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Markolf et al.

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[54] **BONE FIXATION PLATE**

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[52] **U.S. Cl.** ..... **128/92 B**, 128/92 D

[51] **Int. Cl.** **A61f 5/04**

[58] **Field of Search** ..... 128/92 B, 92 R, 92 A, 128/92 D, 92 BB

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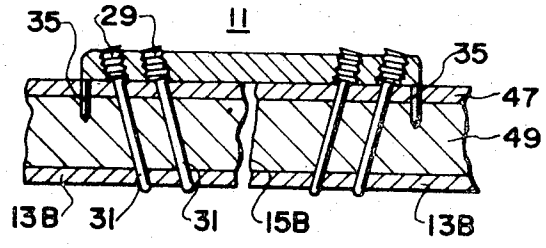
[57] **ABSTRACT**

A device for immobilizing adjacent bones or bone fragments or affixing prostheses or orthopaedic structures to a bone, comprising a rigid plate having pin means removably secured therein so as to extend from the plate at an angle with respect to each other and the plate, whereby, upon insertion of the pins into a bone, the plate and pin assembly will hold the bones, bone fragments, orthopaedic structures, or prostheses in a fixed position.

1 Claim, 7 Drawing Figures



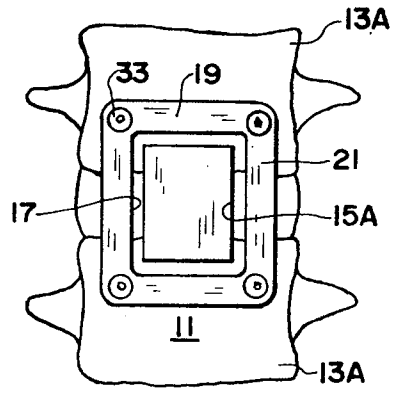


Fig-1

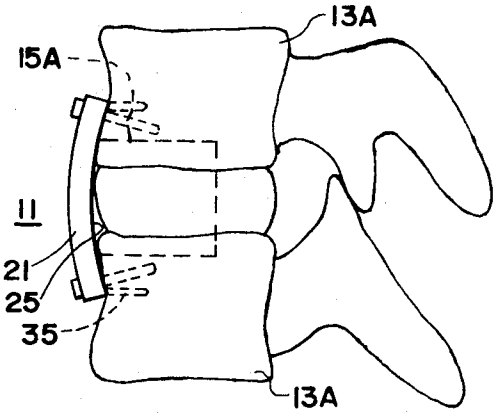


Fig-2

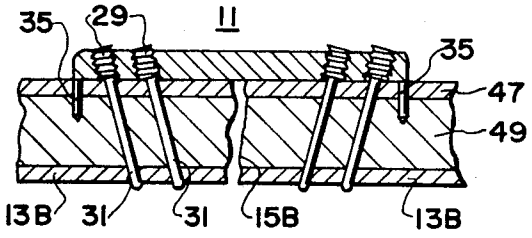


Fig-3

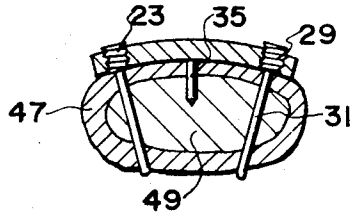


Fig-4

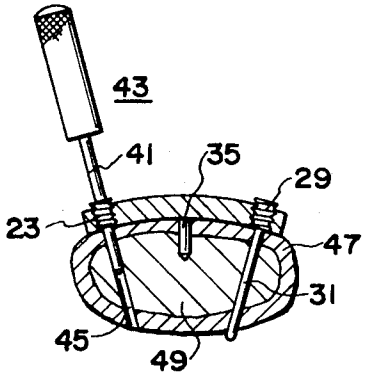


Fig-5

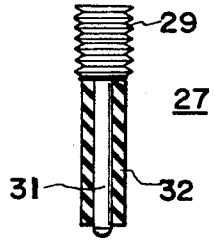


Fig-6

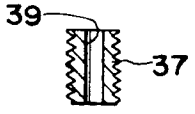


Fig-7

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BONE FIXATION PLATE

BACKGROUND OF THE INVENTION

The present invention relates primarily to orthopaedic fixing devices and, in particular, to a bone fixation plate, which is capable of being attached between two bone fragments or two adjacent bones to hold the bones together, or of immobilizing one or more vertebrae with respect to one another, or of attaching orthopaedic structures or prostheses to a bone.

Problems may arise when it is attempted to immobilize elements of a fractured bone, or two adjacent bones, in order that the bone will heal, or the bones will fuse together, notwithstanding the normal movements of the person.

One means of achieving this immobilization involves affixing a plate between the bones or bone elements and securing the plate to the bones. A major problem which occurs in this procedure is in obtaining firm fixation of the plate to the bone.

DESCRIPTION OF THE PRIOR ART

The traditional means of affixing metal plates to fractured bones by screws passing therethrough has attained a widespread use in orthopaedics. These metal plates are fixed to the separate fragments of the fractured bone during a surgical operation to strengthen the fractured site and, at the same time, to immobilize and hold together the broken fragments so that the bone will heal properly. This procedure has been employed for many years and, although physical techniques, methods for inserting, and design of the plates have constantly improved, the basic concept of a plate affixed by screws to bone during surgery has undergone little modification.

A device now finding common usage comprises a shaped metal plate having holes drilled in each of its ends. The plate is usually placed over a fracture with the drill holes lying on opposite sides thereof. Screws are then passed through the holes and threaded into the separate bone fragments to bring the plate to bear into contact with the outer surface of the bone in much the same manner that a hinge is fastened to a wooden door. The screws simply pass through the holes in the plate, whereby no positive mechanical lock between the screws and the plate occurs. Hence, relative displacement between the screws and the plate can occur if the screws do not clamp the plate to the bone. The screws can work loose, and in this condition, relative displacement between the plate and the bone fragments can occur. If this occurs, the ultimate objective of immobilization of the bone fragments relative to each other is not achieved. Due to the lack of mechanical rigidity between the bone fragments and the screw plate assembly, relative motion may take place, whereby fusing of the bones is delayed or even prevented.

The screws holding the plate to the bone can also create a high contact stress condition within the bone and cause local deterioration of the bone and yielding at the bone-screw interface. This usually results in the screw not being tightly fixed within the bone, and in many cases it may be easily removed after a period of time which is too short for it to achieve the desired results. Likewise, other orthopaedic structures and prostheses have been affixed in a similar manner to bones by screws passing through clearance holes in the plate,

and similar disadvantages exist regarding displacement occurring between the structure and bone.

The present invention overcomes the above-set-forth disadvantages by providing a unique fixation plate having attaching pins which are secured firmly to the plate and have smooth surfaces which enter the bone at an angle to securely fix the plate and the bone together. These features prevent movement of the plate or prostheses relative to the bone.

SUMMARY OF THE INVENTION

The present invention is a fixing device for securing a plate to a bone, or bone fragments, or adjacent bones, comprising a plate having two ends with at least one pin removably secured therein at each end thereof. The pins extend from the same side of the plate and are convergently or divergently angled with respect to each other, whereby, when the pins are inserted into a bone, the angle of the pins will prevent the plate from pulling away from the bone.

The invention further comprises a method for fixing a plate to a bone with pins, whereby the bone and the plate-pin assembly form a mechanically rigid structure immovably held together.

OBJECTS OF THE INVENTION

It is therefore an important object of the present invention to provide a fixation means for securing a plate to a bone or to two vertebrae or two bone fragments.

It is another object of the present invention to provide a bone fixation plate for immobilizing two fragments of a bone, or two adjacent bones relative to each other.

It is a further object of the present invention to provide a bone fixation device having removable angled fixing members which are engageable within the bone and rigidly securable to the plate structure.

It is another object of the present invention to provide a fixation device having fasteners passing therethrough at an angle to engage the bone and prevent the device from pulling off or working out of engagement with the bone.

It is still a further object of the present invention to provide a metal fixation plate wherein the bone engagement elements are locked to the plate, whereby a single, rigid, mechanical unit is formed which is fixable to a bone.

It is yet another object of the present invention to provide a fixation plate wherein the removable pin fasteners are smooth and may be coated with a resilient material to relieve the stiffness mismatch between bone and metal.

It is still another object of the present invention to provide a fixation device for fixing an orthopaedic structure or a prosthesis to a bone.

It is yet a further object of the present invention to provide a fixation device for immobilizing two adjacent bones or bone fragments.

And still a further object of the present invention is the provision of a method for fixing two fragments of a fractured bone together, for fixing two vertebrae together, or for the fixation of a prosthesis or an orthopaedic structure to a bone, whereby the contact stress between the bone and the fixation device is reduced by the use of smooth, coated or non-coated pin fasteners.

DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the present invention will become apparent when the bone fixation device is considered in conjunction with the accompanying drawings, of which:

FIG. 1 is a front elevation view of the spine, showing a bone fixation device mounted in its operative position spanning an intervertebral disc with a bone graft fixing two cervical vertebrae together;

FIG. 2 is a side elevation view of the spine showing the bone fixation plate of FIG. 1;

FIG. 3 is a side elevation view in cross-section of a long bone fixation device mounted in its operative position fixing two long bone fragments together;

FIG. 4 is an end elevation view in cross-section of FIG. 3;

FIG. 5 is similar to FIG. 4, and shows the fastening device with one fastener element removed therefrom and a hollow threaded collar mounted within the plate, whereby the punch member of a hole-forming tool may be passed through the threaded collar for the formation of a hole in the bone fragment for insertion of the pin fastener;

FIG. 6 is an enlarged view of the preferred embodiment of a pin fastener of the present invention coated with resilient material; and

FIG. 7 is an enlarged view of a threaded collar used in the formation of holes.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The preferred embodiment shown in FIGS. 1, 2 and 5 of the drawings relates to the fixation of cervical vertebrae for immobilization thereof as an aid in cervical bone fusion, while the embodiment shown in FIGS. 3 and 4 relates to the fixation of bone fragments. It is to be understood that the fixation device of the present invention may also be used for the immobilization of other bones or attachment of other metal structures or prostheses to a bone. Moreover, the term "bone", as used hereinafter, is applicable to a single bone, long bone fragments or two adjacent bones, such as vertebrae.

Referring now to the drawings, there is shown therein a bone fixation device or plate 11 which can take the form of an orthopaedic structure attached to a bone, as well as a plate for holding bones or bone fragments or bone and prosthesis together. The plate 11 is shown as being mounted over and fixing together a pair of adjacent cervical vertebrae 13A (FIG. 1), separated by a bone graft 15A, or bone fragments 13B (FIG. 3), separated by a fracture (15B). The plate may be of any desired material or shape, but for use in vertebrae fusion, it is preferably a non-corrodable metal compatible with use in the body and rectangular in form. As shown, the plate includes an open central portion 17 surrounded by two end portions 19 and two elongated side portions 21 which may be fixed together in any suitable manner or integrally formed. A bone graft can be inserted through the opening. The device may be provided with sharp edges, but is preferably formed with rounded surfaces or edges to reduce the possibility of abrasion of surrounding tissue.

As shown more clearly in FIG. 2, the side portions 21 are preferably curved so as to conform substantially to the shape of the bone or vertebrae over which the plate lies. If suitable, of course, the end and side portions may be made of any shape, such as flat, but in the preferred embodiment shown, are preferably curved so as to correspond to the outer surface of a sphere (not shown) passing therethrough.

The four corners of the rectangular plate are provided with at least one drilled and partially tapped bore or hole 23 extending therethrough at a predetermined angle, which angle may be acute or obtuse so as to extend convergently or divergently with respect to each other. The bores 23 are only partially tapped, or are so formed that the threaded end portions thereof, adjacent the portion of the plate 25 lying against the vertebrae or bone fragments 13A,13B, are of a different size than the remaining portion of the tapped hole.

Fastener means or pins 27 having enlarged, threaded head portions 29 and elongated, relatively smooth shank portions 31 fixed thereto, are removably mounted in each of the threaded bores 23 and, as shown in FIG. 3, two or more fastener means may be fixed in each corner for added strength. These pins preferably extend from one side of the plate at the same predetermined convergent or divergent angle with respect to each other and to the plate. The enlarged threaded head 29 of each pin is slotted, or provided with a recess 33 into which a screwdriver or Allen wrench may be inserted for locking or loosening of the pins in the bores 23. The relatively smooth shank portion of the pin is preferably provided with a coating of resilient material 32, such as silicone rubber, to prevent the hard surface of the metal pins from working against the bone and causing local deterioration thereof. By so relieving the stiffness mismatch between the bone and the metal of the pin, the immobilization of the fragments is further insured.

At least one of the side portions 21 of plate 11 is further provided with a smooth pin 35 located therein. In a preferred embodiment, a pin is provided at each end, and is integrally cast with the plate or may be permanently attached thereto in any desired manner, such as by welding. As shown in FIGS. 2–5, end pins 35 are centrally located and extend perpendicularly to the point of curvature of the plate where they come into contact with the same. Moreover, the end pins are preferably shorter than the extending smooth pin portions 31 of the fasteners 27.

Turning now to FIG. 5, the method of mounting the plate of the instant invention for fixation and immobilization of adjacent bones, such as the vertebrae of the cervical spine, will be explained. However, it is to be understood that the application of the fixation principles disclosed herein are not limited to bone fractures, but may extend to the fixation and anchoring of other members, such as prostheses, including total or partial joint replacement, such as hip, shoulder or knee joint replacement. It is, of course, understood that in utilizing the plate of the instant invention, the vertebrae 13A must be aligned and brought together by means of surgery. The device or plate 11 is then placed to span the bone graft to be immobilized, whereby at least one of the pins 35 is in contact with one of the separate vertebrae 13A substantially centrally thereof. The pin 35 is normally driven into the vertebrae in any conventional manner, such as by hammering. If suitable, perpendicular holes, spaced apart a predetermined distance, may be formed, in any suitable manner, in each of the segments and pins 35 inserted therein. The plate 11 is then

substantially fixed on the two vertebrae by the pins **35**. To insure proper alignment of the fasteners with respect to the plate, a threaded collar **37** (FIG. 7), having an elongated bore **39** formed therein, is threaded into each of the tapped holes **23**. With a threaded collar **37** fixed in position in each of the tapped holes **23**, the elongated pointed stem **41** of a hole-forming tool **43** is inserted into the bore **39** and guided thereby so that when pressure is applied to the tool **43**, a plurality of bores **45** of a predetermined depth, diameter, and at the proper angle will be formed in the vertebrae. Therefore, upon removal of the threaded collars **37** and insertion of fasteners **27**, the elongated smooth pin portion **31** of each of the fasteners **27** are inserted into the formed bores **45** at the proper angle. The threaded head **29** then may be advanced a predetermined amount into each of the bores **23** until it locks positively with the imperfect threads at the bottom thereof to thereby lock the pins in the plate, forming a rigid structure wherein the pins cannot work loose with respect to the plate. In this position, the plate and the fasteners act as a single, rigid mechanical unit to thereby greatly improve bone fragment fastening and immobilization.

As shown in FIGS. **3–5**, the smooth shanks **31** of the pins may vary in length or extend into different bones for different depths. Preferably, the shanks enter through the cortical bone or cortex **47** at one side of the bone, pass entirely through the cancellous central portion of the bone **49** and into the cortical bone or cortex at the other side thereof. This further ensures that the pins are secured in the bone and that a rigid joint is formed.

As previously pointed out, the bores **23** and, therefore, the fasteners **27** inserted therein, are so formed that they are off normal or extend at a predetermined angular setting to longitudinal and lateral planes passing through the plate. In the preferred embodiment of the invention, the corner fasteners are set in the drilled and tapped holes, so that they extend normally to the surface of a sphere passing through the corner holes and removal of a mounted assembly, in the direction of insertion, is prevented.

It is therefore an important advantage of the present invention that a single structure incorporating the fastener and plate into a single, rigid mechanical assembly is formed, whereby a structure having enhanced strength over existing devices of comparable size is formed.

Furthermore, the structure of the present invention acts in such a manner that it gives rigidity deep within the vertebrae or bone fragment through the use of offset fasteners, thus serving to greatly improve vertebrae or bone fragment fastening and immobilization.

Moreover, the present invention permits the use of coated or non-coated fasteners other than screws, now normally used, whereby a milder stress condition within the bone is achieved and, hence, longer term holding power is provided.

Finally, due to the unique structure of the present invention, a wider range of selection of fasteners having coatings or made from different materials to suit individual variations in bone density and hardness may be obtained.

It will be apparent from the foregoing description of the invention in its preferred form that it will fulfill all the objects attributable thereto, and while it is illustrated and described in detail, the invention is not to be limited to such details as have been set forth except as may be necessitated by the appended claims.

What is claimed is:

1. A bone fixation plate for immobilization of cervical vertebrae to aid in cervical bone fusion, comprising

a generally rectangular plate having the central portion thereof removed and being open to effect a lightweight device and to permit access to the bone disposed thereunder, said plate having generally rounded edges to prevent trauma to the surrounding tissue and being generally curved to conform to the spherical shape of the vertebrae where the fixation plate is attached,

a partially tapped bore formed in the surface of said plate at each corner thereof, said bores being convergently angled with respect to said plate,

at least a pair of parallel positioning pins fixedly attached to said plate proximate the top and bottom edges thereof respectively, said pins being capable of being driven into adjacent vertebrae to position and hold said plate thereon while fixation pins are fitted into said plate, and

an elongated smooth pin having a resilient coating thereon and a threaded head portion engaged with each of the threaded bores in the corners of said plate, said pins being capable of being positively locked in said bores by the interaction of said threaded heads with said partially tapped bores whereby said plate is fixedly secured to said vertebrae by the angulation of said pins with respect to said plate.

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