

[54] **THERMOCONSTRICTIVE SURGICAL APPLIANCE**
 [76] Inventors: Alan A. Johnson, S.W. 620 Dawnview, Pullman, Wash. 99163; Frank P. Alicandri, 511 Emerson Ave., Teaneck, N.J. 07666

[22] Filed: Nov. 22, 1972

[21] Appl. No.: 308,739

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 72,651, Sept. 16, 1970, abandoned.

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

[51] Int. Cl. A61f 5/04

[58] Field of Search.. 128/92 D, 92 R, 92 B, 92 BC; 3/1; 75/175.5

References Cited

UNITED STATES PATENTS

2,645,575 7/1953 Herres et al. 75/175.5

2,880,089 3/1959 Vordahl 75/175.5
 3,091,028 5/1963 Westbrook et al. 75/175.5
 3,093,513 6/1963 McCallum et al. 75/175.5
 3,643,658 2/1972 Steinemann 128/92

Primary Examiner—Richard A. Gaudet
 Assistant Examiner—J. Yasko
 Attorney, Agent, or Firm—Frederick E. Bartholy

[57] **ABSTRACT**

The application of a plate of thermoconstrictive material for extra-medullary fixation of fractured bones is described. The plate, consisting of a nickel-titanium alloy, is subjected to deformation by a tensile stress below its critical transition temperature. Upon securing the plate over the fracture, heat is applied at or above the transition temperature thereof so as to return it to its original state, thereby drawing the fractured bone ends together.

7 Claims, 8 Drawing Figures

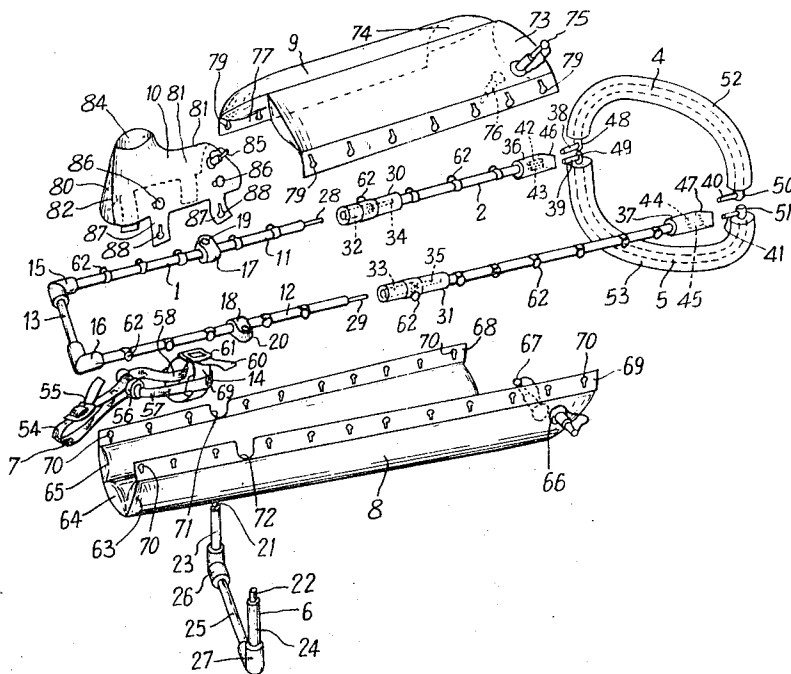


FIG. 1

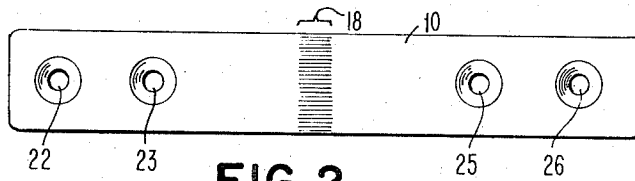
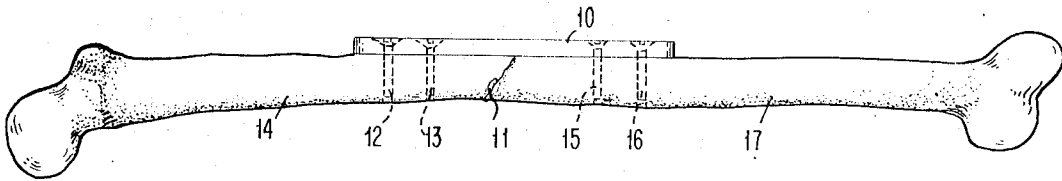


FIG. 2

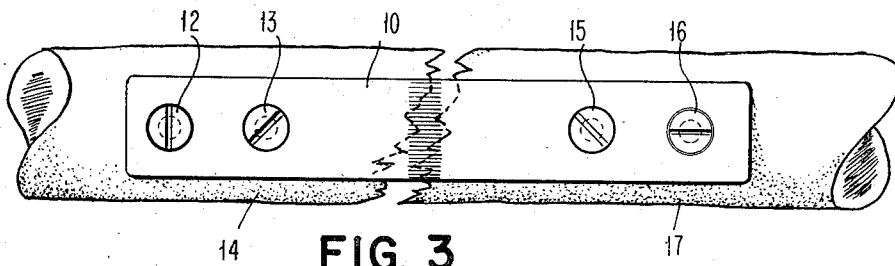
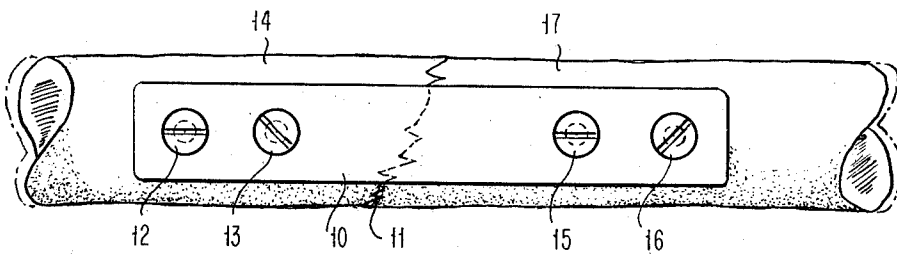


FIG. 3

FIG. 4



INVENTORS

ALAN A. JOHNSON
FRANK P. ALICANDRI

BY *Donald E. Marshall*

ATTORNEY

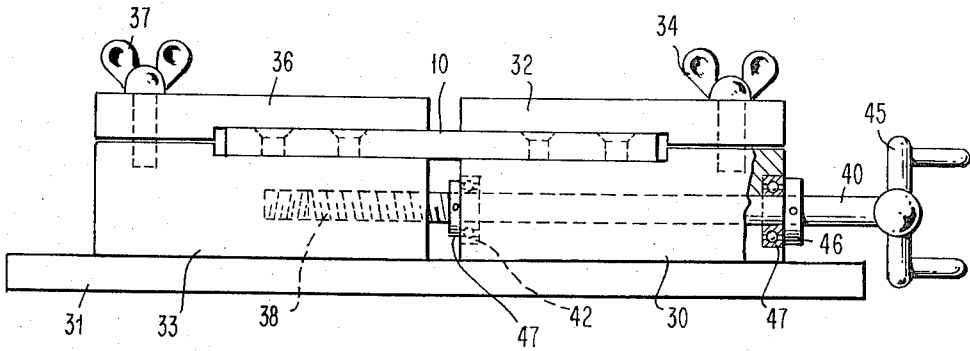


FIG. 5

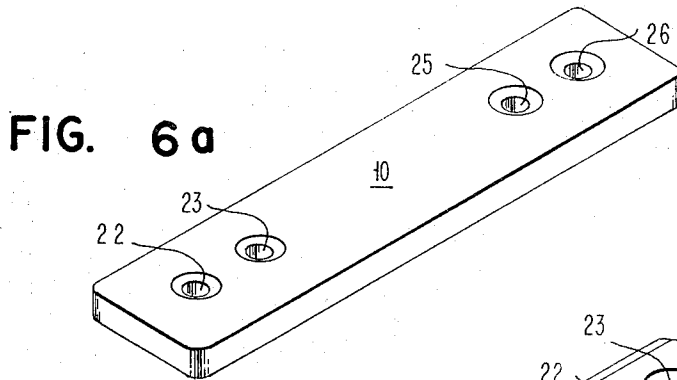


FIG. 6 a

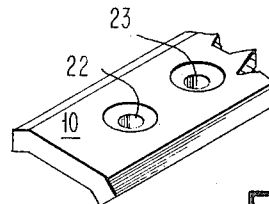


FIG. 6 c

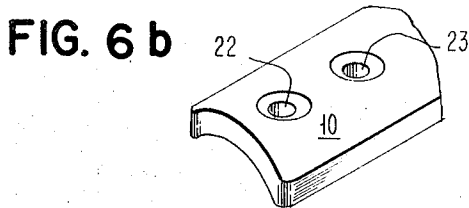


FIG. 6 b

INVENTORS

ALAN A. JOHNSON
FRANK P. ALICANDRI

BY

ATTORNEY

THERMOCONSTRICTIVE SURGICAL APPLIANCE

This application is a continuation-in-part of our pending application, Ser. No. 72,651 filed on Sept. 16, 1970 now abandoned.

This invention relates to surgical appliances and, more particularly, to orthopedic clamping devices or splints for the extra-medullary fixation of fractured bones.

Devices of the above type have been used in various forms for holding two sections of a fractured bone in proper alignment and in abutting relation to insure the knitting together of the fractured ends.

Aside from the requirement of maintaining static condition of the bone sections which the surgeon has carefully placed in proper alignment, it is important that the contracting action of the related muscles be further aided by forceful compression of the juxtaposed ends.

Fracture healing in long bones is accelerated when compression is applied between the fractured bone ends. At present, a widely accepted method employs the use of an internally applied compression bone plate. The plate is affixed by screws to one side of the fractured bone with the plate overlapping the fracture site and extending to the other side of the fractured bone. Before screwing the other side down to the bone, a hand clamp device, available in various designs, is applied to the upper end of the unfastened plate. Compression is now applied to the plate, drawing the fractured bone ends together and thereby effecting compression and rigid fixation to the fractured bone ends. Screws are now inserted in the bone plate on the clamped side, the clamp is removed and the wound closed. This technique is widely accepted in orthopedic practice. However, it has certain disadvantages in that it requires an incision larger than the bone plate, extra manipulation due to the large clamping device, additional screw holes to hold the clamp in place, and generally increased operating time.

Accordingly, it is the primary object of this invention to eliminate the above-mentioned disadvantages by providing a bone plate which requires no clamping devices of any kind for achieving compression of the reduced fracture.

It is a particular feature of the invention that the fixation element, generally in the form of a plate, has such physical properties as to effect compression by virtue of its metallurgical composition and properties.

A particular advantage of the invention resides in the fact that the use of the fixation element is extremely simple, requiring manipulation prior to its application to the bone surface and not during the operation.

Other objects, features, and advantages will be apparent from the following description of the invention, pointed out in particularity in the appended claims, and taken in connection with the accompanying drawings, in which:

FIG. 1 is a pictorial representation of a femur with the bone plate affixed overlapping the fractured ends.

FIG. 2 is a top view of the plate in a prestrained or preformed condition ready for application.

FIG. 3 shows the plate of FIG. 2 affixed to two separated ends of a bone.

FIG. 4 shows the plate in constricted condition firmly holding the bone portions together, exerting compressive force.

FIG. 5 is a schematic representation of a type of tensile stress producing apparatus suitable for the deformation of the bone plate.

FIG. 6a is an isometric view illustrating the general configuration of one form of plate.

FIGS. 6b and 6c illustrate other configurations of plates which may be advantageous in certain cases.

It is known that certain alloys of nickel and titanium exhibit thermo-reactive properties in that, when deformed to a desired configuration, they will return to the original configuration upon being subjected to heat at certain critical temperatures. This behavior of nickel-titanium alloys has given rise to considerable metallurgical investigations and reference to it may be found in the literature, e.g., in the *Journal of Applied Physics*, Vol. 36, No. 10, Oct. 1965, the article entitled "Crystal Structure and a Unique 'Martensitic' Transition of TiNi," describes the crystal structure of Ti-Ni compounds and contains a large number of literature references on the subject.

The above-described properties of such alloys may be taken advantage of in accordance with the present invention by selecting such compositions which exhibit martensitic transformations at temperatures in the range tolerable by the human body. The critical temperature may be varied at will by varying the ratio of nickel to titanium or by replacing a small proportion of the nickel with cobalt.

Experiments performed have shown that a Ni-Ti alloy prepared as shown in the following example has the desired characteristics to be used as fixation elements in orthopedic surgery.

Appropriate quantities of nickel and titanium, or of nickel, titanium and cobalt, are weighed and placed in the hearth of an arc-melting furnace which operates with tungsten electrodes under a reduced pressure of argon. The hearth, which is generally of copper and is water-cooled, contains a depression into which the metals may flow when heated with the arc. After solidification the alloy is turned over and melted again. This procedure is repeated several times to promote homogeneity.

The resulting casting is heated, typically to 700° C., and then rolled into a flat sheet using a conventional rolling mill. Blanks for bone plates are then cut out of the sheet using a conventional milling machine. A drill is used to make the screw holes. After fabrication in this manner the finished bone plates are recrystallized by vacuum encapsulation in quartz, or some other appropriate material, annealed at some appropriate temperature, such as 1,000° C., and cooled to room temperature.

A separate alloy casting is fabricated into rod form using a conventional hot swaging technique. Self-tapping screws for use with the bone plates are then machined from these rods.

When the above-prepared compound is deformed plastically at room temperature, and then its temperature raised within the range of an appropriate higher value, it regains the configuration which it had before its deformation at room temperature.

The above Ni-Ti compound may easily be fabricated into plates or rods of various sizes and it is to be understood that the surgical appliance herein described in the form of a bone plate is a Ni-Ti alloy of the above composition.

The literature references explain in detail the various compositions of such alloys. Some having the temperature range for memory effect for surgical use are commercially available under the trade name "Nitinol."

As examples, the following compositions have been found suitable for surgical use.

A. An alloy containing 50 atomic per cent of nickel and 50 atomic per cent of titanium.

B. An alloy containing 49 atomic per cent of nickel, 1 atomic per cent of cobalt, and 50 atomic per cent of titanium.

C. An alloy containing 49 atomic per cent of titanium, 1 atomic per cent of cobalt, and 50 atomic per cent of nickel.

The presence of cobalt has the tendency of lowering the transition temperature.

The above are merely given as useful examples and may be varied in order to obtain the most desirable temperature range for the memory effect.

Referring to the figures, it is seen that in FIG. 1 the plate 10, of generally oblong configuration, overlaps the fracture 11 and is secured by means of screws 12 and 13 to one portion of the bone 14 and by means of screws 15 and 16 to the other portion thereof. This is the conventional method of application of a metallic splint and the bone plate in accordance with the present invention is affixed in the same manner.

In FIG. 2 the plate 10 is depicted in a strained condition, having been plastically elongated in the mid-section from its original length shown in phantom line to its present length shown in solid line. This is the deformed condition of the plate fabricated of the aforementioned Ni-Ti alloys. The shaded area 18 purports to show the elongation or tensile stressed portion. This is generally chosen to be remote from the area occupied by the bores or screw holes 22, 23, 25, and 26 which accommodate the respective screws as shown in FIG. 1.

In FIG. 3 it is seen that the plate 10, bridging the separated bone portions 14 and 17, is secured thereto by means of screws 12, 13, 15 and 16. For the sake of illustrating the constrictive action of the bone plate, the distance between the bone portions 14 and 17 is exaggerated. In an actual application, the bone ends are carefully placed in abutting relationship so that there is but slight separation between them.

FIG. 4 shows the constricted state of the plate 10 when, by virtue of the application of heat, it returns to nearly its original length.

It was mentioned before that the bone plate in accordance with the present invention must be subjected to a deformation or strain so that, upon application of heat within a suitable range of temperatures, it will be constricted and thereby return to its former state. However, experience has shown that in a simple tensile elongation, the length after thermoconstriction will be approximately 80 percent of the original length. This characteristic must naturally be accounted for in its application for surgical purposes.

In orthopedic practice care must be taken that the elongation be precisely controlled so that the implanted plate should not produce an undesirably strong compression of the bone surface. This would result in seriously disturbing the normal healing processes. In order to precisely produce the required compressive stress, an apparatus of the type schematically shown in FIG. 5 and generally known as a tensile-strain produc-

ing machine may be used. It consists of a stationary jaw 30 affixed to a bed 31. A clamp 32 overlies the jaw 30 and is so dimensioned as to accept the plate 10 to be clamped therein by means of a fastening device such as the winged screw 34.

A similarly constructed jaw 33 having a clamped member 36 and winged screw 37 is slidably disposed on the bed 31 in linear alignment with the jaw 30. The lead screw 38 extends into a threaded portion of the jaw 33 having a shaft 40 supported in bearings 41 and 42 placed in the body of the jaw 30. A handle 45 attached to the shaft 40 is provided for turning the lead screw 38, thereby causing sliding of the jaw 33 toward the jaw 30 in one direction of movement and away from it in the other direction. In this manner, the jaw 33, when moved in the direction away from the jaw 30, will exert a tensile strain on the plate 10 which is firmly clamped between the jaws, causing elongation thereof in the mid-section. The clamping members 32 and 36 and the configuration of the jaws 30 and 33 are so dimensioned as to accept the greater portion of both ends of the plate 10, leaving only a relatively small section where no clamping force is exerted. In this manner, deformation of the plate 10 in the region near the bores which accept the fastening screws is prevented. Retaining collars 46 and 47 attached to the shaft 40 prevent outward movement thereof by virtue of the force exerted when the jaw 33 is moved to produce the required stress on the plate 10. A micrometric scale (not shown here) is generally used to indicate the rotational displacement of the shaft 40 in terms of tensile strain produced.

It must be remembered that the inter-metallic compound of which the plate 10 is fabricated exhibits slight resiliency to the extent to which the elastic strain induced during elongation recovers. The force exerted as a result of thermo-constriction is considerable. Therefore, the tensile stress must be carefully calculated with respect to the compression force to be exerted on the bone sections, bearing in mind that, in the constricted state, only approximately 80 percent of the forced elongation will be compensated. In actual practice, depending upon the skeletal structure to which the bone plate is to be applied in order to achieve proper arthrodesis of the joints, the tensile strain is generally in the order of a few millimeters.

FIGS. 6a, 6b, and 6c show, simply by way of example, various configurations which the plates in accordance with this invention may take. When desired, other configurations for certain specific orthopedic applications may just as easily be fabricated.

It is essential of course that in surgical practice the plate to be imbedded in live tissue be completely sterile. This may be achieved either by conventional heat sterilization in an autoclave or by means of a cold sterilization liquid, such as benzalkonium chloride. Sterilization in an autoclave may not be applied to a pre-deformed plate inasmuch as the heat produced would effect thermoconstriction. On the other hand, cold sterilization is not fully reliable in certain cases where orthopedic appliances must be imbedded in the body.

It is considered preferable to first heat sterilize the plate of the type herein described and afterward effect the necessary tensile stress for its elongation under sterile conditions. The tensile stress apparatus shown in FIG. 5 may be sterilized and placed in a sterile environment in an appropriate enclosure. In this manner heat

sterilized plates may be strained prior to surgical implant. After this procedure, the prestrained plate is applied to the fractured bone after the bone is aligned and screwed to both ends thereof. While the fracture is held stable by this plate, thereby eliminating the use of bone clamps, heat is applied to its mid-section by any suitable means contracting the prestrained metal and applying compression to the fracture site. No clamping device is thus used, no extra metal is introduced into the body, and the incision is smaller. Finally, the wound is now closed as with the conventional plate. This Ni-Ti plate is easier to handle technically than those now available. It has further applications in areas where the present plate cannot be used, such as in smaller bones, i.e., fingers, where compression may be helpful for the fusion of joints. In forearm fractures, where two bones are involved, use of the conventional double plating technique is very cumbersome and many times, after compression is applied to one of the fractured bones, the other fractured bone is made to overlap and cannot be fixed by plates. By the use of the plates in accordance with this invention, each bone of the forearm may be plated separately, held aligned, and each bone in turn is compressed.

While preferred embodiments have been described, it will be apparent that various changes and modifications can be made without departing from the true spirit and scope of the present invention. It is intended that the invention be limited only by the appended claims.

What is claimed is:

1. A surgical appliance for the extra-medullary fixation and compression of the juxtaposed ends of a fractured bone, said appliance comprising:
 1. means connected to a plate to be specified hereinafter for attaching said plate to a fractured bone on either side of the fracture and
 2. a plate which is
 - a. shaped to conform to the exterior of the fractured bone in a manner overlapping the fracture,
 - b. formed of an alloy which exhibits a martensitic transformation at a temperature in the range tolerable by the human body, and
 - c. plastically deformed in the direction of an imaginary line connecting said attachment means by a predetermined amount sufficient to draw the juxtaposed ends of the fractured bone into forceful contact when the plastic deformation is removed by means of martensitic transformation,
 whereby the juxtaposed ends of the fractured bone may be forcefully compressed by raising the temperature of

said plate to a temperature at which the alloy of which it is formed exhibits a martensitic transformation.

2. A surgical appliance as claimed in claim 1 wherein said plate is formed of a nickel-titanium alloy.

3. A surgical appliance as claimed in claim 2 wherein the alloy of which said plate is formed also contains a small amount of cobalt.

4. A surgical appliance as claimed in claim 1 wherein:

1. said plate is of oblong configuration and has transverse bores therein near either end thereof for the accommodation of retaining screws and
2. said means for attaching said plate to the fractured bone comprises retaining screws passed through the transverse bores in said plate and into the bone.

5. A surgical appliance as claimed in claim 4 wherein the plastic deformation of said plate is confined to the region between the transverse holes at either end thereof.

6. A surgical appliance as claimed in claim 1 wherein the plastic deformation of said plate is confined to the region between said means for attaching said plate to the fractured bone on either side of the fracture.

7. The method of applying compression between the juxtaposed ends of a fractured bone which comprises the steps of:

1. plastically deforming a plate which is
 - a. shaped to conform to the exterior of a fractured bone in a manner overlapping the fracture,
 - b. formed of an alloy which exhibits martensitic transformation at a temperature in the range tolerable by the human body, and
 - c. has attachment means connected thereto for attaching said plate to the fractured bone on either side of the fracture in the direction of an imaginary line connecting said attachment means by a predetermined amount sufficient to draw the juxtaposed ends of the fractured bones into forceful contact when the plastic deformation is removed by means of martensitic transformation;
2. placing the juxtaposed ends of the fractured bone in abutting relationship;
3. attaching said plate over the fracture to both bone portions; and
4. applying an amount of heat to said plate sufficient to cause the martensitic transformation of the alloy of which it is formed, thereby causing constriction of said plate and the compression of the juxtaposed ends of the fractured bone.

* * * * *

55

60

65