US006547793B1

(12) United States Patent
McGuire

(10) Patent No.: US 6,547,793 B1
(45) Date of Patent: Apr. 15, 2003

(54) SYSTEMS AND METHODS FOR PRODUCING OSTEOTOMIES

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/506,714**

(22) Filed: **Feb. 18, 2000**

Related U.S. Application Data

(62) Division of application No. 08/985,568, filed on Dec. 5, 1997, now Pat. No. 6,027,504.

(60) Provisional application No. 60/031,989, filed on Dec. 6, 1996, and provisional application No. 60/063,195, filed on Oct. 21, 1997.

(51) **Int. Cl.**[7] **A61B 17/86**

(52) **U.S. Cl.** **606/73**; 606/87

(58) **Field of Search** 606/60, 62, 65, 606/66, 72, 73

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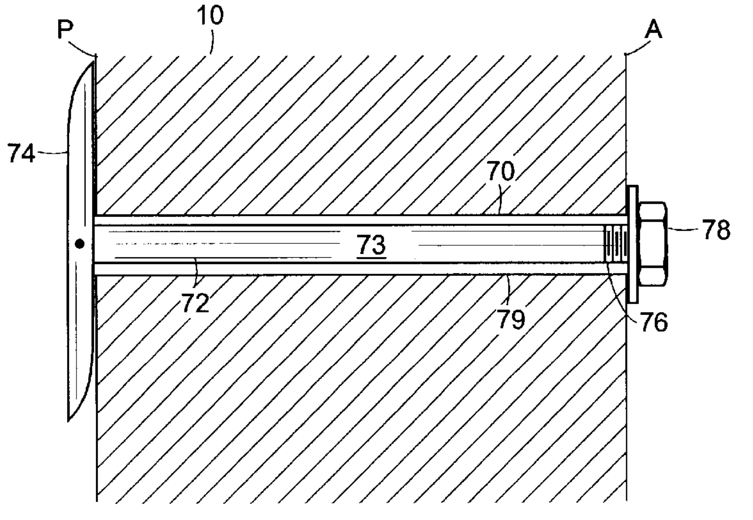
(57) **ABSTRACT**

Systems and methods for producing minimally invasive osteotomies to correct angular deformities of bones in and about the knee are disclosed. A method includes locating a plane in which the angle exhibited by the deformity is situated. An oblique cut is then made along a surface of the bone, such that the cut is transverse to the plane in which the angle is situated. Thereafter, the bone pieces are rotated about the cut relative to one another until a desired alignment between the bone pieces is achieved. To maintain the bone pieces in alignment, a device having an elongated body for extending into a tunnel between the bone pieces is provided. The system also includes a rigid member fixedly positioned at one end of the body. The rigid member is transverse to the body to engage one bone piece. The system further includes a locking mechanism at an opposite end of the body to engage the other bone piece. The system permits the bone pieces to be pulled against one another between the rigid member and the locking mechanism.

13 Claims, 26 Drawing Sheets



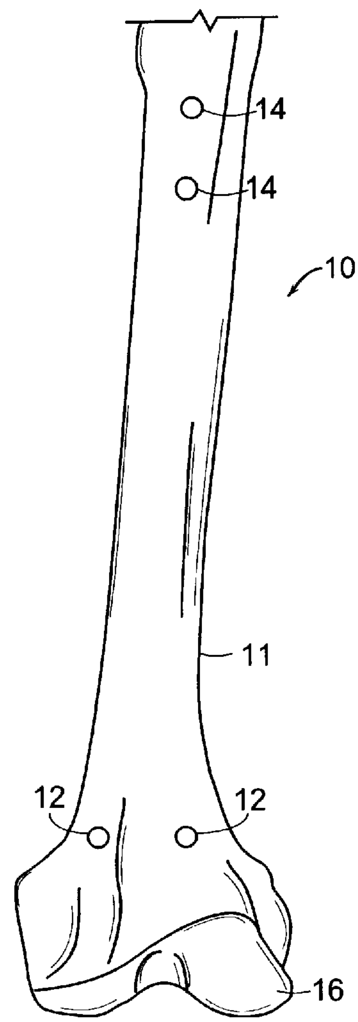


FIG. 1A

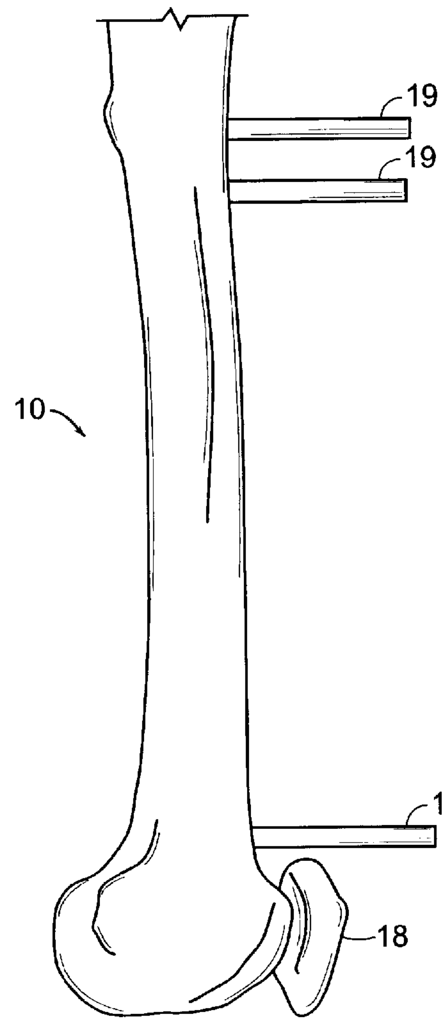


FIG. 1B

FIG. 1D

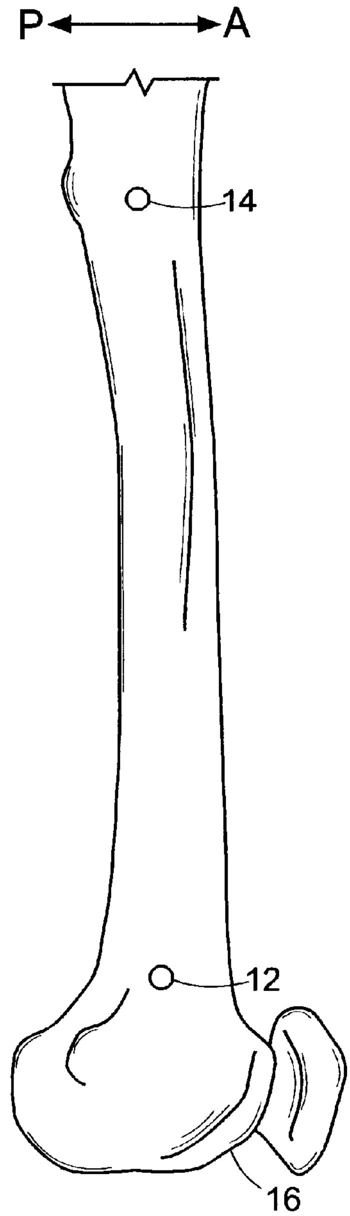


FIG. 1C

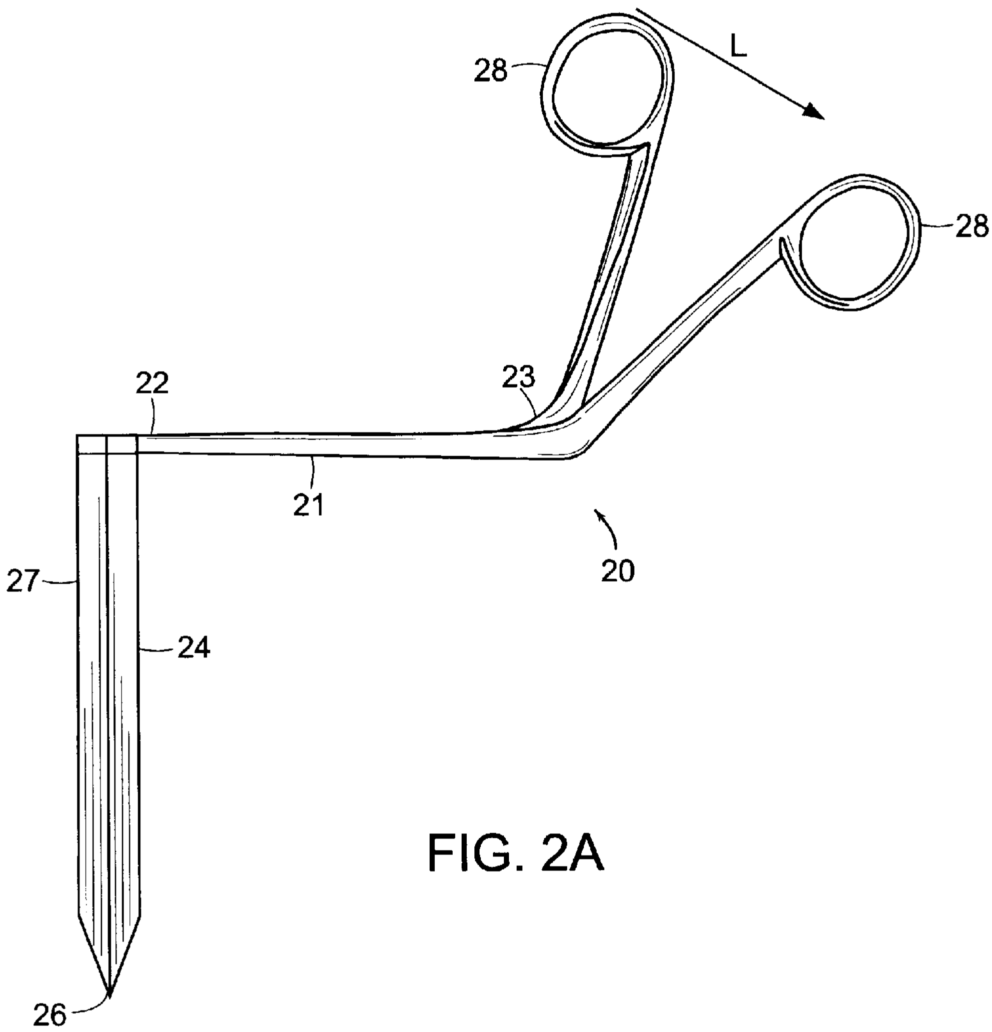
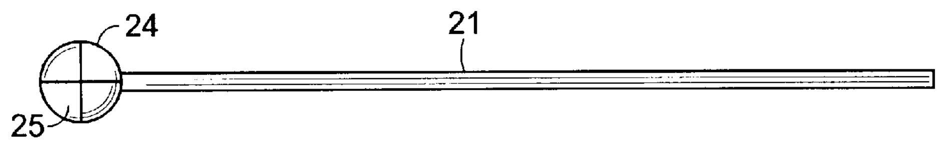


FIG. 2A



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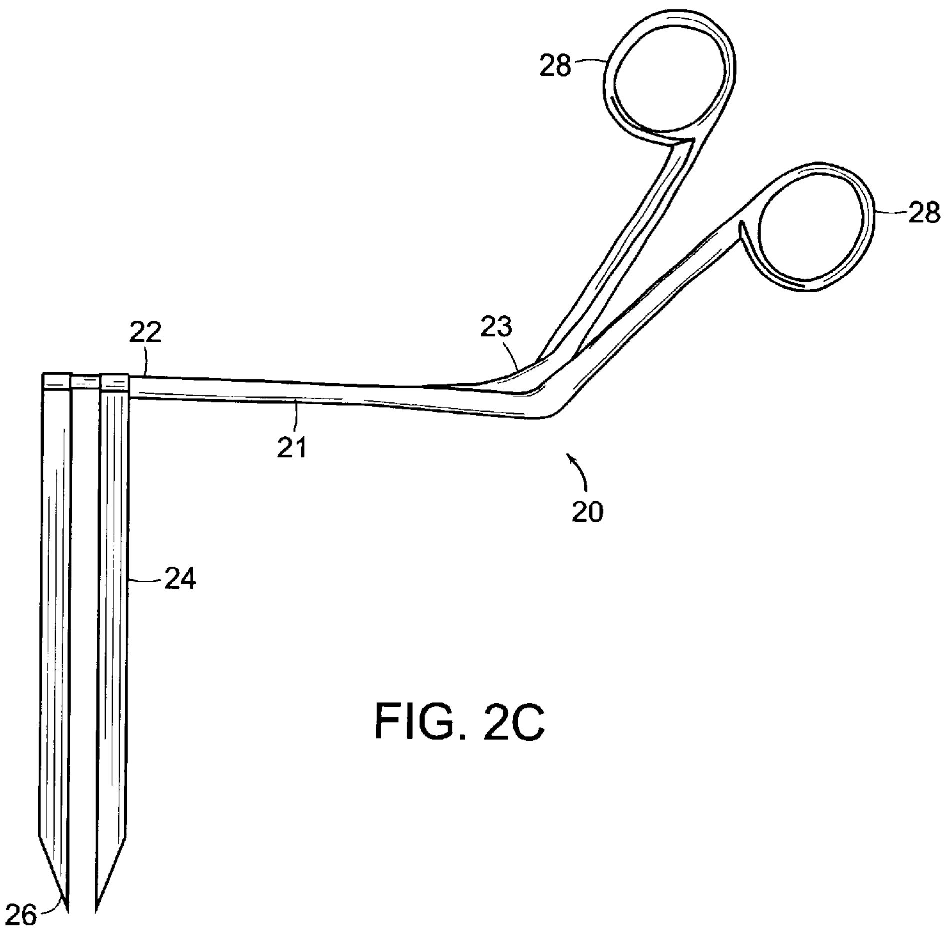

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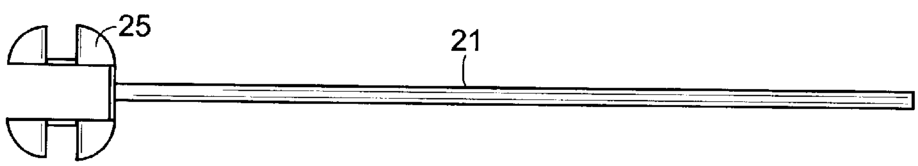

FIG. 2D

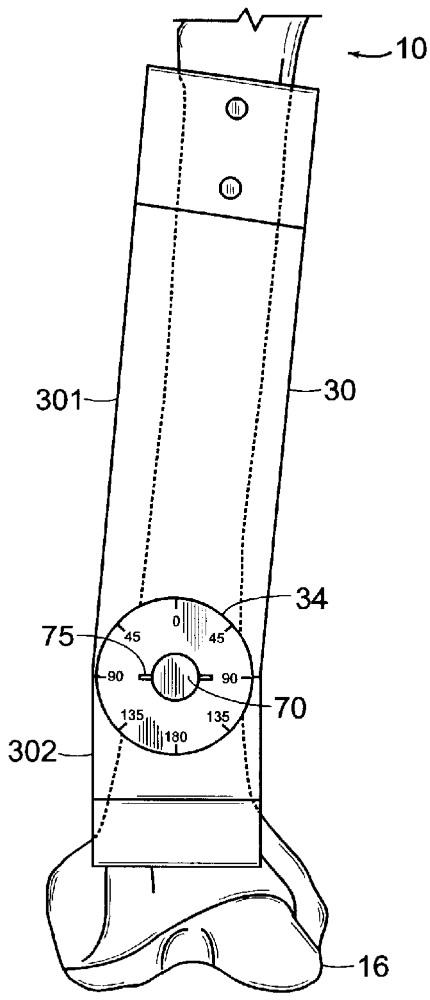
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FIG. 3A

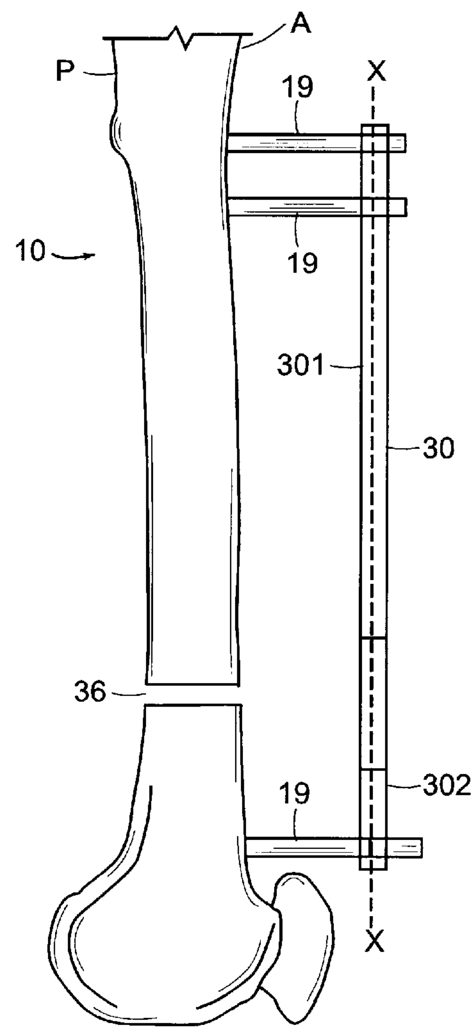
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FIG. 3B

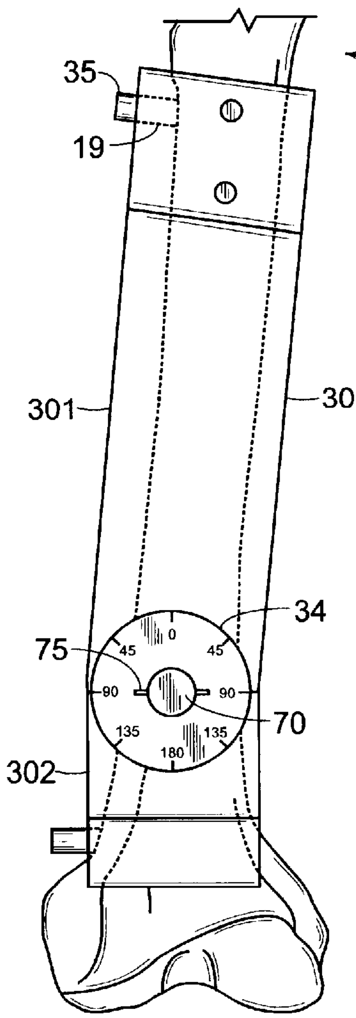

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FIG. 3C

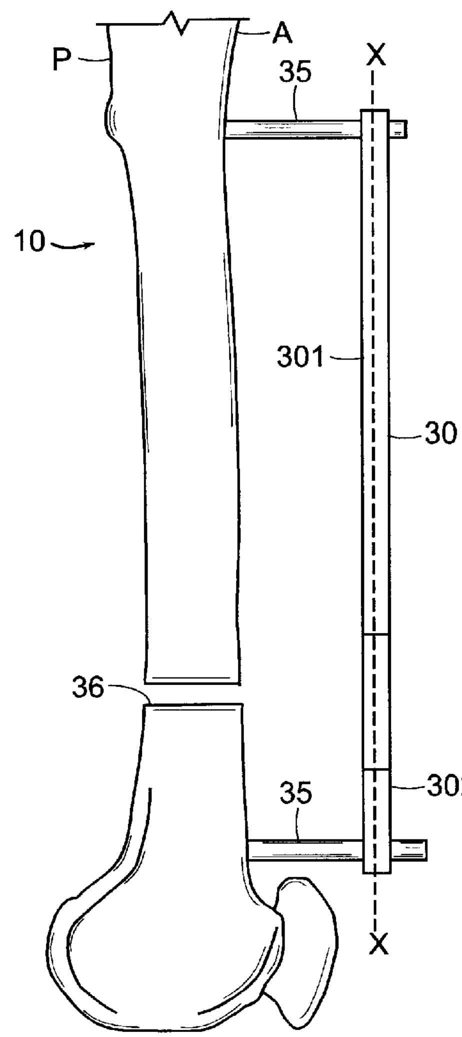

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FIG. 3D

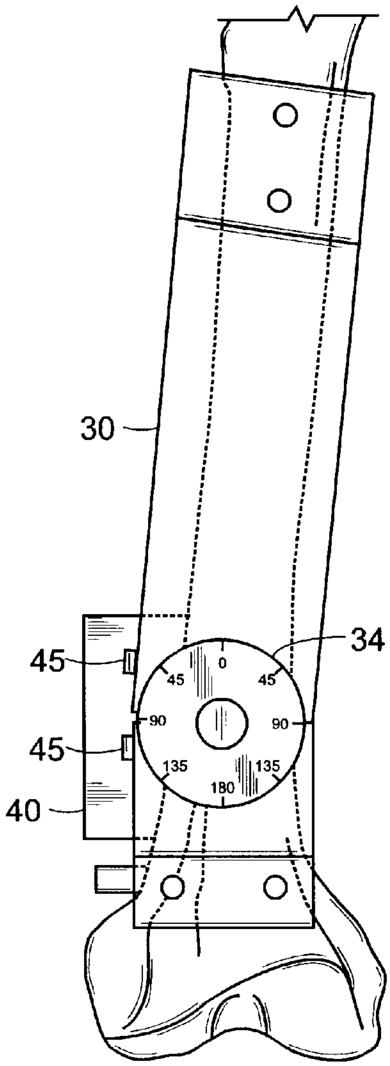
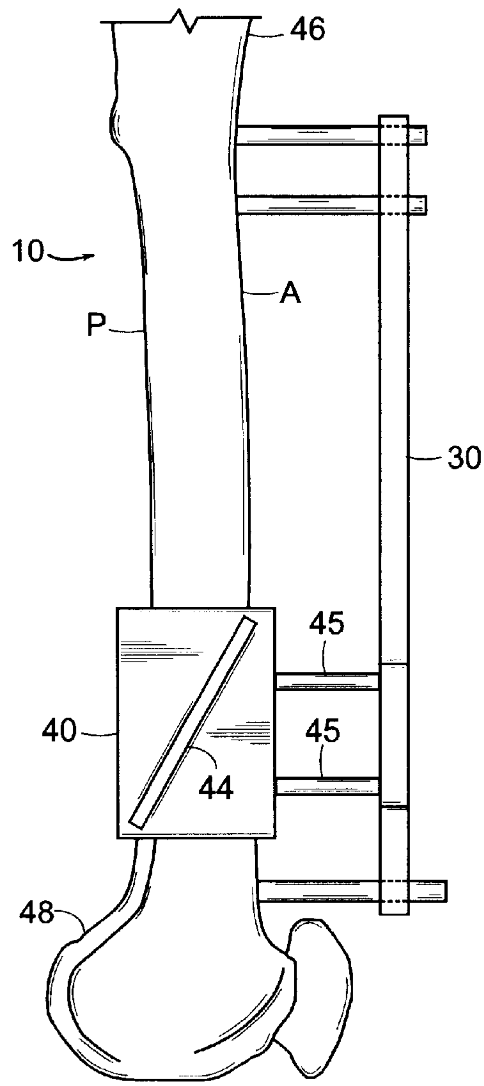


FIG. 4A



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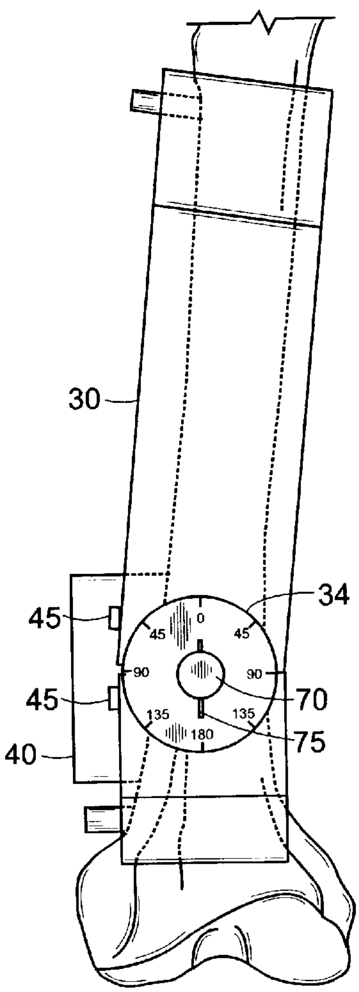

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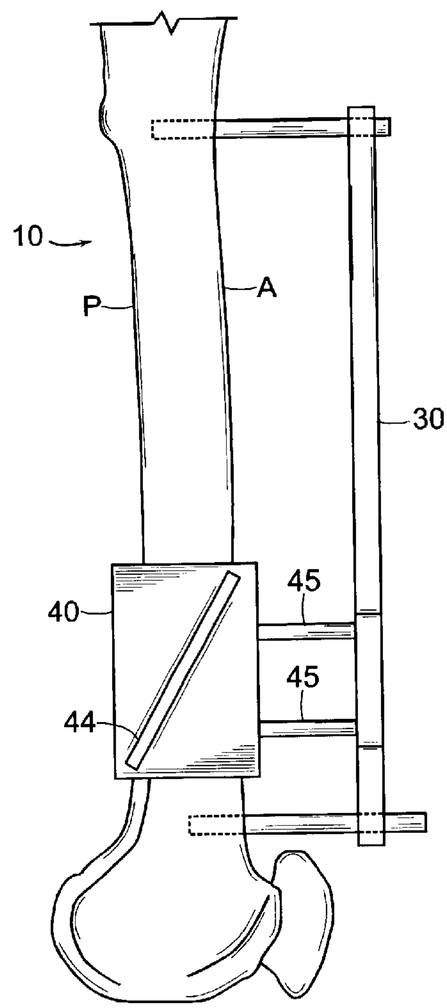

FIG. 4D

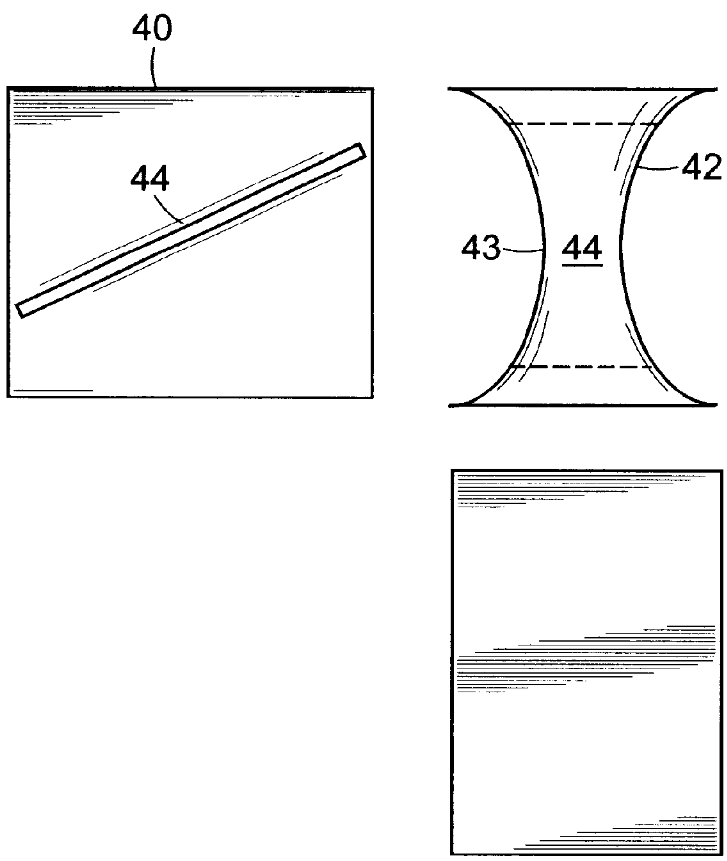

FIG. 5

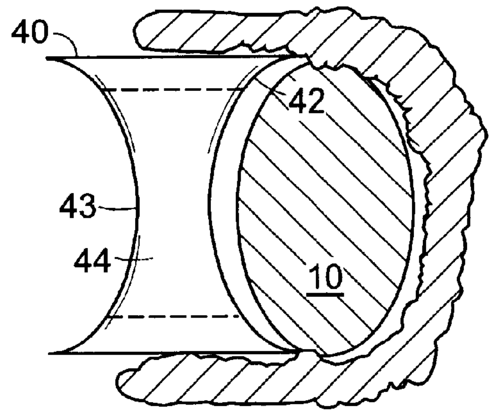

FIG. 6A

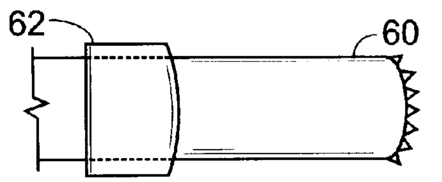

FIG. 6B

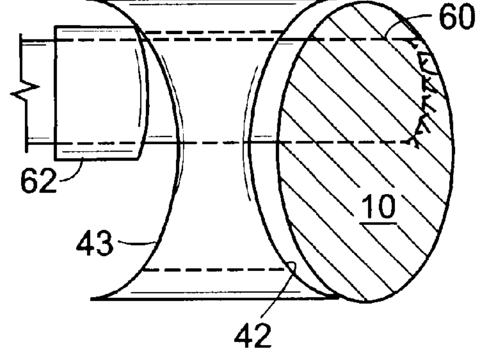

FIG. 6C

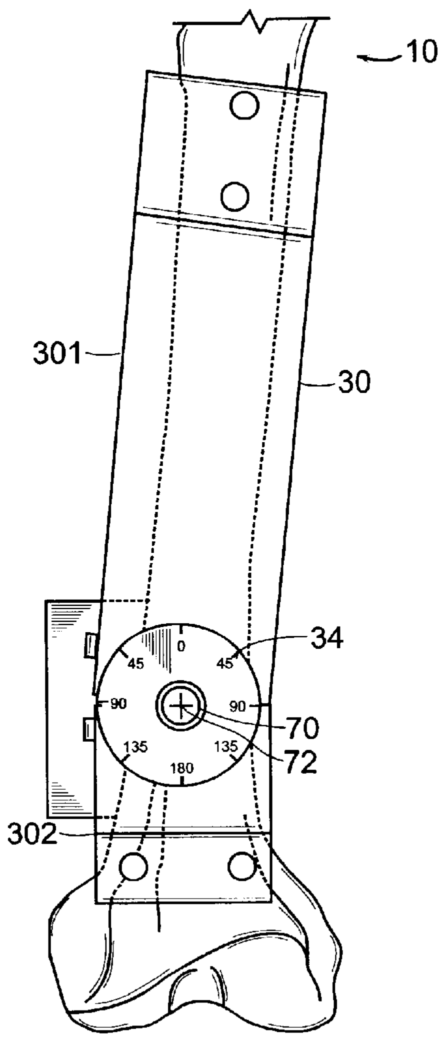
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FIG. 7A

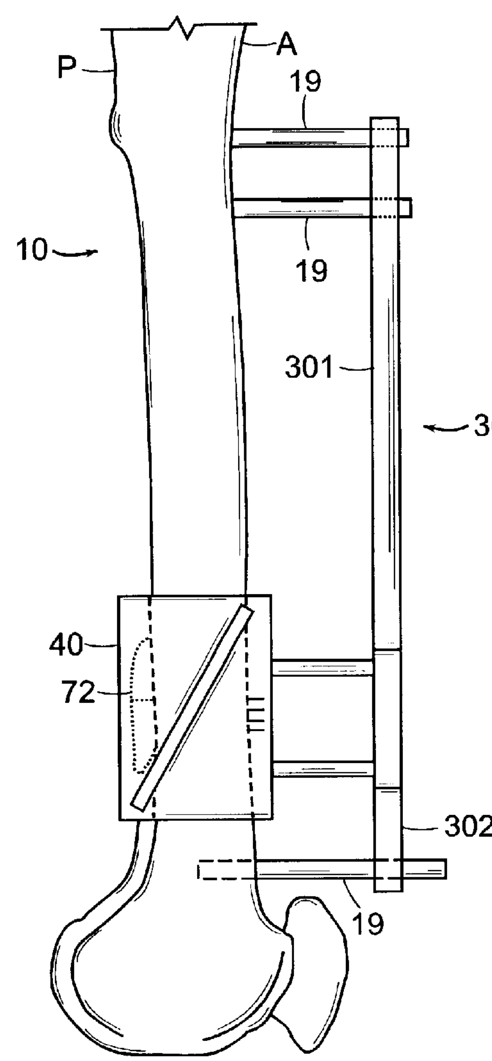
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FIG. 7B

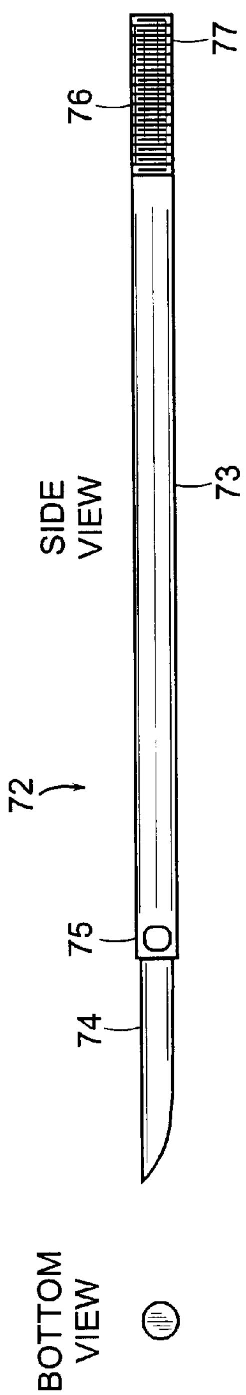
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FIG. 8A

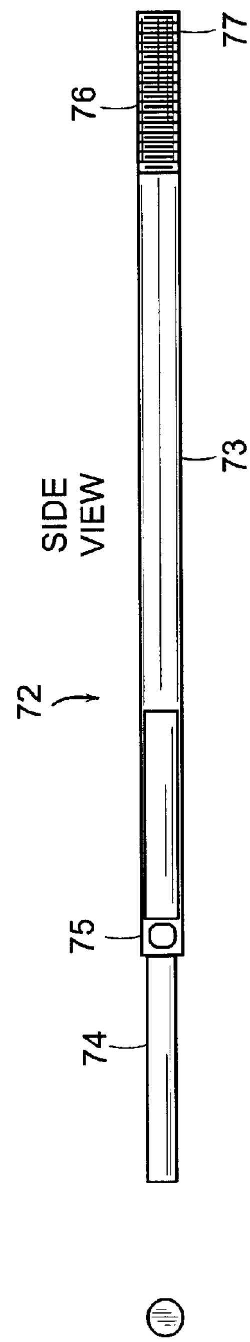
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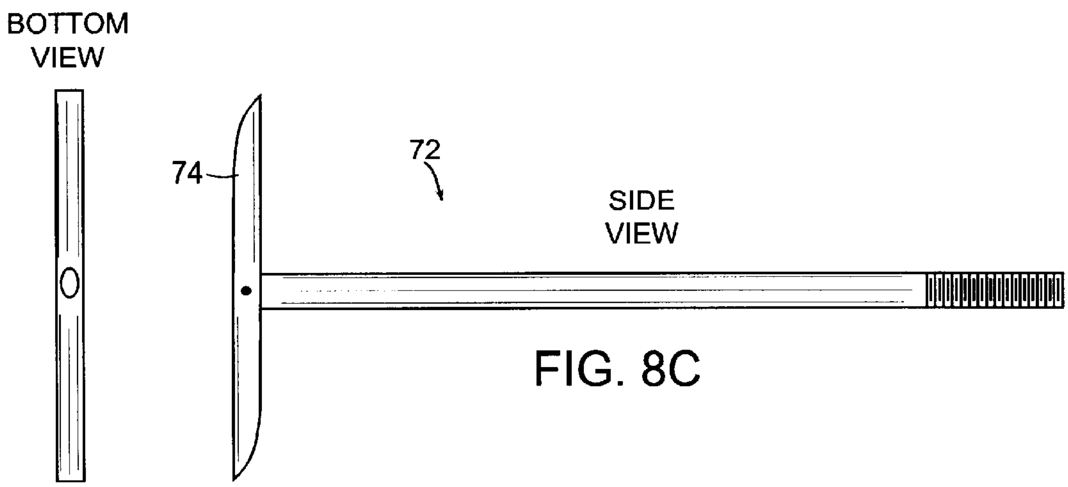
FIG. 8B



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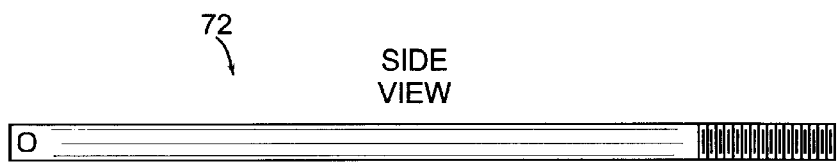

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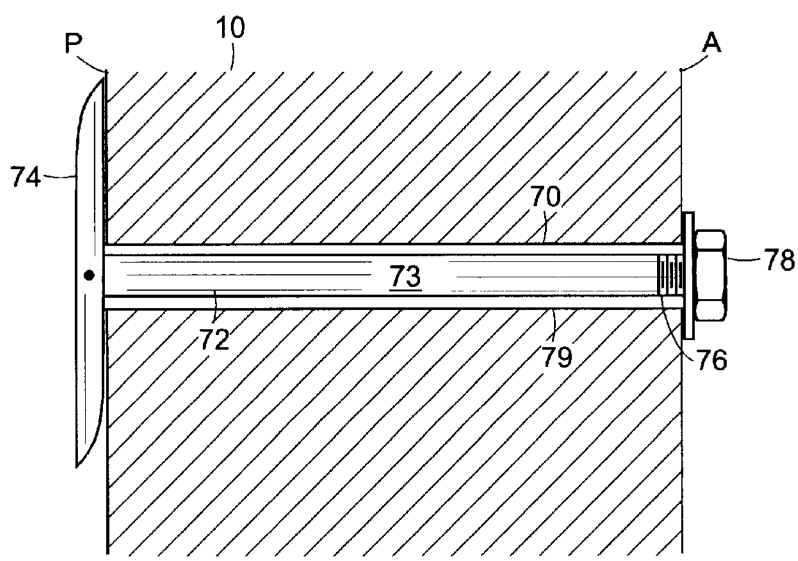


FIG. 8E

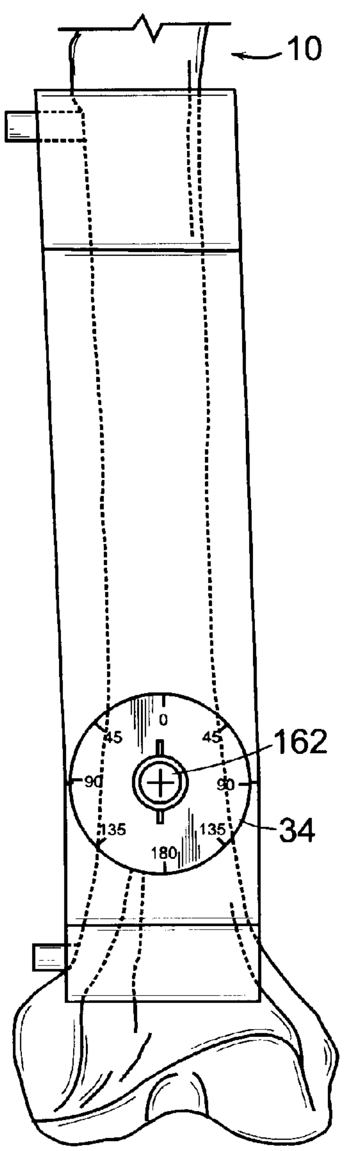


FIG. 9A

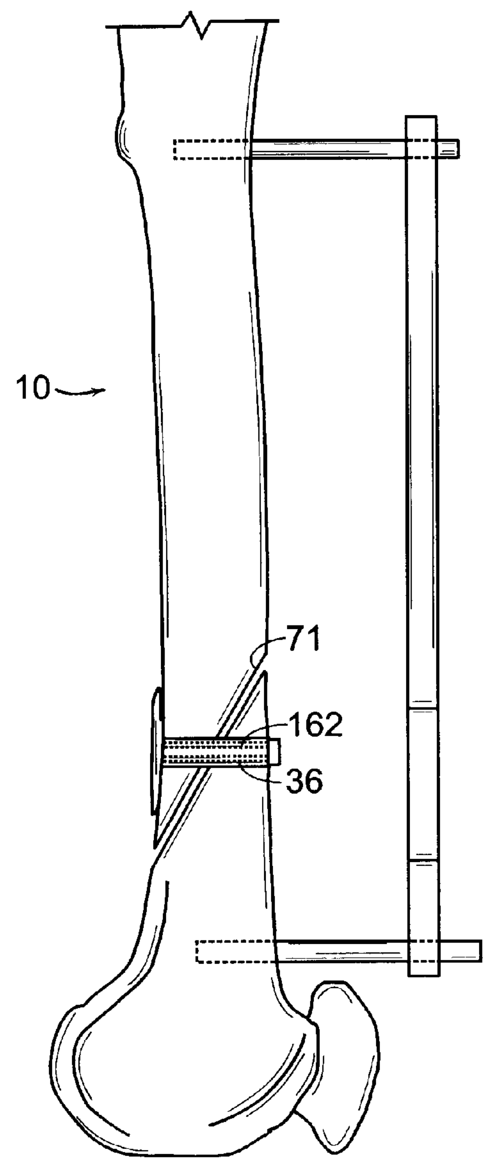
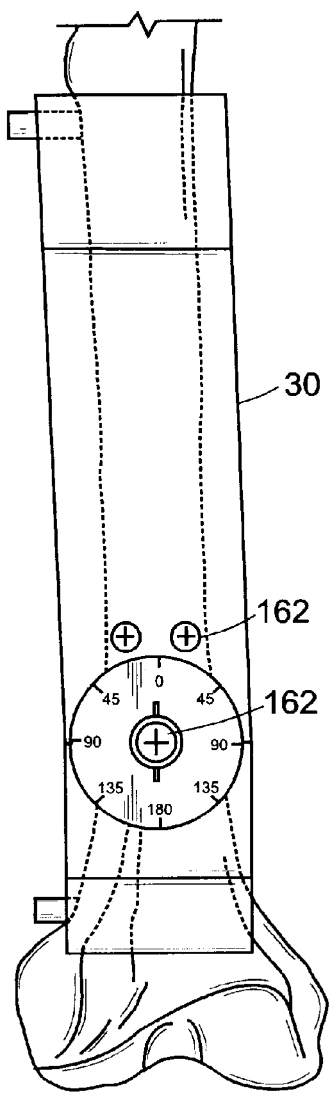


FIG. 9B



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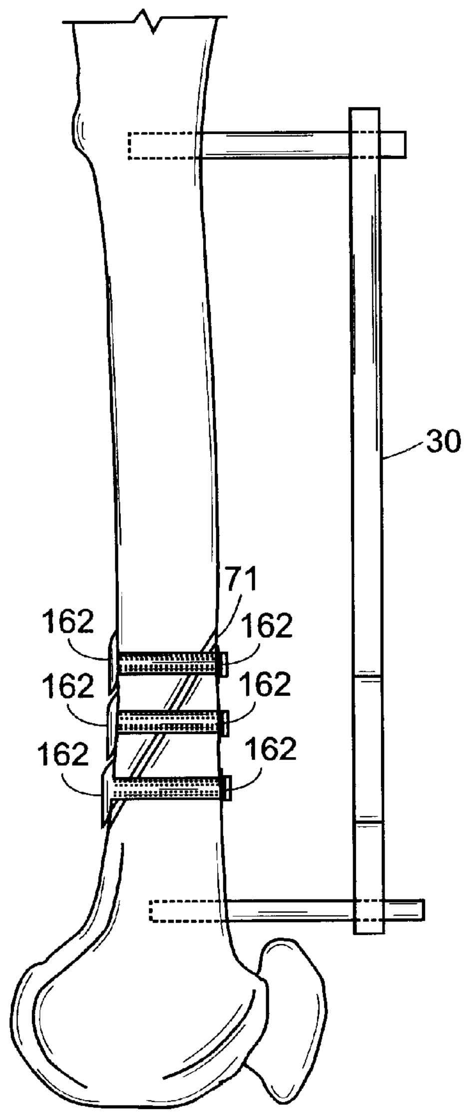

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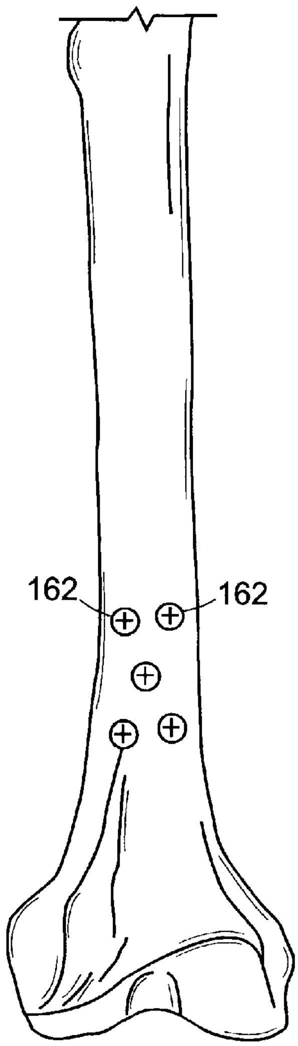


FIG. 11A

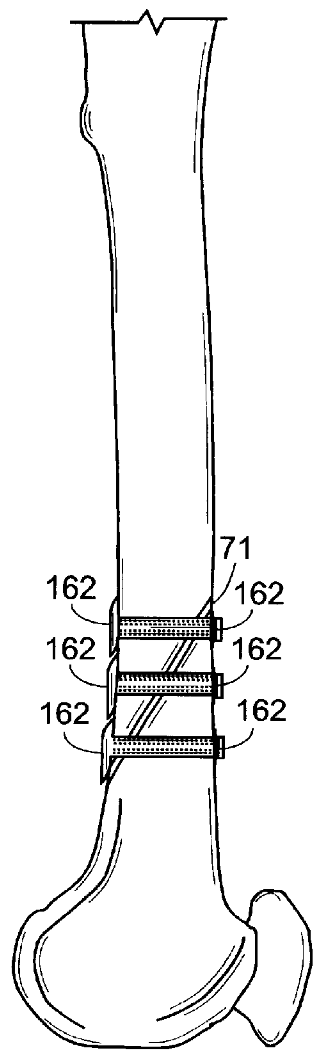


FIG. 11B

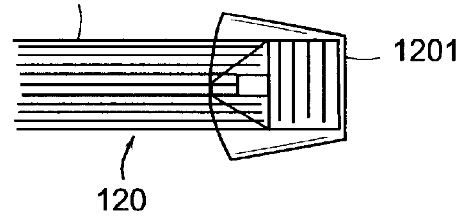


FIG. 12B

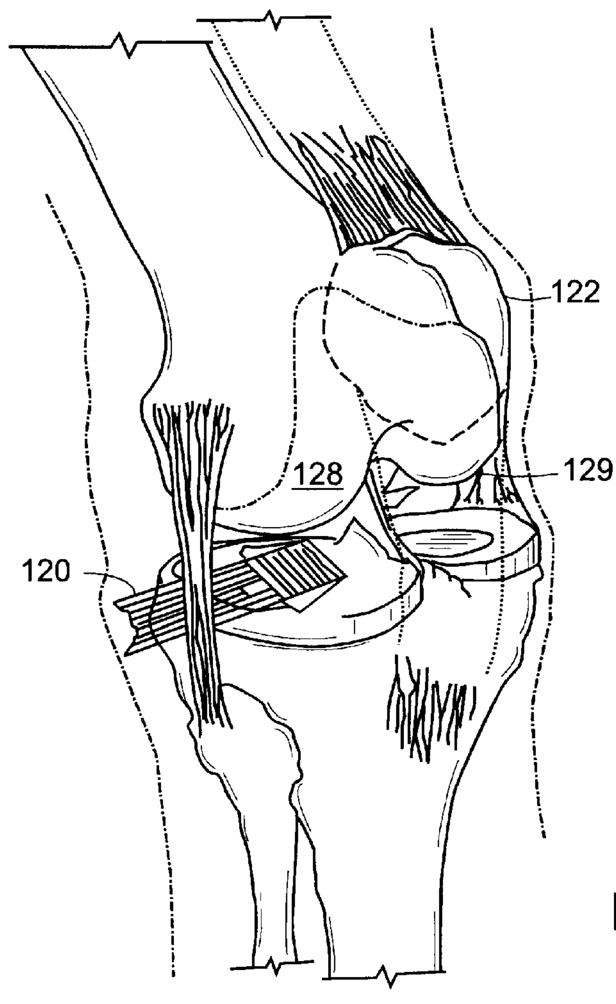


FIG. 12A

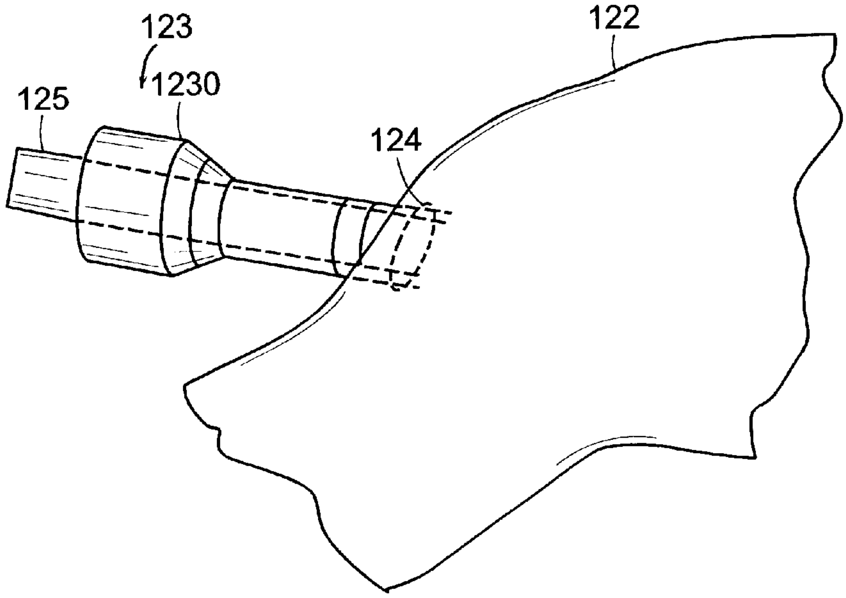


FIG. 12C

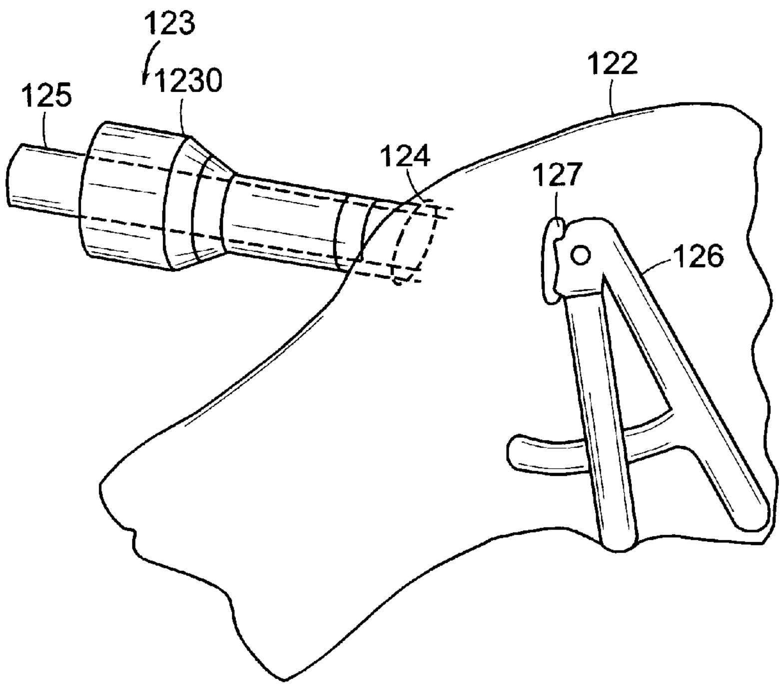


FIG. 12D

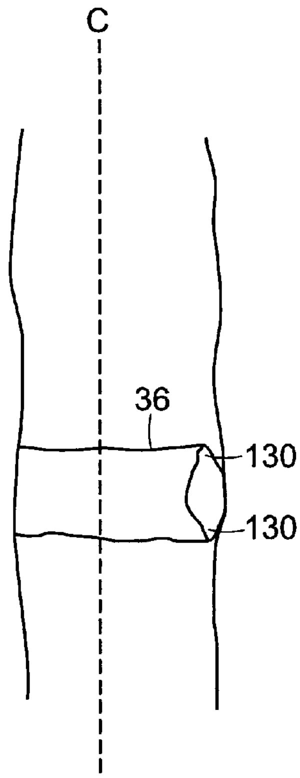


FIG. 13A

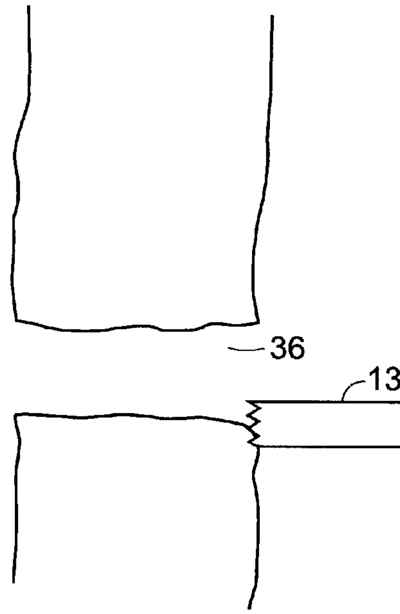


FIG. 13B

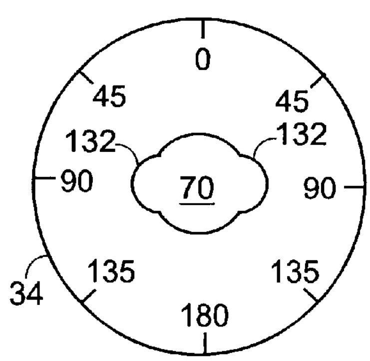


FIG. 13C

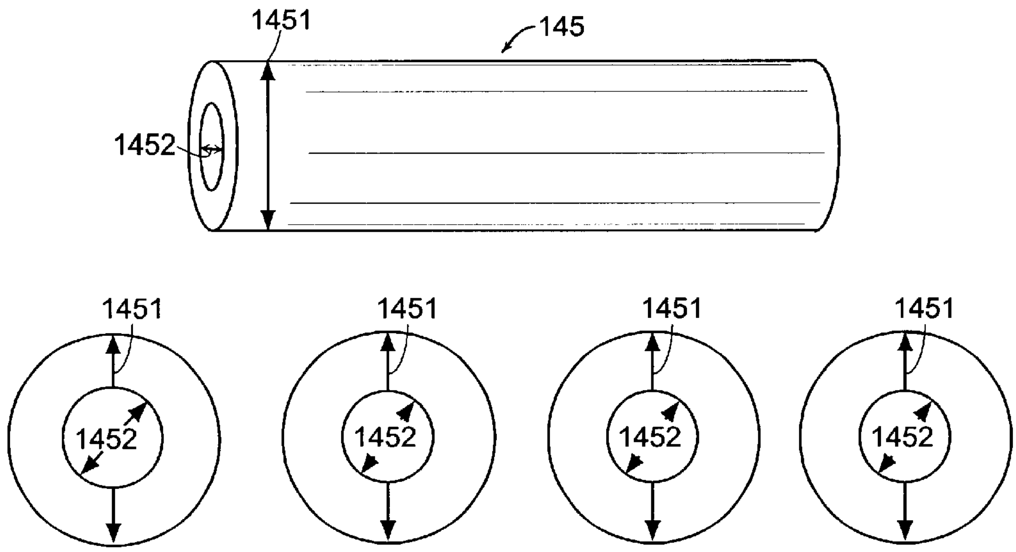
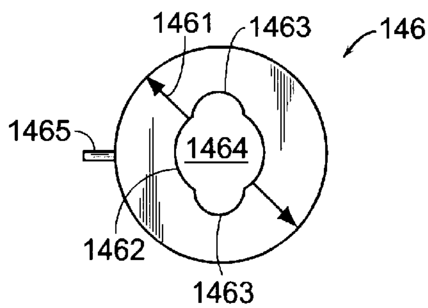


FIG. 14A



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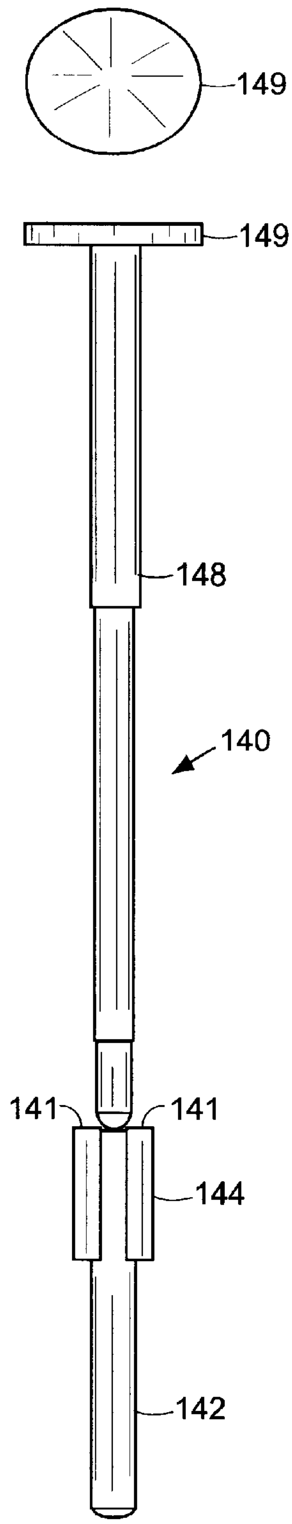


FIG. 14C

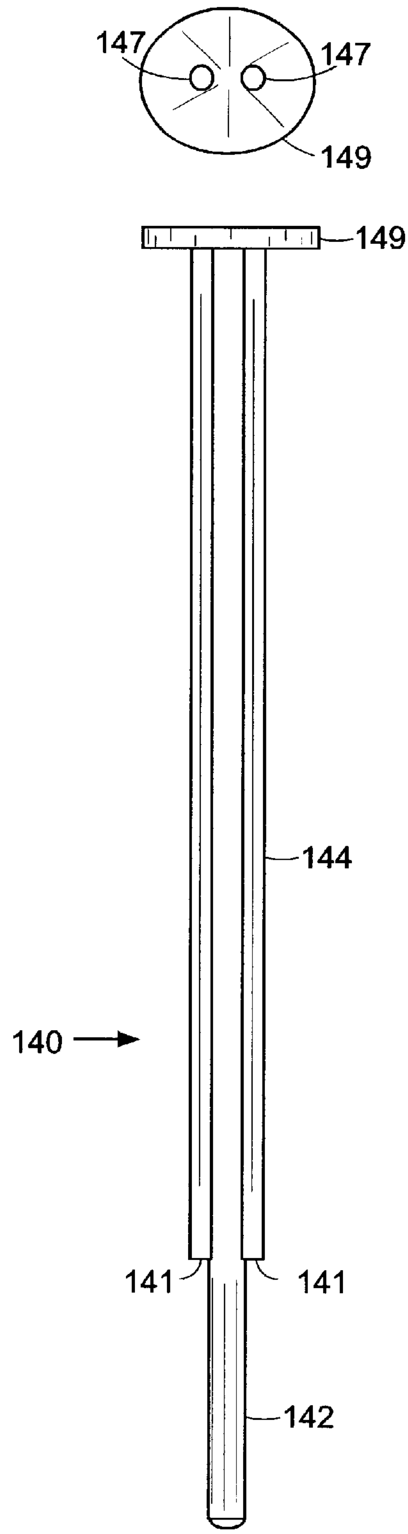
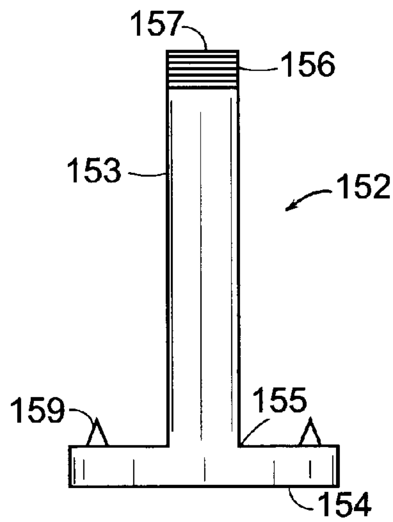


FIG. 14D



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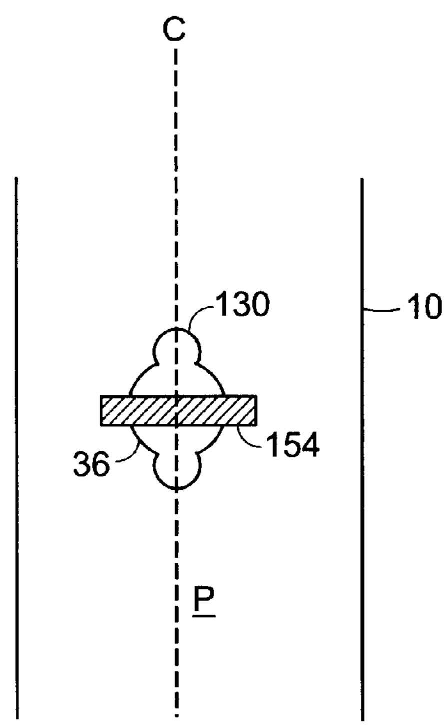

FIG. 15B

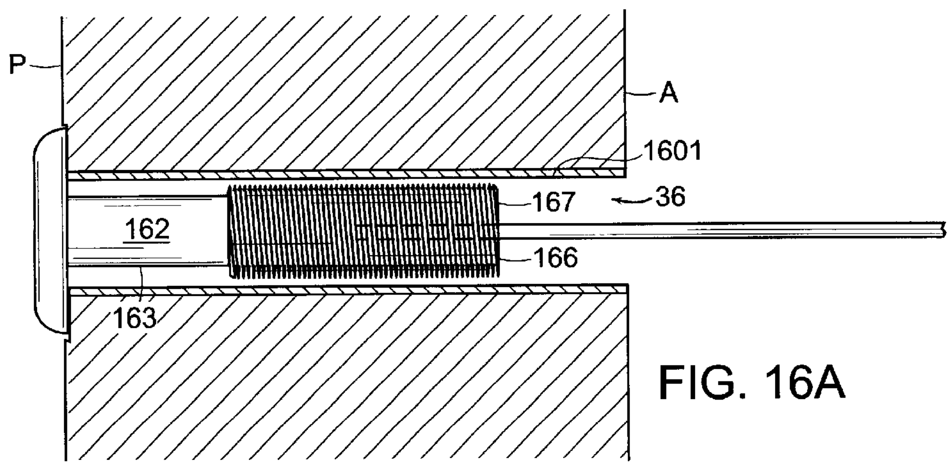

FIG. 16A

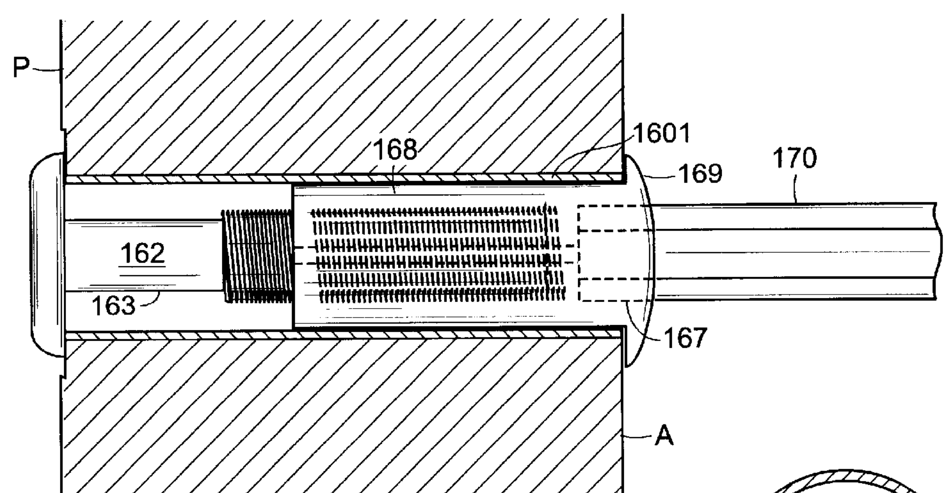

FIG. 16B

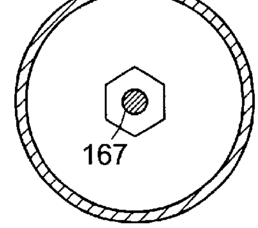

FIG. 16C

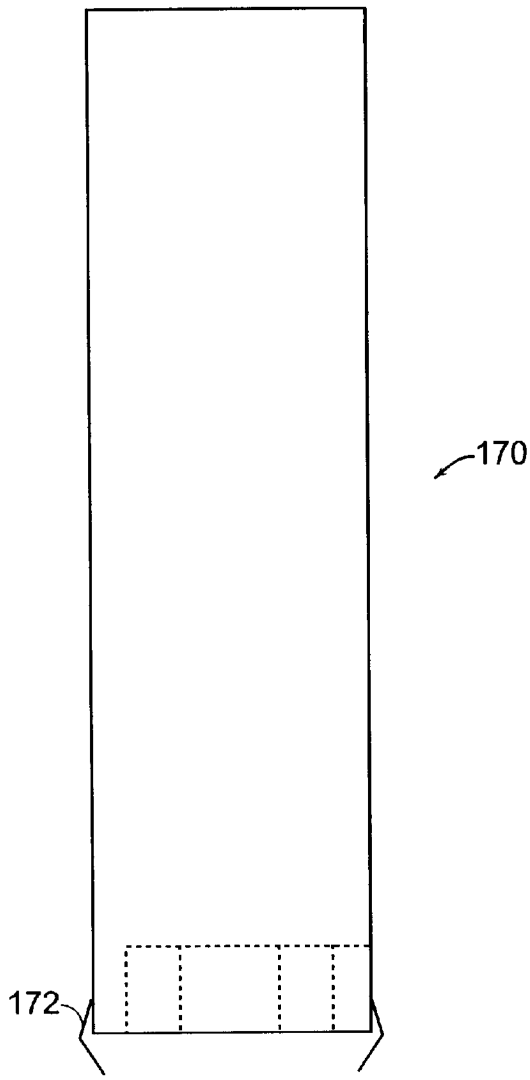

FIG. 17

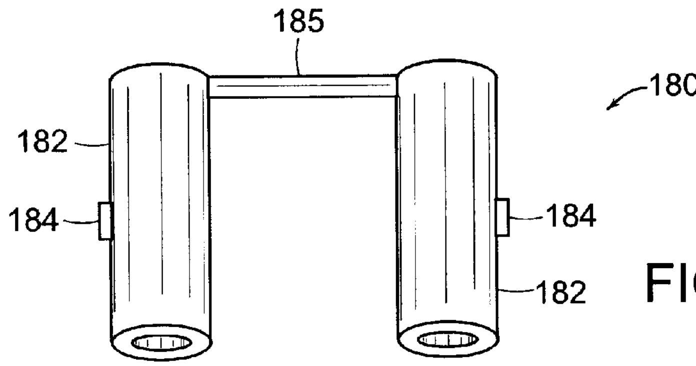

FIG. 18

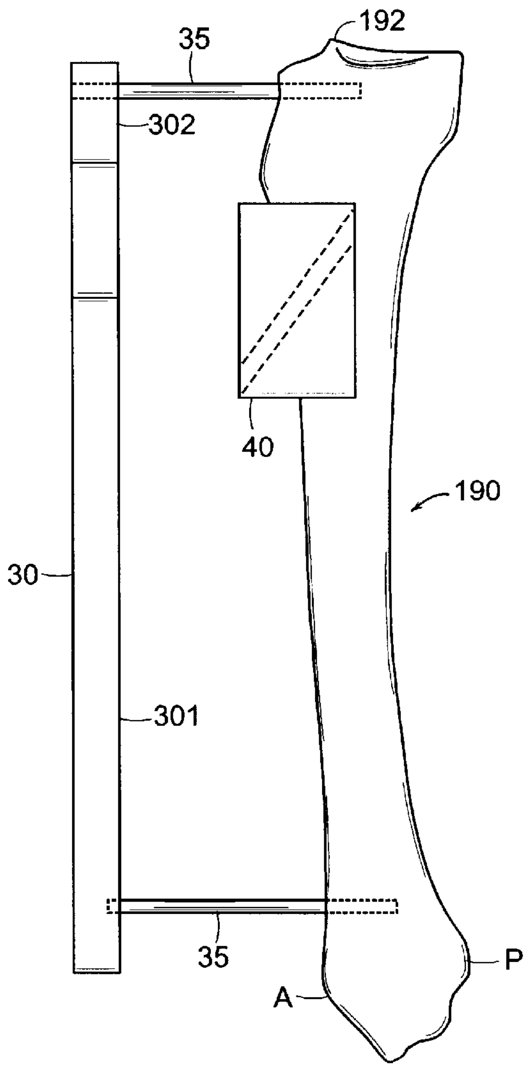

FIG. 19A

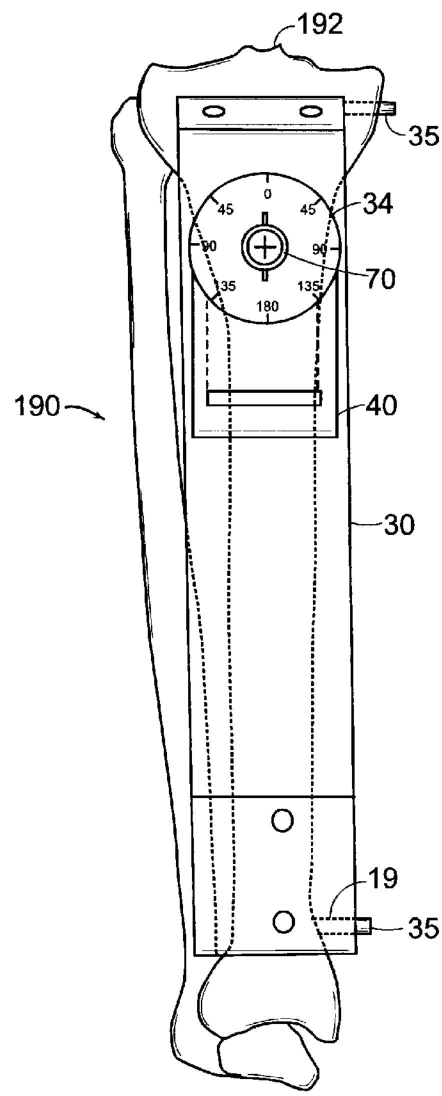

FIG. 19B

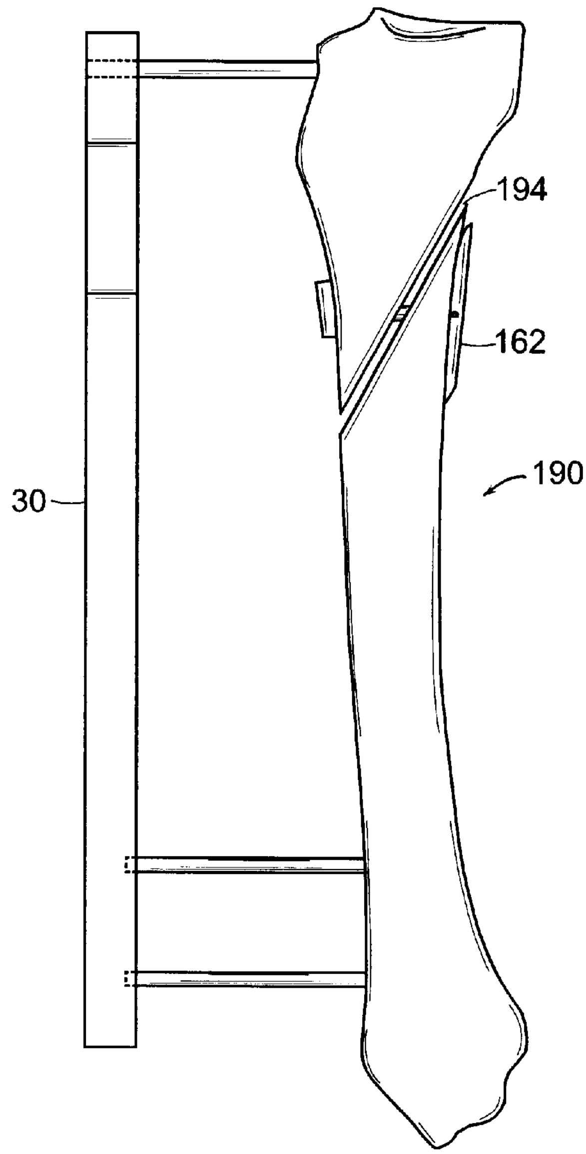

FIG. 19C

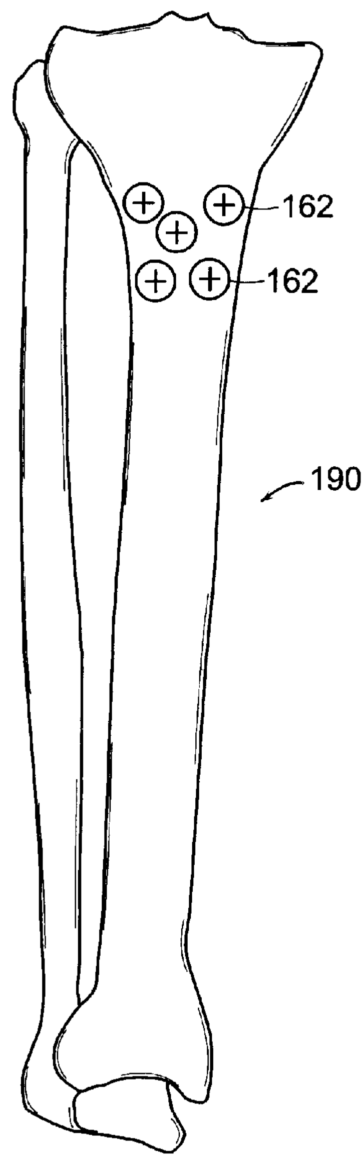

FIG. 19D

SYSTEMS AND METHODS FOR PRODUCING OSTEOTOMIES

RELATED U.S. APPLICATION(S)

The present application claims priority from U.S. Provisional Application No. 60/031,989, filed Dec. 6, 1996 and from U.S. Provisional Application No. 60/063,195, filed Oct. 21, 1997, and is a copendent, divisional application of U.S. Utility application Ser. No. 08/985,568 filed Dec. 5, 1997, now U.S. Pat. No. 6,027,504, which are all hereby incorporated herein by reference.

TECHNICAL FIELD

This invention relates to a device and method for producing osteotomies in bones experiencing angular deformities, and in particular osteotomies associated with angular deformities of the femur and tibia.

BACKGROUND ART

Prior art methods for producing osteotomies to correct angular deformity in a bone mass, such as a femur or tibia, generally require making a large open incision around the deformed site and cutting a wedge, at such site, completely across the deformed bone mass, to initially form two bone pieces. Once the cut has been made in the bone mass and the wedge removed, the bone pieces may be realigned and the angle between the two bone pieces adjusted for corrective purposes. However, because of the invasiveness of the surgery, osteotomy procedures often result in undesirable pain and extended period of immobility for the patient.

In addition to a period of immobility, prior art methods for producing osteotomies have allowed only minimal control of the bone pieces once the bone mass has been divided. For example, as it may be difficult to control the alignment between the two bone pieces of the deformed bone, the correction of the angular deformity may provide clinical results that are unpredictable. Also contributing to the unpredictability of the clinical results is the difficulty in maintaining the bone pieces in approximation after they have been aligned. Moreover, current osteotomy procedures typically involve application of a uniform corrective angle to the bone pieces, regardless of the individual. As individuals vary in height, weight and age, a slight difference in the angle of a deformed bone mass can cause a measurable difference in contact pressure between the articular surfaces of a deformed bone mass and another bone mass (e.g., between a deformed tibia and a femur). A uniform change in the angle of the deformed bone mass for different individuals, therefore, may not result in a sufficient change in the contact pressure between the articular surfaces of the bones, so as to avoid future degenerative problems.

Accordingly, there is a need for a method that produces osteotomies in a minimally invasive, predictable, and measurable manner, in addition to being individualized and reliable, so that the procedure may be performed at an early stage in the course of the disease. Such a method would permit avoidance of severe degenerative changes that frequently accompany current methods for producing osteotomies.

SUMMARY OF THE INVENTION

The present invention is directed to systems and methods for producing minimally invasive osteotomies to correct angular deformities of bones in and about the knee. The method of the present invention is accurate, reliable, predictable, measurable, controllable and reproducible. As hereinafter provided, the method is discussed in association with femoral and/or tibial osteotomies. However, it should be appreciated that the method has applications for other bones beyond those bones about the knee.

In accordance with one embodiment of the present invention, the method for producing osteotomy in a first bone having an angle of deformity includes drilling a tunnel through a surface of a first bone at an area about the angular deformity, such that the tunnel drilled is transverse to a plane in which the angle is situated. Next, an oblique cut is made partially across the bone on a surface that is parallel to the tunnel, so as to provide a cut that is at an angle to the tunnel. In an embodiment of the invention, the angle of the cut is such that when the bone is realigned, the contact pressure between an articular surface of the first bone and an articular surface of a second bone approaches a desirable ratio within a physiologic tolerance. Once the cut is partially made across the first bone, the first bone is secured about the cut, for instance, by placing through the tunnel a device which permits bone pieces of the first bone, once the first bone is completely cut, to be maintained in approximation. The amount of angular correction is then determined so that the contact pressure between the first and second bone may be brought to within physiological tolerance. In accordance with an embodiment of the invention, the angular correction is determined by measuring intra-articular pressure between the contact surfaces of the first and second bones. After the amount of angular correction has been determined, the cut is completed across the first bone to form two bone pieces. The bone pieces are then rotated relative to one another about the tunnel, so as to be brought into an alignment which brings about the desirable contact pressure between the first and second bones. The bone pieces are subsequently secured against one another to maintain alignment and close approximation.

In an embodiment of the present invention, the bone pieces are maintained in approximation by the use of a bone anchor assembly having an elongated body for extending across a juncture between the bone pieces. The elongated body includes a distal end and a proximal end. A rigid member is fixedly positioned at the distal end transverse to the body for engaging one bone piece. A locking mechanism is also provided at the proximal end of the body for engaging the other bone piece. To this end, the bone pieces may be pulled against one another between the rigid member at the distal end and the locking mechanism at the proximal end of the device.

Prior to drilling the tunnel through the deformed bone, a support structure of the present invention is preferably affixed along a surface of the deformed bone adjacent the angular deformity. The support structure is designed so that one end attaches to a first end portion of the bone, and an opposite end attaches to a second end portion of the bone. The support structure is also pivotally movable at an area between its ends. In this manner, once the bone pieces are formed, the support structure may maintain the bone pieces close to one another, so that they may subsequently be pivoted into alignment. To secure and maintain the bone pieces in approximation after alignment, a bone anchor assembly of the present invention is positioned through the tunnel and tightened against the bone pieces.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1A–D illustrate an angularly deformed femur having a plurality of holes formed in accordance with embodiments of the present invention, and having subcutaneously insertable pins situated within the holes.

FIGS. **2**A–D illustrate a separating device for use in the formation of the holes illustrated in FIGS. **1**A–D.

FIGS. **3**A–D correspond to FIGS. **1**A–D respectively and further showing a support structure positioned along the anterior surface of the femur.

FIGS. **4**A–D correspond to FIGS. **3**A–D respectively and further showing a saw guide attached to the lateral surface of the femur.

FIG. **5** illustrates one embodiment of a saw guide for use with the present invention.

FIG. **6**A is a top view of the saw guide of FIG. **5** positioned against the femur in the manner shown in FIGS. **4**A–D.

FIG. **6**B shows a saw blade with a stop for use with the present invention.

FIG. **6**C shows the saw blade of FIG. **6**B in use with the saw guide of FIG. **6**A.

FIGS. **7**A–B illustrate a femur having a bone anchor extending across a cut made by the saw and guide of FIGS. **5** and **6**A–C.

FIGS. **8**A–D show a bone anchor in accordance with one embodiment of the present invention.

FIG. **8**E is a bone anchor shown in FIGS. **8**A–D extending through a femur.

FIGS. **9**A–B illustrate a femur having been corrected of its angular deformity.

FIGS. **10**A–B show the femur of FIGS. **9**A–B with additional bone anchors.

FIGS. **11**A–B illustrate the end results of a corrected femur of FIGS. **10**A–B.

FIG. **12**A illustrates a knee with a pressure transducer portion therein.

FIG. **12**B shows the pressure transducer shown in FIG. **12**A.

FIGS. **12**C–D illustrate a knee having a cannula and trocar inserted through a lateral portal and a grasper inserted through a medial portal.

FIG. **13**A shows an embodiment of a tunnel for use with a bone anchor in accordance with one embodiment of the present invention.

FIG. **13**B illustrates a method for forming a tunnel in FIG. **13**A through a femur.

FIG. **13**C shows a modified goniometer for forming tunnel shown in FIG. **13**A.

FIGS. **14**A–B show alternate embodiments of a guide for forming a bone anchor tunnel. FIG. **14**A shows a longitudinal view, as well as a series of cross-sectional views illustrating progressively smaller inner diameters, in accordance with an embodiment. FIG. **14**B is a cross-sectional view of another guide embodiment illustrating parallel contiguous inner passageways.

FIGS. **14**C–D illustrate other embodiments of a guide for forming a bone anchor tunnel.

FIG. **15**A shows a bone anchor in accordance with another embodiment of the present invention.

FIG. **15**B is a end view of the tunnel formed in FIG. **13**A having the device in FIG. extending therethrough.

FIGS. **16**A–C show a bone anchor in accordance with a further embodiment of the present invention.

FIG. **17** shows a driver for use with the device shown in FIGS. **16**A–C.

FIG. **18** illustrates a guide for forming multiple bone anchor tunnels in accordance with an embodiment of the present invention.

FIGS. **19**A–D illustrate a tibial osteotomy in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

A preferred embodiment of the invention herein provides a device and method for producing minimally invasive osteotomies in and about the knee. In accordance with this embodiment, an osteotomy permits accurate, precise and controllable correction of angular deformities in bones about the knee, such that the amount of trauma typically associated with osteotomy is lessened. In order to provide an overall understanding of the present invention, the embodiments of the method of the invention will be discussed with reference to the embodiments of the devices of the invention. However, it will be understood by persons of ordinary skill in the art that embodiments of the invention are applicable to the production of osteotomies of other bones within the body.

There are two common types of angular deformities usually associated with the femur and tibia, valgus deformity and varus deformity. In either of these conditions, the angular deformity causes a deviation in the amount of contact pressure produced within the intra-articular space between the femur and the tibia, leading to degeneration of the knee joint. In general, valgus deformity, otherwise known as knock-kneed deformity, can be corrected by performing a femoral osteotomy to reduce the relatively high contact pressure between the lateral femoral condyle and the lateral tibial plateau, and increasing the relatively low contact pressure between the femoral medial condyle and the medial tibial plateau. Varus deformity, otherwise known as bow-legged deformity, on the other hand, can be corrected by performing a tibial osteotomy to reduce the relatively high contact pressure between the medial tibial plateau and the medial femoral condyle, and increasing the relatively low contact pressure between the lateral tibial plateau and the lateral femoral condyle.

With reference now to femoral osteotomy, FIGS. **1**A–D illustrate a femur **10** having an angular deformity **11** near its patellar surface **16**. In FIG. **1**A, sets of holes **12** and **14** are shown formed on the anterior surface of the femur **10** relative to the angular deformity **11**. Holes **12** are formed near an end adjacent the patellar surface **16** and substantially parallel to the medial and lateral border of the patella **18**. Holes **14**, on the other hand, are formed toward an opposite end of the femur **10** relative to the deformity **11** and away from holes **12**. Holes **12** and **14** establish sites at which subcutaneously insertable pins **19** may be placed for subsequent attachment of a femur support structure necessary for producing an osteotomy in accordance with an embodiment of the present invention. In a preferred embodiment, FIG. **1**C shows one hole **12** and one hole **14** formed on the lateral surface of the femur **10**. Hole **12** is formed toward the patellar surface **16** and is positioned substantially in the middle of femoral anterior-posterior diameter A-P. Hole **14**, on the other hand, is positioned distal to hole **12** and sufficiently clear of an osteotomy site to be formed, so as not to interfere therewith. The use of a single hole, rather than a set of holes, may be desirable as there is less stripping and thus less damage to the soft tissue surrounding the femur **10**.

Referring now to FIGS. **2**A–D, a device **20** is shown for exposing the underlying femur **10** of FIGS. **1**A–D from the periosteum (i.e., soft tissue) that overlies the femur prior to producing holes **12** and **14**. In accordance with an embodiment of the present invention, the device **20** includes an elongated body **21** having a first end **22** and a second end **23**. The device also includes a spreading mechanism **24** located at the first end **22** of the body **21**. The spreading mechanism **24**, from the bottom view in FIG. **2**B, is substantially cylindrical in cross-section, and includes four similarly shaped members **25**. Each of the members **25** terminates in a sharp end **26**, so as to allow the mechanism **24** to penetrate the soft tissue without the need for an incision or dissection of the soft tissue. A sheath **27**, disposed about the spreading mechanism **24**, is preferably bivalved so that it may conform to the spreading movement of the mechanism **24**. The separating device **20** further includes actuating handles **28** located at the second end **23** of the body **21**. After the mechanism **24** has penetrated the soft tissue, the handles **28**, as shown in FIG. **2**C, may be moved in the direction L of the arrow toward one another to spread the members **25** apart. Spreading the members **25**, in the manner shown in FIG. **2**D, causes spreading of the overlying soft tissue so as to expose the underlying femur **10**. If necessary, a trocar (not shown) may be introduced into the newly created spread area so that subsequently a larger bivalve sheath may be inserted therein. The larger bivalve sheath in turn will allow progressive dilation of the soft tissue without the need for an incision into the soft tissue. Once the underlying femur **10** is exposed, a conventional surgical drill can be used to produce holes **12** and **14**.

Referring again to FIGS. **1**A–D, while FIG. **1**A illustrates a set of two holes **12** and a set of two holes **14**, a single hole can be provided in lieu of the set of holes **12** substantially between and slightly below the holes **12** in FIG. **1**A. Alternatively, or in addition, a single hole may be utilized in lieu of the set of holes **14**, positioned in the vicinity of such holes. Subcutaneously insertable pins **19** may be inserted into holes **12** and **14**, as shown in FIGS. **1**B and **1**D. Pins **19** may be threaded so that they can be securely positioned within holes **12** and **14**. Likewise, holes **12** and **14** may be complementarity threaded to receive threaded pins **19**.

With the subcutaneously insertable pins **19** in place, looking now at FIGS. **3**A–D, a support structure **30** may be affixed to the femur **10** via each of the pins **19**. The support structure **30** is affixed in such a manner so that subsequent to the formation of two bone pieces during the osteotomy (discussed below), the bone pieces may be maintained in a desired alignment in close proximity to one another. Otherwise, it may be difficult to correct the angular deformity and to secure the bone pieces to one another. The support structure **30** includes a first portion **301** positioned away from the patellar surface **16** and a second portion **302** positioned adjacent the patellar surface **16**. The first portion **301** and second portion **302** are mounted so as to pivot in the plane X—X in FIGS. **3**B and **3**D, but to preclude any substantial movement outside of the plane X—X.

With particular reference now to FIGS. **3**C–D, when the pins are situated on the lateral surface of the femur **10**, the support structure **30**, in accordance with a preferred embodiment of the invention, includes bars **35**. Bars **35** are designed to extend at a substantially right angle from the upper and lower portions of the support structure **30** along the lateral surface of the femur **10**, so that the bars **35** may be coupled to the pins **19**. The support structure **30** shown in FIGS. **3**C–D may also include a releasable locking mechanism (not shown) at the intersection between the bars **35** and the first and second portions **301** and **302** to provide rigidity to the support structure **30**. If additional rigidity is desired, pins **19** may also be placed on the medial surface of the femur **10** opposite the pins **19** on the lateral surface, and the support structure **30** provided with additional bars **35** along the medial side for attachment to those pins **19**.

To accurately control the alignment of bone pieces during the osteotomy, a goniometer **34** is positioned between the first portion **301** and the second portion **302** of support structure **30** to provide an accurate read out of the relative angle between the upper and lower portions. The preferred goniometer **34** is configured in such a manner that precise corrections to tenths of a degree or less may be achieved.

Once the support structure **30** has been affixed to the femur **10**, the osteotomy may be performed in a number of ways. In one embodiment, a central tunnel **36**, as shown in FIGS. **3**B and **3**D, is first drilled through the femur **10** near an approximate vertex of the angle exhibited by the deformity **11** and in a direction that is transverse to the plane in which such angle is situated. The tunnel **36** may be formed through opening **70** in the goniometer **40** by using a cannulated coring reamer (not shown) similar to that disclosed in U.S. patent application Ser. No. 08/475,015, entitled "Coring Reamer", filed Jun. 7, 1995, now U.S. Pat. No. 5,865,834, issued Feb. 2, 1999, in the name of the present inventor, and which is hereby incorporated herein by reference. When using the cannulated coring reamer, a guidewire may be placed in the femur **10** to facilitate the drilling of the tunnel **36**. Additionally, the goniometer **34** may be placed at a sufficient distance from the femur **10** so that when the coring reamer moves through opening **70** and into the femur **10**, the goniometer **34** may act as a guide to allow a substantially straight tunnel **36** to be drilled. A conventional drill (not shown) with a drill bit may also be used to form tunnel **36** through opening **70** in a similar manner. To guard against damage to the soft tissue surrounding the posterior surface of the femur, the coring reamer and the drill may be equipped with a stop (not shown) to limit the distance beyond which they can extend from the posterior surface of the femur. The tunnel **36** created in this embodiment is preferably substantially cylindrical in shape, and is intended for use with a suitable bone anchor (discussed below), such as shown in FIGS. **8**A–8E, FIGS. **15**A–B and FIGS. **16**A–C.

Referring now to FIGS. **14**A–D, to facilitate drilling of a substantially cylindrical tunnel **36**, a rigid cylindrical guide **145**, shown in FIG. **14**A may be provided. Guide **145**, in one embodiment, is provided with an outer diameter **1451** that is substantially similar to that of opening **70** in goniometer **34**, and an inner diameter **1452** that is substantially similar to the diameter of the coring reamer or drill bit. If there arises a need to increase or decrease the diameter of the tunnel **36**, a set of cylindrical guides **145** may be provided, whereby each guide would have the same outer diameter **1451**, but a different inner diameter **1452** to match the diameter of the tunnel **36** to be created.

In a related embodiment of the present invention, tunnel **36** may be modified, as shown in FIGS. **13**A–B to include a pair of parallel contiguous passageways **130** on opposite sides of the tunnel to accommodate another style of bone anchor described below, such as illustrated in FIGS. **15**A–15B and **16**A–16C. To form passageways **130**, a second reamer **131** having a diameter substantially smaller than the diameter of the cannulated coring reamer is used. The second reamer **131**, like the coring reamer, may be cannulated for use with a guidewire. A first passageway **130** may be formed by placing the second reamer against an edge on one side of tunnel **36** (FIG. **13**B) and pushing the second reamer through the femur **10** along the entire length of the tunnel. In order to place the second reamer against an edge of the tunnel **36**, it should be appreciated that opening **70** in goniometer **34** may need to be modified so that its profile matches that of tunnel **36** shown in FIG. **13**A. The opening **70**, therefore, may be provided with widened areas **132**, shown in FIG. **13**C, to accommodate the second reamer when it is introduced along the sides of tunnel **36**. After one passageway is formed, a second passageway **130** may then be formed along an opposite side of the tunnel **36** by placing the second reamer through the other widened area **132**. The passageways **130** are formed so that each intersects or overlaps with an edge of the tunnel **36**.

The passageways **130** along opposite sides of tunnel **36** may also be formed by using a reamer or drill bit in combination with a rigid cylindrical guide **146**, illustrated in FIG. **14**B. Cylindrical guide **146**, in accordance with a preferred embodiment of the invention, includes an outer diameter **1461** that is substantially similar to that of the opening **70** in the goniometer **34**, and an inner profile **1462** that includes widened areas **1463** on opposite sides of a central opening **1464**. To form passageways **130** using guide **146**, a cylindrical guide **145** with an inner diameter **1452** sufficiently sized to accommodate a bone anchor may initially be used to form a cylindrical tunnel **36**. Thereafter, the cylindrical guide **145** is removed from the opening **70** and replaced with the guide **146**. Guide **146** preferably includes a profile wherein the central opening **1464** is similar in diameter to the cylindrical tunnel **36** just created, and wherein the widened areas **1463** extend radially from the central opening. By way of example, if the goniometer **34** is provided with an opening **70** having a diameter of about 10 millimeters to about 12 millimeters (mm), the cylindrical guide **145** preferably includes an inner diameter **1452** for forming a tunnel that is about 6 mm to about 8 mm in diameter, and the guide **146** should have an inner profile **1462** with a central opening **1464** that is about **6**mm and widened areas **1463** that extend radially about 1 mm to about 2 mm on each side of the central opening **1464**. Once the guide **146** is in place, passageways **130** may be formed by drilling through the widened areas **1463**. In an embodiment of the invention, the passageways **130** are formed so that they aligned longitudinally along a central axis C of the femur **10**, such as that shown in FIGS. **13**A and **15**B. To ensure that the passageways **130** are directly opposite one another, guide **146** must be prevented from rotating from its original position after the formation of one passageway **130**. To this end, the guide **146** may be configured to include at least one protrusion **1465** on its outer diameter **1461**, and the goniometer **34** may be configured to include at least one slot **75**, as shown in FIGS. **3**A and **3**D, abutting the opening **70** to receive the protrusion **1465**. Of course, the passageways **130** may be formed so that they are through to the axis C. The slot **75**, in this embodiment, would then be moved to a position shown in FIG. **4**C to accommodate the protrusion **1465**.

Substantially straight passageways **130** may also be formed along opposite sides of tunnel **36** by employing a guide **140**, shown in FIGS. **14**C and **14**D. The guide **140** includes a distal portion **142** to be inserted into tunnel **36**. The distal portion **142** preferably has a width substantially similar to the diameter of tunnel **36**. In this manner, guide **140** can snugly fit within tunnel **36**. The guide **140** further includes an optional sleeve **144** axially attached to the distal portion **142**. The optional sleeve **144** is provided with at least two (2) opposing channels **141**, so as to guide a reamer or drill bit alongside the tunnel **36**. If desired, additional opposing channels may be provided circumferentially about the sleeve **144**, so as to decrease the amount of rotational alignment needed for drilling the passageways. Extending posteriorly from the sleeve **144** is an elongated proximal portion **148**, which terminates in a stop **149**. The stop **149** may include holes **147** corresponding in number and in alignment with channels **141**. The proximal portion **148** and stop **149** provide a surgeon with a place to hold and maneuver the guide **140** into the tunnel **36**. If desired, the elongated proximal portion **148** may be removably attachable to the sleeve **144**. Alternatively, the elongated proximal portion **148** may be made integral with sleeve **144**. Once the guide **140** is in place, a reamer or drill bit may be introduced through a hole **147** in the stop **149**, through a channel **146** in sleeve **144**, and along the proximal portion **148** to drill a substantially straight passageway **130**. The optional sleeve **144** with channels **146** facilitate alignment of the drill parallel with that of bone tunnel **36**. Guide **140** may also include a protrusion, similar to protrusion **1465** in guide **146**, for mating with a slot **75** in the goniometer **34** to insure that the passageways **130** are substantially opposite to one another when being drilled.

Subsequent to the formation of the tunnel **36**, a saw guide **40** may be positioned against a lateral surface of the femur **10** and attached to the support structure **30** (FIGS. **4**A–**4**D). The attachment of the saw guide **40** to the support structure **30** may be accomplished using a clamping mechanism **45** or other means known in the art. Once secured, the saw guide **40** permits a fast and accurate cut to be made across the width of the femur **10**. The saw guide **40**, shown in FIG. **5**, includes opposing concave surfaces **42** and **43**. The concave surfaces are designed so that surface **42** may engage the femur **10** (FIGS. **6**A and **6**C), while surface **43** may guide a cutting blade along a path defined by its concave surface. A slot **44** extends from concave surface **43** to concave surface **42** and is positioned diagonally across the guide **40**. As illustrated in FIG. **4**B, when the saw guide **40** is situated against the lateral surface of the femur **10** adjacent the angular deformity, the slot **44** extends from a proximal portion **46** of the femur to a distal portion **48** and lies diagonally from the anterior surface A to posterior surface P of the femur **10**. In this manner, a predictable, and relatively ellipsoidal arc, similar to surface **43**, can be produced on the medial surface of the femur **10** when a cut is made obliquely along the lateral surface. The saw guide **40** is intended for use with a horizontally situated oscillating blade **60** (FIG. **6**B). Blade **60** is preferably designed with a rounded portion. The rounded portion on blade **60** allows the femur **10** to be cut, as shown in FIG. **6**C, without the need to strip the periosteum (i.e., soft tissue) from all sides of the femur **10** (FIG. **6**A). The blade **60** is also provided with a stop **62**, which conforms to concave surface **43** of the saw guide **40**, to accurately control the distance the blade **60** extends once it has penetrated through the femur **10**. The ability to control the extension distance prevents tissue on the other side of the femur from being damaged by the blade **60**. The stop **62**, when used in combination with the blade **60**, allows for controllable extension of the blade **60** to a distance of a millimeter or less from the opposite side of the femur **10**. In one embodiment, the blade **60** is detachable and adjustable, for example, by means of a set screw, so that the depth of the cut may be further controlled and precisely varied. The ability to precisely control the cutting depth obviates the possibility of injury to medial structures, even though the periosteum (i.e., soft tissue) is not stripped. If desirable, prior to cutting the femur **10**, a depth gauge may be used as a tap so that holes may subsequently be drilled through the femur **10** sequentially from the proximal anterior position to the distal posterior position along the slot **44** of the saw guide **40**. This procedure will allow for a very precise measurement of the ellipsoidal arc.

Referring now to FIGS. **7**A and **7**B, after the tunnel **36** has been formed, an oblique cut may be made through the slot **44** of the saw guide **40**, shown in FIG. **7**B. The oblique cut is preferably made on a surface of the femur **10** which is parallel to the tunnel **36**. In the present illustration, the cut is made on the lateral surface of the femur **10**. The oblique cut is initially formed partially across the femur **10**, from the posterior surface P toward the anterior surface A. In a preferred embodiment, the cut extends from approximately ⅔ to approximately ¾ of the way across the width of the femur **10**.

Once the initial partial cut has been made, a bone anchor assembly for maintaining the bone pieces in approximation may be placed through the tunnel **36** and loosely secured therein. In one embodiment of the present invention, when a tunnel similar to cylindrical tunnel **36** (FIGS. **3**B and **3**D) is formed in the femur **10**, a bone anchor assembly **72**, as shown in FIGS. **8**A and **8**B, is employed. The bone anchor **72** includes an elongated body **73** for placement through the cylindrical tunnel **36**. The bone anchor **72** further includes a pivoting member **74** situated, at a first end **75** of the body **73** and a threaded portion **76** located at the second end **77** of the body **73**. In its non-deployed position in FIGS. **8**A and **8**B, the pivoting member **74** extends from the first end **75** and is axially aligned to the body **73**. The pivoting member **74**, after being introduced through opening **70** in goniometer **34** and into the tunnel **36**, is capable of being deployed into a position transverse to the body **73** (FIGS. **8**C–E) to act as an anchor against the posterior surface P of the femur **10**. Once the bone anchor **72** is deployed, the threaded member **76** on the body **73** preferably remains extended from the anterior surface A of the femur **10**. In this manner, a complementarity threaded member **78**, for example, a washer, may engage the threaded portion **76** to form a locking mechanism to secure the bone anchor against the bone pieces. Of course other locking mechanisms may be provided so long as they remain capable of securing the bone anchor within the tunnel while maintaining the bone pieces in close approximation. Prior to placing the bone anchor **72** through the tunnel, a rigid sleeve **79** may be provided extending along the length of the tunnel **36**. The sleeve **79**, in one embodiment, includes a substantially smooth interior surface, so that it may act as a lining along which the bone anchor **72** can easily slide through the tunnel **36** without interference from loose tissue which may be present in the tunnel. In addition, the sleeve **79** assures a close and precise fit within the tunnel **36** so that translation of the bone pieces, often associated with other osteotomy procedures, may be avoided. The sleeve **79** may also be used to provide rigidity to the tunnel and a limit to the compression experienced by the bone when the anchor assembly is securely tightened in place.

In another embodiment of the invention, looking now at FIGS **15**A–B, when a tunnel is formed with opposing passageways **130**, a bone anchor **152** is employed. The bone anchor **152**, in a preferred-embodiment, includes an elongated body **153** for placement through the tunnel **36**. The bone anchor **152** further includes a cross member **154** situated at a first end **155** of the body **153**, and a threaded portion **156** at a second end **157** of the body **153**. This design is similar to that of FIGS. **8**A and **8**B, except that the cross member **154** is configured in fixed relation to the body **153**, whereas in FIGS. **8**A–B, the corresponding member **74** is pivoted. The cross member **154** is transverse to the body **153** so as to act as an anchor against the posterior surface P of the femur **10**. This embodiment of a bone anchor is used in connection with the tunnel configuration discussed above in connection with FIGS. **13**A–C and **14**A–D, and is inserted as illustrated in FIG. **15**B. Prior to placing the bone anchor through the tunnel **36**, shown in FIG. **15**B, a rigid sleeve (not shown) having a cross-sectional profile similar to that of tunnel **36** is placed within the tunnel. This rigid sleeve, similar to rigid sleeve **79**, acts as a lining along which the bone anchor **152** can easily slide through the tunnel **36** without interference from loose tissue within the tunnel. The sleeve may also act to provide rigidity to the tunnel and to limit the compression experienced by the bone when the bone anchor **152** is securely tightened in place. To place the bone anchor **152** through the tunnel **36**, the distal end **155** of the bone anchor is initially positioned so that the cross member **154** spans from one passageway **130** to the opposing passageway **130**. Thereafter, the cross member **154** may be pushed through the tunnel, along the rigid sleeve, toward the posterior surface P of the femur **10**, as shown in FIG. **8**E and **15**B. Once the cross member **154** extends from the tunnel **36** and passageways **130**, the bone anchor **152** may be rotated in either a clockwise or counterclockwise direction so that the cross member **154** becomes offset from the opposing passageways **130**. In one embodiment, the cross member **154** may be positioned at approximately ninety degrees to the passageways **130**, as illustrated in FIG. **15**B. The cross member **154** is then pulled against the posterior surface P of the femur **10**. To secure the cross member **154** in place, the threaded portion **156** of the bone anchor **152** preferably remains extended from the anterior surface of the femur **10** so that a mating internally threaded member **158** may engage the threaded portion **156** to form a locking mechanism through the tunnel **36** to secure the bone anchor **152** against the bone pieces. Spikes or protrusions **159** may be provided on cross member **154** so as to dig into the posterior surface P of the femur **10**. In this manner, the cross member **154** may securely act as an anchor against the posterior surface P of the femur **10**.

In a further embodiment of the invention, looking now at FIGS. **16**A–B, bone anchor **162** is modified from that shown in FIG. **15**, so that its elongated body **163** does not extend beyond the tunnel **36**. To secure such a modified bone anchor within tunnel **36**, bone anchor **162**, in an embodiment, is designed so that the elongated body **163** is threaded to receive a complementary threaded member **168**. Threaded member **168**, as shown in FIG. **16**B, is capable of extending into the tunnel **36** and over the body **163**. The threaded member **168**, as shown in FIG. **16**B, is preferably provided with a flared end **169** to engage the anterior surface A of the femur **10**. In addition, the threaded member **168** preferably includes a diameter which approaches that of the tunnel **36**. In this manner, the threaded member **168** allows the bone anchor **162** to securely engage against the bone pieces. The threaded member **168** also preferably includes a recess **167** for receiving a driver **170**, such as an alien wrench, designed to rotate the threaded member **168** onto the elongated body **163**. Recess **167** may be of any shape for sufficiently receiving a complementary-shaped driver **170**. In a preferred embodiment of the invention, recess **167**, as shown in FIG. **16**C, and driver **170** are hexagonal in shape. A sleeve **1601** may also be provided extending along the entire length of the tunnel to provide rigidity to the tunnel **36**.

Referring now to FIG. **17**, driver **170** includes retractable teeth **172** at its distal end for engaging recess **167** of member **168**. The teeth allow the member **168** to be maintained on the driver **170** when the member is being maneuvered into the tunnel **36** and rotated onto the elongated body **163**. Once the member **168** is securely tightened about elongated body

163, the teeth 172 may be retracted, for example, by a switch (not shown) on the driver, and the driver 170 removed from the tunnel 36.

The bone anchor, in the illustrated embodiments, may be cannulated to receive a guidewire so as to facilitate the placement of the bone anchor through the tunnel 36. The driver for placing the threaded member onto the elongated body of each bone anchor may also be cannulated. In addition, because the bone anchor must come in contact with biological tissue and must be sufficiently strong, so as to maintain the bone pieces in approximation, it is preferable that the bone anchor be made from a biocompatible material, for instance, stainless steel or plastic. The bone anchor may also made from a bioabsorbable material, for instance polylactic acid (PLA).

The angle of the correction on the femur 10 may next be determined. Looking now at FIGS. 12A–D, in accordance with one embodiment of the present invention, intra-articular pressure between the femur 10 and the tibia may next be measured by using a pressure transducer 120. In general, intra-articular pressure between the femur and the tibia tends to vary from individual to individual and is often dependent on the height, weight and age of the individual. To this end, the employment of a pressure transducer allows for variations in individual characteristics to be taken into account, so that, for each particular individual, a more precise cut angle can be made on the femur 10. Otherwise, the cut may be inappropriate, and may result in a bone alignment that is insufficient to reduce the intra-articular pressure between the femur and the tibia. According to an embodiment of the invention, the angle of the cut determined from intra-articular pressure measurements preferably allows pressure applied by the femur on its lateral femoral condyle and medial femoral condyle to substantially approach a desired ratio within a physiologic tolerance, once the correction has been made.

The pressure transducer 120, in a preferred embodiment of the invention, is a TekScan pressure transducer, manufactured by TekScan Inc. of Boston, Mass. Pressure transducer 120 includes a sensing tip 1201 and a body 1202 along which measurement information may be transmitted to a reading display (not shown). Looking now at FIGS. 12C and 12D, to measure the contact pressure within the intra-articular space of, for example, a right knee 122 of an individual, in one embodiment of the invention, a cannula 123 is first introduced through a lateral portal 124, such that its proximal end 1230 remains on the exterior of the knee 122. The cannula 123 is preferably hollow to receive a trocar 125. Once the cannula 123 is in place, the pressure transducer 120 may be introduced into the knee 122 by first maneuvering its sensing tip 1201 through the proximal end 1230 of the cannula 123, then pushing the body 1202 medially along the cannula using the trocar 125. A grasper 126 is next introduced through a medial portal 127 to pull the pressure transducer 126 from the cannula 123 into the knee. The sensing tip 1201 of pressure transducer 120, looking again at FIG. 12A, may subsequently be positioned about the lateral aspect of the knee, for example, under the lateral femoral condyle 128. Once in position, the lateral condyle 128 is made to press down onto the sensing tip 1201, in order to measure the contact pressure thereat. The sensing tip 1201 is then maneuvered to the medial aspect of the knee, for example, under the medial femoral condyle 129, and the contact pressure again measured. By measuring the contact pressure along at least two points within the intra-articular space, for example, the lateral and medial condyles, a cut may subsequently be made across the femur 10, such that after realignment of the bone pieces, the intra-articular pressure about the lateral and medial aspects of the knee joint substantially approaches a desirable ratio within a physiologic tolerance.

Although the present invention contemplates the use of the pressure transducer in order to determine the angle of correction, it should be appreciated that other methods may also be employed. Examples include but are not limited to, radiographic means, visual means, MRI, laser, and bone scans. These and other similar visualization methods are adequate, so long as they permit the actual amount of correction in the deformed bone to approach a physiologic tolerance.

Once the contact pressure has been determined, saw blade 60 may be inserted into the slot 44 of guide 40, and into the partial oblique cut on the femur 10 at a position distal to the loosely secured bone anchor, for instance, bone anchor 162. The partial oblique cut is then completed across the femur 10 to form two bone pieces. It should be appreciated that each of the resulting bone pieces includes a portion of the tunnel 36, and is held in position relative one another by the bone anchor and the support structure 30. Looking now at FIG. 9A, the bone pieces may be pivoted relative to one another about the bone anchor 162 by the precisely geared goniometer 34 until a desired angle of alignment is reached, for instance, an angle which conforms to the amount of correction previously determined. In this manner, a precise degree of correction and alignment between the bone pieces may subsequently be achieved. Once the correction and alignment have been obtained, the bone anchor 162 is tightly secured against the femur 10 at cut 71 (FIG. 9B), so that the bone pieces may be pulled against one another. The bone anchor 162, when secured through the tunnel 36, acts to pull the bone pieces in a direction transverse to the cut 71 so that the bone pieces may remain in approximation and alignment. Although reference has been made to the bone anchor 162, it should be understood that bone anchors 152 or 72 may also be used.

To ensure that alignment between two bone pieces is maintained and no subsequent translational movement will occur, multiple bone anchors 162 may be secured through the femur 10 along the cut 71 (FIGS. 10A–B and 11A–B). To form the tunnels that will accommodate the additional bone anchors, referring now to FIG. 18, an apparatus 180 is employed. Apparatus 180, in one embodiment of the invention, includes a pair of parallel substantially cylindrical members 182, configured so that either may be positioned within the opening 70 of goniometer 34. The members are coupled to one another by a connector 185. Each member 182 may include a protrusion 184, similar to protrusion 1465 illustrated in FIG. 14B, for engaging slot 75 in goniometer 34 to prevent the apparatus 180 from rotating during formation of the tunnel 36 and/or passageways 130. When one cylindrical member 182 is placed within the opening 70, the other cylindrical member 182 is preferably extended by connector 185 beyond the goniometer 34 for subsequently guiding a coring reamer into the femur 10. The connector 185 may be adjustable in order to vary the distance between members 182 and thus between the tunnels formed. Each cylindrical member 182 is provided with an inner diameter designed to accommodate either cylindrical guide 145 or guide 146, discussed above in connection with FIGS. 14A–B. In an embodiment, the member 182 that is not to be positioned within the opening 70 of the goniometer 34 may be substituted with a ring. The ring is preferably sufficiently rigid and includes an inner diameter that is capable of accommodating the either guide 145 or guide 146. The procedure previously described may thereafter be employed, that is drilling a tunnel through the femur, placing a bone anchor through the tunnel, and securely tighten the bone anchor against the femur.

When securing with additional bone anchors **162**, the support structure **30** and/or the goniometer **34** may be provided with a locking mechanism (not shown) so that the alignment between the bone pieces may be maintained prior to the placement of the additional bone anchors **162** into the femur **10**. In one embodiment of the invention, at least two bone anchors **162** are used. The location and number of the additional bone anchors **162**, to a certain extent, are limited only by the size of the bone. FIG. **11A** illustrates a configuration wherein a total of five bone anchors **162** are positioned in the femur **10**. The use of multiple bone anchors provides added rigidity to the cut and resistance to translational movement between the bone pieces, such that the support structure **30** may subsequently be removed. In addition, as the fixation is sufficiently secured, no external fixators, for instance, transfixion screws, lag screws, and similar devices will be needed.

Although the above described methods are directed to femoral osteotomy, the same methods are applicable to tibial osteotomy. It is contemplated that the sequence of steps outlined above would be followed. However, unlike the femoral osteotomy, the tibial osteotomy is distal to the tibial tubercle and extends from a proximal posterior position on the tibia to a distal anterior position.

In order to achieve such a cut, referring now to FIGS. **19**A–D, the support structure is positioned along the anterior surface of the tibia **190** such that the first portion **301** is distal to the tibia tubercle **192** and the second portion **302** is proximal to the tibial tubercle **192**. The support structure **30** of FIGS. **19**A–D corresponds to the embodiment shown in FIG. **3**C, and is affixed to subcutaneously insertable pins **19** on the medial surface of the tibia **190** byway of bars **35**. In an alternate embodiment, the support structure **30** may correspond to the embodiment shown in FIG. **3**A, and may be affixed to multiple subcutaneously insertable pins **19** on the anterior surface of the tibia **190**, as shown in FIG. **19**B. Furthermore, whereas in a femoral osteotomy the guide **40** is placed on a lateral surface of the femur **10**, in tibial osteotomy the guide **40** is placed of the anterior surface of the tibia **190**. The position of the guide **40**, however, is distal to the opening **70** in goniometer **34** and provides a cut that traces the geometry of the posterior surface of the tibia. More particularly, as seen from the medial surface of the tibia **190**, the cut is similar to cut **194** in FIG. **19**C. Once the cut is made, the procedure described above in connection with the femoral osteotomy may be employed to secure a bone anchor **162** across the cut **194**. Multiple anchoring pins **162** (FIG. **19**D) may also be employed to ensure a secure alignment of the tibial bone pieces. In general, a tibial osteotomy may be easier to perform than a femoral osteotomy in terms of fixation, but slightly more difficult in terms of cutting.

While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modification. This application is intended to cover any variations, uses, or adaptations of the invention and including such departures from the present disclosures as come within known or customary practice in the art to which the invention pertains. For example, the above procedure may also be used to easily fix a horizontal, spiral oblique fracture of the humerus, as well as fractures in other bones of the body.

What is claimed is:

1. A device for maintaining in approximation bone pieces produced from an osteotomy procedure, the device comprising:

an elongated body for extending into a tunnel between the bone pieces, the body having a distal and a proximal end;

an anchoring member rotatably positioned at the end transverse to the body to engage one bone piece;

a locking mechanism at the proximal end of the body to engage the other bone piece, such that the bone pieces may be pulled against one another between the rigid member and the locking mechanism wherein the locking mechanism comprises a threaded portion along the proximal end of the body and a complementarity threaded member for engaging the threaded portion; and

a rigid sleeve having a substantially smooth interior surface extending along the length of the bone tunnel so as to permit the elongated body to slide through the tunnel.

2. A device as set forth in claim **1**, wherein the elongated body has a length sufficiently long so as to allow the device to extend through both bone pieces.

3. A device as set forth in claim **2**, wherein the locking mechanism remains substantially outside of the bone tunnel.

4. A device as set forth in claim **1**, wherein the elongated body is situated entirely within the bone tunnel.

5. A device as set forth in claim **4**, wherein the locking mechanism extends into the bone tunnel.

6. A device as set forth in claim **1**, wherein the rotatably positioned anchoring member is axially aligned to the elongated body when said anchoring member is in a non-deployed mode.

7. A device as set forth in claim **1**, wherein the rotatably positioned anchoring member is capable of being deployed after introduction into the bone tunnel, such that said anchoring member is transverse to the elongated body when in a deployed mode.

8. A device for maintaining in approximation bone pieces produced from an osteotomy procedure, the device comprising:

an elongated body for extending into a tunnel between the bone pieces, the body having a distal end and a proximal end;

an anchoring member positioned at the distal end of the body for engaging against one bone piece; and

a locking mechanism at the proximal end of the body to engage the other bone piece, such that the bone pieces may be pulled against one another between the anchoring member and the locking mechanism;

a locking mechanism at the proximal end of the body to engage the other bone piece, such that the bone pieces may be pulled against one another between the rigid member and the locking mechanism wherein the locking mechanism comprises a threaded portion along the proximal end of the elongated body and a complementarily threaded member for engaging the threaded portion; and a rigid sleeve having a substantially smooth interior surface extending along the length of the bone tunnel so as to permit the elongated body to slide through the tunnel.

9. A device as set forth in claim **8**, wherein the device is made from a biocompatible material sufficiently strong to pull the bone pieces against one another.

10. A device as set forth in claim **8**, wherein the anchoring member is pivotally-connected to the elongated body.

11. A device as set forth in claim **8**, wherein the elongated body has a length sufficiently long so as to allow the device to extend through both bone pieces.

12. A device as set forth in claim **11**, wherein the locking mechanism remains substantially outside of the bone tunnel.

13. A device as set forth in claim **8**, wherein the elongated body is situated entirely within the bone tunnel.

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