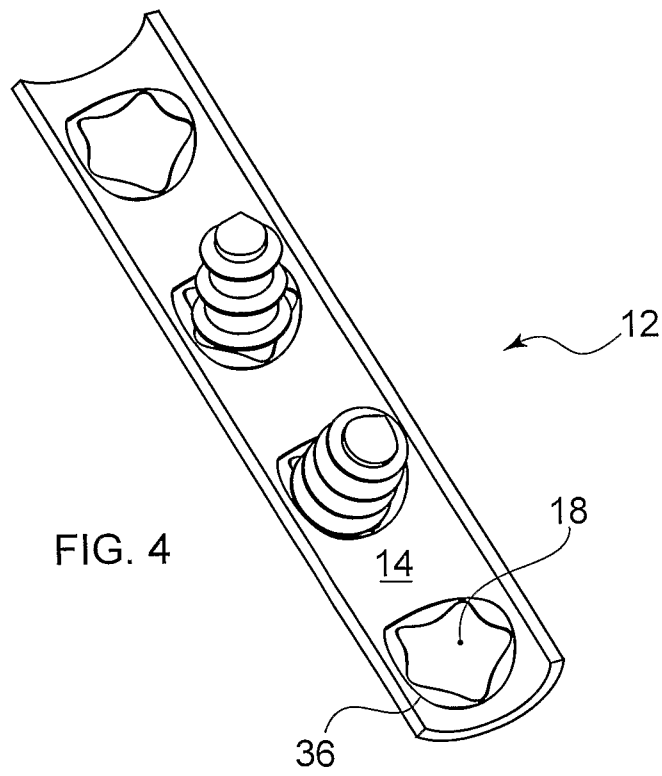
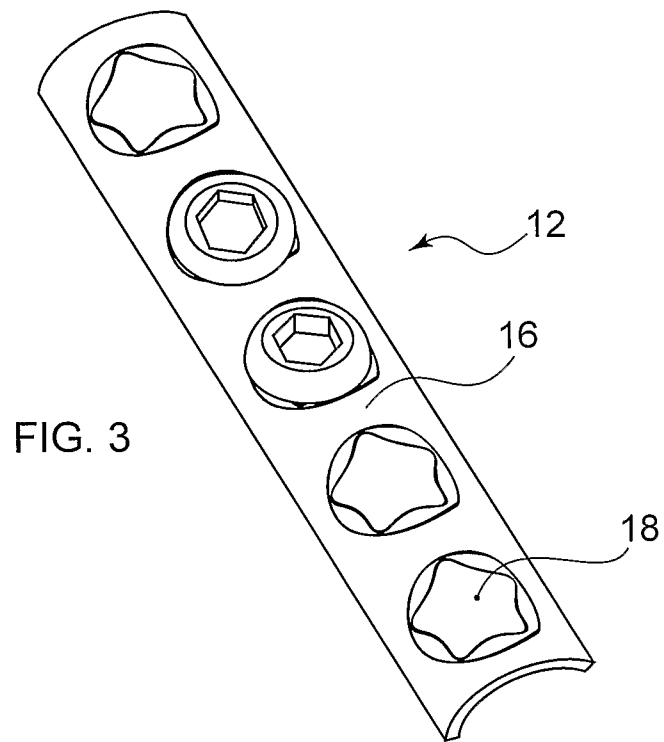


FIG. 2



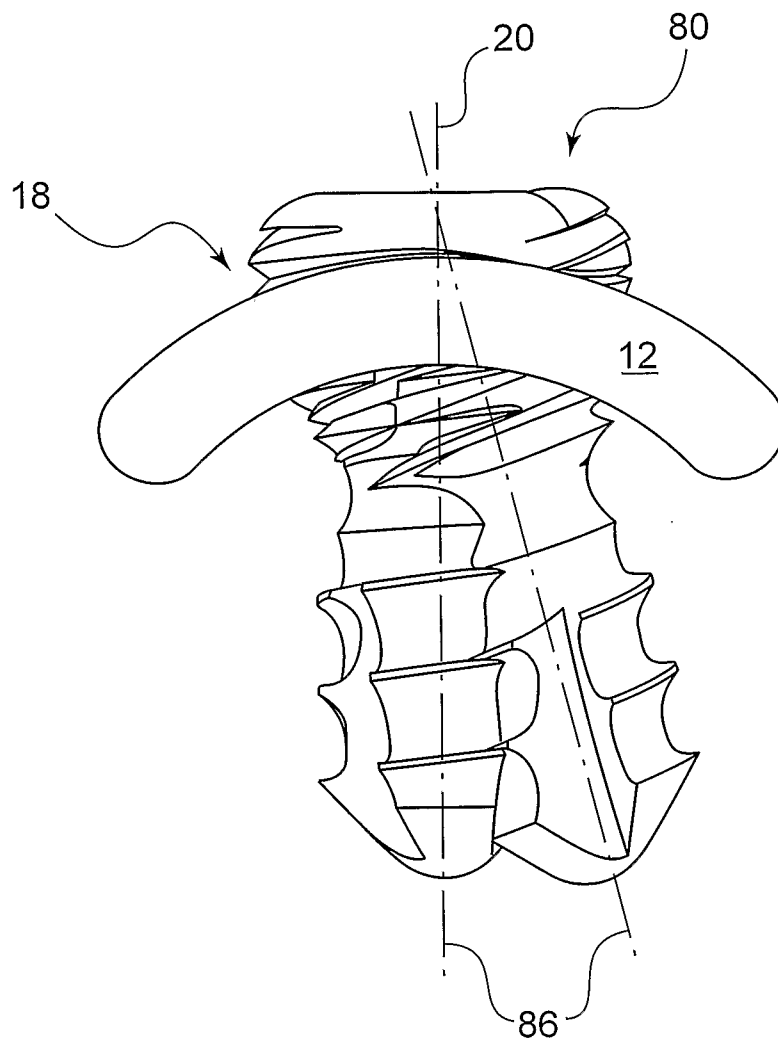


FIG. 5

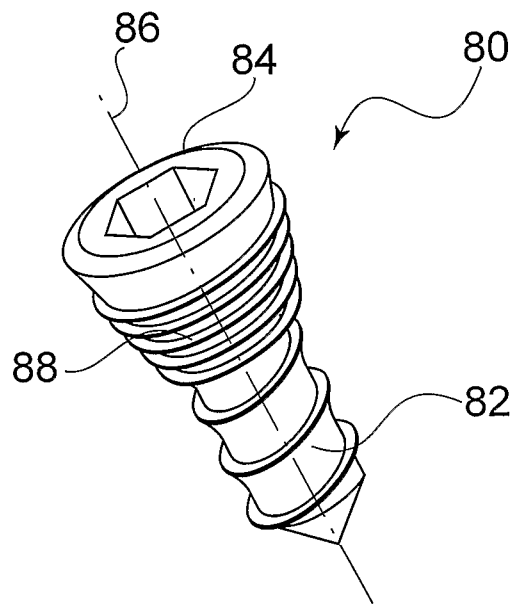


FIG. 6

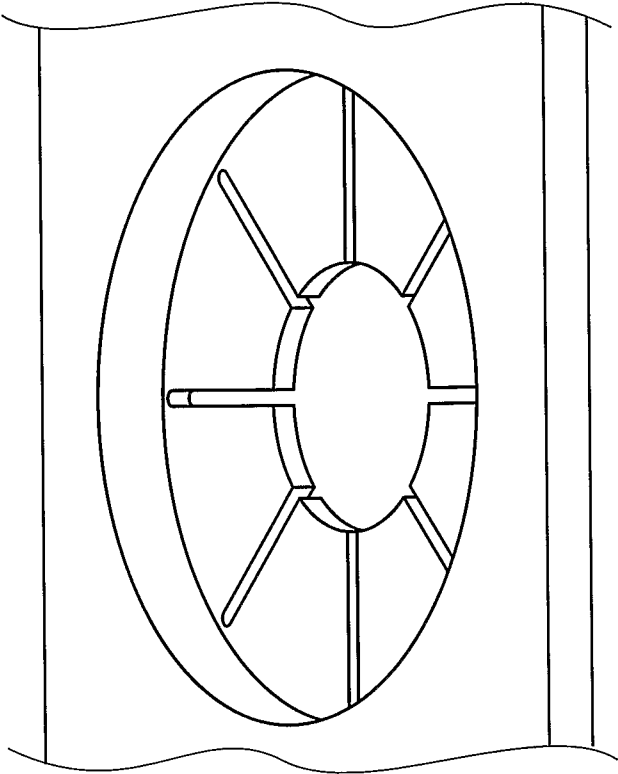


FIG. 8

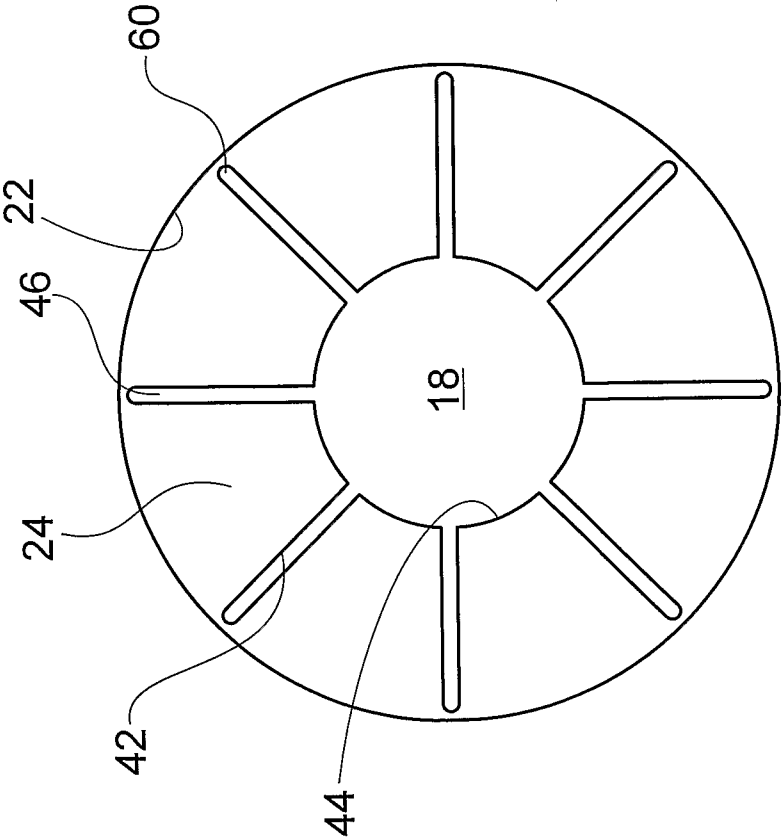


FIG. 7

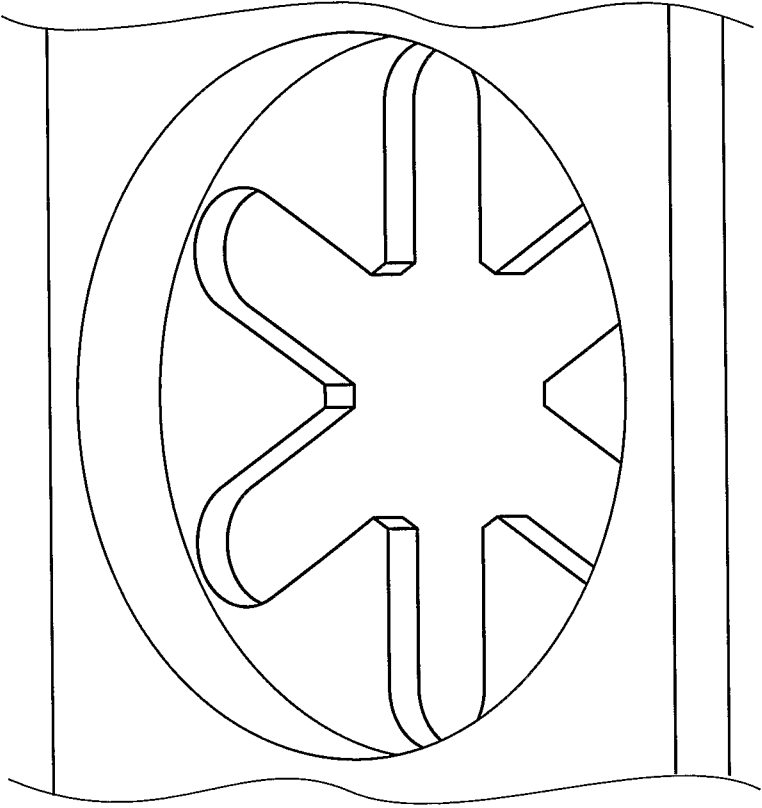


FIG. 10

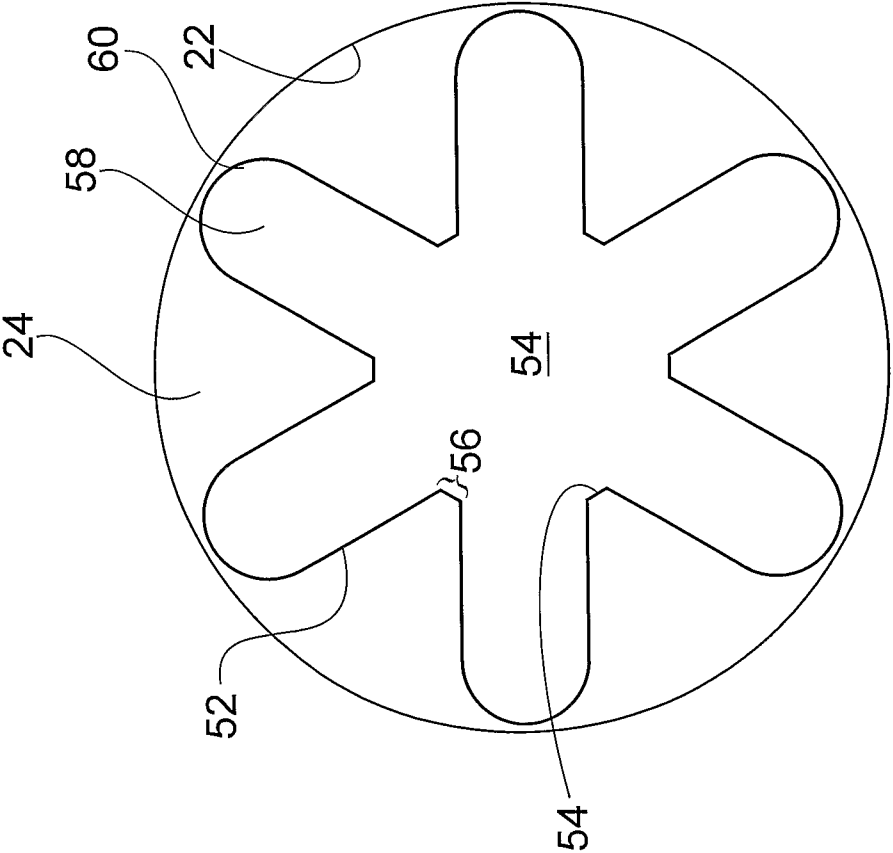


FIG. 9

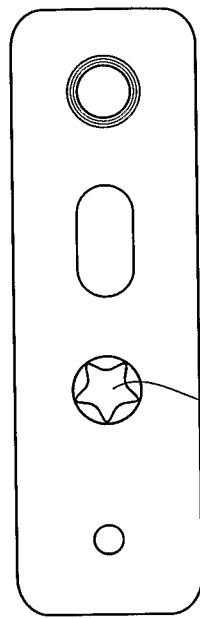


FIG. 11

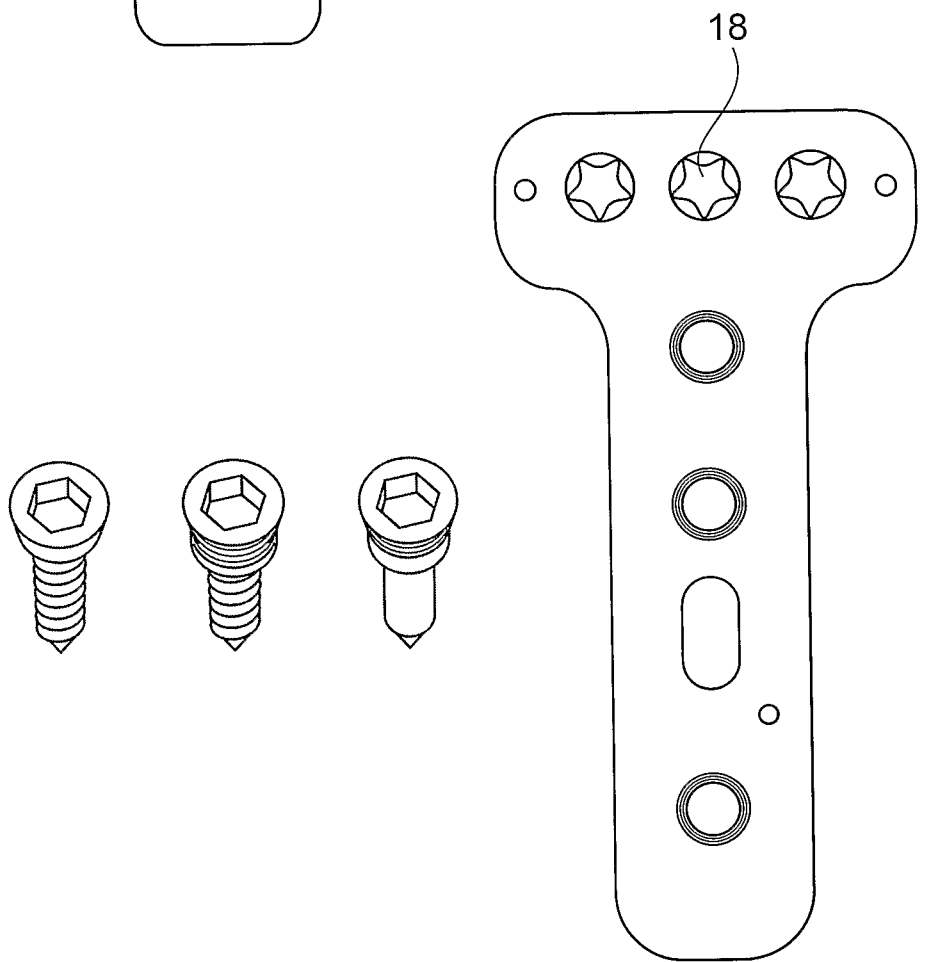


FIG. 12

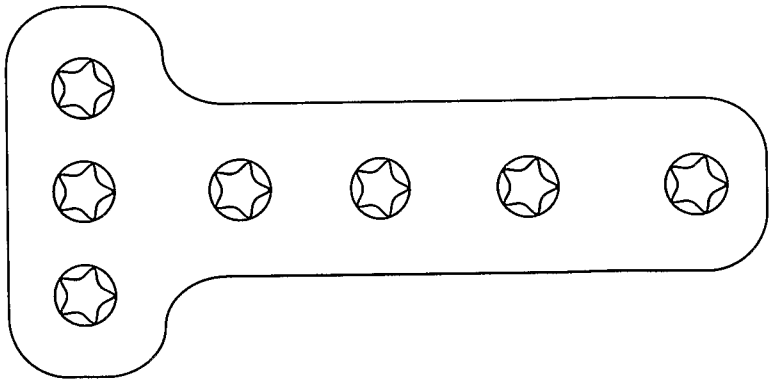


FIG. 15

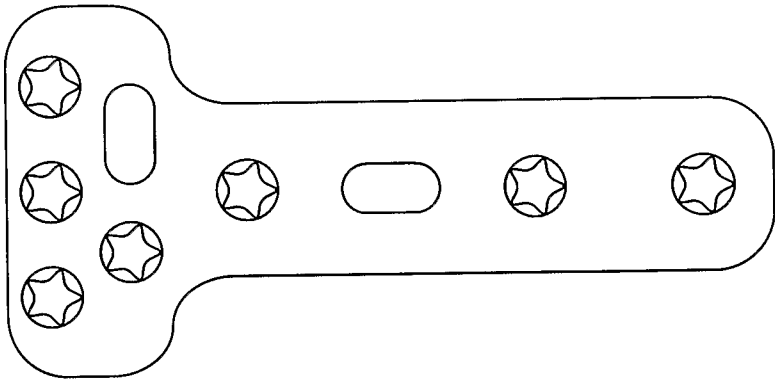


FIG. 14

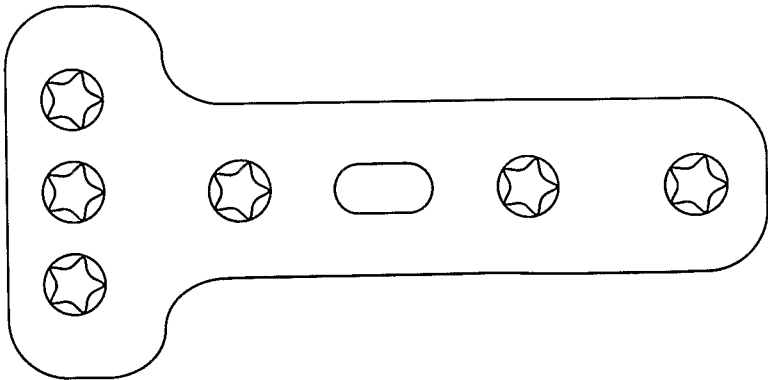


FIG. 13

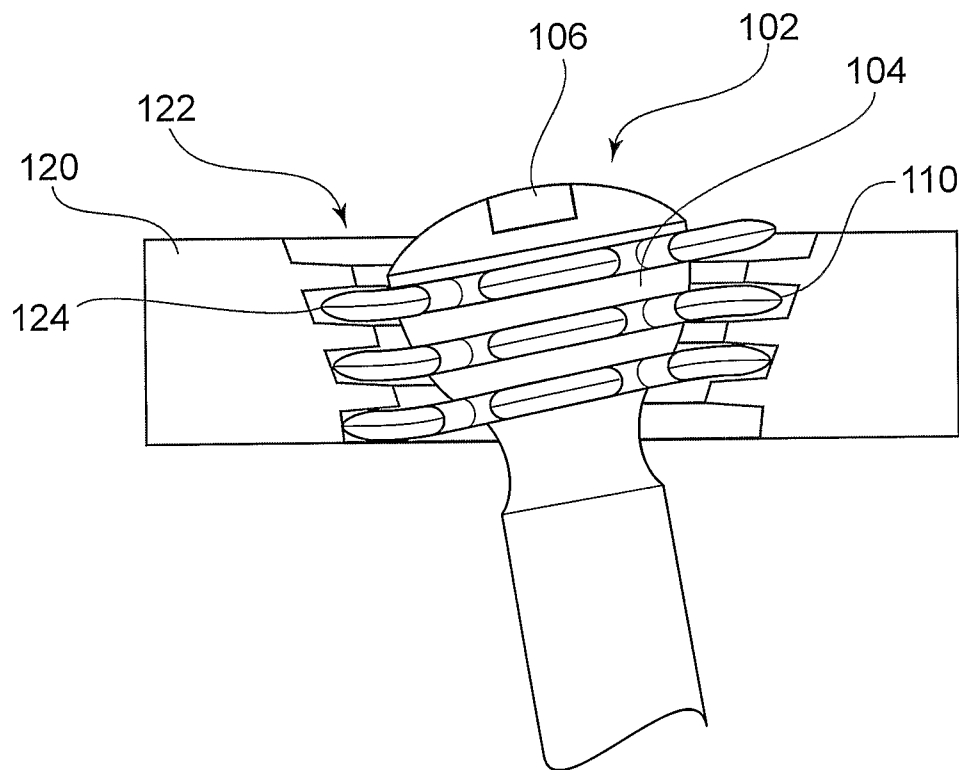


FIG. 16

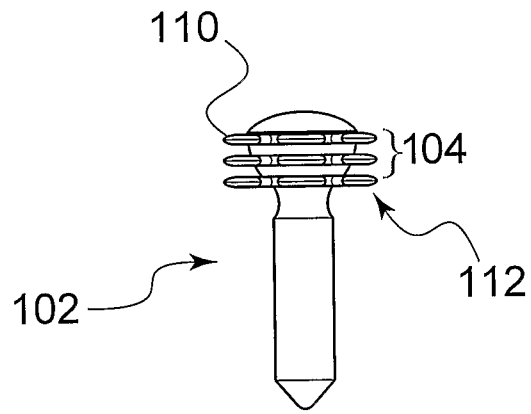


FIG. 17

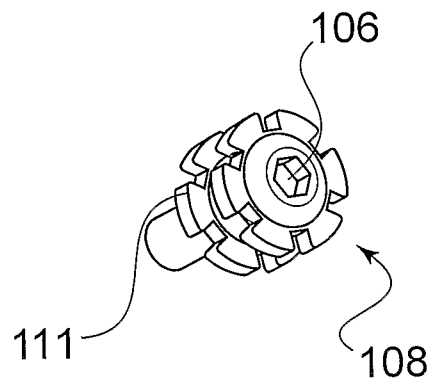


FIG. 18

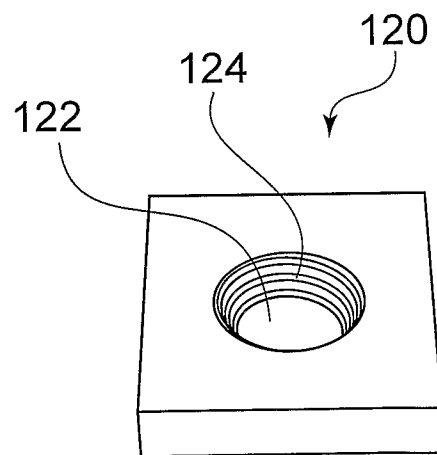


FIG. 19

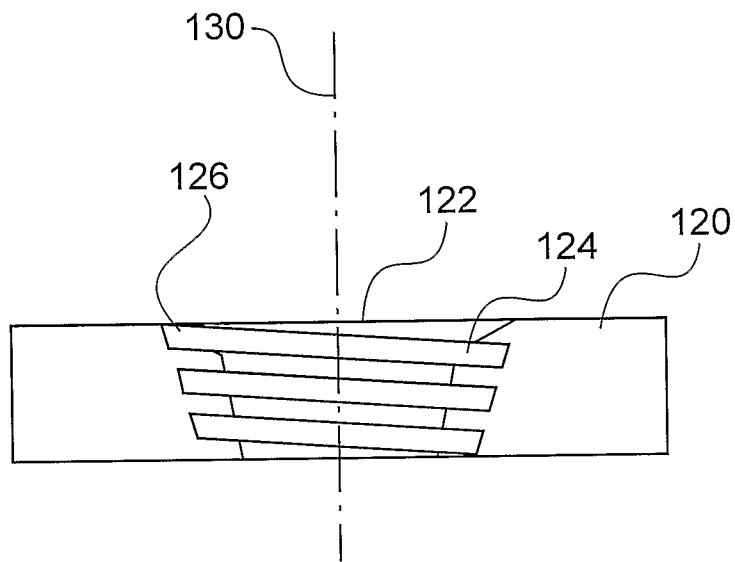


FIG. 20

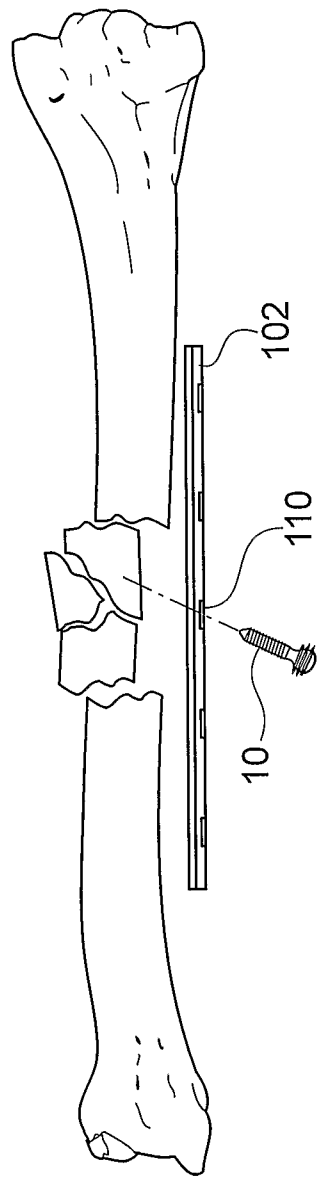


FIG. 21