



US006638279B2

(12) **United States Patent**
Bonutti(10) **Patent No.:** **US 6,638,279 B2**
(45) **Date of Patent:** ***Oct. 28, 2003**(54) **METHOD OF POSITIONING BODY TISSUE
RELATIVE TO A BONE**(75) Inventor: **Peter M. Bonutti**, Effingham, IL (US)(73) Assignee: **Bonutti 2003 Trust-A**, Effingham, IL
(US)(*) Notice: Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 180 days.This patent is subject to a terminal dis-
claimer.(21) Appl. No.: **09/835,473**(22) Filed: **Apr. 16, 2001**(65) **Prior Publication Data**

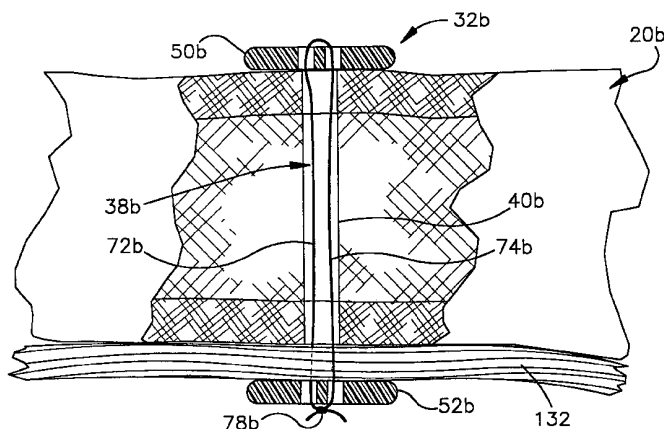
US 2002/0019634 A1 Feb. 14, 2002

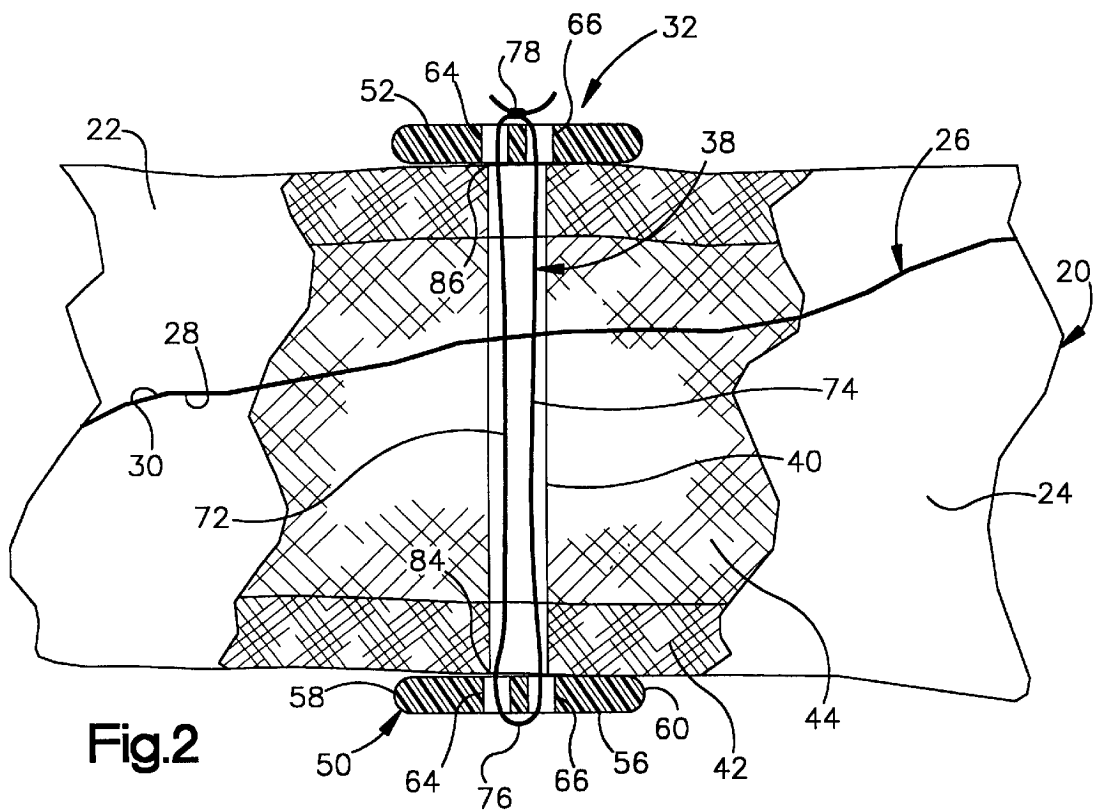
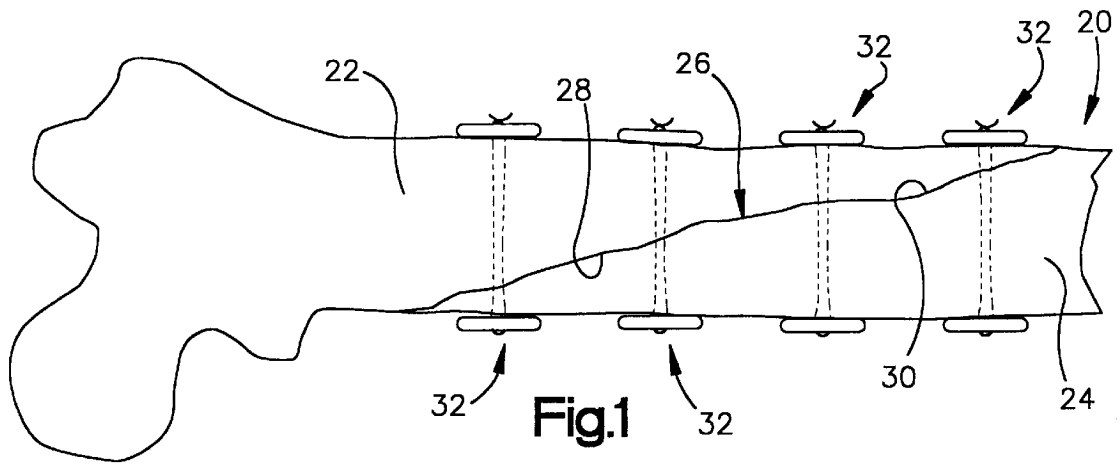
Related U.S. Application Data(63) Continuation of application No. 09/532,942, filed on Mar.
22, 2000, now Pat. No. 6,238,395, which is a continuation
of application No. 09/363,707, filed on Jul. 29, 1999, now
Pat. No. 6,045,551, which is a continuation-in-part of appli-
cation No. 09/323,488, filed on Jun. 1, 1999, now Pat. No.
6,117,160, which is a continuation of application No.
09/019,977, filed on Feb. 6, 1998, now Pat. No. 5,921,986.(51) **Int. Cl.**⁷ **A61B 17/56**(52) **U.S. Cl.** **606/60; 606/57; 606/86;**
606/105(58) **Field of Search** 606/60, 57, 215,
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Bongini Bianco; Paul D. Bianco; Martin Fleit(57) **ABSTRACT**

An anchor connected with a suture is moved through a passage between opposite sides of a bone. The anchor is then pivoted to change its orientation. A second anchor is connected with the suture. While tension is maintained in the suture, the suture is secured against movement relative to the anchors. This may be done by tying the suture or by using a suture retainer to hold the suture. A suture retainer may be used in place of the second anchor. The passage may extend across a fracture in the bone. The passage may have either a nonlinear or linear configuration. A tubular member may be positioned in the passage with the tubular member extending into portions of the passage on opposite sides of the fracture. Opposite end portions of the tubular member may be disposed in a compact outer layer of the bone. If desired, a member other than a suture may be used as a force transmitting member between the two anchors. The tubular member may be formed of bone.

14 Claims, 7 Drawing Sheets



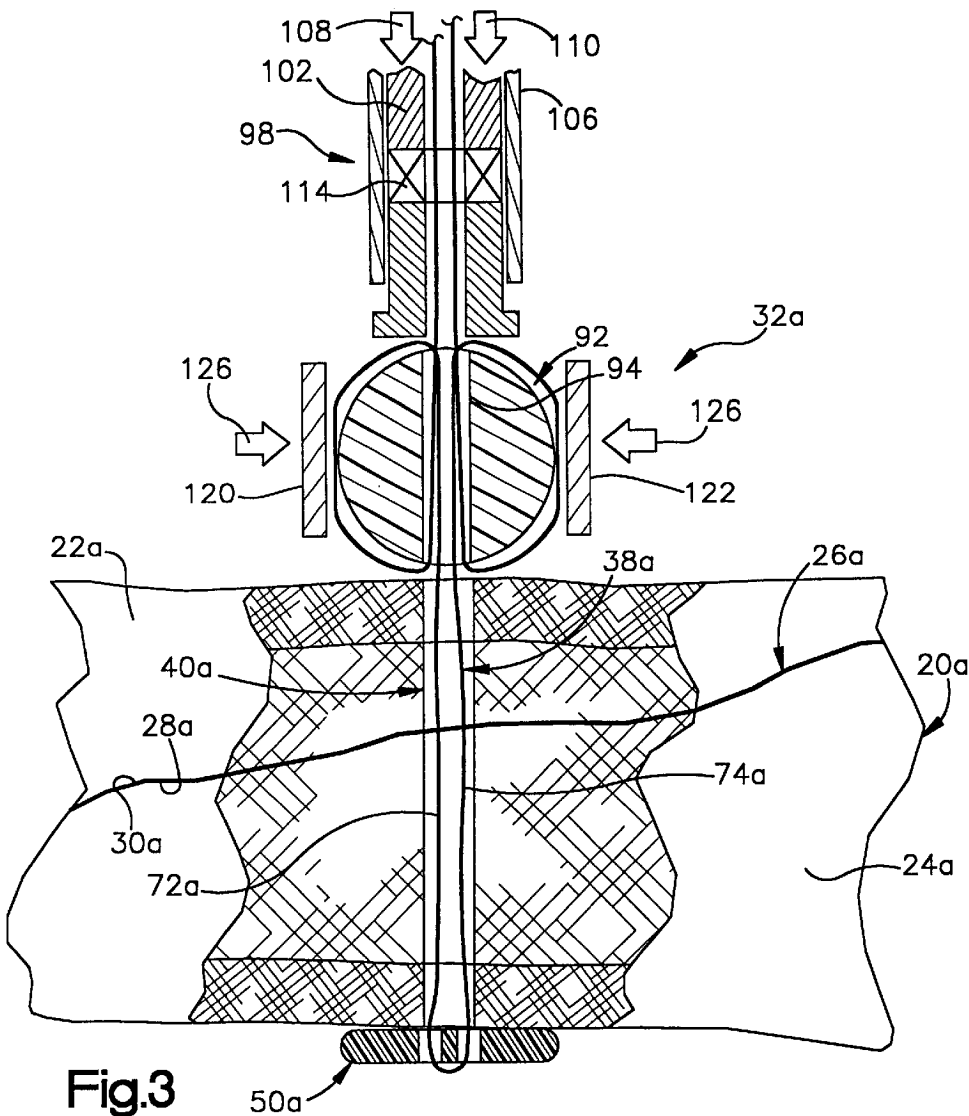


Fig.3

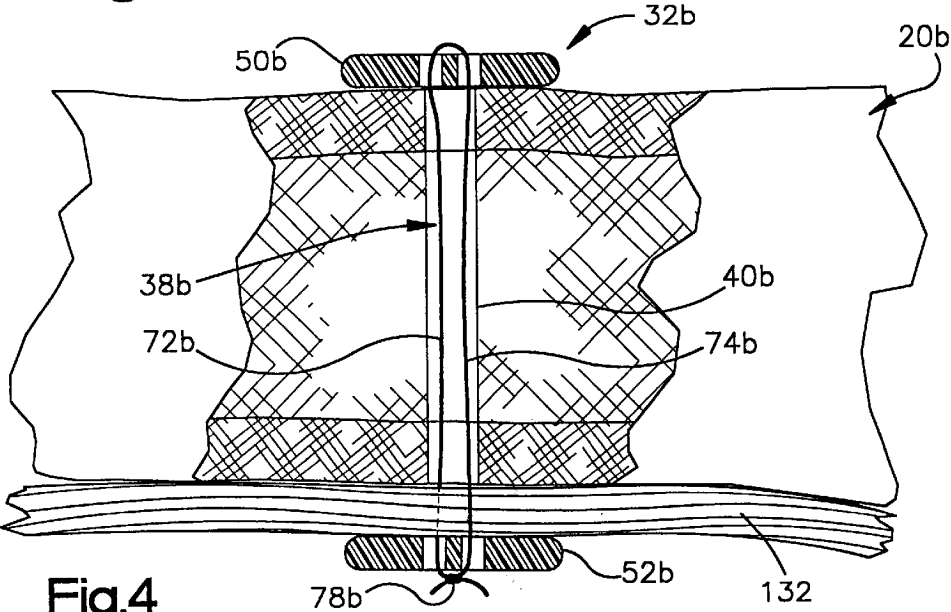
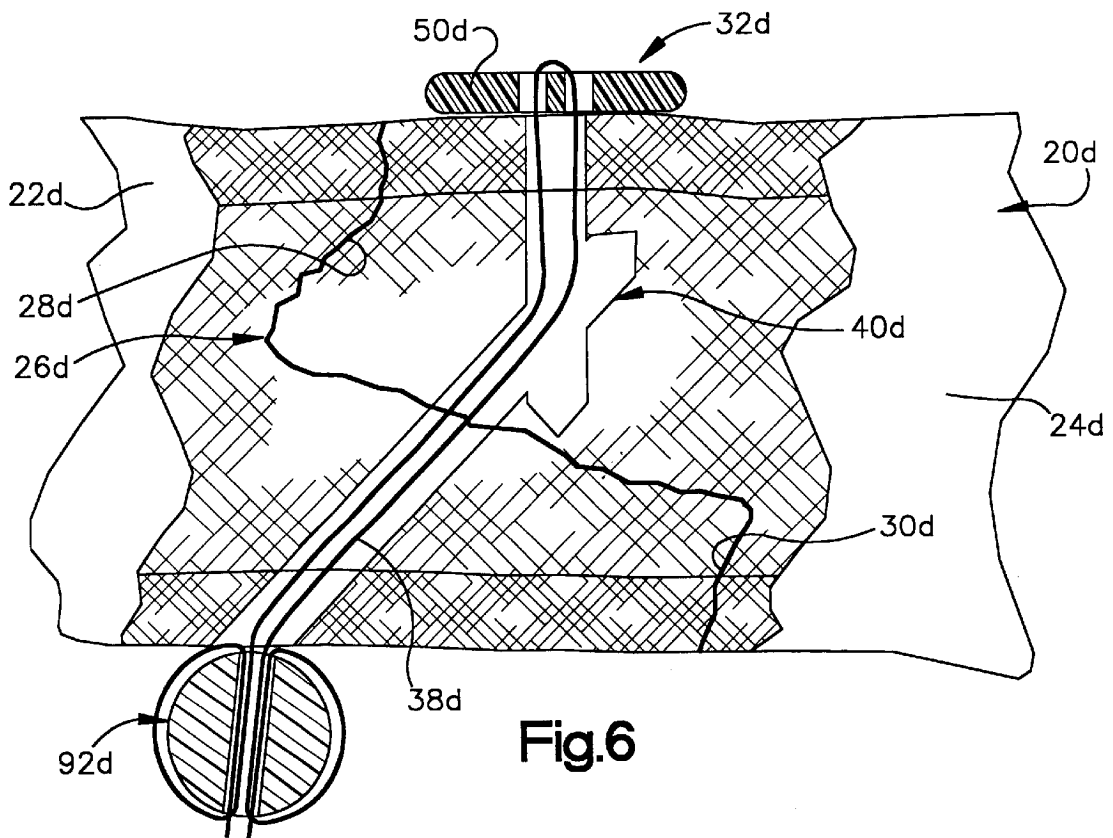
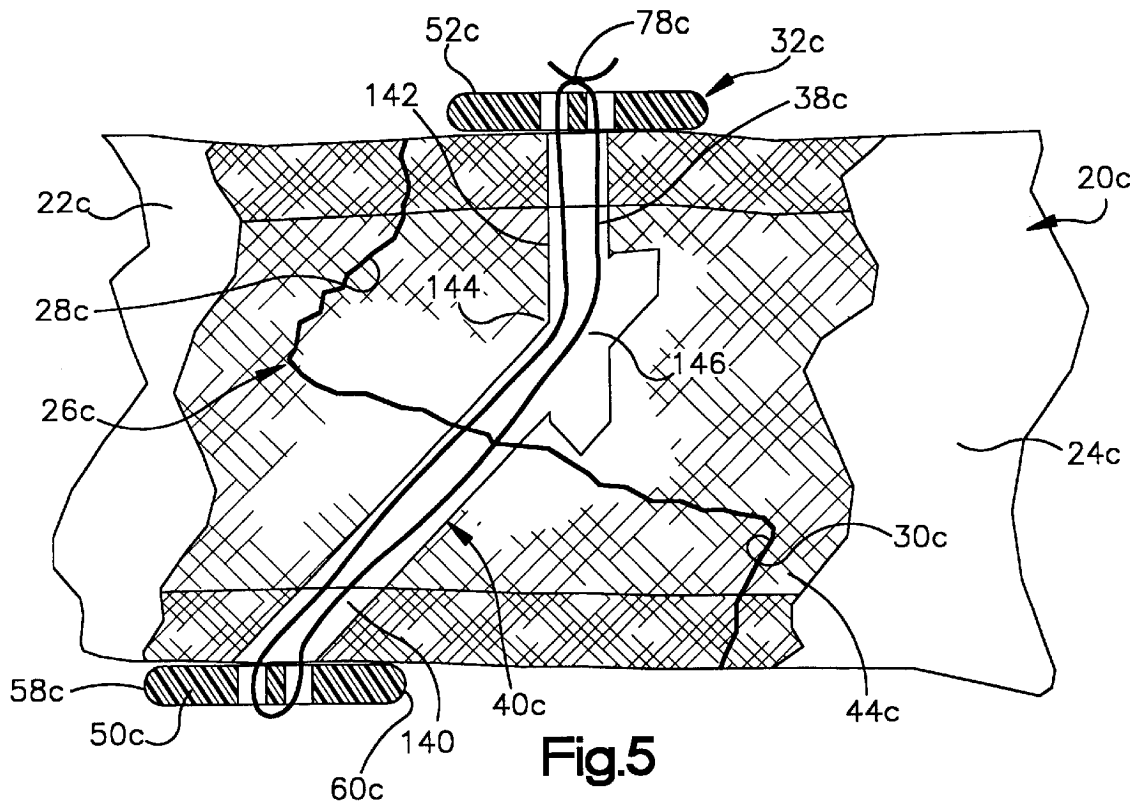


Fig.4



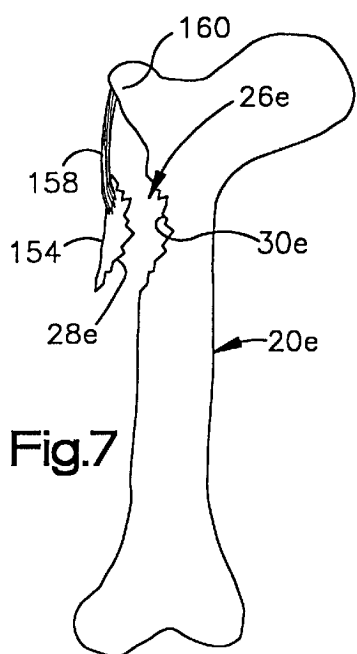


Fig. 7

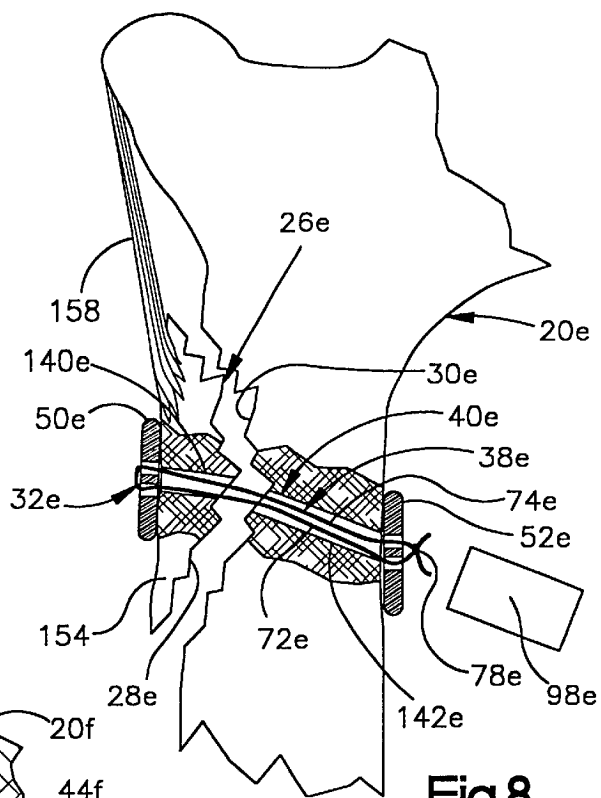


Fig. 8

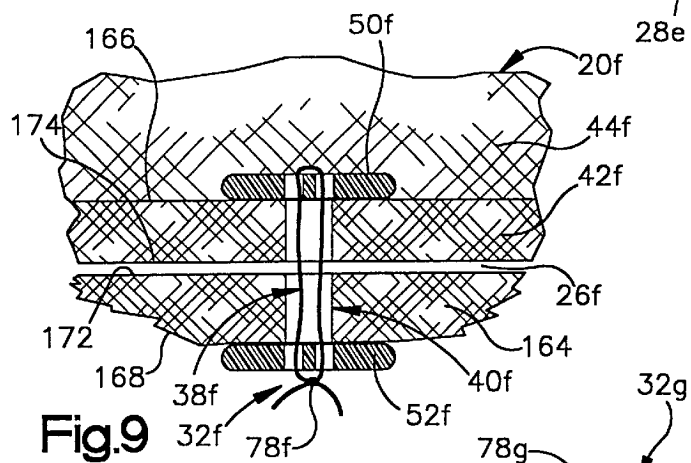


Fig. 9

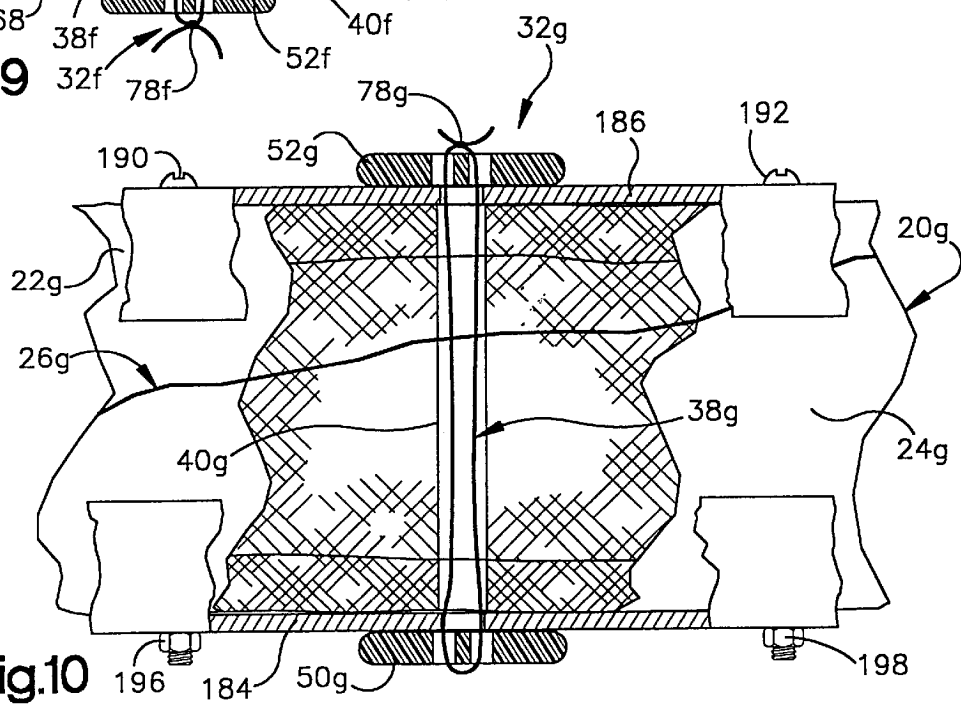
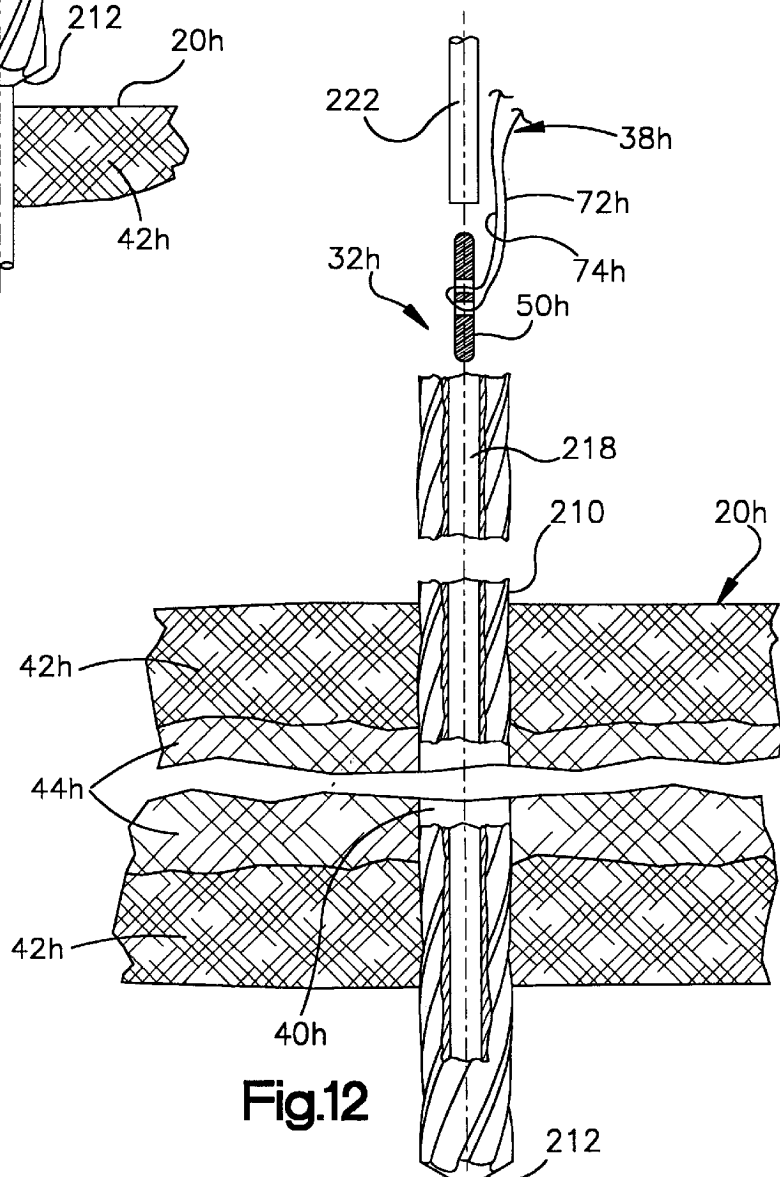
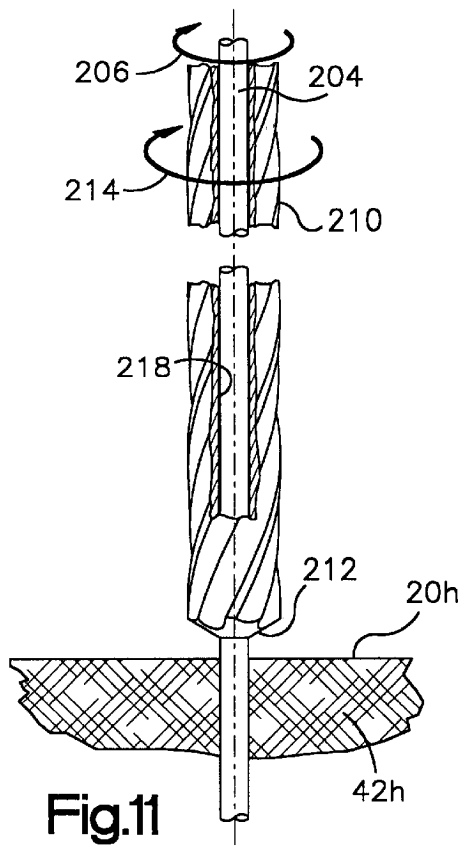
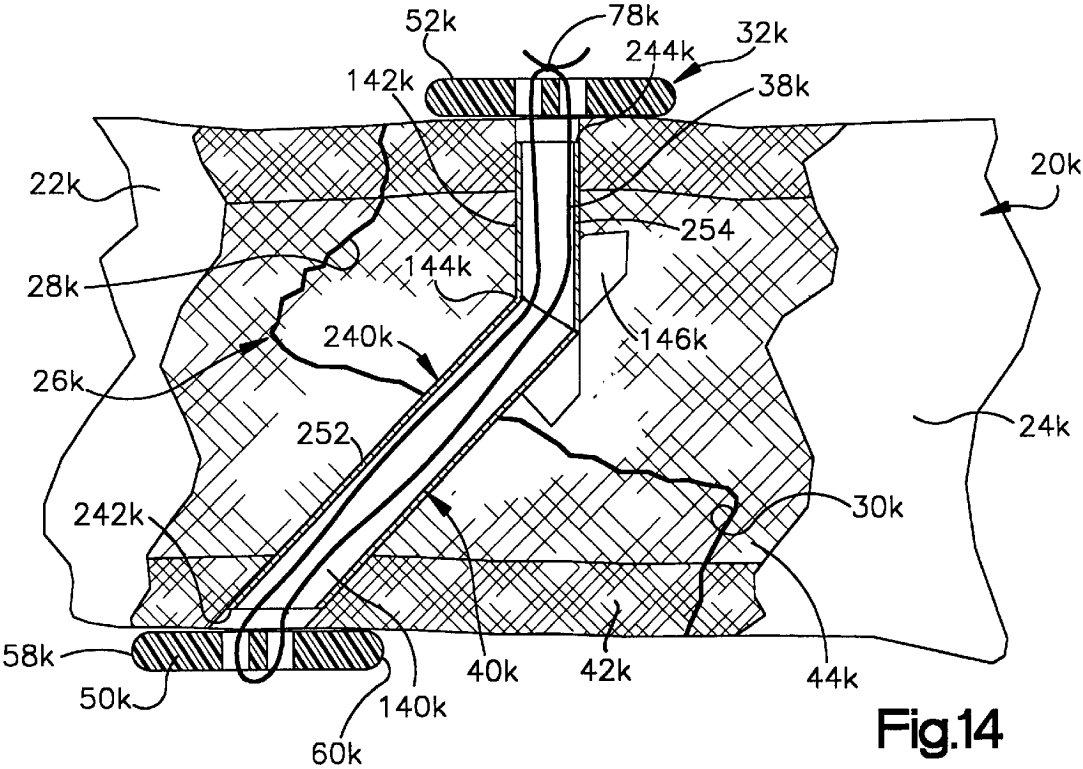
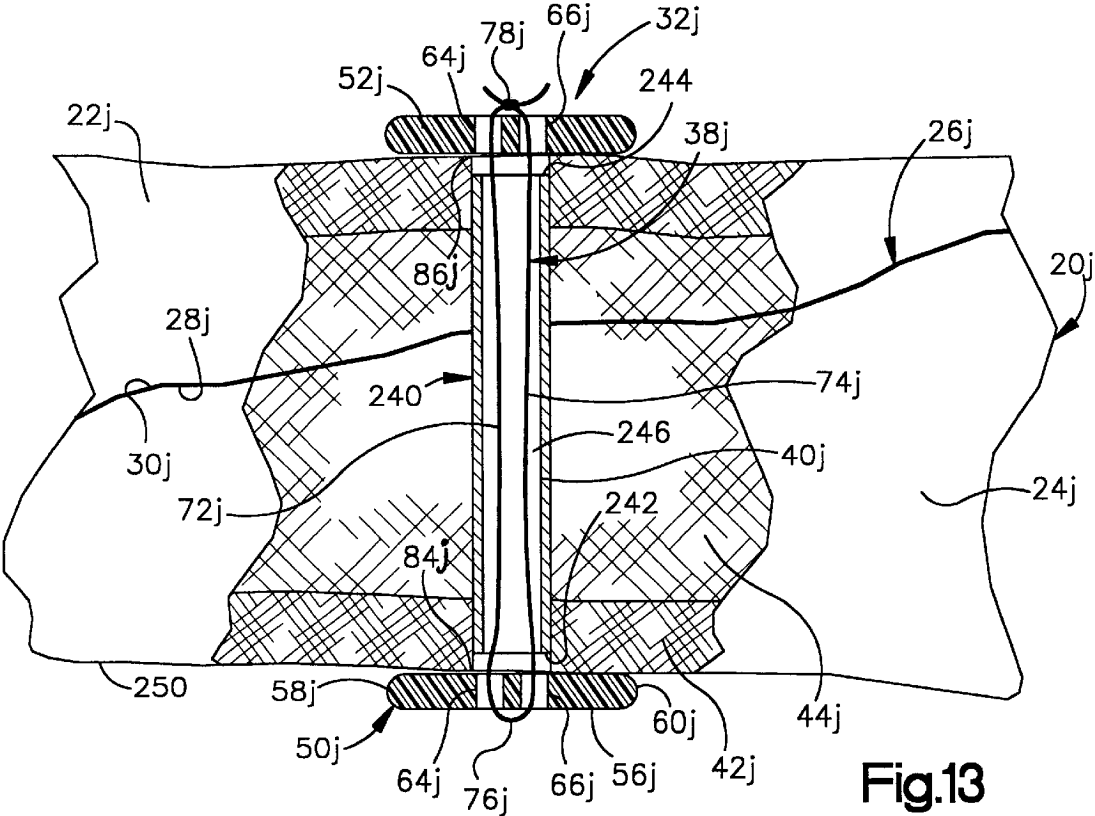
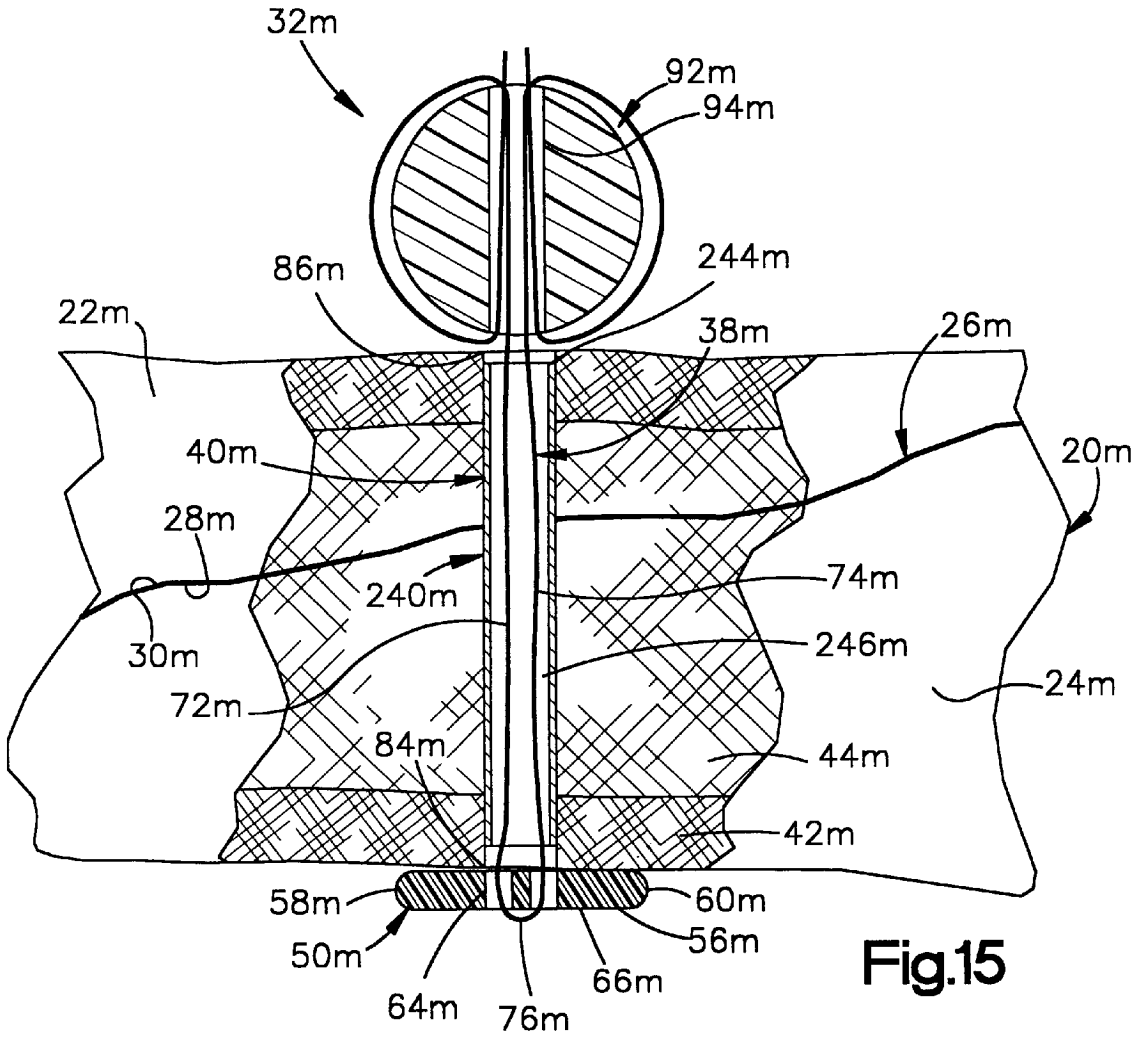


Fig. 10







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METHOD OF POSITIONING BODY TISSUE RELATIVE TO A BONE

RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 09/532,942 filed Mar. 22, 2000 by Peter M. Bonutti and entitled "Bone Suture". The aforesaid application Ser. No. 09/532,942 is itself a continuation of application Ser. No. 09/363,707 filed Jul. 29, 1999 (now U.S. Pat. No. 6,045,551). The aforementioned application Ser. No. 09/363,707 is a continuation-in-part of U.S. patent application Ser. No. 09/323,488, filed Jun. 1, 1999 by Peter M. Bonutti and entitled "Bone Suture" (now U.S. Pat. No. 6,117,160). The aforementioned application Ser. No. 09/323,488 is itself a continuation of U.S. patent application Ser. No. 09/019,977 filed Feb. 6, 1998 by Peter M. Bonutti and entitled "Bone Suture" (now U.S. Pat. No. 5,921,986). The benefit of the earlier filing date of the aforementioned application Ser. Nos. 09/532,942; 09/363,707; 09/323,488 and 09/019,977 is claimed for all subject matter common to the aforementioned applications and this application.

BACKGROUND OF THE INVENTION

The present invention relates to a new and improved method and apparatus for securing sections of a fractured bone and/or securing body tissue to bone.

When a bone is broken or fractured, it is necessary to press sections of the bone on opposite sides of the fracture together in order to promote healing of the bone. Bone screws have been used with or without metal plates to hold the sections of the fractured bone against movement relative to each other. In addition, it has been suggested that avulsion fractures could be treated by using wire sutures between sections of bone in a manner similar to that disclosed in U.S. Pat. No. 5,474,554. It has also been suggested that an anchor could be retained in a bone in a manner disclosed in U.S. Pat. Nos. 5,527,343 and 5,534,012.

SUMMARY OF THE INVENTION

The present invention relates to a method of securing sections of a fractured bone. Sections of a fractured bone are held against movement relative to each other by a force transmitting member, such as a suture, which extends through a passage in the bone. The passage in the bone may have a linear or nonlinear configuration. Tension is maintained in the force transmitting member to press surfaces on the fracture together by securing anchors and/or retainers to opposite ends of the force transmitting member. It is believed that a suture may advantageously be used as the force transmitting member.

A tubular member is positioned in a linear or nonlinear passage through the bone. The tubular member extends into portions of the passage on opposite sides of the fracture. End portions of the tubular member may be positioned in a compact outer layer of the bone. The tubular member may be formed of bone. The force transmitting member may be formed of bone or other body tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the invention will become more apparent upon a consideration of the following description taken in connection with the accompanying drawings wherein:

FIG. 1 is a schematic illustration of a bone having a fracture which has been treated with sutures and suture anchors;

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FIG. 2 is an enlarged fragmentary schematic sectional view of a portion of the bone of FIG. 1 and illustrating the manner in which a suture extends across the fracture and interconnects suture anchors on opposite sides of the fracture;

FIG. 3 is a schematic illustration, generally similar to FIG. 2, illustrating the manner in which a suture retainer is used to maintain tension in a suture which extends across a fracture to a suture anchor;

FIG. 4 is a schematic illustration, generally similar to FIGS. 2 and 3, illustrating the manner in which body tissue is connected with a bone using a suture and suture anchors;

FIG. 5 is a schematic illustration, generally similar to FIGS. 2-4, illustrating the manner in which a suture extends between suture anchors through a nonlinear passage;

FIG. 6 is a schematic illustration, generally similar to FIG. 5, illustrating the manner in which a suture extends between a suture anchor and a suture retainer through a nonlinear passage;

FIG. 7 is a schematic illustration depicting a bone which has been fractured in such a manner as to have a bone fragment connected with the bone by muscle or other fibrous tissue;

FIG. 8 is a schematic illustration depicting the manner in which the bone fragment of FIG. 7 is connected to the bone by a suture and a pair of suture anchors;

FIG. 9 is a schematic illustration depicting the manner in which a bone fragment is connected with a bone by a suture which extends between an anchor within the bone and an anchor which engages the bone fragment;

FIG. 10 is a schematic illustration, generally similar to FIGS. 2-4 and illustrating in the manner in which plates and rigid fasteners are used in association with a suture and anchors to treat a bone fracture;

FIG. 11 is a schematic illustration depicting the manner in which a thin elongated member is moved through bone and the manner in which a drill is moved along the thin elongated member to enlarge a passage formed in the bone by the thin elongated member;

FIG. 12 is a schematic illustration depicting the manner in which an anchor is moved through a passage in the drill of FIG. 11 after the thin elongated member has been removed from the passage in the drill;

FIG. 13 is a schematic illustration, generally similar to FIG. 2, illustrating the manner in which a tubular member is positioned in a passage in the bone;

FIG. 14 is a schematic illustration, generally similar to FIG. 5, illustrating the manner in which tubular members are positioned in a nonlinear passage in a bone; and

FIG. 15 is a schematic illustration, generally similar to FIG. 3, illustrating the manner in which a suture retainer is used with a tubular member which is positioned in a passage in a bone.

DESCRIPTION OF SPECIFIC PREFERRED EMBODIMENTS OF THE INVENTION

A bone 20 which has been fractured is illustrated in FIG. 1. The bone 20 is divided into two sections 22 and 24 by a fracture 26. Opposite side surfaces 28 and 30 of the fracture 26 are pressed together by bone suture assemblies 32.

It should be understood that the bone suture assemblies 32 may be utilized in the treatment of any one of many different types of fractures. The fractures may or may not result in the formation of one or more bone fragments. In FIG. 1, the

bone suture assemblies **32** have been illustrated as interconnecting sections **22** and **24** of a complete bone fracture of the spiral type. However, the bone suture assemblies **32** could be utilized to connect a fragment of a bone to the main portion of the bone from which the fragment was broken off.

Each of the bone suture assemblies **32** has the same construction. However, the bone suture assemblies **32** could have different constructions if desired. The construction of one of the identical bone suture assemblies **32** is illustrated in FIG. 2.

The bone suture assembly **32** (FIG. 2) includes a flexible suture **38** which extends across the fracture **26**. The suture **38** is disposed in a straight cylindrical passage **40** which extends diametrically across a generally cylindrical portion of the bone **20**. The passage **40** extends through hard compact tissue of an outer layer **42** of the bone and through spongy or cancellous bone tissue **44** which is enclosed by the hard outer layer. Although the passage **40** has a linear configuration, the passage could have a nonlinear configuration if desired.

The suture **38** extends between a first suture anchor **50** disposed on one side of the fracture **26** and a second suture anchor **52** disposed on the opposite side of the fracture. Tension is maintained in the suture **38** to press the suture anchors **50** and **52** against opposite sides of the bone **20** with a predetermined force. This force presses the side surfaces **28** and **30** of the fracture **26** firmly together to promote healing of the fracture. If desired, buttons or other force distributing members could be provided between the anchors **50** and **52** and the bone **20**. Body tissue could be disposed between the anchors **50** and **52** and the bone **20**.

The suture **38** and/or suture anchors **50** and **52** may be formed of any desired natural or artificial material. For example, the suture **38** may be formed of either a polymeric material or a metal. The suture **38** may be biodegradable. Any known suture material may be utilized to form the suture **38**.

The suture anchors **50** and **52** have the same construction. However, the anchor **50** could have a construction which is different than the construction of the anchor **52**. The anchor **50** has a cylindrical outer side surface **56** which extends between smooth rounded end portions **58** and **60**. A pair of parallel cylindrical openings **64** and **66** extend diametrically through the anchor **50**. The anchor **50** is free of sharp corners or projections to avoid cutting or abrading of body tissue disposed adjacent to the anchor.

The suture anchor **50** is made of a biocompatible material. Suitable materials include stainless steel or titanium, cobalt chrome and other biocompatible metals. Polymeric material may also be used, suitable polymeric materials includes polyethylene, polypropylene, and biodegradable material such as PLA and PGA. It is believed that it may be preferred to form the suture anchors **50** and **52** from biodegradable or bioerodible copolymers. If desired, the anchor **50** could be formed of body material or hydrophilic materials.

It is contemplated that the anchor **50** may have any desired configuration. For example, the anchor **50** could have any one of the configurations disclosed in U.S. Pat. No. 5,522,846 issued Jun. 4, 1996 and entitled "Suture Anchor". Alternatively, the suture anchor **50** could have the configuration disclosed in U.S. Pat. No. 5,534,012 issued Jul. 9, 1996 and entitled "Method and Apparatus for Anchoring a Suture".

Although the anchor **50** may have any desired configuration, the cross-sectional size of the anchor is such as to enable the anchor to be moved through the passage **40**.

In addition, the length of the anchor **50** is such as to enable it to span an opening at an end of the passage **40** and transmit force from the suture **38** to a substantial area on the outer layer **42** of the bone **20**. It is believed that it will be preferred to form the anchor **50** in such a manner as to eliminate any sharp corners or projections.

In the illustrated embodiment of the invention, the anchor **50** has a cylindrical configuration. This particular anchor has an axial length of about two millimeters and a diameter of about one millimeter. The length of the anchor **50** may be approximately three times the diameter of the anchor. The openings **64** and **66** have a diameter of about one-half millimeter.

It should be understood that the foregoing dimensions have been set forth herein for purposes of clarity of description and it is contemplated that the size of the anchor **50** may vary as a function of the size of the bone being treated. Thus, relatively small anchors may be used in association with treatment of small bones in a wrist, hand, foot or ankle of a patient. Relatively large anchors may be used in association with treatment of larger bones in an arm, shoulder, leg or hip of a patient. It should be understood that the bone suture assembly **32** may be used in conjunction with many different bones other than the specific bones previously mentioned.

Only a single anchor **50** or **52** has been shown at opposite ends of the passage **40**. It is contemplated that a plurality of anchors could be provided at each end of the passage **40**. For example, a pair of separate or interconnected anchors could be provided in a manner similar to that disclosed in the aforementioned U.S. Pat. No. 5,534,012.

In the embodiment of the invention illustrated in FIG. 2, the suture **38** has a pair of limbs or sections **72** and **74** which extend through the openings **64** and **66** in the suture anchors **50** and **52**. A connector section **76** interconnects the two limbs **72** and **74** of the suture **38** and engages a portion of the anchor **50**. A knot **78** is formed in the opposite ends of the limbs **72** and **74** to interconnect the two limbs of the suture **38**.

When the knot **78** is formed, a predetermined tension is present in the limbs **72** and **74** of the suture **38**. This results in the suture anchors **50** and **52** being pressed firmly against the bone **20** with a predetermined force. This predetermined force is maintained during and after tying of the knot **78**.

When the bone suture assembly **32** is to be used to treat the fracture **26** in the bone **20**, the two sections **22** and **24** of the bone are pressed together at the fracture **26** to align the side surfaces **28** and **30** of the fracture. A drill is then used to form the passage **40** which extends diametrically through the generally cylindrical bone **20**. Of course, the passage **40** could be formed by the use of a tool other than a drill. If desired, the passage **40** could have a noncircular cross-sectional configuration.

Once the passage **40** has been formed in the two sections **22** and **24** of the bone **20**, a tubular cylindrical member is inserted into the passage **40** and extends diametrically through the bone **20**. The leading end of the tubular cylindrical member is aligned with a circular outlet **84** from the passage **40**. The opposite end of the tubular member is aligned with a circular inlet **86** to the passage **40**. The tubular member has a thin cylindrical wall which engages the sections **22** and **24** of the bone **20**. A cylindrical inner side surface of the tubular member defines a passage having a diameter which is only slightly less than the diameter of the passage **40**.

By inserting the tubular member into the passage **40**, the portions of the passage disposed on opposite sides of the

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fracture 26 are maintained in alignment. The tubular member may be flexible to enable the tubular member to be inserted into a nonlinear passage 40 through the bone 20. The tubular member may be formed of metal or a polymeric material. If the tubular member is formed of a polymeric material, it may be preferred to form the tubular member from a biodegradable or bioerodible copolymer.

The suture 38 is formed into a loop which extends through the openings 64 and 66 in the anchor 50. At this time, the suture 38 has a length which is substantially greater than the length illustrated in FIG. 2. The cylindrical anchor 50, with the suture 38 connected thereto, is then positioned in axial alignment with the tubular member which extends through the passage 40. Thus, the anchor 50 is moved to an orientation in which a longitudinal central axis of the anchor is coincident with the longitudinal central axis of the cylindrical passage in the tubular member which extends through the passage 40 in the bone 20.

The leading end 58 of the anchor 50 is then moved into the cylindrical tubular member which forms a liner for the passage 40. A pusher member pushes the anchor 50 from an upper (as viewed in FIG. 2) end of the tubular member along the passage 40 in the bone 20 and through the outlet 84 from the passage. As the anchor 50 moves through the passage 40, the suture 38 is pulled through the passage 40 by the anchor.

The orientation of the anchor 50 is then changed from an orientation in which the longitudinal central axis of the anchor 50 is aligned with the longitudinal central axis of the passage 40 to an orientation in which the longitudinal central axis of the anchor 50 extends generally perpendicular to the longitudinal central axis of the passage 40, i.e., the orientation shown in FIG. 2. To pivot the anchor 50 to the orientation shown in FIG. 2, as the anchor emerges from the outlet 84, the suture 38 is tensioned. The combination of the tension in the suture 38 and force applied against the trailing end 60 of the anchor by the pusher member causes the anchor to pivot about the trailing end 60 of the anchor. The pusher member is then withdrawn and the suture tensioned to move the anchor to the position shown in FIG. 2 in a manner similar to that described in the aforementioned U.S. Pat. Nos. 5,527,343 and 5,534,012.

Although it is believed that it may be preferred to change the orientation of the anchor 50 after it has emerged from the passage 40, the anchor could be blocked from reentering the passage in other ways if desired. Thus, the anchor could expand after emerging from the passage 40. This could be accomplished by having spring biased arms held in a retracted position by engagement of spring biased arms with the inner side surface of the tubular cylindrical member which lines the passage 40. Upon emerging from the passage, the arms would move outward under the influence of spring forces and extend radially outward beyond the edge of the exit from the passage 40. If desired, the anchor 50 could be constructed so as to expand in a manner similar to that disclosed in U.S. Pat. No. 5,397,331 and/or U.S. Pat. No. 4,409,974.

Rather than expanding under the influence of stored energy, such as spring force, the anchor 50 could expand by absorbing body fluids. Thus, the anchor 50 may be compressed when it moves through the passage 40 and will expand and absorb body fluids after emerging from the passage 40. It is contemplated that the anchor 50 could be constructed so as to expand in any one of the ways disclosed in U.S. patent application Ser. No. 08/699,553 filed Aug. 19, 1996 by Peter M. Bonutti and entitled "Suture Anchor".

The cylindrical tubular member is then withdrawn from the passage 40. It should be understood that the cylindrical

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tubular member is used to line the passage 40 in the bone 20 during movement of the anchor 50 through the passage. The use of the tubular member to line the passage 40 may be omitted if desired. However, if the use of the tubular member to line the passage 40 is omitted, the anchor 50 and pusher member would be exposed to the cancellous bone tissue 44 during movement of the anchor through the passage.

The limbs 72 and 74 of the suture 38 are then threaded through openings 64 and 66 in the second suture anchor 52. The limbs 72 and 74 of the suture 38 are tensioned and the second anchor 52 is pressed against the outer side surface of the bone 20. While a predetermined tension force is maintained in the limbs 72 and 74 of the suture 38, the knot 78 is tied in the suture to interconnect the two suture anchors 50 and 52 with the suture 38. The suture 38 is then trimmed to the desired length.

Once the knot 78 has been tied between the limbs 72 and 74 of the suture 38, the tension in the suture 38 presses the side surfaces 28 and 30 of the fracture 26 together. This pressure between the side surfaces 28 and 30 of the fracture 26 is maintained by the suture 38 and suture anchors 50 and 52 until the fracture heals. It is believed that it may be preferred to form the suture 38 and suture anchors 50 and 52 of a biodegradable material which, after the fracture 26 has healed, will dissolve in the patient's body.

The cylindrical tubular member which is inserted into the passage 40 through the bone 20 performs the dual functions of lining the inside of the passage 40 and maintaining the two sections 22 and 24 of the bone in alignment. The cylindrical tubular member could have a slot formed in a side wall of the tubular member to facilitate insertion of the tubular member into the passage 40. It is contemplated that the cylindrical tubular member could be left in the passage 40 after the bone suture assembly 32 has been installed. If the slotted or unslotted cylindrical tubular member is to be left in the passage 40, the cylindrical tubular member may be formed of a biodegradable or bioerodible copolymer. When the cylindrical tubular member remains in the passage 40, the suture 38 extends through the tubular member.

Although only a knot 78 has been shown in FIG. 2 adjacent to the second anchor 52, a suture retainer could be provided to further hold the limbs 72 and 74 of the suture 38. If a suture retainer is to be used in association with the knot 78, the suture retainer will be moved along the limbs of the suture 38 toward the knot before the limbs 72 and 74 of the suture are trimmed to the short length shown in FIG. 2. The suture retainer would then be plastically deformed to grip the limbs 72 and 74 of the suture 38. Thereafter, the suture limbs 72 and 74 would be trimmed to a desired length.

BONE SUTURE ASSEMBLY—SECOND EMBODIMENT

In the embodiment of the invention illustrated in FIG. 2, a pair of suture anchors 50 and 52 are connected with the suture 38 to maintain tension in the suture and pressure against opposite side surfaces 28 and 30 of the fracture 26. In the embodiment of the invention illustrated in FIG. 3, a suture retainer is used in place of one of the suture anchors. Since the embodiment of the invention illustrated in FIG. 3 is generally similar to the embodiment of the invention illustrated in FIG. 2, similar numerals will be utilized to designate similar components, the suffix letter "a" being associated with the embodiment of the invention illustrated in FIG. 3 to avoid confusion.

A bone 20a has sections 22a and 24a which are separated by a fracture 26a. The fracture 26a has side surfaces 28a and

30a which are pressed together by a bone suture assembly 32a. A suture 38a extends through a cylindrical passage 40a which extends diametrically through the generally cylindrical bone 20a. The suture 38a has a pair of limbs or sections 72a and 74a which are connected with a suture anchor 50a. The suture anchor 50a has the same construction as the suture anchor 50 of FIG. 2.

In accordance with a feature of this embodiment of the invention, a suture retainer 92 is used in place of the suture anchor 52 of FIG. 2. The suture retainer 92 has a spherical configuration. A cylindrical passage 94 extends through the center of the spherical suture retainer 92. The sections 72a and 74a of the suture 38a extend around the spherical outer side surface of the suture retainer 92. Thus, a loop is formed in each of the sections 72a and 74a around portions of the suture retainer 92.

If desired, the suture retainer 92 could have a different configuration. For example, the suture retainer 92 could have an oval or elliptical configuration. Although the passage 94 has a linear central axis, the passage could have a nonlinear central axis. If desired, a plurality of passages having the same or different configurations could be provided in the suture retainer 92.

After the suture 38a has been inserted through the suture retainer 92, in the manner illustrated schematically in FIG. 3, the suture retainer 92 is moved along the sections 72a and 74a of the suture 38a toward the bone 20a. The suture retainer 92 is formed as one piece of a polymeric material having a relatively low coefficient of friction. Therefore, the two sections 72a and 74a of the suture 30a can readily slide along the surfaces of the suture retainer 52a while the suture retainer moves toward the bone 20a.

A predetermined tension is maintained in the sections 72a and 74a of the suture 38a while the suture retainer 92 is pressed against the bone 20a. This results in the suture 38a being pulled tightly against the suture anchor 50a. The tension in the suture 38a is effective to press the suture anchor 50a and retainer 92 against opposite sides of the bone 20a with a predetermined force.

Once the suture retainer 92 has been moved along the suture 38a and is being pressed against the bone 20a with a predetermined force, the suture retainer is plastically deformed to grip the sections 72a and 74a of the suture 38a. An apparatus 98 for pressing the suture retainer 92 against the bone 20a includes a tubular cylindrical plunger 102 (FIG. 3) having a cylindrical central passage through which the sections 72a and 74a of the suture 38a extend. The plunger 102 is enclosed by a tubular cylindrical housing 106. The plunger 102 is pressed downward, relative to the housing 106 with a predetermined force, indicated by arrows 108 and 110 in FIG. 3. An annular transducer or load cell 114 provides an output indicative of the magnitude of the force 108 and 110 with which the suture retainer 92 is pressed against the bone 20a by the plunger 102.

While the sections 72a and 74a of the suture 38a are being tensioned with a predetermined force and while the plunger 102 is being pressed against the suture retainer 92 with a predetermined force, the suture retainer 92 is plastically deformed. To plastically deform the suture retainer 92, a plurality of force applying or clamp members 120 and 122 are pressed against the suture retainer 92 with a predetermined minimum force, indicated schematically by arrows 126 in FIG. 3. The force application members 120 and 122 may have an arcuate configuration to conform to the spherical configuration of the suture retainer 92 or may have a flat configuration. The force applied against the suture retainer

92 by the force applying members 120 and 122 is sufficient to cause plastic deformation of the material of the suture retainer.

The force 126 is applied against the suture retainer 92 while the suture retainer is at a temperature which is below the transition temperature of the biodegradable polymer which forms the suture retainer 92. Thus, the suture retainer 92 is at approximately the same temperature as the bone 20a when the force 126 is applied against the suture retainer. The force 126 causes the material of the suture retainer 92 to flow and grip the sections 72a and 74a of the suture 38a.

Upon disengagement of the force application members 120 and 122 from the suture retainer 92, the application of downward (as viewed in FIG. 3) force against the suture retainer 92 is interrupted. The upward tensioning of the sections 72a and 74a of the suture 38a is also interrupted. At this time, the plastically deformed suture retainer 92 securely grips the two sections 72a and 74a of the suture 38a to maintain the tension in the suture 38a. If desired, a knot may be formed between the sections 72a and 74a of the suture as additional protection against the suture working loose over an extended period of time.

The suture retainer 92 may be formed of many different materials. However, it is believed that it will be preferred to form the suture retainer 92 of a biodegradable polymer. One biodegradable polymer which may be utilized is polycaprolactone. Alternatively, the suture retainer 92 could be formed of polyethylene oxide terephthalate or polybutylene terephthalate. It is also contemplated that other biodegradable or bioerodible copolymers could be utilized.

Although it is preferred to form the suture retainer 92 of a biodegradable material, the suture retainer could be formed of a material which is not biodegradable. For example, the suture retainer 92 could be formed of an acetyl resin, such as "DELIRIN" (trademark). Alternatively, the suture retainer 92 could be formed of para-dimethylamino-benzenediazo sodium sulfonate, such as "DEXON" (trademark). The construction of the suture retainer 92 and the manner in which it cooperates with the suture 38a is the same as is disclosed in U.S. patent application Ser. No. 08/905,084 filed Aug. 1, 1997 by Peter M. Bonutti et al. and entitled "Method and Apparatus for Securing a Suture".

The suture retainer 92 is plastically deformed to grip the limbs 72a and 74a of the suture 38a. However, the suture retainer 92 could be constructed so as to be mechanically actuated to grip the suture 38a. If desired, a combination of a mechanical gripping action and plastic deformation could be utilized by a retainer to grip the suture 38a.

Retaining Body Tissue against Bone

In the embodiment of the invention illustrated in FIG. 2, a bone suture assembly 32 is utilized to press surfaces 28 and 30 of a fracture 26 together. In the embodiment of the invention illustrated in FIG. 4, the suture anchor assembly is utilized to hold body tissue against movement relative to a bone. Since the embodiment of the invention illustrated in FIG. 4 is generally similar to the embodiments of the invention illustrated in FIGS. 2 and 3, similar numerals will be utilized in association with similar components, the suffix letter "b" being associated with the numerals of FIG. 4 to avoid confusion.

A cylindrical passage 40b extends diametrically through a generally cylindrical bone 20b. A bone suture assembly 32b is utilized to retain body tissue 132 against movement relative to the bone 20b. The body tissue 132 may be a muscle, ligament, cartilage or other tissue which is to be held against movement relative to the bone 20b.

The bone suture assembly **32b** includes a first suture anchor **50b** and a second suture anchor **52b**. A suture **38b** extends through the passage **40b** and interconnects the suture anchors **50b** and **52b**. Tension in the suture **38b** presses the body tissue **132** against a side surface area on the bone **20b**. The suture **38b** has sections or limbs **72b** and **74b** which extends through openings in the suture anchors **50b** and **52b** in the manner previously explained. A knot **78b** interconnects the sections **72b** and **74b** of the suture **38b** to press the suture anchor **52b** firmly against the body tissue **132**. Although the illustrated suture has a pair of sections **72b** and **74b**, the suture could have a single section if desired.

The suture anchor assembly **32b** is installed in association with the bone **20b** and body tissue **132** in the same manner as previously explained in conjunction with the embodiment of the invention illustrated in FIG. 2. Thus, the passage **40** (FIG. 4) is formed in the bone **20b** by drilling or other methods. The body tissue **132** may be offset to one side of the location where the passage **40b** is formed during formation of the passage. This enables the passage **40b** to be formed in the bone **20b** without damaging the body tissue **132**.

The suture anchor **50b** is moved through the passage **40b** with a longitudinal central axis of the suture anchor aligned with the longitudinal central axis of the passage **40b**. When the suture anchor **50b** emerges from the passage **40b**, the anchor is pivoted to the orientation shown in FIG. 4. Alternatively, the anchor **50b** may be mechanically expanded after emerging from the passage **40b**. A cylindrical tubular member may be used to line the passage **40a** during movement of the anchor **50b** through the passage in the manner previously described in connection with the embodiment of FIG. 2.

After the anchor **50b** has been moved to the position shown in FIG. 4, the body tissue **132** is positioned between the limbs **72b** and **74b** of the suture **38b**. The limbs **72b** and **74b** of the suture **38b** are then inserted through the openings in the suture anchor **52b**. While a predetermined tension is maintained in the suture **38b**, the knot **78b** is tied between the limbs **72b** and **74b** of the suture. This results in the body tissue **132** being pressed against the bone **20b** with a predetermined force. A button or other force distributing member may be provided between the suture anchor **52b** and body tissue **132** if desired.

In the embodiment of the invention illustrated in FIG. 4, two suture anchors **50b** and **52b** are utilized to press the body tissue **132** against the bone **20b**. However, a suture retainer could be substituted for one or more of the suture anchors **50b** or **52b**. For example, a suture retainer having the same construction and installed in the same manner as the suture retainer **92** of FIG. 3 could be substituted for the anchor **52b** of FIG. 4. It should be understood that the suture retainer substituted for the anchor **52b** of FIG. 4 could have any desired construction. Thus, a suture retainer having the construction of any one of the suture retainers disclosed in the aforementioned U.S. patent application Ser. No. 08/905,084, filed Aug. 1, 1997 by Peter M. Bonutti et al. and entitled "Method and Apparatus for Securing a Suture" could be utilized in place of the anchor **52b** and/or the anchor **50b**.

When a suture retainer is used in place of the anchor **52b**, the suture retainer applies force against the body tissue **132** to press the body tissue against the bone **20b**. If desired, a force distribution member could be provided between the suture retainer and the body tissue **132**.

Although the passage **40b** has been illustrated in FIG. 4 as having a linear configuration, the passage could have a nonlinear configuration if desired.

In the embodiment of the invention illustrated in FIG. 4, body tissue **132** is disposed adjacent to only one side of the bone **20b**. However, if desired, body tissue could be disposed adjacent to opposite sides of the bone **20b**. The body tissue could be connected with the anchor **50b** in many different ways. For example, a separate length of suture could be connected with the body tissue and anchor **50b** or with the suture **38b** adjacent to the anchor **50b**.

An alternative manner of connecting body tissue with the side of the bone adjacent to the anchor **50b** would be to insert the body tissue between the limbs **72b** and **74b** of the suture **36b** in the same manner as shown with the anchor **52b**. If this is to be done, an end portion of the body tissue may be manually inserted between the limbs **72b** and **74b** of the suture **38b**. If a central portion of the body tissue is to be disposed between the anchor **50b** and the bone **20b**, the connector section **76b** of the suture could be cut. One of the limbs **72b** or **74b** of the suture would then be separated from the anchor **50b**. The body tissue would be inserted between the limbs of the suture **38**. The separated end of the suture would then be inserted through the anchor **50b** and connected with the other limb of the suture **38b**.

In the embodiment of the invention illustrated in FIG. 4, the body tissue **132** is pressed against a bone **20b** which has not been fractured. However, it is contemplated that the bone suture assembly **32** could be utilized to perform the dual functions of pressing body tissue against a bone and of pressing opposite side surfaces of a fracture together. This would result in the body tissue being pressed against the bone **20b** in the manner illustrated in FIG. 4 and in opposite side surfaces of a fracture being pressed together in the manner illustrated in FIG. 2 for the opposite side surfaces **28** and **30** of the fracture **26**.

Nonlinear Suture Passage

In the embodiment of the invention illustrated in FIG. 2, the passage **40** through which the suture **38** extends has a linear configuration. In the embodiment of the invention illustrated in FIG. 5, the passage through which the suture extends has a nonlinear configuration. Since the embodiment of the invention illustrated in FIG. 5 is generally similar to the embodiment of the invention illustrated in FIGS. 2-4, similar numerals will be utilized to identify similar components, the suffix letter "c" being associated with the components of the embodiment of the invention illustrated in FIG. 5 to avoid confusion.

A bone **20c** as a fracture **26c** which divides the bone into two sections **22c** and **24c**. Opposite side surfaces **28c** and **30c** of the fracture **26c** are pressed together by a bone suture assembly **32c**. The bone suture assembly **32c** includes a suture **38c** which extends between first and second suture anchors **50c** and **52c**.

In accordance with a feature of this embodiment of the invention, the suture **38c** is disposed in a passage **40c** having a nonlinear configuration. Thus, the passage **40c** includes a first section **140** which is skewed relative to a second section **142** of the passage **40c**. A bend **144** is formed in the passage **40c** at an intersection **146** of the first and second sections **140** and **142** of the passage **40c**. The flexible suture **38c** extends around the bend **144** along a nonlinear path between the suture anchors **50c** and **52c**. At the bend **144**, the suture **38c** applies force against the section **24c** of the bone **20c** urging the section **24c** toward the left (as viewed in FIG. 5). This force presses the sections **22c** and **24c** of the bone **20c** firmly together at the fracture **26c**.

The suture anchors **50c** and **52c** have the same cylindrical construction as the suture anchors **50** and **52** in the embodi-

ment of the invention illustrated in FIG. 2. A knot 78c (FIG. 5) is provided between limbs of the suture 38c to maintain a desired tension in the suture 38c. This tension pulls the suture anchors 50c and 52c toward each other. In addition, this tension presses the section 24c of the bone 20c firmly against the section 22c of the bone at the fracture 26c.

The first section 140 of the passage 40c is formed at an angle to and extends through a longitudinal central axis of the generally cylindrical bone 20c. The second section 142 of the passage 40c is formed in a direction perpendicular, i.e., along a radius, of the generally cylindrical bone 20c. The two sections 140 and 142 of the passage 40c terminate in the spongy cancellous bone tissue 44c.

When the suture assembly 32c is to be used to treat the fracture 26c in the bone 20c, the two sections 22c and 24c of the bone are pressed together at the fracture 26c to align the side surfaces 28c and 30c of the fracture. A drill or other hole forming apparatus is then used to form the first section 140 of the passage 40c. The drill or other hole forming apparatus is then used to form the second section 142 of the passage 40c. When the second section 142 of the passage 40c intersects the first section 140 of the passage 40c, formation of the section 142 of the passage 40c is interrupted.

Once the nonlinear passage 40c has been formed in the two sections 22c and 24c of the bone 20c, a tubular cylindrical liner (not shown) is inserted into the passage 40c. The tubular cylindrical liner may be formed by two separate tubular members which are inserted at opposite ends of the passage 40c. Alternatively, the tubular cylindrical liner may be formed by a single flexible tubular member which is inserted into the section 140 of the passage 40c and then moved around the bend 144 into the section 142 of the passage 40c. It should be understood that the tubular cylindrical liner for the passage 40c could be omitted if desired.

The cylindrical anchor 50c, with the suture 38c connected thereto, is then positioned in axial alignment with the section 142 of the passage 40c. The leading end 58c of the anchor 50c is then moved into the lined section 142 of the passage 40c. A flexible pusher member applies force against the trailing end 60c of the anchor 50c and pushes the anchor around the bend 144 and through the section 140 of the passage 40c.

Alternatively, a flexible wire or other member could be inserted into the section 140 of the passage 40c. The wire would move around the bend 144 and extend outward from the section 142 of the passage. The wire would then be connected with the anchor 50c and suture 38c. The leading end 58c of the anchor 50c would then be inserted into the section 142 of the passage 40c. Tension on the wire would pull the anchor 50c around the bend 144 and out of the section 140 of the passage 40c.

Once the anchor 50c has been moved out of the passage 40c, the tubular liner for the passage may be withdrawn. If a one-piece tubular liner is used, it may be withdrawn from the open end of the section 142 of the passage 40c. If a two-piece liner is used, one of the pieces may be withdrawn from the open end of the passage section 140 and slit to clear the suture 38c. Alternatively, the slit could be formed in the piece of the liner before it is inserted into the passage section 140. The other piece of the liner would be withdrawn from the open end of the passage section 142. Alternatively, the tubular liner for the passage 40c may be left in place. Of course, the use of a tubular liner for the passage 40c may be omitted.

The suture 38c is then threaded through openings in the suture anchor 52c. The suture 38c is then tensioned and the

second anchor 52c is pressed against the outer side surface of the bone 20c. While a predetermined tension force is maintained in the suture 38c, the knot 78c is tied.

In the illustrated embodiment of the invention, the two sections 140 and 142 of the passage 40c have a straight cylindrical configuration. However, it is contemplated that the sections 140 and 142 of the passage 40c could have a different configuration if desired. For example, the section 140 and/or 142 of the passage 40c could have a nonlinear central axis and could have a noncircular cross-sectional configuration of desired.

Body tissue, corresponding to the body tissue 132 of FIG. 4 could be disposed between the anchor 50c and/or 52c and the bone 20c. Although the suture 38c has been illustrated as having a pair of limbs or sections which extend between the anchors 50c and 52c, the suture 38c could have a single limb or section if desired. The anchor 50c could mechanically expand, by absorbing body liquid or under the influence of expansion springs, after the anchor has emerged from the passage 40c to prevent the anchor from being pulled back through the passage.

Nonlinear Passage—Second Embodiment

In the embodiment of the invention illustrated in FIG. 5, the bone suture assembly 32c associated with the nonlinear passage 40c includes a pair of suture anchors 50c and 52c. In the embodiment of the invention illustrated in FIG. 6, a suture retainer is substituted for one of the suture anchors in much the same manner as previously described in conjunction with the embodiment of the invention illustrated in FIG. 3. Since the embodiment of the invention illustrated in FIG. 6 is generally similar to the embodiment of the invention illustrated in FIGS. 2–5, similar numerals will be utilized to designate similar components, the suffix letter “d” being associated with the numerals of FIG. 6 in order to avoid confusion.

A bone 20d has a fracture 26d which divides the bone into two sections 22d and 24d. The fracture 26d has side surfaces 28d and 30d which are pressed together by a bone suture assembly 32d. The bone suture assembly 32d includes a suture 38d which extends through a nonlinear passage 40d having the same construction as the nonlinear passage 40c of FIG. 5.

In accordance with a feature of this embodiment of the invention, the bone suture assembly 32d includes a suture anchor 50d having the same construction as the suture anchor 50 of FIG. 2, and a suture retainer 92d having the same construction as the suture retainer 92 of FIG. 3. The suture anchor 50d and suture retainer 92d maintain a predetermined tension in the suture 38d. This results in the suture anchor 50d being firmly pressed against the section 24d of the bone 20d. The suture retainer 92d is firmly pressed against the section 22d of the bone 20d by the tension in the suture 38d.

Since the passage 40d has a nonlinear configuration, the suture 38d is effective to apply a force component to the section 24d of the bone 20d urging the section 24d of the bone toward the left (as viewed in FIG. 6). This results in the surface 30d of the fracture 26d being pressed firmly against the surface 28d of the fracture.

The suture retainer 92d is plastically deformed to grip the suture 38d in the same manner as previously described herein in conjunction with the suture retainer 92 of FIG. 3. However, the suture retainer 92d could be constructed so as to form a mechanical connection with the suture 38d. If desired, a suture retainer could be substituted for the anchor 50d.

Although both the suture retainer 92*d* and anchor 50*d* have been illustrated in FIG. 6 as being disposed in engagement with the bone 20*d*, a force distributing member could be provided between the anchor and/or suture retainer and the bone. It is contemplated that body tissue, similar to the body tissue 132 of FIG. 4, could be disposed between the anchor 50*d* and/or the suture retainer 92*d* and the bone 20*d*.

Tissue Tensioning With Bone Fragment Retaining

In the embodiment of the invention illustrated in FIG. 2, the fracture in a portion of a bone is treated. In the embodiment of the invention illustrated in FIGS. 7 and 8, a fracture results in a fragment of a bone being separated from a main portion of the bone. The bone fragment is connected with the main portion of the bone by muscle, tendon, ligament, cartilage or other fibrous body tissue. In the embodiment of the invention illustrated in FIGS. 7 and 8, the fibrous body tissue is tensioned as the bone fragment is positioned relative to the main portion of the bone. Since the embodiment of the invention illustrated in FIGS. 7 and 8 is generally similar to the embodiment of the invention illustrated in FIGS. 2-6, similar numerals will be utilized to designate similar components, the suffix "e" being associated with the numerals of FIGS. 7 and 8 in order to avoid confusion.

A bone fragment 154 is separate from a main bone 20*e* (FIG. 7). The fragment 154 is connected with the main bone 20*e* by fibrous body tissue 158, i.e., muscle, tendon, ligament, cartilage, etc. The fibrous body tissue 158 extends between the bone fragment 154 and a portion 160 of the main bone 20*e*. The bone fragment 154 has a side surface 28*e* with a configuration which matches the configuration of a side surface 30*e* of a fracture 26*e* which occurred in the main bone 20*e*.

In order to promote healing of the main bone 20*e*, a bone suture assembly 32*e* (FIG. 8) is utilized to pull the bone fragment 154 toward the main bone 20*e*. As this occurs, the fibrous body tissue 158 is tensioned and the side surface 28*e* on the bone fragment 154 is pressed against the side surface 30*e* on the main bone 20*e*. The bone fragment 154 is pressed firmly against the main bone 20*e* by the bone suture assembly 32*e*. Thus, the gap illustrated schematically in FIG. 8, between the side surfaces 28*e* and 30*e* of the fracture 26*e*, is eliminated and the side surfaces of the fracture are pressed firmly together by the bone suture assembly 32*e*. If desired, the bone fragment 154 may be manually pressed against the main bone 20*e* before the bone suture assembly is pulled tight.

The bone suture assembly 32*e* includes a suture 38*e* having limbs or sections 72*e* and 74*e*. The suture 38*e* extends through openings in a first suture anchor 50*e*. The suture then extends into a passage 40*e* formed in the bone fragment 154 and the main bone 20*e*.

The passage 40*e* includes a first section 140*e* which extends through the bone fragment 154. In addition, the passage 40*e* includes a second section 142*e* which extend through the main bone 20*e*. The limbs or section 72*e* and 74*e* of the suture 38*e* extends through a second anchor 52*e*.

During installation of the bone suture assembly 32*e*, the limbs 72*e* and 74*e* of the suture 38*e* are gripped by a force or tension measurement device 98*e*. The tension measurement device 98*e* includes a load cell which measures the amount of tension applied to the limbs 72*e* and 74*e* of the suture 38*e*.

As tension is applied to the limbs 72*e* and 74*e* of the suture 38*e*, the bone fragment 154 is pulled toward the right

(as viewed in FIG. 8) to move the side surface 28*e* on the bone fragment into alignment with the side surface 30*e* on the main bone 20*e*. As this occurs, the fibrous body tissue 158 is stretched or tensioned. While a predetermined force is transmitted through the limbs 72*e* and 74*e* to the suture anchor 50*e* and the bone fragment 154 to firmly press the bone fragment against the main bone 20*e*, a knot 78*e* is tied to interconnect the limbs 72*e* and 74*e*. While the predetermined tension is maintained and the knot 78*e* tied, the second anchor 52*e* is firmly pressed against the side surface of the main bone 20*e*.

Although the passage 40*e* could have a linear configuration if desired, in the embodiment of the invention illustrated in FIG. 8, the passage 40*e* has a nonlinear configuration. Thus, the first section 140*e* of the passage 40*e* has a central axis which is skewed relative to a central axis of the second section 142*e* of the passage 40*e*. This enables the flexible suture 38*e* to apply force to the bone fragment 154 having components urging the bone fragment rightward (as viewed in FIG. 8) against the surface 30*e* on the main bone 20*e* and downward (as viewed in FIG. 8) to maintain the tension in the fibrous body tissue 158.

When the passage 40*e* is to be formed in the bone fragment 154 and main bone section 20*e*, a hole is drilled through the bone fragment 154 to form the first section 140*e* of the passage. The second portion 142*e* of the passage 40*e* is drilled in the main bone 20*e*. It should be understood that the passage 40*e* could be formed in many different ways other than drilling. For example, a cutting tool or laser could be used to form the passage 40*e*.

The second section 142*e* of the passage 40*e* has a longitudinal central axis which is skewed at an acute angle relative to the longitudinal central axis of the first section 140*e* of the passage in the bone fragment 154. Thus, the first portion 140*e* of the passage 40*e* in the bone fragment 154 has a central axis which is close to being perpendicular to a longitudinal central axis of the main bone 20*e*. The second portion 142*e* of the passage 40*e* has a longitudinal central axis which is angularly offset to a substantial arc relative to the longitudinal central axis of the main bone 20*e*.

The anchor 50*e* is moved through the first section 140*e* of the passage 40*e* and positioned in engagement with an outer side surface of the bone fragment. The free ends of the limbs 72*e* and 74*e* of the suture 38*e* are then moved rightward (as viewed in FIG. 8) through the second portion 142*e* of the passage 40*e*. The free ends of the suture 38*e* are then threaded through openings in the second anchor 52*e*.

After the suture 38*e* has been inserted through openings in the second anchor 52*e*, the force or tension measuring device 98*e* is utilized to pull the free ends of the suture 38*e* toward the right (as viewed in FIG. 8). This tension pulls the bone fragment 154 into engagement with the main bone 20*e*. The knot 78*e* is tied in the free ends of the suture 38*e* while the tension is maintained in the suture.

If desired, the bone suture assembly 32*e* could be positioned relative to the bone 20*e* and the bone fragment 154 by moving the anchor 50*e* first through the second section 142*e* of the passage disposed in the main bone 20*e* and then through the first section 140*e* of the passage disposed in the fragment 154. The free ends of the suture would then be inserted through the second anchor 52*e*. The suture 38*e* would be tensioned to pull the bone fragment 154 into place with the side surface 28*e* in aligned engagement with the surface 30*e* on the main bone 20*e*. The knot 78*e* would then be tied while maintaining the desired tension in the suture 38*e*.

It should be understood that the anchor **52e** and knot **78e** could be positioned adjacent to the bone fragment **154** and the anchor **50e** positioned adjacent to the bone **20e**. Although only a single bone suture assembly **32e** has been illustrated in FIG. 8, multiple bone suture assemblies could be used to position the bone fragment **154** relative to the bone **20e**.

In the embodiment of the invention illustrated in FIGS. 7 and 8, the bone suture assembly **32e** includes a pair of anchors **50e** and **52e**. If desired, a suture retainer could be substituted for either or both of the anchors **50e** and **52e**. Thus, a suture retainer having a construction similar to the construction of the suture retainer **92** of FIG. 3 could be used in place of the second anchor **52e**. It should be understood that the suture retainer **92** could have the same construction as any one of the suture retainers disclosed in the aforementioned U.S. patent application Ser. No. 08/905,084 filed Aug. 1, 1997 by Peter M. Bonutti et al. and entitled "Method and Apparatus for Securing a Suture".

In the embodiment of the invention illustrated in FIG. 8, the anchors **50e** and **52e** are placed in engagement with the bone of fragment **154** and main bone **20e**. However, it is contemplated that the anchor **50e** and/or **52e** could be positioned in engagement with body tissue other than bone. For example, the anchor **50e** could be positioned in engagement with a portion of the fibrous body tissue **158** to position the fibrous body tissue **158** relative to the bone fragment **154** and to more securely interconnect the fibrous body tissue and the bone fragment. If desired, body tissue could be positioned between the anchor **52e** and the main bone **20e**.

In FIG. 8, there is a single bone fragment **154**. However, fractures may occur in such a manner as to have a plurality of bone fragments. A plurality of bone suture assemblies **32e** could be utilized to interconnect the plurality of bone fragments and the main bone.

When a fracture occurs in such a manner as to form a plurality of bone fragments, it may be desired to use bone suture assemblies **32e** in association with only the larger bone fragments. If desired, a bridge or cover member could extend across the bone fragments to position the bone fragments relative to each other. One or more bone suture assemblies **32e** would extend through one or more of the larger bone fragments and through the bridge or cover member. Force applied against the bridge or cover member by an anchor or anchors in a bone suture assembly or assemblies **32e** would urge the bridge or cover member toward the main bone **20e** to position the smaller bone fragments relative to the larger bone fragments and main bone **20e** and to press the bone fragments against each other and against the main bone.

One or more of the anchors **50e** and **52e** could be formed of body tissue or of material which absorbs body fluid and expands. Alternatively, one or more of the anchors **50e** or **52e** could be mechanically expanded to block movement into the passage **50e**.

Bone Fragment Retention

In the embodiment of the invention illustrated in FIG. 2, the bone suture assembly **32** extends between diametrically opposite outer side surface areas on the bone **20**. This results in the first suture anchor **50** being disposed against an outer side surface of the hard outer layer **42** of the bone **20** (FIG. 1) and the suture anchor **52** being disposed against the outer side surface of the hard outer layer **42** on the opposite side of the bone. In the embodiment of the invention illustrated in FIG. 9, one of the anchors is disposed within the bone and

the other anchor is disposed outside of the bone. Since the embodiment of the invention illustrated in FIG. 9 is generally similar to the embodiment of the invention illustrated in FIGS. 2-8, similar numerals will be utilized to identify similar components, the suffix letter "f" being associated with the numerals of FIG. 9 in order to avoid confusion.

A bone **20f** has a hard outer layer **42f** which encloses spongy cancellous bone tissue **44f**. A fragment **164** has been broken away from the hard outer layer **42f**. A bone suture assembly **32f** is used to position and hold the fragment **164** in engagement with the bone **20f**. The bone suture assembly **32f** includes a first suture anchor **50f** which is disposed in engagement with an inner side surface **166** of the outer layer **42f** of bone. A second anchor **50f** is disposed in engagement with an outer side surface **168** of the fragment **164**. A suture **38f** extends between the first and second anchors **50** and **52f**. The suture **38f** extends through a passage **40f** which extends across a fracture **26f**.

When the bone suture assembly **32f** is used to position the fragment **164** against the outer layer **42f** of the bone **20f**, the fragment **164** is aligned with the outer layer **42f** of the bone **20f**. At this time, a side surface **172** on the fragment **164** is disposed in aligned engagement with a side surface **174** on the bone **20f**. The two side surfaces **172** and **174** were formed by breaking away of the fragment **164** from the outer layer **42f** of the bone.

Once the fragment **164** has been aligned with the bone **20f**, the linear passage **40f** is formed by drilling or other methods through the fragment **164** and the outer layer **42f** of bone. A cylindrical tubular member (not shown) having a thin cylindrical side wall is then inserted through the passage **40f**. The first anchor **50f** is moved to an orientation in which a longitudinal central axis of the first anchor is aligned with a longitudinal central axis of the cylindrical tubular member.

The first anchor **50f** is then moved through the cylindrical tubular member, across the fracture **26f** and into the spongy cancellous bone tissue **44**. A pusher member applies force against a trailing end of a first anchor **50f** to push the anchor through the tubular member. When the leading end of the first anchor **50f** emerges from the passage **40f**, the longitudinal central axis of the first anchor is aligned with the longitudinal central axis of the passage **40f**.

The first anchor **50f** is then pivoted through 90° to change its orientation to the orientation shown in FIG. 9. The tubular member is then withdrawn from the passage **40f**. The free ends of the suture **38f** are then inserted through openings in the anchor **52f**. The suture is tensioned to press the anchor **50f** against the inner side surface **166** on the outer layer **42f** of the bone **20f**. The second anchor **52f** is pressed against the outer side surface **168** or the fragment **164** with a predetermined force by the tension in the suture **38f**. A knot **78f** is then tied in the free ends of the suture **38f** to maintain the desired tension in the suture.

Although it is believed that it may be desired to remove the tubular member from the passage **40f**, the tubular member could be left in the passage if desired. If the tubular member is to be left in the passage **40f**, the tubular member may be formed of a biodegradable or bioerodible copolymer. Of course, the use of the tubular member could be eliminated if desired.

It should be understood that a suture retainer, having a construction similar to the construction of the suture retainer **92** of FIG. 3, could be used in place of the second anchor **52f** if desired. Although the suture anchor **52f** has been shown in FIG. 9 as being disposed in direct abutting engagement with the outer side surface **168** of the bone fragment **164**, a layer

of body tissue could be provided between the suture anchor **52f** and the outer side surface **168** of the bone fragment **164** to hold the body tissue against movement relative to the bone **20f**. If desired, a plurality of bone suture assemblies **32f** could be utilized to hold the bone fragment **164**.

Use of Plates with Bone Suture Assembly

In the embodiment of the invention illustrated in FIG. 2, the suture anchors **50** and **52** are disposed in abutting engagement with an outer side surface of a bone. In the embodiment of the invention illustrated in FIG. 10, a pair of bone plates and rigid fasteners are used in association with a bone suture assembly. Since the embodiment of the invention illustrated in FIG. 10 is generally similar to the embodiment of the invention illustrated in FIGS. 2-9, similar numerals will be utilized to designated similar components, the suffix "g" being associated with the numerals of FIG. 10 to avoid confusion.

A bone **20g** has sections **22g** and **24g** which are separated by a fracture **26g**. In accordance with a feature of this embodiment of the invention, a pair of plate members **184** and **186** are used in association with a bone suture assembly **32g**. The plate members **184** and **186** may be formed of any desired biocompatible material. Thus, the plate members may be formed of metal or a polymeric material. If the plate members **184** and **186** are formed of polymeric material, biodegradable or bioerodible copolymers could be utilized.

In the illustrated embodiment of the invention, the plate members **184** and **186** are rigid and are shaped to engage the bone **20g**. If desired, the plate members **184** and **186** could have sufficient flexibility to enable the plate members to be plastically deformed to the configuration of the bone **20g** after having been positioned in engagement with the bone.

A first suture anchor **50g** is pressed against the plate member **184** by tension in a suture **38g**. The suture **38g** extends through a passage **40g** in the bone **20g**. A second anchor **52g** is pressed against the plate member **186** by the tension in the suture **38g**. A knot **78g** is provided in the suture **38g**.

A pair of screws **190** and **192** extend diametrically through the bone **20g** between the plate members **184** and **186**. The screws **190** and **192** are engaged by nuts **196** and **198** which engage the plate member **184**. The screws **190** and **192** and nuts **196** and **198** cooperate to press the plate members **184** and **186** against the bone **20g**. If desired, bone suture assemblies having the same construction as the bone suture assembly **32g** could be substituted for the screws **190** and **192** and nuts **196** and **198** so that the plates **184** and **186** would be held in position against the bone **20g** by only the plurality of bone suture assemblies **32g**.

The screws **190** and **192** and nuts **196** and **198** may be formed of any desired biocompatible material. Thus, the screws **190** and **192** and nuts **196** and **198** may be formed of metal or a polymeric material. If the screws **190** and **192** and nuts **196** and **198** are formed of polymeric material, biodegradable or bioerodible copolymers could be utilized.

In the illustrated embodiment of the invention, the screws **190** and **192** extend through the bone **20g**. It is contemplated that shorter screws could be utilized if desired. These shorter screws would have relatively coarse bone engaging thread convolutions to hold the short screws and plate members **184** and **186** in place. The shorter screws would have a length which is less than diameter of the bone **20g**.

In the illustrated embodiment of the invention, the bone suture assembly **32g** extends through a linear passage **40g**. If desired, the passage **40g** could have a nonlinear configu-

ration. If bone suture assemblies **32g** are substituted for the screws **190** and **192** and nuts **196** and **198**, some of the bone suture assemblies could extend through linear passages while other bone suture assemblies extend through nonlinear passages.

Installation Method

In the embodiment of the invention illustrated in FIG. 2, the passage **40** is formed in the bone **20** by any desired method. A thin walled cylindrical tubular member is then inserted into the passage and the first suture anchor **50** moved through the thin walled member. In the embodiment of the invention illustrated in FIGS. 11 and 12, a cannulated drill is used to drill a passage through a bone and to guide movement of the first anchor through the bone. Since the embodiment of the invention illustrated in FIGS. 11 and 12 is generally similar to the embodiments of the invention illustrated in FIGS. 2-10, similar numerals will be utilized to identify similar components, the suffix "h" being associated with the numerals in FIGS. 11 and 12 to avoid confusion.

A bone **20h** has a fracture (not shown). When the fracture is to be treated with a bone suture assembly **32h** (FIG. 12), a thin elongated cylindrical member or K-wire **204** is first inserted through the bone **20h**. This may be done by rotating the thin elongated member **204** with a drill drive mechanism in the manner indicated by an arrow **206** in FIG. 11. The drill drive mechanism is provided with a passage which extends through a drive shaft for the mechanism. While the thin elongated member **204** is being rotated by the drill drive mechanism, the K-wire extends through the passage in the drill drive mechanism.

As the thin elongated member **204** is rotated by the drill drive mechanism, it is pressed against the bone **20h**. As the thin elongated member **204** is rotated, in the manner indicated by the arrow **206** in FIG. 11, the thin elongated member is moved diametrically through the generally cylindrical bone **20h** until the leading end of the thin elongated member **204** extends from the opposite side of the bone. Thus, the thin elongated member **204** is moved through the hard outer layer **42h** (FIG. 12) at one side of the bone **20h**, through the spongy or cancellous bone tissue **44h**, and through the hard outer layer at the diametrically opposite side of the bone. When this has been done, the thin elongated member **204** will extend across the fracture in the bone.

The drill drive mechanism is then disengaged from the thin elongated member **204**. A cannulated drill **210** is moved axially along the thin elongated member until the leading end portion **212** of the drill **210** engages the bone **20h** (FIG. 11). The drill **210** is then gripped by the drill drive mechanism.

While the thin elongated member **204** remains stationary, the drill **210** is rotated about the thin elongated member in the manner indicated by an arrow **214** in FIG. 11. As the drill **210** is rotated about the stationary thin elongated member **204**, the drill is moved axially into the bone **20h**. As this occurs, the leading end **212** of the drill enlarges the hole or passage formed in the bone **20h** by the thin elongated member **204**. The drill **210** is moved along the thin elongated member **204** until the drill extends diametrically across the bone **20h**. This movement of the drill **210** is guided by engagement of the thin elongated member **204** with a side wall of a cylindrical passage **218** which extends axially through the drill **210**. Movement of the drill **210** through the bone **20h** forms a passage **40h** which extends through a fracture in the bone.

Once the drill **210** has been moved diametrically through the generally cylindrical bone **20h** (FIG. 12), the thin elongated member **204** is withdrawn from the drill. This leaves an open cylindrical passage **218** extending through the drill **210** and across the bone **20h**. The passage **218** has a diameter which is just slightly greater than the diameter of a cylindrical first anchor **50h** of the bone suture assembly **32h**. The cylindrical first anchor **50h** is axially aligned with the passage **218** in the drill **210**, in the manner shown in FIG. 12. At this time, the suture **38h** has been inserted through openings in the first anchor **50h** and suture limbs or sections **72h** and **74h** extend away from the first anchor **50h**, in the manner indicated schematically in FIG. 12.

A cylindrical pusher member **222** is axially aligned with the first anchor **50h** and the passage **218** through the drill **210**. The pusher member **222** is utilized to push the first anchor **50h** through the drill **210** to the far side of the bone **20h**.

As the first suture anchor **50h** emerges from the passage **28** in the drill **210**, the anchor is pivoted through ninety degrees. This pivotal movement changes the orientation of the anchor **50h** from an orientation in which the longitudinal central axis of the anchor **50h** is aligned with the longitudinal central axis of the passage **218** and drill **210** to an orientation in which a longitudinal central axis of the cylindrical anchor **50h** extends perpendicular to the longitudinal central axis of the passage and drill. The manner in which the anchor **50h** is pivoted is the same as is described in the aforementioned U.S. Pat. Nos. 5,527,343 and 5,534,012.

The pusher member **222** is then withdrawn from the drill **10** and the drill is withdrawn from the passage formed through the bone **20h**. As this occurs, the suture **38h** is tensioned to hold the anchor **50h** in place against the bone **20h**. The drill **210** is then disengaged from the suture **38h**. The free limbs **72** and **74** of the suture **38h** are then inserted through a second anchor corresponding to the anchor **52** in FIG. 2. While a predetermined tension is maintained in the suture **38h**, the suture is tied to hold the second suture anchor, corresponding to the suture anchor **52** in FIG. 2, against the bone **20h** on a side of the bone opposite from the anchor **50h**.

In the foregoing description, the drill **210** has been a rigid drill which has been used to form a linear passage to the bone **20h**. However, it is contemplated that a flexible drill could be utilized to drill a passage through the bone. If this was done, the drill could be guided in such a manner as to form a nonlinear passage in the bone.

The foregoing description of how the passage **40h** is formed has been in conjunction with a bone **20h** having a fracture similar to the fracture **26** of FIG. 2. However, it is contemplated that the thin elongated member **204** and drill **210** could be used to form a passage in a bone which has not been fractured (FIG. 4). The thin elongated member **204** and **210** could be used to form a passage which extends only part way through a bone (FIG. 9).

In the description of the embodiments of the invention illustrated in FIGS. 1-12, the suture **38** (FIG. 2) has a pair of limbs or sections **72** and **74**. It is contemplated that the suture **38** could have only a single limb which would be connected at one end with the first anchor **50** and at the opposite end with the second anchor **52**. This single limb could either be tied off at the second anchor **52** or gripped by a suture retainer, similar to the suture retainer **92** of FIG. 3.

In the embodiments of the invention illustrated in FIGS. 112, the suture **38** has been formed separately from the first

suture anchor **50**. It is contemplated that the first suture anchor **50** could be formed as one piece with the suture **38**. For example, the suture and anchor could be formed as one piece in a manner similar to that disclosed in U.S. Pat. No. 4,669,473 or in U.S. Pat. No. 4,741,330.

The anchors **50** and **52** in the embodiment of FIGS. 2-12 could have any one of many different constructions. For example, the anchors could expand by absorbing body fluid. The anchor **50**, which is moved through a passage **40** in the embodiments of FIGS. 2-12, could mechanically expand upon exiting from the passage.

Positioning of Tubular Member

In the embodiment of the invention illustrated in FIG. 13, a tubular member is positioned in the passage which extends through the bone. Since the embodiment of the invention illustrated in FIG. 13 is generally similar to the embodiments of the invention illustrated in FIGS. 1-12, similar numerals will be utilized to designate similar components, the suffix letter "j" being associated with the numerals of FIG. 13 to avoid confusion.

A bone **20j** which has been fractured is illustrated in FIG. 1. The bone **20j** is divided into two sections **22j** and **24j** by a fracture **26j**. Opposite side surfaces **28j** and **30j** of the fracture **26j** are pressed together by bone securing assemblies **32j**.

It should be understood that the bone securing assemblies **32j** may be utilized in the treatment of any one of many different types of fractures. The fractures may or may not result in the formation of one or more bone fragments. In FIG. 13, the bone securing assembly **32j** has been illustrated as interconnecting sections **22j** and **24j** of a complete bone fracture of the spiral type. However, the bone securing assemblies **32j** could be utilized to connect a fragment of a bone to the main portion of the bone from which the fragment was broken off.

The bone securing assembly **32j** (FIG. 13) includes a force transmitting member **38j** which extends across the fracture **26j**. The force transmitting member **38j** may be any one of many different types of force transmitting members. The force transmitting member **38j** may be formed of human or animal body tissue. However, it is presently preferred to use a suture as the force transmitting member **38j**. Therefore, the force transmitting member **38j** will be referred to herein as a suture.

The suture **38j**, that is, the force transmitting member, is disposed in a straight cylindrical passage **40j** which extends diametrically across a generally cylindrical portion of the bone **20j**. The passage **40j** extends through hard compact tissue of an outer layer **42j** of the bone and through spongy or cancellous bone tissue **44j** which is enclosed by the hard outer layer. Although the passage **40j** has a linear configuration, the passage could have a nonlinear configuration if desired.

The suture **38j** extends between a first suture anchor **50j** disposed on one side of the fracture **26j** and a second suture anchor **52j** disposed on the opposite side of the fracture. Tension is maintained in the suture **38j** to press the suture anchors **50j** and **52j** against opposite sides of the bone **20j** with a predetermined force. This force presses the side surfaces **28j** and **30j** of the fracture **26j** firmly together to promote healing of the fracture. If desired, buttons or other force distributing members could be provided between the anchors **50j** and **52j** and the bone **20j**. Body tissue could be disposed between the anchors **50j** and **52j** and the bone **20j**.

The suture **38j** and/or suture anchors **50j** and **52j** may be formed of any desired natural or artificial material. For

example, the suture **38j** may be formed of either a polymeric material or a metal. The suture **38j** may be biodegradable. Any known suture material may be utilized to form the suture **38j**.

The suture anchors **50j** and **52j** have the same construction. However, the anchor **50j** could have a construction which is different than the construction of the anchor **52j**. The anchor **50j** has a cylindrical outer side surface **56j** which extends between smooth rounded end portions **581** and **60j**. A pair of parallel cylindrical openings **64j** and **66j** extend diametrically through the anchor **50j**. The anchor **50j** is free of sharp corners or projections to avoid cutting or abrading of body tissue disposed adjacent to the anchor.

The suture anchor **50j** is made of a biocompatible material. Suitable materials include stainless steel or titanium, cobalt chrome and other biocompatible metals. Polymeric material may also be used, suitable polymeric materials includes polyethylene, polypropylene, and biodegradable material such as PLA and PGA. It is believed that it may be preferred to form the suture anchors **50j** and **52j** from biodegradable or bioerodible copolymers. If desired, the anchor **50j** could be formed of body material or hydrophilic materials.

It is contemplated that the anchor **50j** may have any desired configuration. For example, the anchor **50j** could have any one of the configurations disclosed in U.S. Pat. No. 5,522,846 issued Jun. 4, 1996 and entitled "Suture Anchor". Alternatively, the suture anchor **50j** could have the configuration disclosed in U.S. Pat. No. 5,534,012 issued Jul. 9, 1996 and entitled "Method and Apparatus for Anchoring a Suture".

The cross-sectional size of the anchor **50j** may be such as to enable the anchor to be moved through the passage **40j**. However, the anchor **50j** could have a size and configuration which would prevent movement of the anchor **50j** through the passage **40j**. For example, the anchors **50j** and **52j** could have the same construction as the retainer **92** of FIG. 3.

The length of the anchor **50j** is such as to enable it to span an opening at an end of the passage **40j** and transmit force from the suture **38j** to a substantial area on the outer layer **42j** of the bone **20j**. The length of the anchor **50j** may be approximately three times the diameter of the anchor. It is believed that it will be preferred to form the anchor **50j** in such a manner as to eliminate any sharp corners or projections.

In the illustrated embodiment of the invention, the anchor **50j** has a cylindrical configuration. This particular anchor has an axial length of about two millimeters and a diameter of about one millimeter. The openings **64j** and **66j** have a diameter of about one-half millimeter.

It should be understood that the foregoing dimensions have been set forth herein for purposes of clarity of description and it is contemplated that the size of the anchor **50j** may vary as a function of the size of the bone being treated. Thus, relatively small anchors may be used in association with treatment of small bones in a wrist, hand, foot or ankle of a patient. Relatively large anchors may be used in association with treatment of larger bones in an arm, shoulder, leg or hip of a patient. It should be understood that the bone securing assembly **32j** may be used in conjunction with many different bones other than the specific bones previously mentioned.

Only a single anchor **50j** or **52j** has been shown at opposite ends of the passage **40j**. It is contemplated that a plurality of anchors could be provided at each end of the passage **40j**. For example, a pair of separate or intercon-

nected anchors could be provided in a manner similar to that disclosed in the aforementioned U.S. Pat. No. 5,534,012.

In the embodiment of the invention illustrated in FIG. 13, the suture **38j** has a pair of limbs or sections **72j** and **74j** which extend through the openings **64j** and **66j** in the suture anchors **50j** and **52j**. A connector section **76j** interconnects the two limbs **72j** and **74j** of the suture **38j** and engages a portion of the anchor **50j**. A knot **78j** is formed in the opposite ends of the limbs **72j** and **74j** to interconnect the two limbs of the suture **38j**.

When the knot **78j** is formed, a predetermined tension is present in the limbs **72j** and **74j** of the suture **38j**. This results in the suture anchors **50j** and **52j** being pressed firmly against the bone **20j** with a predetermined force. This predetermined force is maintained during and after tying of the knot **78j**.

When the bone securing assembly **32j** is to be used to treat the fracture **26j** in the bone **20j**, the two sections **22j** and **24j** of the bone are pressed together at the fracture **26j** to align the side surfaces **28j** and **30j** of the fracture. A drill is then used to form the passage **40j** which extends diametrically through the generally cylindrical bone **20j**. Of course, the passage **40j** could be formed by the use of a tool other than a drill. If desired, the passage **40j** could have a noncircular cross-sectional configuration.

Once the passage **40j** has been formed in the two sections **22j** and **24j** of the bone **20j**, a tubular cylindrical member **240** is inserted into the passage **40j** and extends diametrically through the bone **20j**. The leading end **242** of the tubular cylindrical member **240** is aligned with a circular outlet **84j** from the passage **40j**. The opposite or trailing end **244** of the tubular member is aligned with a circular inlet **86j** to the passage **40j**. The tubular member **240** has a thin cylindrical wall which engages the sections **22j** and **24j** of the bone **201**. A cylindrical inner side surface of the tubular member **240** defines a cylindrical passage having a diameter which is only slightly less than the diameter of the passage **40j**.

The leading end **242** of the tubular member **240** is disposed in the compact outer layer **42j** of the bone **20j**. Similarly, the trailing end **244** of the tubular member **240** is disposed in the compact outer layer **42j** of the bone **20j**. The tubular member **240** extends across the fracture **26j** and stabilizes the two sections **22j** and **24j** of the bone **20j**. Since the opposite end portions of the tubular member **240** are disposed in the compact outer layer **42j** of the bone **20j**, the tubular member is solidly supported and holds the two sections **22j** and **24j** of the bone **20j** in alignment at the fracture **26j**.

The opposite ends **242** and **244** of the tubular member **240** are axially spaced from a generally cylindrical outer side surface **250** on the bone **20j**. This enables the anchors **50j** and **52j** to be pressed against the outer side surface **250** of the bone **20j**. Therefore, tension forces in the suture **38j** are transmitted through the anchors **50j** and **52j** to the bone **20j**.

By inserting the tubular member **240** into the passage **40j**, the portions of the passage disposed on opposite sides of the fracture **26j** are maintained in alignment. The tubular member **240** may be flexible to enable the tubular member to be inserted into a nonlinear passage **40j** through the bone **20j**. The tubular member **240** may be formed of metal or a polymeric material. If the tubular member **240** is formed of a polymeric material, it may be preferred to form the tubular member from a biodegradable or bioerodible copolymer.

In accordance with one of the features of this embodiment of the invention, the tubular member **240** is formed of bone.

By forming the tubular member 240 of bone, tissue growth into the tubular member is promoted. The tubular member 240 may be packed with bone or bone graft. The tubular member 240 may contain bone osteoinductive protein (BMP). Bone growth inducing materials containing apatite compositions with collagen and/or other materials may be utilized. The tubular member 240 may be formed of either human or animal bone.

It is contemplated that it may be preferred to form the tubular member 240 of freeze dried human bone obtained from a cadaver. The freeze dried bone will absorb body fluids. As this occurs, the tubular member 240 will expand and grip the two sections 22j and 24j of the bone 20j. The body fluids will be conducted into bone growth promoting materials contained in the tubular member 240. If desired, antibiotics and/or other medicants may be provided in the bone or bone graft with which the tubular member 240 is packed. Of course, the tubular member 240 may be formed of other materials, such as biodegradable materials, if desired.

The suture 38j is formed into a loop which extends through the openings 64j and 66j in the anchor 50j. At this time, the suture 38j has a length which is substantially greater than the length illustrated in FIG. 2. The cylindrical anchor 50j, with the suture 38j connected thereto, is then positioned in axial alignment with the tubular member 240 which extends through the passage 40j. Thus, the anchor 50j is moved to an orientation in which a longitudinal central axis of the anchor is coincident with the longitudinal central axis of the cylindrical passage 246 in the tubular member 240 which extends through the passage 40j in the bone 20j.

The leading end 58j of the anchor 50j is then moved into the cylindrical tubular member 240 which forms a liner for the passage 40j. A pusher member pushes the anchor 50j from an upper (as viewed in FIG. 13) end 244 of the tubular member 240 along the passage 246 in the tubular member 240 and the passage 40j in the bone 20 and through the outlet 84j from the passage. As the anchor 50j moves through the passages 40j and 246, the suture 38j is pulled through the passages by the anchor.

The orientation of the anchor 50j is then changed from an orientation in which the longitudinal central axis of the anchor 50j is aligned with the coincident longitudinal central axes of the passages 40j and 246 to an orientation in which the longitudinal central axis of the anchor 50j extends generally perpendicular to the longitudinal central axis of the passages 40j and 246, i.e., the orientation shown in FIG. 13. To pivot the anchor 50j to the orientation shown in FIG. 13, as the anchor emerges from the outlet 84, the suture 38j is tensioned. The combination of the tension in the suture 38j and force applied against the trailing end 60j of the anchor 50j by the pusher member causes the anchor to pivot about the trailing end 60j of the anchor. The pusher member is then withdrawn and the suture 38j tensioned to move the anchor to the position shown in FIG. 13 in a manner similar to that described in the aforementioned U.S. Pat. Nos. 5,527,343 and 5,534,012.

Although it is believed that it may be preferred to change the orientation of the anchor 50j after it has emerged from the passages 40j and 246, the anchor could be blocked from reentering the passage in other ways if desired. Thus, the anchor could expand after emerging from the passages 40j and 246. This could be accomplished by having spring biased arms held in a retracted position by engagement of spring biased arms with the inner side surface of the tubular cylindrical member 240 which lines the passage 40j. Upon

emerging from the passages 40j and 246, the arms would move outward under the influence of spring forces and extend radially outward beyond the edge of the exit from the passage 40j. If desired, the anchor 50j could be constructed so as to expand in a manner similar to that disclosed in U.S. Pat. No. 5,397,331 and/or U.S. Pat. No. 4,409,974.

Rather than expanding under the influence of stored energy, such as spring force, the anchor 50j could expand by absorbing body fluids. Thus, the anchor 50j may be compressed when it moves through the passages 40j and 246 and will expand and absorb body fluids after emerging from the passages 40j and 246. It is contemplated that the anchor 50j could be constructed so as to expand in any one of the ways disclosed in U.S. patent application Ser. No. 08/699,553 filed Aug. 19, 1996 by Peter M. Bonutti and entitled "Suture Anchor".

Once the anchor 50j has been moved through the passage 246, the passage is packed with bone particles and/or bone graft. The bone particles and/or bone graft contains bone growth inducing materials. In addition, the bone particles and/or bone graft may contain medicinal substances along with osteoinductive protein.

The limbs 72j and 74j of the suture 38j are then threaded through openings 64j and 66j in the second suture anchor 52j. The limbs 72j and 74j of the suture 38j are tensioned and the second anchor 52j is pressed against the outer side surface 250 of the bone 20j. While a predetermined tension force is maintained in the limbs 72j and 74j of the suture 38j, the knot 78j is tied in the suture to interconnect the two suture anchors 50j and 52j with the suture 38j. The suture 38j is then trimmed to the desired length.

Once the knot 78j has been tied between the limbs 72j and 74j of the suture 38j, the tension in the suture 38j presses the side surfaces 28j and 30 of the fracture 26j together. This pressure between the side surfaces 28 and 30j of the fracture 26j is maintained by the suture 38 and suture anchors 50j and 52j until the fracture heals. It is believed that it may be preferred to form the suture 38j and suture anchors 50j and 52j of a biodegradable material which, after the fracture 26j has healed, will dissolve in the patient's body.

The cylindrical tubular member 240 which is inserted into the passage 40j through the bone 20j performs the dual functions of lining the inside of the passage 40j and maintaining the two sections 22j and 24j of the bone in alignment. The cylindrical tubular member 240 could have a slot formed in a side wall of the tubular member to facilitate insertion of the tubular member into the passage 40j. It is contemplated that the cylindrical tubular member 240 could be left in the passage 40j after the bone securing assembly 32j has been installed. If the slotted or unslotted cylindrical tubular member 240 is to be left in the passage 40j, the cylindrical tubular member 240 may be formed of a biodegradable or bioerodible copolymer. When the cylindrical tubular member remains in the passage 40j, the suture 38j extends through the tubular member.

Although only a knot 78j has been shown in FIG. 13 adjacent to the second anchor 52j, a suture retainer could be provided to further hold the limbs 72j and 74j of the suture 38j. If a suture retainer is to be used in association with the knot 78j, the suture retainer will be moved along the limbs of the suture 38j toward the knot before the limbs 72j and 74j of the suture are trimmed to the short length shown in FIG. 13. The suture retainer would then be plastically deformed to grip the limbs 72j and 74j of the suture 38j. Thereafter, the suture limbs 72j and 74j would be trimmed to a desired length.

Although it is preferred to use a suture as the force transmitting member **38j**, it should be understood that the anchors **50j** and **52j** could be interconnected by other force transmitting members, such as a rod formed of bone. Although the anchors **50j** and **52j** have constructions which enable them to be used with a suture, the anchors could be constructed so as to be used with other types of force transmitting members. For example, the anchors **50j** and **52j** could have thread convolutions to engage thread convolutions on a force transmitting member formed by a rod.

In the embodiment of the invention illustrated in FIG. 13, the member **240** is tubular. However, it is contemplated that a solid member could be used to transmit force to bone on opposite sides of the fracture **26j**. Thus, the member **240** could be a solid cylindrical member formed of bone. The cylindrical member may be formed of freeze dried bone.

When the member **240** is a solid member, the suture or other force transmitting member **38j** is eliminated. The solid member formed of bone becomes the force transmitting member. Anchors, corresponding to the anchors **50j** and **52j**, are connected to opposite ends of the solid member **240** formed of bone. The anchors may have internal thread convolutions which engage external thread convolutions on the solid member **240** formed of bone. Of course, other known connectors could be utilized to connect anchors with opposite ends of the solid member **240** formed of bone.

Nonlinear Suture Passage—Tubular Member

In the embodiment of the invention illustrated in FIG. 13, the passage **40j** through which the suture **38j** extends has a linear configuration. In the embodiment of the invention illustrated in FIG. 14, the passage through which the suture extends has a nonlinear configuration. Since the embodiment of the invention illustrated in FIG. 14 is generally similar to the embodiment of the invention illustrated in FIGS. 1–13, similar numerals will be utilized to identify similar components, the suffix letter “k” being associated with the components of the embodiment of the invention illustrated in FIG. 14 to avoid confusion.

A bone **20k** as a fracture **26k** which divides the bone into two sections **22k** and **24k**. Opposite side surfaces **28k** and **30k** of the fracture **26k** are pressed together by a bone suture assembly **32k**. The bone suture assembly **32k** includes a suture **38k** which extends between first and second suture anchors **50k** and **52k**.

The suture **38k** is disposed in a passage **40k** having a nonlinear configuration. Thus, the passage **40k** includes a first section **140k** which is skewed relative to a second section **142k** of the passage **40k**. A bend **144k** is formed in the passage **40k** at an intersection **146k** of the first and second sections **140k** and **142k** of the passage **40k**. The flexible suture **38k** extends around the bend **144k** along a nonlinear path between the suture anchors **50k** and **52k**. At the bend **144k**, the suture **38k** applies force against the section **24k** of the bone **20k** urging the section **24k** toward the left (as viewed in FIG. 5). This force presses the sections **22k** and **24k** of the bone **20k** firmly together at the fracture **26k**.

The suture anchors **50k** and **52k** have the same cylindrical construction as the suture anchors **50**, **52**, **50j** and **52j** in the embodiment of the invention illustrated in FIG. 2 and 13. A knot **78k** (FIG. 14) is provided between limbs of the suture **38k** to maintain a desired tension in the suture **38k**. This tension pulls the suture anchors **50k** and **52k** toward each other. In addition, this tension presses the section **24k** of the bone **20k** firmly against the section **22k** of the bone at the fracture **26k**.

The first section **140k** of the passage **40k** is formed at an angle to and extends through a longitudinal central axis of the generally cylindrical bone **20k**. The second section **142k** of the passage **40k** is formed in a direction perpendicular, i.e., along a radius, of the generally cylindrical bone **20k**. The two sections **140k** and **142k** of the passage **40k** terminate in the spongy cancellous bone tissue **44k**.

When the suture assembly **32k** is to be used to treat the fracture **26k** in the bone **20k**, the two sections **22k** and **24k** of the bone are pressed together at the fracture **26k** to align the side surfaces **28k** and **30k** of the fracture. A drill or other hole forming apparatus is then used to form the first section **140k** of the passage **40k**. The drill or other hole forming apparatus is then used to form the second section **142k** of the passage **40k**. When the second section **142k** of the passage **40k** intersects the first section **140k** of the passage **40k**, formation of the section **142k** of the passage **40k** is interrupted.

Once the nonlinear passage **40k** has been formed in the two sections **22k** and **24k** of the bone **20k**, a tubular cylindrical liner **240k** is inserted into the passage **40k**. The tubular cylindrical liner **240k** is formed by two separate cylindrical tubular members **252** and **254** which are inserted at opposite ends of the passage **40k**. Alternatively, the tubular cylindrical liner **240k** may be formed by a single flexible tubular member which is inserted into the section **140k** of the passage **40k** and then moved around the bend **144k** into the section **142k** of the passage **40k**.

It is believed that it may be preferred to form the tubular members **252** and **254** of bone. The bone forming the tubular members **252** and **254** may be either human or animal bone. The tubular members **252** and **254** may be formed of freeze dried human bone.

The leading end **242k** of the tubular member **252** is disposed in the compact outer layer **42k** of the bone **20k**. Similarly, the trailing end **244k** of the tubular member **254** is disposed in the compact outer layer **42k** of the bone **20k**. The tubular member **252** extends across the fracture **26k** and stabilizes the two sections **22k** and **24k** of the bone **20k**. Since the end portions **242k** and **244k** of the tubular members **252** and **254** are disposed in the compact outer layer **42k** of the bone **20k**, the tubular members are solidly supported and hold the two sections **22k** and **24k** of the bone **20k** in alignment at the fracture **26k**.

The opposite ends **242k** and **244k** of the tubular members **252** and **254** are axially spaced from a generally cylindrical outer side surface **250k** on the bone **20k**. This enables the anchors **50k** and **52k** to be pressed against the outer side surface **250k** of the bone **20k**. Therefore, tension forces in the suture **38k** are transmitted through the anchors **50k** and **52k** to the bone **20k**.

The cylindrical anchor **50k**, with the suture **38k** connected thereto, is then positioned in axial alignment with the section **142k** of the passage **40k**. The leading end **58k** of the anchor **50k** is then moved into the section **142k** of the passage **40k** lined by the tubular member **254**. A flexible pusher member applies force against the trailing end **60k** of the anchor **50k** and pushes the anchor around the bend **144k** and through the section **140k** of the passage **40k** lined by the tubular member **252**.

Alternatively, a flexible wire or other member could be inserted into the section **140k** of the passage **40k**. The wire would move around the bend **144k** and extend outward from the section **142k** of the passage. The wire would then be connected with the anchor **50k** and suture **38k**. The leading end **58k** of the anchor **50k** would then be inserted into the

section 142*k* of the passage 40*k*. Tension on the wire would pull the anchor 50*k* around the bend 144*k* and out of the section 140*k* of the passage 40*k*.

The passages in the tubular members 252 and 254 may be packed with bone particles and/or bone graft. Bone osteoinductive protein (BMP) may be provided in the tubular members. Antibiotics and/or other medicants may be included along with collagen.

The suture 38*k* is then threaded through openings in the suture anchor 52*k*. The suture 38*k* is then tensioned and the second anchor 52*k* is pressed against the outer side surface of the bone 20*k*. While a predetermined tension force is maintained in the suture 38*k*, the knot 78*k* is tied.

In the illustrated embodiment of the invention, the two sections 140*k* and 142*k* of the passage 40*k* have a straight cylindrical configuration. However, it is contemplated that the sections 140*k* and 142*k* of the passage 40*k* could have a different configuration if desired. For example, the section 140*k* and/or 142*k* of the passage 40*k* could have a nonlinear central axis and could have a noncircular cross-sectional configuration of desired.

Body tissue, corresponding to the body tissue 132 of FIG. 4 could be disposed between the anchor 50*k* and/or 52*k* and the bone 20*k*. Although the suture 38*k* has been illustrated as having a pair of limbs or sections which extend between the anchors 50*k* and 52*k*, the suture 38*k* could have a single limb or section if desired. The anchor 50*c* could mechanically expand, by absorbing body liquid or under the influence of expansion springs, after the anchor has emerged from the passage 40*k* to prevent the anchor from being pulled back through the passage.

Retainer and Tubular Member

In the embodiment of the invention illustrated in FIG. 13, a pair of suture anchors 50*j* and 52*j* are connected with the suture 38*j* to maintain tension in the suture and pressure against opposite side surfaces 28*j* and 30*j* of the fracture 26*j*. In the embodiment of the invention illustrated in FIG. 15, a suture retainer is used in place of one of the suture anchors. Since the embodiment of the invention illustrated in FIG. 15 is generally similar to the embodiment of the invention illustrated in FIG. 13, similar numerals will be utilized to designate similar components, the suffix letter "m" being associated with the embodiment of the invention illustrated in FIG. 15 to avoid confusion.

A bone 20*m* has sections 22*m* and 24*m* which are separated by a fracture 26*m*. The fracture 26*m* has side surfaces 28*m* and 30*m* which are pressed together by a bone suture assembly 32*m*. A suture 38*m* extends through a cylindrical passage 40*m* which extends diametrically through the generally cylindrical bone 20*m*. The suture 38*m* has a pair of limbs or sections 72*m* and 74*m* which are connected with a suture anchor 50*m*. The suture anchor 50*m* has the same construction as the suture anchor 50 of FIG. 2.

Once the passage 40 has been formed in the two tubular sections 22*m* and 24*m* of the bone 20*m*, a tubular cylindrical member 240*m* is installed into the passage 40*m* and extends diametrically through the bone 20*m*. The leading end 242*m* of the cylindrical member 240*m* is aligned with a circular outlet 84*m* from the passage 40*m*. The opposite or trailing end 244*m* of the tubular member 240*m* is aligned with a circular inlet 86*m* to the passage 40*m*.

The tubular member 240*m* has a thin cylindrical wall which engages the sections 22*m* and 24*m* of the bone 20*m*. A cylindrical inner side surface of the tubular member 240*m* defines a cylindrical passage 246*m* having a diameter which

is only slightly less than the diameter of the passage 40*m*. The tubular member 240*m* is formed of bone. Alternatively, the tubular member 240*m* could be formed of a biodegradable material.

The leading end 242*m* of the tubular member 240*m* is disposed in the compact outer layer 42*m* of the bone 20*m*. Similarly, the trailing end 244*m* of the tubular member 240*m* is disposed in the compact outer layer 42*m* of the bone 20*m*. The tubular member 240*m* extends across the fracture 26*m* and stabilizes the two sections 22*m* and 24*m* of the bone 20*m*. Since the opposite end portions of the tubular member 240*m* are disposed in the compact outer layer 42*m* of the bone 20*m*, the tubular member is solidly supported and holds the two sections 22*m* and 24*m* of the bone 20*m* in alignment at the fracture 26*m*.

The opposite ends 242*m* and 244*m* of the tubular member 240*m* are axially spaced from a generally cylindrical outer side surface 250*m* on the bone 20*m*. This enables the anchors 50*m* and 92*m* to be pressed against the outer side surface 250*m* of the bone 20*m*. Therefore, tension forces in the suture 38*m* are transmitted through the anchors 50*m* and 92*m* to the bone 20*m*.

The tubular member 240*m* is formed of freeze dried human bone. The tubular member 240*m* is packed with bone and/or bone graft. The tubular member 240*m* also contains bone osteoinductive protein (BMP). Suitable medicants may be provided in the tubular member 240*m*.

A suture retainer 92*m* is used in place of the suture anchor 52 of FIG. 2. The suture retainer 92*m* (FIG. 15) has a spherical configuration. A cylindrical passage 94*m* extends through the center of the spherical suture retainer 92*m*. The sections 72*m* and 74*m* of the suture 38*m* extend around the spherical outer side surface of the suture retainer 92*m*. Thus, a loop is formed in each of the sections 72*m* and 74*m* around portions of the suture retainer 92*m*.

If desired, the suture retainer 92*m* could have a different configuration. For example, the suture retainer 92*m* could have an oval or elliptical configuration. Although the passage 94*m* has a linear central axis, the passage could have a nonlinear central axis. If desired, a plurality of passages having the same or different configurations could be provided in the suture retainer 92*m*.

After the suture 38*m* has been inserted through the suture retainer 92*m*, the suture retainer 92*m* is moved along the sections 72*m* and 74*m* of the suture 38*m* toward the bone 20*m*. The suture retainer 92*m* is formed as one piece of a polymeric material having a relatively low coefficient friction. Therefore, the two sections 72*m* and 74*m* of the suture 30*m* can readily slide along the surfaces of the suture retainer 52*m* while the suture retainer moves toward the bone 20*m*.

A predetermined tension is maintained in the sections 72*m* and 74*m* of the suture 38*m* while the suture retainer 92*m* is pressed against the bone 20*m*. This results in the suture 38*m* being pulled tightly against the suture anchor 50*m*. The tension in the suture 38*m* is effective to press the suture anchor 50*m* and retainer 92*m* against opposite sides of the bone 20*m* with a predetermined force.

While the sections 72*m* and 74*m* of the suture 38*m* are being tensioned with a predetermined force, the suture retainer 92*m* is plastically deformed in the same manner as previously described in conjunction with the embodiment of the invention illustrated in FIG. 3. To plastically deform the suture retainer 92*m*, a plurality of force applying or clamp members are pressed against the suture retainer with a predetermined minimum force. The force applied against the

suture retainer **92m** by the force applying members is sufficient to cause plastic deformation of the material of the suture retainer.

The force is applied against the suture retainer **92m** while the suture retainer is at a temperature which is below the transition temperature of the biodegradable polymer which forms the suture retainer **92m**. Thus, the suture retainer **92m** is at approximately the same temperature as the bone **20m** when the force is applied against the suture retainer. The force causes the material of the suture retainer **92m** to flow and grip the sections **72m** and **74m** of the suture **38m**.

The suture retainer **92m** may be formed of many different materials. However, it is believed that it will be preferred to form the suture retainer **92m** of a biodegradable polymer. One biodegradable polymer which may be utilized is polycaprolactone. Alternatively, the suture retainer **92m** could be formed of polyethylene oxide terephthalate or polybutylene terephthalate. It is also contemplated that other biodegradable or bioerodible copolymers could be utilized.

Although it is preferred to form the suture retainer **92m** of a biodegradable material, the suture retainer could be formed of a material which is not biodegradable. For example, the suture retainer **92m** could be formed of an acetyl resin, such as "DELRIN" (trademark). Alternatively, the suture retainer **92m** could be formed of para-dimethylamino-benzenediazo sodium sulfonate, such as "DEXON" (trademark). The construction of the suture retainer **92m** and the manner in which it cooperates with the suture **38m** is the same as is disclosed in U.S. patent application Ser. No. 08/905,084 filed Aug. 1, 1997 by Peter M. Bonutti et al. and entitled "Method and Apparatus for Securing a Suture".

The suture retainer **92m** is plastically deformed to grip the limbs **72m** and **74m** of the suture **38m**. However, the suture retainer **92m** could be constructed so as to be mechanically actuated to grip the suture **38m**. If desired, a combination of a mechanical gripping action and plastic deformation could be utilized by a retainer to grip the suture **38m**.

Conclusion

In view of the foregoing description, it is apparent that the present invention relates to a method of securing sections **22** and **24** of a fractured bone **20**. Sections **22** and **24** of a fractured bone **20** are held against movement relative to each other by a force transmitting member, such as a suture **38**, which extends through a passage **40** in the bone. The passage **40** in the bone may have a linear or nonlinear configuration. Tension is maintained in the force transmitting member **38** to press surfaces **28** and **30** on the fracture together by securing anchors **50** and **52** or suture retainers **92** to opposite ends of the force transmitting member **38**. It is believed that a suture **38** may advantageously be used as the force transmitting member.

A tubular member **240** is positioned in a linear passage (FIGS. **13** and **15**) or a nonlinear passage (FIG. **14**) through the bone **20**. The tubular member **240** extends into portions of the passage **40** on opposite sides of the fracture **26**. End portions of the tubular member may be positioned in a compact outer layer **42** of the bone. The tubular member **240** may be formed of bone. The force transmitting member **38** may be formed of bone or other body tissue.

Having described the invention, the following is claimed:

1. A method of positioning body tissue relative to a bone, said method comprising the steps of positioning an anchor connected with a suture relative to the bone, tensioning the suture with a predetermined force, pressing body tissue against the bone under the influence of force transmitted

through the suture while tensioning the suture with the predetermined force, and forming a passage extending across a fracture in the bone, wherein said step of positioning an anchor connected with the suture relative to the bone includes positioning the anchor in a first side of the fracture with the suture extending across the fracture, said step of pressing body tissue against the bone includes pressing body tissue against a portion of the bone disposed on a second side of the fracture.

2. A method of positioning body tissue relative to a bone, the method comprising the steps of:

positioning a first anchor connected with a suture relative to a bone, the suture including two substantially parallel sections disposed in a linear passage extending through the bone; and,

tensioning the suture with a predetermined force causing first body tissue to become engaged with the bone.

3. A method as set forth in claim 2 further including the step of positioning a second anchor relative to the first body tissue.

4. A method as set forth in claim 3 wherein the step of tensioning the suture with a predetermined force causing the first body tissue to become engaged with the bone includes tensioning the suture between the first and second anchors with a predetermined force causing the first body tissue to become engaged with the bone.

5. A method as set forth in claim 4 wherein the step of tensioning the suture between the first and second anchors with a predetermined force causing the first body tissue to become engaged with the bone includes tensioning the suture between the first and second anchors with a predetermined force causing the first body tissue and a second body tissue to become engaged with the bone.

6. A method of positioning body tissue relative to a bone, the method comprising the steps of:

providing a first anchor connected with a suture having two substantially parallel sections;

passing the first anchor through a linear passage extending through a bone, wherein a longitudinal axis of the first anchor is aligned with a longitudinal axis of the linear passage;

changing the first anchor from a first to a second configuration causing the first anchor to become impassable through the linear passage; and,

tensioning the suture with a predetermined force causing first body tissue to become engaged with the bone.

7. A method as set forth in claim 6 wherein the step of changing the first anchor from a first to a second configuration causing the first anchor to become impassable through the linear passage includes pivoting the first anchor relative to the bone causing the longitudinal axis of the first anchor to become generally perpendicular to the longitudinal axis of the linear passage.

8. A method as set forth in claim 7 further including the step of providing a second anchor positioned relative to the first body tissue.

9. A method as set forth in claim 8 wherein the step of tensioning the suture with a predetermined force causing the first body tissue to become engaged with the bone includes tensioning the suture with a predetermined force causing the first and second anchors to connect the first body tissue with the bone.

10. A method as set forth in claim 9 wherein the step of tensioning the suture with a predetermined force causing the first and second anchors to connect the first body tissue with the bone includes tensioning the suture with a predetermined

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force causing the first and second anchors to connect the first body tissue and a second body tissue with the bone.

11. A method as set forth in claim 6 wherein the step of changing the first anchor from a first to a second configuration causing the first anchor to become impassable through the linear passage includes expanding the first anchor relative to the bone causing the first anchor to become generally larger than the diameter of the linear passage.

12. A method as set forth in claim 11 further including the step of providing a second anchor positioned relative to the first body tissue.

13. A method as set forth in claim 12 wherein the step of tensioning the suture with a predetermined force causing the

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first body tissue to become engaged with the bone includes tensioning the suture with a predetermined force causing the first and second anchors to connect the first body tissue with the bone.

14. A method as set forth in claim 13 wherein the step of tensioning the suture with a predetermined force causing the first and second anchors to connect the first body tissue with the bone includes tensioning the suture with a predetermined force causing the first and second anchors to connect the first body tissue and a second body tissue with the bone.

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