



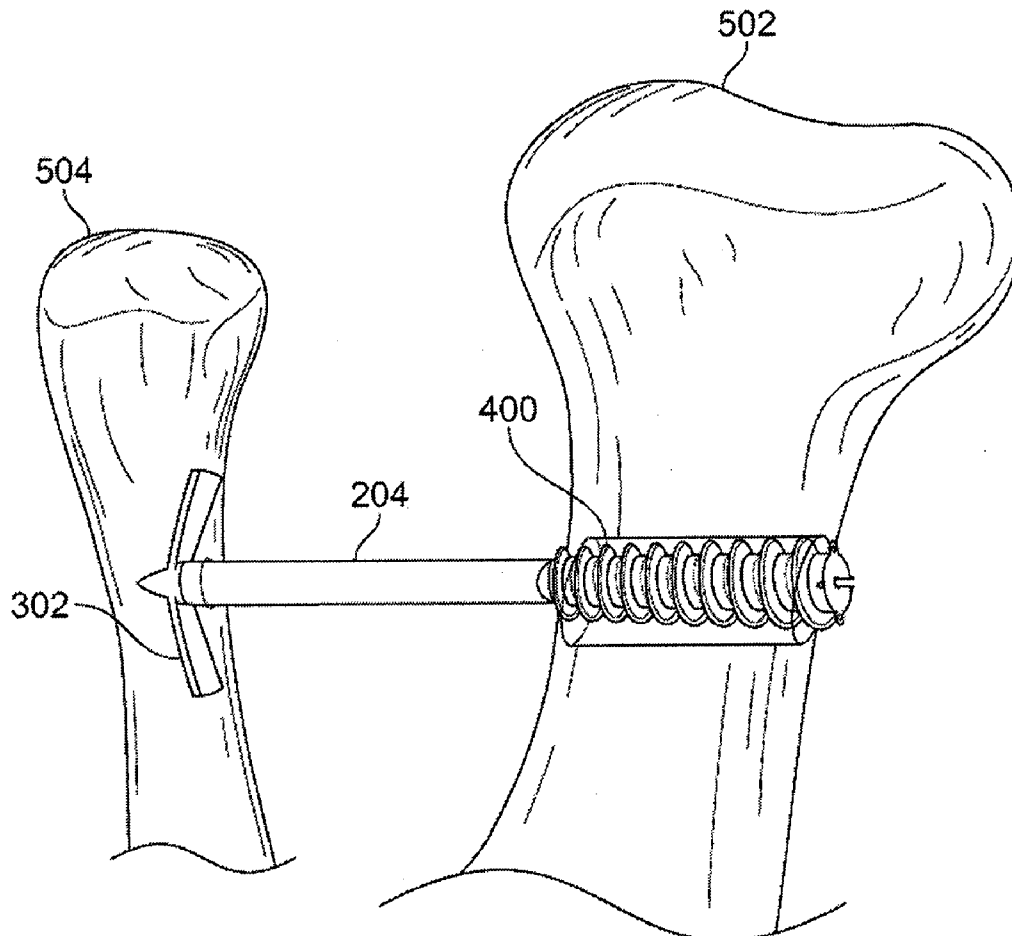
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(19) **United States**(12) **Patent Application Publication**  
**Kartalian et al.**(10) **Pub. No.: US 2009/0036893 A1**(43) **Pub. Date: Feb. 5, 2009**(54) **FIXATION AND ALIGNMENT DEVICE AND  
METHOD USED IN ORTHOPAEDIC  
SURGERY****Related U.S. Application Data**(60) Provisional application No. 60/953,657, filed on Aug.  
2, 2007.**Publication Classification**(51) **Int. Cl.****A61B 17/56** (2006.01)**A61F 5/00** (2006.01)**A61B 17/58** (2006.01)**A61B 17/04** (2006.01)(52) **U.S. Cl.** ..... **606/60; 606/86 R; 606/96; 606/301**(57) **ABSTRACT**

Surgical anchoring systems and methods are employed for the correction of bone deformities. The anchoring system and its associated instrument may be suitable for surgical repair of hallux valgus, tarsometatarsal sprains, ankle ligament reconstruction, spring ligament repair, knee ligament reinforcement, acromioclavicular sprains, coracoclavicular sprains, elbow ligament repair, wrist and hand ligamentous stabilization or similar conditions. The anchoring system may include a fixation system for anchoring two or more sections of bone or other body parts and a system for aligning of one section relative to another section.

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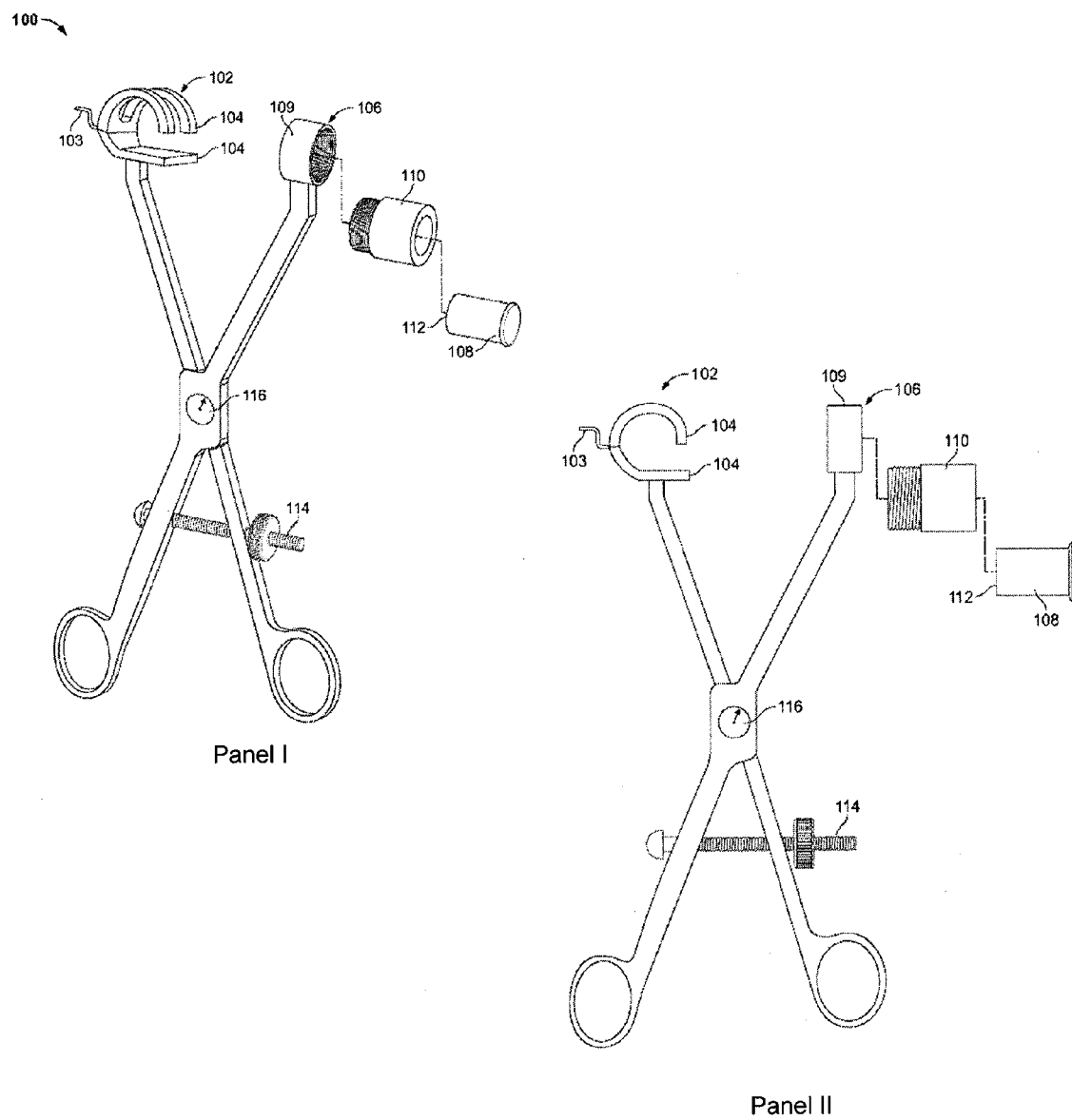
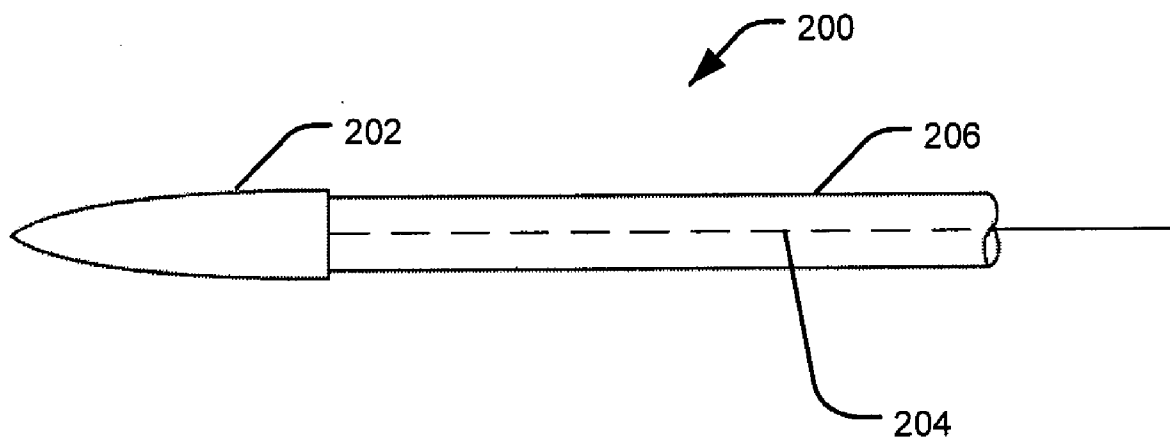


FIGURE 1

**FIGURE 2**

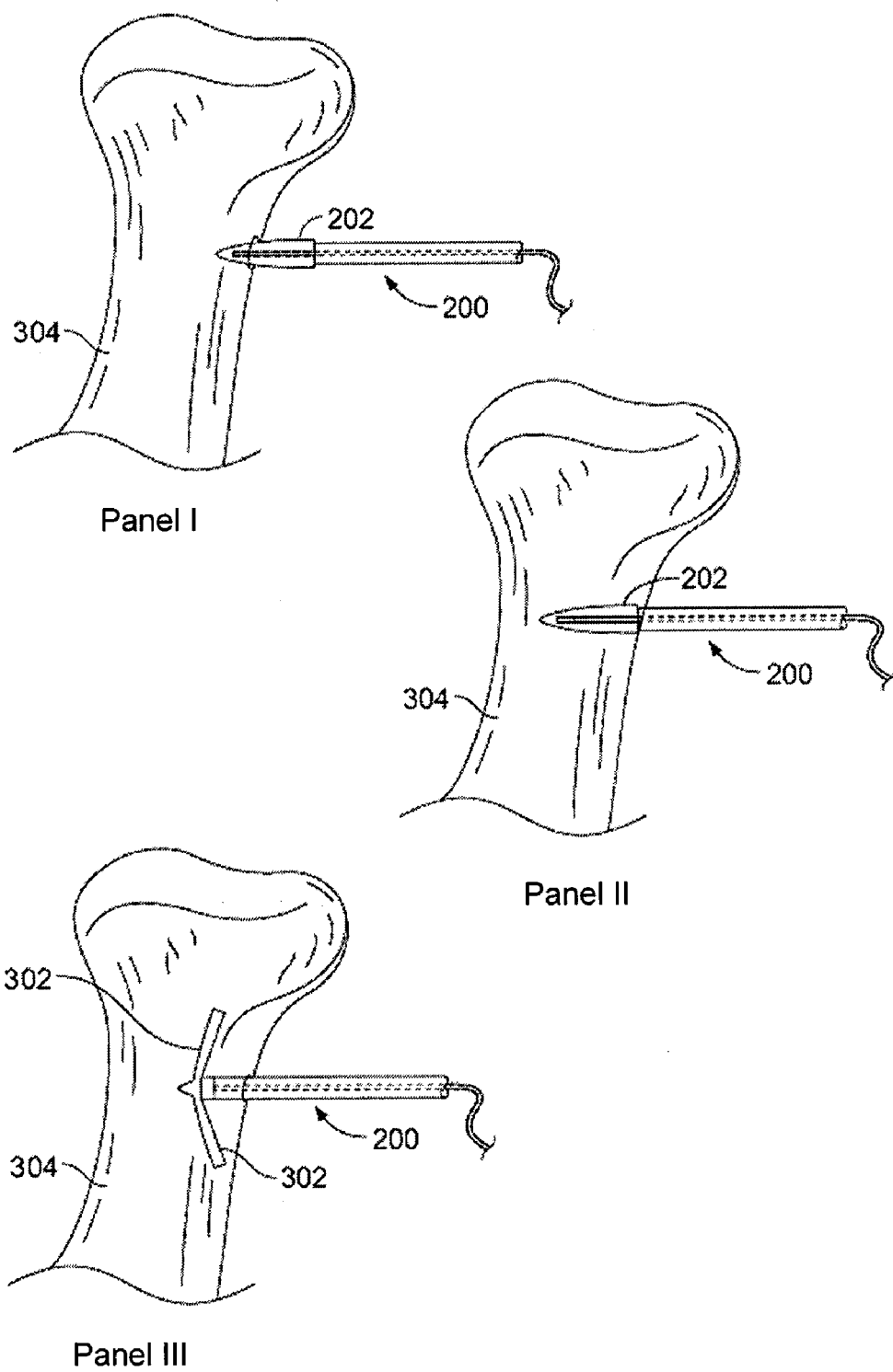


FIGURE 3

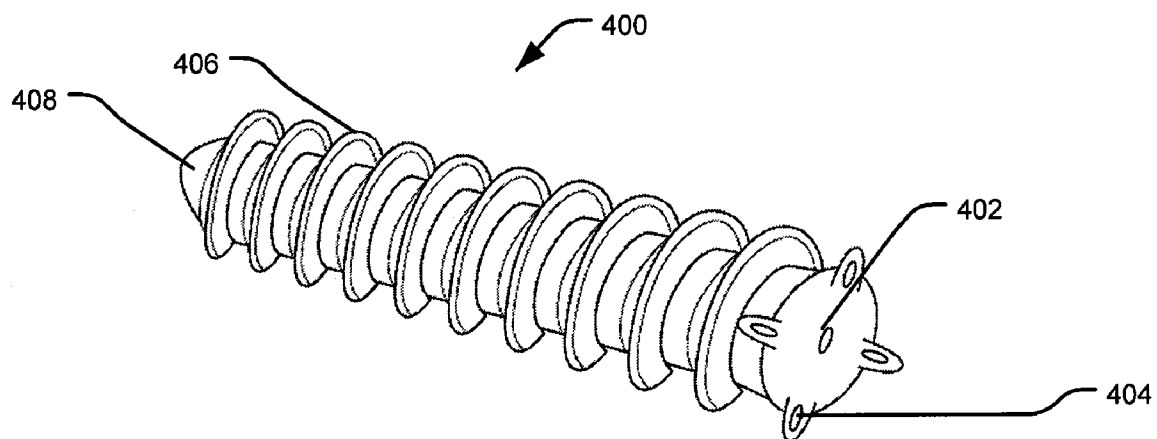


FIGURE 4

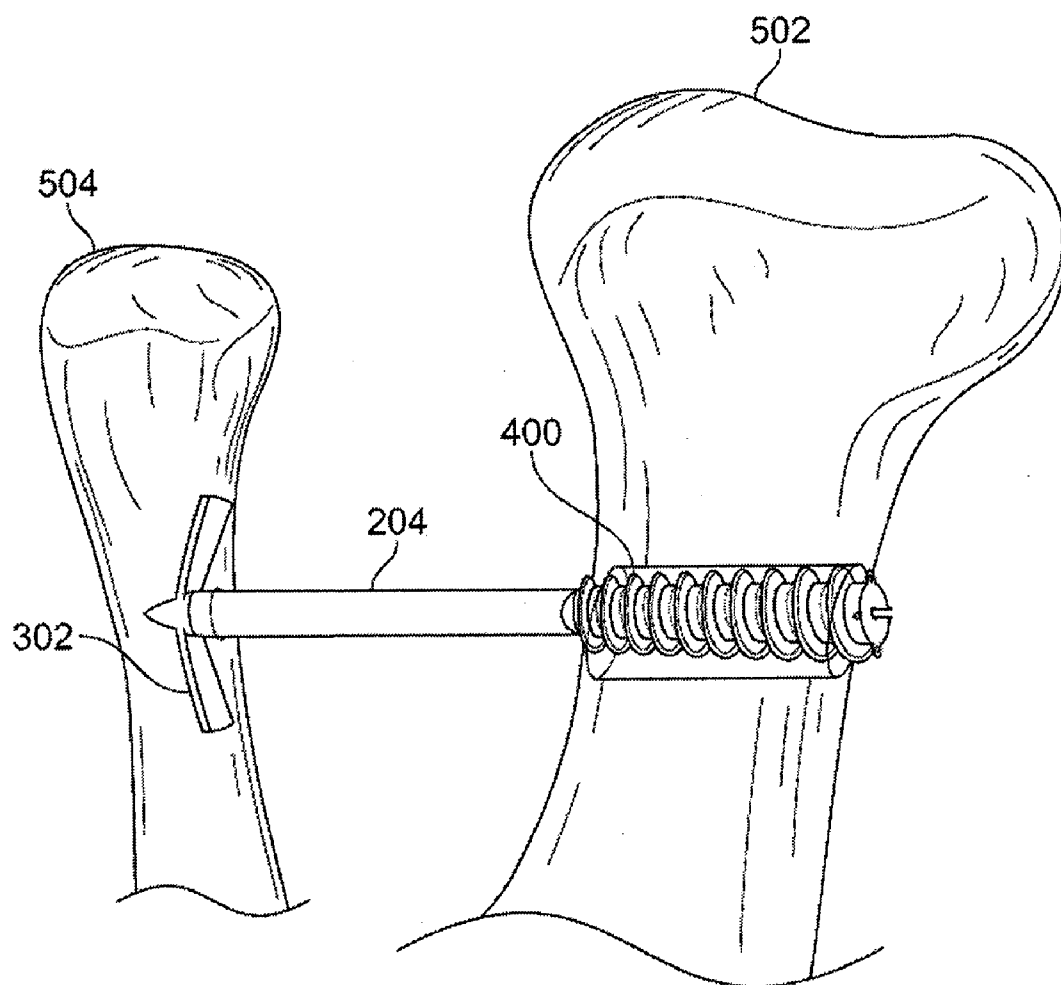


FIGURE 5

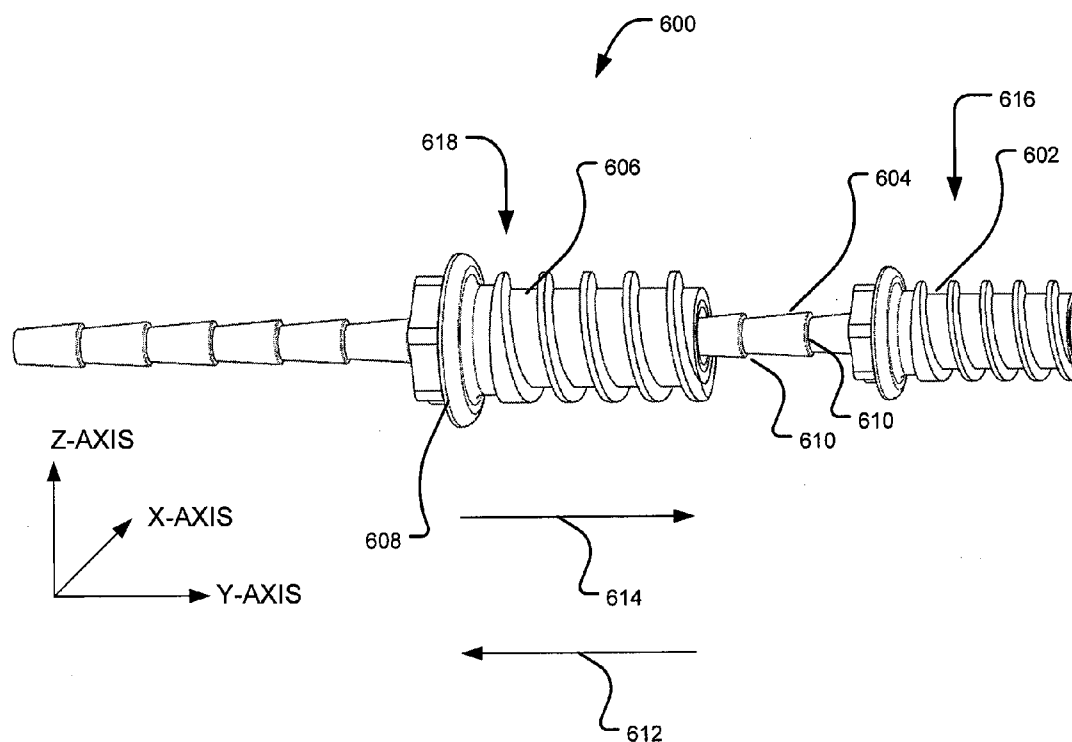


FIGURE 6

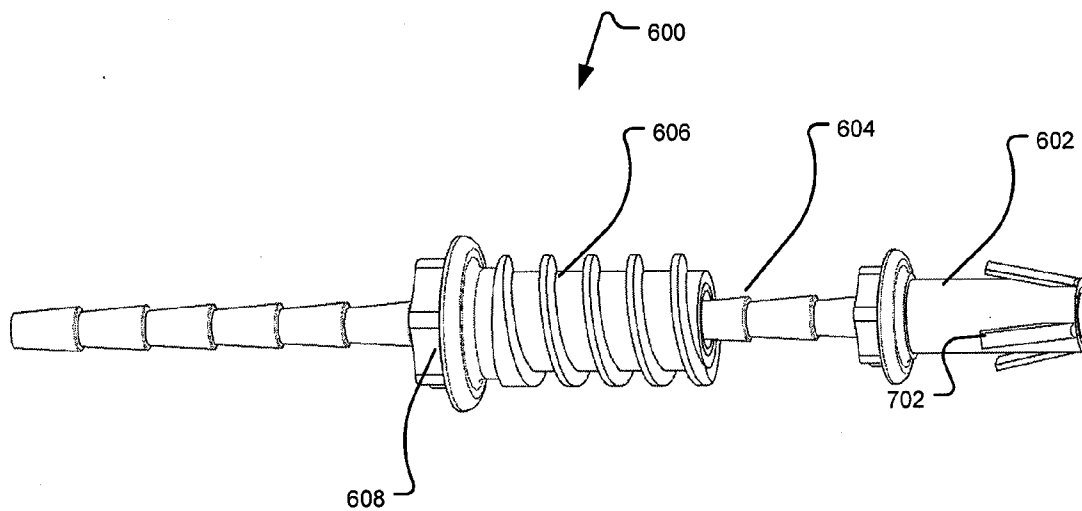
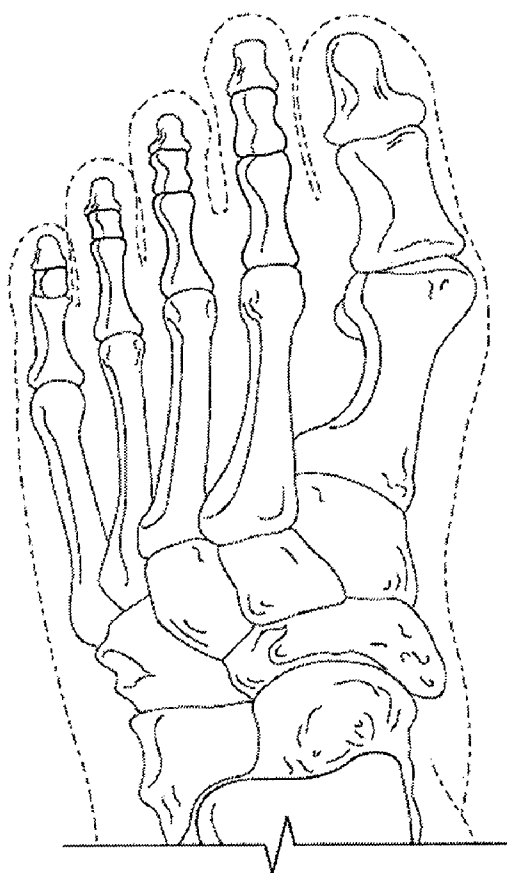
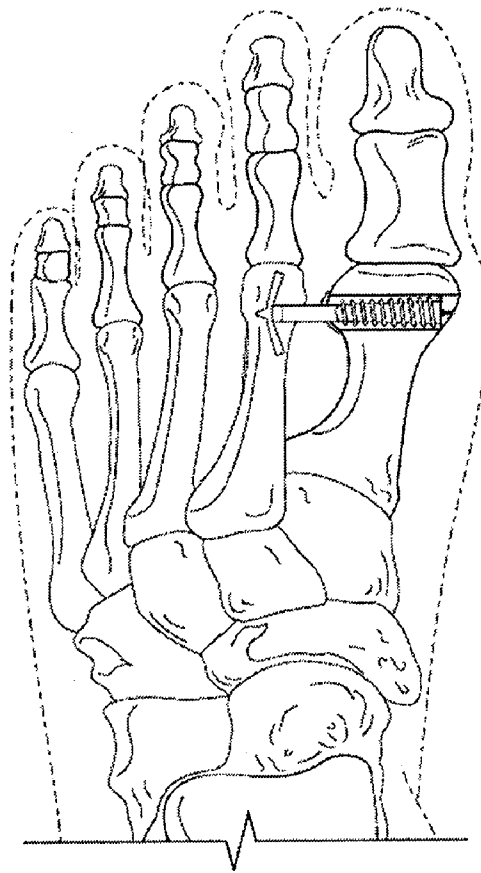


FIGURE 7



Panel I



Panel II

FIGURE 8

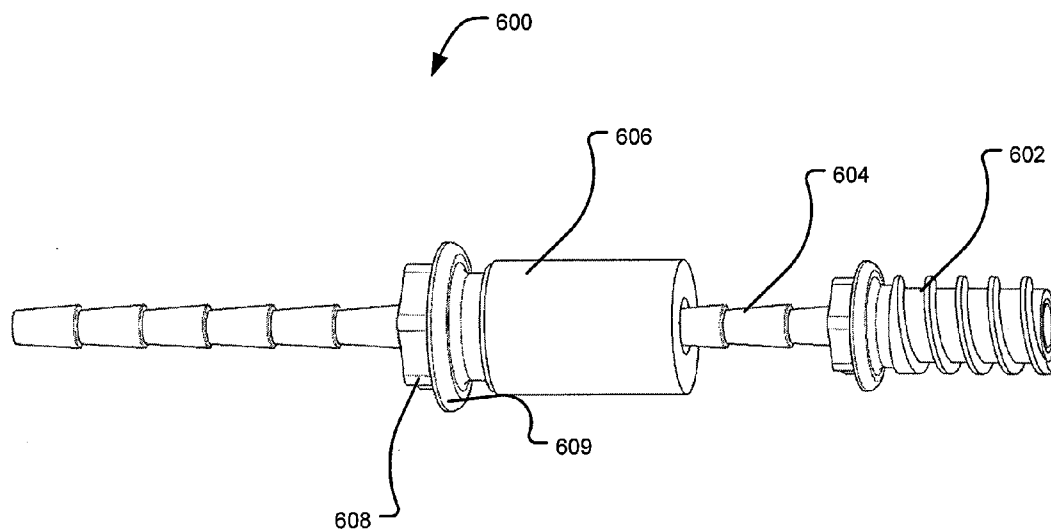


FIGURE 9

# FIXATION AND ALIGNMENT DEVICE AND METHOD USED IN ORTHOPAEDIC SURGERY

## CROSS-REFERENCES TO RELATED APPLICATIONS

**[0001]** This application is related to and claims benefit under 35 U.S.C. §119(e) to provisional application Ser. No. 60/953,657, filed on Aug. 2, 2007, the disclosure of which is herein incorporated by reference in its entirety herein.

## BACKGROUND OF THE INVENTION

### **[0002]** 1. Field of the Invention

**[0003]** The invention relates generally to an anchoring system and an associated surgical instrument, which may have multiple uses in orthopaedic surgery such as joint stabilization, bunion correction, ligament reconstruction and similar procedures. More particularly, the anchoring system of the invention may include a system for anchoring two or more body parts together and a system for aligning movement of one anchored body parts relative to another.

### **[0004]** 2. Related Art

**[0005]** Various devices and methods have been used in the prior art for bone realignment, fixation of the bones or bone portions, and ligament reconstruction repair in order to correct for various orthopaedic conditions, such as hallux valgus, tarsometatarsal sprains, ankle ligament reconstruction, and spring ligament repair.

**[0006]** Hallux valgus is a common foot disorder of several etiologies, which can lead to significant foot pain and deformity. Hallux valgus may be defined as a static subluxation of the first metatarsophalangeal (MTP) joint with lateral deviation of the great toe and medial deviation of the first metatarsal. Moreover, the condition may be accompanied by rotational pronation of the great toe in severe cases. The skeletal deformity results in increased sensitivity to any pressure created by contact. The condition may be self-perpetuating because the pressure that the bunion creates against the patient's footwear causes the metatarsal bone at the point of contact to thicken. A direct result of the thickening of the head of the metatarsal increases the size of the resulting bunion, which increases the severity of the condition and patient discomfort associated with the condition.

**[0007]** One of the most common causes of hallux valgus is prolonged deformation of the foot caused by wearing shoes that do not fit properly, such as high-heeled shoes and narrowly pointed toe shoes. Here, the big toe is forced into an abnormal orientation for a long period of time, which eventually stretches out the joint capsule and promotes abnormal migration of the muscles. There are other factors that may contribute to hallux valgus, which include rounded unstable MTP joint surfaces and oblique joint surfaces located at the proximal first metatarsal joint.

**[0008]** The initial symptom of hallux valgus may be pain at the joint prominence when wearing certain shoes. The capsule may be tender at any stage. Later symptoms may include a painful warm, red, cystic, movable fluctuant swelling located medially and swelling and mild inflammation affecting the entire joint which is more circumferential.

**[0009]** The diagnosis of a hallux valgus condition may include accurately defining a number of critical measurements through the use of x-rays taken of the foot's bone structure. First, the intermetatarsal angle (IM angle) may be

determined. The IM angle may be defined by the relationship of the first metatarsal shaft compared to the line of the second metatarsal shaft. Under normal conditions, the IM angle may be in the range of about 6 degrees to about 9 degrees. Secondly, the hallux valgus angle (HV angle), which may be defined by the angle of the line created at the MTP joint between the first metatarsal bone shaft and the first phalangeal bone shaft may be determined. Under normal conditions, the HV angle may in the range of about 9 degrees to 10 degrees. The HV angle may be considered to be in the abnormal range if the measurements are greater than about 15 degrees. Finally, the condition of the MTP joint may be evaluated to determine whether there has been a lateral subluxation of the joint. The combined evaluation of these and other factors will determine the course of action to be taken.

**[0010]** There are numerous types of surgical procedures that may be employed to correct a bunion. Currently, the state of the art consists of various osteotomies to realign the first metatarsal (MT) and the first MTP joint. These procedures do not function through the axis of deformity. Rather, they attempt to realign the bone and joint by translating and rotating the MT through a location that is accessible and minimizes complications. However, there are several complications related to altering blood supply of the MT, and to altering the length and position of the MT associated with this surgical procedure. Furthermore, the surgical exposure required, the trauma to and shortening of the bone from sawing, and the prolonged healing time required all lead to less than satisfactory results.

**[0011]** One alternative to using an osteotomy to treat hallux valgus is to perform a corrective arthrodesis of the tarsometatarsal joint. The advantage of this approach is that the deformity is corrected where it is occurring, and allows for a powerful correction of large deformities. The disadvantages, however, to this approach is that a normal joint is being sacrificed, which alters the subsequent biomechanics of the foot. Additionally, the surgical technique has been found to have a high rate of complications including a high rate of not healing properly.

## BRIEF SUMMARY OF THE INVENTION

**[0012]** The invention provides an anchoring system and an associated instrument, and surgical methods to optimize the surgical correction of bone deformities from a biomechanical and biological standpoint that provides numerous advantages over conventional devices and techniques currently used for joint stabilization, bunion correction or ligament reconstruction surgery and similar procedures. The invention may be implemented in a number of ways.

**[0013]** According to one aspect of the invention, a surgical instrument to align bones and/or guide a surgical device may include a body having a first proximal arm and a second distal arm and a cannulated sleeve supported by one of said arms. The sleeve may be configured to guide a surgical device. The alignment device may be supported by the other of the arms. The alignment device may be configured and arranged to hold a bone in proper alignment for the surgical device. The instrument may also include an angle indicator and a locking clamp.

**[0014]** The cannulated sleeve may be removably attached to the one arm. Moreover, the cannulated sleeve may function as a drill guide and the surgical device may be a drill. The alignment device may include an adjustable dorsal and plantar plate.

**[0015]** According to another aspect of the invention, a surgical method for repair of hallux valgus is provided. The surgical method may include entering the tissues of the foot affected with hallux valgus using at least one incision. The at least one incision may include making a medial incision at the first metatarsal, an incision lateral to the second metatarsal at its distal portion, and a first web space incision. Further, the method may include performing a soft-tissue release to release the abductor tendon, fibular sesamoid attachments and the lateral metatarsalphalangeal (MTP) joint capsule, shaving the exostosis, and stabilizing and reorienting a first metatarsal, which may be accomplished by placing the surgical instrument of the invention on the first and second metatarsal. The first proximal arm of the surgical instrument may be placed on the first metatarsal and the second distal arm of the surgical instrument may be placed on the second metatarsal.

**[0016]** The surgical method may also include creating a tunnel across the first metatarsal, creating a pilot hole in the second metatarsal, embedding an anchor in the pilot hole in the second metatarsal, and inserting an interference screw in the first metatarsal. The anchor may include anchor region and a connector region. Furthermore, the anchor region may be non-absorbable and/or osteogenic and fabricated from a material such as stainless steel, titanium, or other suitable metallic materials. Also, the anchor region may be bioabsorbable and fabricated from a material such as polylactic acid, bone allograft, and hydroxyapatite coral. The connector region of the anchor may be fabricated from a material such as human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable or a nonabsorbable suture, and umbilical tape, for example. Also, the anchor region may be osteogenic and coated with a bone growth factor. The interference screw may include at least one suture receiving portion and that may function to secure a reduction in the hallux valgus (HV) angle of the first toe. The interference screw may be bioabsorbable and may be fabricated from a material such as polylactic acid, bone allograft, and hydroxyapatite coral. The interference screw may be osteogenic and coated with a bone growth factor.

**[0017]** According to another aspect of the invention, a surgical anchor system for use in the repair of an orthopaedic condition is provided. The anchor system may include an anchor having a collapsed position for delivery to a canal of a first bone and an expanded position for securing the anchor within the bone canal, and a connector extending between the anchor and a fixation device configured to be fixedly attached to a second body part. The orthopaedic condition may be hallux valgus, tarsometatarsal sprains, ankle ligament reconstruction, spring ligament repair, knee ligament reinforcement, acromioclavicular sprains, coracoclavicular sprains, elbow ligament repair, and wrist and hand ligamentous stabilization.

**[0018]** The anchor may include two resilient arms made of a biocompatible material. Moreover, the anchor region may be bioabsorbable and may be fabricated from a material such as polylactic acid, bone allograft, and hydroxyapatite coral. The anchor region may also be osteogenic and coated with a bone growth factor. The connector region may be fabricated from a material such as human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine

skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable suture, nonabsorbable suture, and umbilical tape.

**[0019]** The fixation device may be an interference screw. The interference screw may be bioabsorbable and may be fabricated from a material such as polylactic acid, bone allograft, and hydroxyapatite coral. The interference screw may be osteogenic and coated with a bone growth factor. The interference screw may include at least one suture receiving portion that may function to secure a reduction in the HV angle between the first metatarsal and the proximal phalanx. The second body part may be a second bone. The first bone may be a first metatarsal and the second bone may be a second metatarsal.

**[0020]** According to another aspect of the invention, a surgical anchor system for use in the repair of an orthopaedic condition may include a primary anchor adapted to engage a first bone, a secondary anchor adapted to engage a second bone, a connector component extending between said primary and secondary anchors, and at least one of said first anchor and said secondary anchor being connected to said connector component in one of a plurality of predetermined, lockable positions disposed along the length of said connection component.

**[0021]** The connection component may comprise a one-way or a two-way ratcheting mechanism. The ratcheting mechanism may comprise a mating engagement between an interior surface of the primary anchor and/or the secondary anchor and the connection component.

**[0022]** The primary anchor may be fixedly attached to the first bone by at least one of screw threads, barbs, loops, and cuffs. The primary anchor may comprise an expandable material having resilient arms to fix said primary anchor in place in the canal of the first bone.

**[0023]** The secondary anchor may be connected to the connection component via said ratcheting mechanism. The secondary anchor may be fixedly attached to the second bone by at least one of screw threads, barbs, loops, and cuffs. The secondary anchor may have a first portion disposed in a canal of the second bone and a second portion disposed against an outer surface of the second bone. The first bone may be a second metatarsal and the second bone may be the first metatarsal.

**[0024]** The primary anchor and the secondary anchor may be bioabsorbable and may be fabricated from a material such as polylactic acid, bone allograft, and hydroxyapatite coral. The primary anchor and the secondary anchor may be non-bioabsorbable and may be fabricated from a material such as stainless steel and titanium. The primary anchor and the secondary anchor may be osteogenic and may be coated with a bone growth factor.

**[0025]** The connection component may be fabricated from a material such as human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable suture, non-absorbable suture, and umbilical tape. The connection component may be fixedly attached to the primary anchor and/or the secondary anchor in at least one direction. The connection component may be fixedly attached to the primary and/or secondary anchor in two directions. The connection component may be pivotally attached to the primary anchor and/or the secondary anchor.

The connection component functions to secure a reduction between the HV angle of the first metatarsal and a proximal phalanx.

**[0026]** Additional features, advantages, and embodiments of the invention may be set forth or apparent from consideration of the following detailed description, drawings, and claims. Moreover, it is to be understood that both the foregoing summary of the invention and the following detailed description are exemplary and intended to provide further explanation without limiting the scope of the invention as claimed.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0027]** The accompanying drawings, which are included to provide a further understanding of the invention, are incorporated in and constitute a part of this specification; illustrate embodiments of the invention and together with the detailed description serve to explain the principles of the invention. No attempt is made to show structural details of the invention in more detail than may be necessary for a fundamental understanding of the invention and various ways in which it may be practiced.

**[0028]** FIG. 1 is a schematic showing one embodiment of a surgical instrument constructed according to principles of the invention, which instrument may be employed to insert an anchoring system of the invention or similar device. Panel I is a side view of the surgical instrument constructed to principles of the invention and Panel II is a front view of the surgical instrument constructed to principles of the invention.

**[0029]** FIG. 2 is a schematic illustrating one embodiment of an anchoring system constructed according to principles of the invention.

**[0030]** FIG. 3 schematically shows insertion of the anchoring system of the invention into the canal of the target bone. Panel I shows the anchoring system as it passes through the cortex of the bone. Panel II shows insertion of the anchoring system into the canal of the bone. Panel III shows the anchoring system securing itself within bone canal. In Panel III, the arms of the anchoring system are released in opposite directions to secure the system, according to principles of the invention.

**[0031]** FIG. 4 is a schematic showing one embodiment of an interference screw constructed according to principles of the invention.

**[0032]** FIG. 5 is a schematic showing the final configuration of the anchoring system of the invention employed for surgical correction of hallux valgus.

**[0033]** FIG. 6 is a schematic showing one embodiment of the anchoring system of the invention having screw threads as the anchoring mechanism for both the primary and secondary anchors for positioning the anchors relative to each other and a ratcheting mechanism.

**[0034]** FIG. 7 is a schematic showing one embodiment of the anchoring system of the invention having an expandable material as the locking mechanism of the primary anchor.

**[0035]** FIG. 8 is a schematic showing a final configuration of the anchoring system FIG. 7 employed for surgical correction of hallux valgus. Panel I shows hallux valgus of the joint of the first metatarsal. Panel II shows correction of hallux valgus of the first metatarsal after correction using the anchoring system of FIG. 7.

**[0036]** FIG. 9 is a schematic showing one embodiment of the anchoring system of the invention in which the secondary

anchor includes a bushing portion disposed inside a bone canal and a flange disposed against the outside of the bone.

#### DETAILED DESCRIPTION OF THE INVENTION

**[0037]** It is understood that the invention is not limited to the particular methodology, protocols, and reagents, etc., described herein, as these may vary as the skilled artisan will recognize. It is also to be understood that the terminology used herein is used for the purpose of describing particular embodiments only, and is not intended to limit the scope of the invention. It also is to be noted that as used herein and in the appended claims, the singular forms “a,” “an,” and “the” include the plural reference unless the context clearly dictates otherwise. This, for example, a reference to “a capsule” is a reference to one or more capsules and equivalents thereof known to those skilled in the art.

**[0038]** Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art to which the invention pertains. The embodiments of the invention and the various features and advantageous details thereof are explained more fully with reference to the non-limiting embodiments and/or illustrated in the accompanying drawings and detailed in the following description. It should be noted that the features illustrated in the drawings are not necessarily drawn to scale, and features of one embodiment may be employed with other embodiments as the skilled artisan would recognize, even if not explicitly stated herein.

**[0039]** Any numerical values recited herein include all values from the lower value to the upper value in increments of one unit provided that there is a separation of at least two units between any lower value and any higher value. As an example, if it is stated that the concentration of a component or value of a process variable such as, for example, size, angle size, pressure, time and the like, is, for example, from 1 to 90, specifically from 20 to 80, more specifically from 30 to 70, it is intended that values such as 15 to 85, 22 to 68, 43 to 51, 30 to 32 etc., are expressly enumerated in this specification. For values which are less than one, one unit is considered to be 0.0001, 0.001, 0.01 or 0.1 as appropriate. These are only examples of what is specifically intended and all possible combinations of numerical values between the lowest value and the highest value enumerated are to be considered to be expressly stated in this application in a similar manner.

**[0040]** Moreover, provided immediately below is a “Definition” section, where certain terms related to the invention are defined specifically. Particular methods, devices, and materials are described, although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the invention. All references referred to herein are incorporated by reference herein in their entirety.

**[0041]** BMP is bone morphogenetic protein

**[0042]** bFGF is basic fibroblast growth factor

**[0043]** GAMs are gene-activated matrices

**[0044]** IM is the intermetatarsal angle

**[0045]** HV is the hallux valgus angle

**[0046]** MT is metatarsal

**[0047]** MTP joint is metatarsophalangeal joint

**[0048]** PLA is polylactic acid

**[0049]** The term “intermetatarsal angle” or “IM angle,” as used herein generally refers to the angle that may be measured between the line of the first and second metatarsal shafts. In the normal foot, the IM angle is in the range of about 6 degrees

to about 9 degrees. In a patient afflicted with hallux valgus, the IM angle is about 15 degrees.

**[0050]** The term “hallux valgus angle” or “HV angle,” as used herein generally refers to the angle that may be measured between the line of the first metatarsal shaft and the proximal phalanx. In the normal foot, the HV angle is in the range of about 9 degrees to about 10 degrees. In a patient afflicted with hallux valgus, the HV angle is about 30 degrees.

**[0051]** The terms “active agent,” “drug,” “therapeutic agent,” and “pharmacologically active agent” are used interchangeably herein to refer to a chemical material or compound which, when administered to an organism (human or animal) induces a desired pharmacologic effect. Included are derivatives and analogs of those compounds or classes of compounds specifically mentioned that also induce the desired pharmacologic effect. In particular, the therapeutic agent may encompass a single biological or abiological chemical compound, or a combination of biological and abiological compounds that may be required to cause a desirable therapeutic effect.

**[0052]** By the terms “effective amount” or “therapeutically effective amount” of an agent as provided herein are meant a nontoxic but sufficient amount of the agent to provide the desired therapeutic effect. The exact amount required will vary from subject to subject, depending on the age, weight, and general condition of the subject, the severity of the condition being treated, the judgment of the clinician, and the like. Thus, it is not possible to specify an exact “effective amount.” However, an appropriate “effective” amount in any individual case may be determined by one of ordinary skill in the art using only routine experimentation.

**[0053]** The terms “treating” and “treatment” as used herein refer to reduction in severity and/or frequency of symptoms, elimination of symptoms and/or underlying cause, prevention of the occurrence of symptoms and/or their underlying cause, and improvement or remediation of damage. Thus, for example, the present method of “treating” individuals afflicted with hallux valgus, as the term “treating” is used herein, encompasses treatment of hallux valgus in a clinically symptomatic individual.

**[0054]** The terms “condition,” “disease” and “disorder” are used interchangeably herein as referring to a physiological state that can be detected, prevented or treated by the surgical techniques, devices and/or therapeutic agent as described herein. Exemplary diseases and conditions in which the anchoring system, methods, and therapeutic agents of the invention may be used may include, but are not limited to, hallux valgus, Lis-Franc injury, midfoot sprains, flat feet, acromioclavicular sprains, coracoclavicular sprains, tarsal-metatarsal sprains, or similar conditions.

**[0055]** The term “patient” as in treatment of “a patient” refers to a mammalian individual afflicted with or prone to a condition, disease or disorder as specified herein, and includes both humans and animals.

**[0056]** The term “biomaterial,” as used herein generally refers any suitable natural, synthetic material, absorbable, non-absorbable, or recombinant material such as extracellular matrix bioscaffolds, cadaveric fascia, suture-type materials, or umbilical tape that may be used as part of the anchoring system of the invention.

**[0057]** The term “bioabsorbable” as used herein generally may include a bioabsorbable material such as poly-D, L-lactic acid, polyethylene glycol, polydioxanone, polylactic acid, 70L/30DL polylactide, polyglycolide, poly(orthoester), cal-

cium sodium metaphosphate, hydroxyapatite, calcium phosphate, polytetra fluoroethylene, collagen I, II, IX, X, and XI, durapatite, and hydrogel.

**[0058]** The terms “polymer” or “biopolymer,” as used herein generally refer to a compound having two or more monomer units, and is intended to include linear and branched polymers, and copolymers, the term “branched polymers” encompassing simple branched structures as well as hyperbranched and dendritic polymers. The term “monomer” is used herein to refer to compounds that are not polymeric. “Polymers” or “biopolymers” herein may be naturally occurring, chemically modified, or chemically synthesized.

**[0059]** The term “cortex” as used herein, generally refers the outer wall of a bone.

**[0060]** The anchoring system of the invention may have multiple uses in orthopaedic surgery. In particular, the invention may be used in a surgical procedure for insertion of the anchoring system and an associated surgical instrument to facilitate proper insertion of the anchoring system. The anchoring system of the invention may include a system for aligning two or more body parts, such as sections of bone, ligaments, tendons, tissues, and the like, and a system for fixing one section of relative to another section. As such, the anchoring system, including the fixation system and an alignment system may be made of any biocompatible material, and specifically, a bioabsorbable material. Alignment may refer to any change in position along various geometric axes (X, Y and Z) in isolation or in concert. More particularly, the anchoring system and its associated instrument may be suitable for surgical repair of hallux valgus, tarsometatarsal sprains, ankle ligament reconstruction, spring ligament repair, knee ligament reinforcement, acromioclavicular sprains, coracoclavicular sprains, elbow ligament repair, wrist and hand ligamentous stabilization, and similar conditions.

**[0061]** Referring to FIG. 1, a surgical instrument **100** is illustrated that may be employed for insertion of an anchor device of the invention suitable for the alignment and stabilization of the target bone(s). Instrument **100** may be fabricated from stainless steel, titanium, or any other material or combinations of material to produce an instrument that is relatively hard, impervious to damage by accidental contact with a drill bit, non-corrosive, and biocompatible. Instrument **100** may have a first end **102** and a second end **106**, which are shown from different perspectives to better illustrate their features. End **102** may function as a caliper, which may be configured as a towel clip or configured to include two vertically spaced plates **104** that may function to center instrument **100** on the desired bone, such as a metatarsal. Thus, one of the plates may be curved or other shape to conform to the parts being clamped, and include two prongs as shown in FIG. 1. The plates may be spring biased towards each other by any means known in the art. Moreover, once the plates have been placed around the bone, the position of the plates may be secured by a locking mechanism **103**, which may fix the relative positions of the plates by any conventional means.

**[0062]** Alternatively, the first arm **102** of the instrument **100** may use a cerclage wire around the metatarsal instead of the plates **104**. Once the wire is passed around the metatarsal, each limb of the wire may be passed through cannulated guides on the second arm **102**. The more distal, or lateral, guide may be a part of a curved plate that may rest along the plantar and lateral surface of the metatarsal. The more medial limb of the wire may pass through an adjustable guide that

may slide down to the dorsal surface of the metatarsal and lock in place. This locking mechanism may provide secure fixation while centralizing the distal arm **102** along the second metatarsal regardless of variations in width.

**[0063]** The second end **106** may be configured as a cannulated sleeve **108** to function as a drill guide. Specifically, sleeve **108** may have an outer sleeve **110** and an inner sleeve **112**. The sleeve **108** may be removably attached to ring **109** by a connection with its outer sleeve **110**, such as by threads for engaging complementary threads on ring **109**. The outer sleeve **110** may be attached to ring **109** by any other known mechanical connection such as interference fit, and the like. The instrument **100** may act as reduction forceps to align two bones or reduce the distance between the bones, as desired. Moreover, instrument **100** may allow for correction of any rotational deformity (pronation) when used for surgical correction of a bunion.

**[0064]** In a further embodiment, instrument **100** may include a locking clamp **114** to hold the instrument **100** in position once the final alignment of the bones has been achieved. The locking clamp may be fabricated and configured as understood by those skilled in the art. Furthermore, instrument **100** may include an automatic angle indicator **116** to provide the surgeon with an estimate of the angle between the bones requiring correction. Specifically, one skilled in the art appreciates that trigonometry may be used to estimate the angle between the two bones using known data regarding the length of the bones from x-rays or from anthropomorphic averages along with the final distance between the instrument arm **118** and instrument arm **120** to estimate the angle. The instrument **100** then may be suitably calibrated to show the angle between the bones.

**[0065]** In one embodiment, the anchoring system of the invention and an associated instrument for insertion of the anchoring system may be employed for surgical repair of hallux valgus or bunion correction. The surgical correction may involve a soft-tissue release, placement of instrument **100** on the first metatarsal and the second metatarsal to properly insert an anchoring and alignment system of the invention, properly aligning and securing the reduction of the IM angle of the first metatarsal, and subsequent removal of instrument **100**, as described immediately below.

**[0066]** The surgical repair of hallux valgus may commence with a medial incision at the first metatarsal and an incision lateral to the second metatarsal at its distal portion followed by a web space soft-tissue release through a small dorsal incision, followed by placement of instrument **100**. Specifically, the distal soft tissue procedure may involve release of the adductor hallucis and the flexor hallucis brevis as they are elevated from the lateral sesamoid and released from their attachment to the fibular side of the first proximal phalanx. The soft-tissue release may result in release of the adductor tendon, fibular sesamoid attachments, and the lateral MTP joint capsule, which aids in correction of the bones and placement of the surgical instrument **100**. This is followed by a Silver bunionectomy to shave the exostosis, which results in further release of the medial soft tissue. Next, the surgical instrument **100** may be placed to the targeted location, which may be on two separate bones or across a joint requiring correction.

**[0067]** After the instrument **100** is placed on the bones and the bone is set in the desired orientation, the reduction or realignment may occur to the desired angle as estimated by the angle indicator **116**. For example, first end **102** may be

placed on the distal second bone (second metatarsal) and second end **106** may be placed on the proximal first bone (first metatarsal). The sleeve **108** on the proximal end of instrument **100** may be used as a drill guide. Initially, a first sleeve **108** having an inner diameter **112** in the range of about 3 millimeters (mm) to about 4 mm, which is capable of accommodating a large diameter drill, may be used as a guide to create a tunnel across the proximal first bone in line with the end **102**. Subsequently, sleeve **108** is removed and replaced with a new sleeve **108** having a smaller inner diameter **112** in the range of about 1 mm to about 2 mm. The new sleeve **108** may then serve as a guide for a smaller diameter drill to make a pilot hole in the distal second bone.

**[0068]** In a further embodiment, a small anchor as depicted in FIG. 2 is set in the pilot hole created in the distal second bone. Referring to FIG. 2, anchor **200** includes an anchor region **202** and a connector region **204**. The anchor region **202** may be capable of functioning as an intramedullary fixation device, a suspension fixation device, a drill and screw type fixation device or the like. If the anchor region **202** is an intramedullary type, it may have two arms that release in opposite directions within the bone canal to gain secure purchase. Alternatively, the anchor region **202** may be of a specific geometric shape that allows one-way passage through the cortical drill hole, but will subsequently become rigidly fixed within the bone canal once it passes through the cortex of the bone. The anchor region **202** may be non-absorbable and/or osteogenic and may be fabricated from, but not limited to stainless steel, titanium, and other suitable materials. Additionally, the anchor region **202** may be absorbable and/or osteogenic and may be fabricated from, but not limited to, polylactic acid, bone allograft, and hydroxyapatite coral.

**[0069]** In yet a further embodiment, the connector region **204**, which is placed across the first and second metatarsals and functions to secure the reduction of the IM angle, may be fabricated from any suitable biocompatible material (biomaterial) and may be surrounded by a hollow sleeve **206**. For example, the biomaterial may include any natural or synthetic materials such as Graff Jacket® (Wright Medical Technology), human dermis, Restore® (Depuy Orthopaedics), porcine intestinal mucosa, Cuffpath® (Arthrotek), porcine testicular mucosa, TissueMend® (TEI Biosciences), fetal bovine skin, Permacol® (Tissue Science Laboratories), porcine skin, cadaveric fascia, polytetrafluoroethylene, polypropylene, marlex mesh, Ethibond®, FiberWire® (Mitek), any other absorbable and/or non-absorbable sutures, Arthrex®, and umbilical tape. The biomaterial **204** in communication with the anchor may be either tubular or flat. The length, shape, geometry and thickness of the biomaterial may be dependent upon usage. Moreover, hollow sleeve **206** may provide rigidity for placement if the anchor is passed through the first proximal bone and into the second distal bone. Further, the hollow sleeve **206** may be absorbable and may be fabricated out of, but not limited to, polylactic acid, bone allograft, and hydroxyapatite coral. After the anchor **200** is secured within the second bone, the hollow sleeve **206** may be removed and the biomaterial passed through the hole in the first proximal bone.

**[0070]** FIG. 3 schematically shows the progression of setting an anchor **200** in the pilot hole created in the distal second bone. As shown in FIG. 3, the anchor region **202** is similar to an intramedullary fixation device having two arms **302** that release outwardly in opposite directions within the bone canal **304** to secure the anchor **200** in place. The arms **302** may be

pushed out of the sleeve 206 mechanically, be formed of thermally activated materials such as nitinol, or expanded by any other means known in the art.

[0071] In yet a further embodiment, an interference screw may be inserted in the tunnel created in the proximal first bone after anchor 200 is properly engaged in the bone canal of the second distal bone. Turning to FIG. 4, an interference screw 400 is depicted having a throughbore 402 and a plurality of loops 404 or other attachment devices configured to allow a suture to pass through. Additionally, the screw 400 may be externally threaded 406 to engage the bone of the canal. Specifically, screw 400 may be threaded along its length and the threads may stop near its tip 408. As the biomaterial 204 is held at the desired length and tension, the screw may be inserted into the hole in the first proximal bone and may be advanced until a secure interference fit is achieved. The biomaterial 204 may be threaded through loops 404 to secure the repair. Once the screw 400 is set within the canal of the bone, instrument 100 may then be removed. After removal of the instrument 100, soft tissue repair may be initiated by tightening the capsular tissue to a fixed point into the attachment sites 404 of the screw 400. If the screw 400 is tightened further, tension and rotational correction may be achieved and the biomaterial 204 may be achieved to reinforce the repair, thereby resulting in a more secure repair.

[0072] Turning to FIG. 5, the final configuration of the anchoring system is schematically shown after a surgical bunion repair, according to principles of the invention such as described above. Here, a proximal first bone 502, a distal second bone 504, anchor region 202, connector region 204, and interference screw 400 are shown. The anchor region 202 with its two expanded arms 302 is embedded within the canal of bone 504, and the connector region 204 extends from the distal second bone 504 and threaded through the throughbore of the interference screw 400 embedded in the proximal first bone 502.

[0073] In an alternate embodiment of the invention, the instrument 100 and anchor device 200 may be used to correct or repair other orthopaedic conditions, such as mid-foot or tarsometatarsal sprains. The instrument 100 may achieve and may maintain a reduction along the path of the ruptured ligament. After the smaller anchor 200 is set in the second metatarsal, the biomaterial 204 may be used to reconstruct the Lis Franc ligament with the remaining biomaterial 204 secured within the first bone such as the medial cuneiform. The instrument 100 may have the second distal arm centered around the proximal second metatarsal and the first or proximal arm may be placed on the medial cuneiform. Instrument 100 may then assist in performing the reduction of the Lis Franc joint. A drill sleeve 108 with a larger diameter may then be used on the proximal arm to create a tunnel through the medial cuneiform. The drill sleeves with the larger diameter is removed and replaced with a drill sleeve having a smaller diameter. Next, a small pilot hole may be made in the base of the second metatarsal. The anchor 200 may be set into the pilot hole of the second metatarsal and the biocompatible material 204 may be pulled through the medial cuneiform along the anatomic path of the Lis Franc ligament. The biomaterial 204 may then be secured in the medial cuneiform with the interference screw 400.

[0074] According to yet further embodiments of the invention, the anchoring systems illustrated in FIGS. 6-8 may be used for anchoring and stabilizing the first metatarsal via fixation to the second metatarsal. In these embodiments, at

least one of the anchors may be disposed on and locked in place on the connector component via a one-way or two-way ratcheting mechanism to achieve precise positioning, as described in more detail below. In FIG. 6, an anchoring system 600 having a distal portion 616, a proximal portion 618, a primary anchor 602, a connection component 604, a proximal secondary anchor 606, and a flange 608 is shown. Anchoring system 600 may be employed using the methods along with device 100, as described above, for fixating the relative position first metatarsal to the second metatarsal and thereby reducing the IM angle of the first metatarsal. The primary anchor 602 and/or the secondary anchor 606 may be bio-absorbable for short-term use or bioactive for long-term tissue integration and/or may also be coated to reduce the potential for infection or to promote tissue in-growth, as described below.

[0075] In a specific embodiment, the connection component 604 and secondary anchor 606 may provide for precise relative positioning and locking of the secondary anchor in a number of predetermined positions along the axial length of the connection component via a one-way ratcheting locking mechanism. For example, the outer surface of connection component 604 may have a plurality of spaced protrusions such as angular teeth, ridges, barbs, detents, ribs, or the like, which are adapted to be retained in a mating surface provided on the inside surface of the secondary anchor 606. The mating connections may function to resist motion of the connection component 604 in at least one direction. The locking action formed by the mating connection acts as a one-way ratcheting mechanism. As shown in FIG. 6, the mating connections may be forward facing to facilitate motion of the connection component 604 in one direction 614 while resisting movement of the connection component 604 in a opposite direction 612. Thus, connection component 604 may have fixed stops precut into the connection component 604 for the secondary anchor 606 to lock against. The ratcheting mechanism thus functions similar to a "cable tie," where a locking component slides over the connection component, adjusting its finished length. In addition, the arrangement of the mating connections may be reversed so the projections may be disposed on the inner surface of the secondary anchor and matingly received in the connection component. Other one-way or two-way locking mechanisms may also be employed such as Velcro type connections or other suitable fabrics.

[0076] The position of the secondary anchor 606 may be adjusted by pulling on the connector component to move the component 604 relative to anchor 606 and secure it in place via the locking/ratcheting mechanism. This adjustment could also be accomplished by a variety of mechanical means including winding the connector component onto a screw or using a lever for tension. The ratcheting may be automatic or may be actuated by the user. The ratcheting may be permanent or allow for future adjustment. Thus, the locking device may take the form of a releasable, two-way ratcheting mechanism known in the art. Regardless, the invention should not be construed to be limited to any particular locking or ratcheting mechanism, as these types of mechanisms are well known in the art and can be readily made by techniques known to those of ordinary skill in the art.

[0077] The connection component 604 of system 600 may be composed of suture material that may be elastic, braided, or monofilament in nature, or may be a wire, a polymeric strap, or any other suitable ratcheting material. The connection component 604 may be attached directly to one or both

anchors or may be attached by an intermediate mechanism. The connection may be asymmetric to provide greater stiffness or flexibility in one direction over another.

**[0078]** The primary anchor **602** and the secondary anchor **606** may be composed of a single body and may be secured into the second metatarsal and first metatarsal, respectively, using such means as screw threads (as shown in FIG. 6), barbs, loops/cuffs, and the like to result in an interference fit. In an alternate embodiment, primary anchor **602** and/or secondary anchor **606** may be composed of a material that expands to lock the anchor in place. For example, FIG. 7 shows system **600** with primary anchor **602** having material **702**, connection component **604**, and secondary anchor **606**. Subsequent to insertion of primary anchor **602** into the second metatarsal, material **702** expands to secure primary anchor **602** in the bone canal of the second metatarsal. FIG. 8 is a schematic illustrating a final configuration of the anchoring system of FIG. 7 (Panel II) for the correction of hallux valgus of the first metatarsal as shown in FIG. 8, Panel I.

**[0079]** FIG. 9 illustrates yet another embodiment of the invention where the secondary anchor **606** is adapted to have a slideable fit within the first metatarsal and/or has an outer dimension that allows the secondary anchor to act as a bushing to take up the space drilled in the first metatarsal or other bone. For example, secondary anchor **606** may have a smooth outer surface like a washer or a bushing having dimensions selected to slide within the hole drilled in the first metatarsal. The secondary anchor **606** has a flange **608** with a surface **609**, which abuts the proximal side of the first metatarsal thereby "sandwiching" the first metatarsal between the secondary anchor **606** and the primary anchor **602** fixed within the bone canal of the second metatarsal.

**[0080]** Alternatively, primary anchor **602** and/or secondary anchor **606** may be connected a linkage to allow for a greater range of motion of the anchoring system, such as a ball joint and/or formed from a somewhat flexible material. In other words, if the axial motion of the anchoring system is along the y-axis of connection component **604**, the linkage would permit motion along the x- or z-axis or a combination of x- and z-axes. For example, a ball joint or another type of lost-motion connection may be used to connect the primary anchor **602** and the connection component **604** and/or the connection component and the secondary anchor. This enables the relative position of the metatarsal to be adjusted in all three dimensions.

**[0081]** According to another feature of the invention, bony healing may be induced during the surgical procedure of the invention by introducing bone growth factors such as bone morphogenetic proteins (BMPs) and basic fibroblast growth factor (bFGF) to the target area undergoing correction. These two classes of bone growth factors have been shown to accelerate bone regeneration, bone healing to prosthetic-like implants, and increase strength and stability to the bony callus. The bone growth factors could be delivered to the target area by a variety of methods. One method may be to introduce the bone growth factors in combination with a collagen matrix, which could be a gel- or sponge-like material, to the target area. The bone growth factor may then stimulate the patient's own bone cells into action, while the collagen may provide the scaffolding into which the stimulated bone cells can grow. In the end, bone could replace the collagen scaffold, which may be eventually resorbed.

**[0082]** Another method of delivery may be to coat the anchor screws or interference screws with the bone growth

factor in combination with hydroxyapatite, which may have a synergic stimulative effect on the bone cells. For this to be accomplished, an effective amount of the bone growth factor would be absorbed to a gritblasted hydroxyapatite coated anchor or screw prior to implantation into the bone.

**[0083]** However, an alternate method to the delivery of recombinant bone growth factors may be through gene therapy. Delivery by gene therapy may be more cost effective because ex vivo production of DNA for clinical use is inexpensive compared with traditional methods of protein production. Also, gene therapy may be a more efficient way to deliver the bone growth factors compared with traditional protein delivery. One desirable way to utilize gene therapy in the surgical procedure of the invention may be to introduce plasmid-encoded proteins capable of inducing bone growth to the area of distraction. This may be accomplished by introducing biodegradable matrices, such as collagen sponges, containing expression plasmid DNA encoding bone growth factors, also known as gene-activated matrices (GAMs), to the target area.

**[0084]** The description and examples given above are merely illustrative and are not meant to be an exhaustive list of all possible embodiments, applications or modifications of the invention. Thus, various modifications and variations of the described methods and systems of the invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. Indeed, various modifications of the described modes for carrying out the invention which are obvious to those skilled in the medical sciences, orthopedic surgery, or related fields are intended to be within the scope of the appended claims.

**[0085]** The disclosures of all references and publications cited above are expressly incorporated by reference in their entireties to the same extent as if each were incorporated by reference individually.

What is claimed is:

1. A surgical instrument to align bones and/or guide a surgical device, said instrument comprising:

a body having a first proximal arm and a second distal arm;  
a cannulated sleeve supported by one of said arms, said sleeve being configured to guide the surgical device; and  
an alignment device supported by the other of said arms, said alignment device configured and arranged to hold a bone in proper alignment for the surgical device.

2. The surgical instrument of claim 1, further comprising an angle indicator.

3. The surgical instrument of claim 1, further comprising a locking clamp.

4. The surgical instrument of claim 1, wherein said cannulated sleeve is removably attached to said one arm.

5. The surgical instrument of claim 1, wherein said cannulated sleeve comprises a drill guide and the surgical device comprises a drill.

6. The surgical instrument of claim 1, wherein said alignment device comprises a pair of opposed plates.

7. The surgical instrument of claim 6, wherein said plates comprise an adjustable dorsal plate and plantar plate.

8. A surgical method for repair of hallux valgus, said method comprising the steps of:

entering the tissues of the foot affected with hallux valgus by performing at least one incision;

performing a soft-tissue release to release the abductor tendon, fibular sesamoid attachments and the lateral metatarsalphalangeal (MTP) joint capsule; shaving the exostosis; and stabilizing and reorienting a first metatarsal by placing the surgical instrument of claim 1 on the first metatarsal and on a second metatarsal.

9. The method of claim 8, wherein the at least one incision comprises a medial incision at the first metatarsal.

10. The method of claim 8, wherein the at least one incision comprises a lateral incision to the second metatarsal at its distal portion.

11. The method of claim 8, wherein the at least one incision comprises a first web space incision.

12. The method of claim 8, wherein the first proximal arm is placed on the first metatarsal and the second distal arm is placed on the second metatarsal.

13. The method of claim 8, further comprising the steps of: creating a tunnel across the first metatarsal; creating a pilot hole in the second metatarsal; embedding an anchor in the pilot hole in the second metatarsal; and

inserting an interference screw in the first metatarsal.

14. The method of claim 13, wherein the anchor in said embedding step comprises an anchor region and a connector region.

15. The method of claim 14, wherein the anchor region is non-absorbable and fabricated from a material selected from the group consisting of stainless steel and titanium.

16. The method of claim 14, wherein the anchor region is bioabsorbable and fabricated from a material selected from the group consisting of polylactic acid, bone allograft, and hydroxyapatite coral.

17. The method of claim 14, wherein the connector region is fabricated from a material selected from the group consisting of human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable suture, and umbilical tape.

18. The method of claim 13, wherein the anchor is osteogenic and coated with a bone growth factor.

19. The method of claim 13, wherein the interference screw in said inserting step is bioabsorbable and fabricated from a material selected from the group consisting of polylactic acid, bone allograft, and hydroxyapatite coral.

20. The method of claim 13, wherein the interference screw is osteogenic and coated with a bone growth factor.

21. The method of claim 13, wherein the interference screw includes at least one suture receiving portion and wherein the suture functions to secure a reduction in the hallux valgus (HV) angle of the first toe.

22. A surgical anchor system for use in the repair of an orthopaedic condition, said system comprising:

an anchor having a collapsed position for delivery to a canal of a first bone and an expanded position for securing the anchor within the bone canal;

a fixation device configured to be fixedly attached to a second body part; and

a connector extending between said anchor and said fixation device.

23. The surgical anchor system of claim 22, wherein said anchor comprises two resilient arms made of a biocompatible material.

24. The surgical anchor system of claim 22, wherein the orthopaedic condition is at least one condition selected from the group consisting of hallux valgus, tarsometatarsal sprains, ankle ligament reconstruction, spring ligament repair, knee ligament reinforcement, acromioclavicular sprains, coracoclavicular sprains, elbow ligament repair, and wrist and hand ligamentous stabilization.

25. The surgical anchor system of claim 22, wherein said anchor is bioabsorbable and fabricated from a material selected from the group consisting of polylactic acid, bone allograft, and hydroxyapatite coral.

26. The surgical anchor system of claim 22, wherein said anchor is non-absorbable and fabricated from a material selected from the group consisting of stainless steel and titanium.

27. The surgical anchor system of claim 22, wherein said connector is fabricated from a material selected from the group consisting of human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable suture, non-absorbable suture, and umbilical tape.

28. The surgical anchor system of claim 22, wherein said anchor is osteogenic and coated with a bone growth factor.

29. The surgical anchor system of claim 22, wherein said fixation device comprises an interference screw.

30. The surgical anchor system of claim 29, wherein said interference screw is bioabsorbable and fabricated from a material selected from the group consisting of polylactic acid, bone allograft, and hydroxyapatite coral.

31. The surgical anchor system of claim 29, wherein said interference screw is osteogenic and coated with a bone growth factor.

32. The surgical anchor system of claim 29, wherein said interference screw includes at least one suture receiving portion and wherein the suture functions to secure a reduction between the HV angle of the first metatarsal and a proximal phalanx.

33. The surgical anchor system of claim 22, wherein said second body part comprises a second bone.

34. The surgical anchor system of claim 33, wherein said first bone is a first metatarsal and said second bone is a second metatarsal.

35. A surgical anchor system for use in the repair of an orthopaedic condition, said system comprising:

a primary anchor adapted to engage a first bone;

a secondary anchor adapted to engage a second bone;

a connector component extending between said primary and secondary anchors; and

at least one of said first anchor and said secondary anchor being connected to said connector component in one of a plurality of predetermined, lockable positions disposed along the length of said connection component.

36. The anchor system of claim 35, wherein said connection component comprises a one-way or a two-way ratcheting mechanism.

37. The anchor system of claim 36, wherein said ratcheting mechanism comprises a mating engagement between an interior surface of at least one of said primary anchor and said secondary anchor and said connection component.

38. The anchor system of claim 35, wherein said primary anchor is fixedly attached to the first bone by at least one of

screw threads, barbs, loops, and cuffs, and said secondary anchor is connected to said connection component via said ratcheting mechanism.

39. The anchor system of claim 35, wherein said primary anchor comprises an expandable material having resilient arms to fix said primary anchor in place in the canal of the first bone.

40. The anchor system of claim 35, wherein said secondary anchor is fixedly attached to the second bone by at least one of screw threads, barbs, loops, and cuffs.

41. The anchor system of claim 35, wherein said secondary anchor has a first portion disposed in a canal of the second bone and a second portion disposed against an outer surface of the second bone.

42. The anchor system of claim 35, wherein the first bone is a second metatarsal and the second bone is the first metatarsal.

43. The anchor system of claim 35, wherein said primary anchor and said secondary anchor are bioabsorbable and fabricated from a material selected from the group consisting of polylactic acid, bone allograft, and hydroxyapatite coral.

44. The anchor system of claim 35, wherein said primary anchor and said secondary anchor are non-bioabsorbable and fabricated from a material selected from the group consisting of stainless steel and titanium.

45. The anchor system of claim 35, wherein said primary anchor and said secondary anchor are osteogenic and coated with a bone growth factor.

46. The anchor system of claim 35, wherein said connection component is fabricated from a material selected from the group consisting human dermis, porcine intestinal mucosa, porcine intestinal mucosa, fetal bovine skin, porcine skin, cadaveric fascia, polytetrafluorethylene, polypropylene, marlex mesh, absorbable suture, non-absorbable suture, and umbilical tape.

47. The anchor system of claim 35, wherein said connection component is fixedly attached to at least one of said primary anchor and said secondary anchor in at least one direction.

48. The anchor system of claim 47, wherein said connection component is fixedly attached to at least one of said primary and secondary anchor in two directions.

49. The anchor system of claim 35, wherein said connection component is pivotally attached to at least one said primary anchor and said secondary anchor.

50. The anchor system of claim 35, wherein said connection component functions to secure a reduction between the HV angle of the first metatarsal and a proximal phalanx.

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