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surface disposed at generally opposite ends. The first and the second tapered surfaces are configured to frictionally engage the first and the second tapered mating surfaces of the first and the second element, respectively, to form frictional interference connections therebetween.

SYSTEM AND METHOD FOR BONE FIXATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The application claims the benefit of U.S. Provisional Application Serial No. 61/579,318, filed December 22, 201 1, which is fully incorporated herein by reference.

FIELD

[0002] This disclosure relates to biological medical devices and methods, and particularly to biological medical implants and methods for bone fixation.

BACKGROUND

[0003] In many circumstances, it may be desirable to couple two or more bone segments together. For example, a single bone may be damaged in two or more portions and/or two or more adjacent bones may be out of alignment with respect to each other. The joint between two bones may have wear or other problems. In either situation, it may be beneficial to couple and/or secure the bones/bone segments together such that the bones/bone segments are generally anatomically aligned with respect to each other.

BRIEF DESCRIPTION OF THE DRAWINGS

[0004] Features and advantages of the present invention are set forth by description of embodiments consistent with the present invention, which description should be considered in conjunction with the accompanying drawings wherein:

[0005] FIG. 1 is a cross-sectional view exploded view of a fixation system consistent with one embodiment of the present disclosure;

[0006] FIG. 2 is a cross-sectional view of the assembled fixation system of FIG. 1;

[0007] FIGS. 3-8 illustrate various steps of securing two bones together using a fixation system consistent with the present disclosure;

[0008] FIGS. 9a-9b illustrate various views of a fixation system consistent with another embodiment of the present disclosure;

[0009] FIGS. 10a-10b illustrate various views of a fixation system consistent with yet another embodiment of the present disclosure;

[0010] FIGS, lla-lld illustrate various views of a fixation system consistent with yet a further embodiment of the present disclosure;

[0011] FIGS. 12a-12d illustrate various view of a fixation system consistent with yet a further embodiment of the present disclosure;

[0012] FIG. 13 is a cross-sectional exploded view of another fixation system consistent with the present disclosure;

[0013] FIG. 14 generally illustrates one embodiment of a fixation system securing two bones in a foot consistent with one embodiment of the present disclosure; and[0014] FIG. 15 generally illustrates one embodiment of a fixation system securing two bones in a hand consistent with one embodiment of the present disclosure.

DETAILED DESCRIPTION

[0015] By way of summary, one embodiment of the present disclosure may feature a fixation system and method for coupling together two bone or bone segments. The fixation system may include a first and a second fixation element (e.g., but not limited to, a screw) and an interconnect. The first and second fixation elements are coupled to a first and second bone, respectively, and each includes a tapered cavity. The interconnect include a first and a second tapered protrusion configured to be frictionally received in the tapered cavities of the first and second fixation elements, respectively. Once assembled, the frictional forces between the tapered surfaces form a frictional connection which generally locks the position of the first and second fixation elements together with respect to each other (though the fixation system may also be configured to allow some movements relative to each other).

[0016] Turning now to **FIGS. 1** and **2**, one embodiment of a fixation system 10 is generally illustrated in an unassembled (i.e., exploded) cross-sectional view (see **FIG. 1**) and an assembled cross-sectional view (see **FIG. 2**). The fixation system 10 includes a first and a second fixation element 12, 14 as well as an interconnect 16. As described herein, the fixation system 10 may be used to couple and/or secure to bones and/or bone segments (collectively generally referred to as simply bones for ease of reference) together with respect to each other. The fixation system 10 may therefore be used to arrange or position the bones in a generally anatomically alignment. As used herein, the term "generally anatomically alignment" is intended to mean a positioning of the bones corresponding to the generally accepted medical definition. The term "generally anatomically alignment" may therefore allow for some deviation based on the patient's overall condition, the skill of the surgeon, and pathology being treated.

[0017] In the illustrated embodiment, the first fixation element 12 is configured as a screw 18. According to one embodiment, the screw 18 includes a body portion 20 having one or more external threaded portions 22 configured to threadably engage with a portion of a first bone. The threaded portion 22 may include a self-taping thread. While the first fixation element 12 is shown having an external threaded portion 22, the body 20 of the first fixation element 12 may alternatively (or in addition) include one or more ribs or protrusions configured to engage the bone to secure the first fixation element 12 to the bone. A portion of the body 20 may have a tapered configuration which decreases from a first end 24 (e.g., a proximal end) to a second end 26 (e.g., a distal end).

[0018] At least a portion of the body 20 (e.g., but not limited to, the proximal end 24) defines a first cavity 28. The first cavity 28 may include a generally cylindrical region 30 having a tapered inner surface/sidewall 32. The tapered sidewall 32 decreases in diameter from the opening 34 of the cavity 28 towards the distal end 26. As described herein, the opening 34 of the cavity 28 is configured to receive a corresponding tapered portion of the interconnect 16 to form a frictional interference connection/coupling as generally illustrated in **FIG. 2**.

[0019] The proximal end 24 may also include one or more notches 36. Consistent with the illustrated embodiment, the screw 18 may be rotatably driven, i.e., screwed, into the bone using a driver (not shown for clarity) configured to engage the notches 36 to rotate the screw 18. Alternatively (or in addition), the first cavity 28 may include a keyed region 38 configured to engage with a corresponding keyed region of the driver to rotate the first fixation element 12 into the bone.

[0020] The second fixation element 14 is configured to be secured to a second bone and may generally correspond to the first fixation element 12. For example, the second fixation element 14 may be the same as the first fixation element 12. Alternatively, the second fixation element 14 may have a different diameter, length, pitch, taper, length of cannulated passage, and/or the like. The dimensions of the first and second fixation elements 12, 14 will depend on the intended application and related size of the first and second fixation elements 12, 14 dimensions and condition of the first and second bones to be coupled together. For example, the dimensions of the first and second fixation elements 12, 14 may be generally about 5 mm in diameter at the proximal outer diameter, tapering down over the 12mm length of the screw to a 2.5 mm diameter at the distal outer diameter. The interconnect 16 may be approximately 2 mm in diameter and may vary from 6 mm to 13 mm in overall length.

[0021] The interconnect 16 is configured to couple the first and second fixation elements 12, 14, and therefore the first and second bones. The interconnect 16 includes a first and a second generally cylindrical region 38, 40 each having a tapered external surface/sidewall 42, 44, respectively. The tapered sidewalls 42, 44 have a taper which generally corresponds to the tapered sidewalls 32 of the first and second fixation elements 12, 14, respectively, to form a frictional or interference fit. In particular, when the interconnect 16 is received within the first and second fixation elements 12, 14, the precision tapered sidewalls 32 of the first and second fixation elements 12, 14 abut against the precision tapered sidewalls 42, 44 of the interconnect 16 so closely that the friction between the sidewalls 32, 42, 44 mates the first and second fixation elements 12, 14 to the interconnect 16 as generally illustrated in **FIG. 2**.

[0022] The interconnect 16 may optionally include one or more shoulders, protrusions, or the like 46. The shoulder 46 extends radially outwardly from the body 48 of the interconnect 16. According to one embodiment, the shoulder 46 extends circumferentially around the entire perimeter of the body 48. Alternatively, the shoulder 46 may extend radially outwardly around a portion of the body 48. The shoulder 46 may separate the first and second sidewalls 42, 44 as generally illustrated FIG. 1 and may limit the distance which the interconnect 16 may be inserted into a cavity 28 of fixation elements 12, 14 as generally illustrated in FIG. 2.

[0023] The interconnect 16 may also optionally define one or more internal cavities 49a, 49b. As described herein, the internal cavities 49 may be configured to receive an alignment device to facilitate alignment of an adjacent fixation element (e.g., the second fixation element 14).

[0024] Turning now to FIGS. 3-8, one embodiment of a method for coupling a first and a second bone together using a fixation system 10 consistent with at least one embodiment of the present disclosure is generally illustrated. In particular, an end 50 of a first bone 52 may be prepared as generally illustrated in FIG. 3. For example, a portion of the end 50 of the bone 52 may be removed to provide additional space for the fixation system 10 and/or to align the bone 52 with respect to the adjacent bones. Optionally, a pilot hole or the like 54 may be formed in the end 50 of the bone 52. The pilot hole 54 may be formed using a drill and/or a guide wire (not shown). The

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pilot hole 54 in the bone 52 may be configured to receive a portion of the first fixation element 12. For example, the pilot hole 54 may be configured to receive the first fixation element 12 and may have a diameter smaller than the outside diameter of the threads 22 of the first fixation element 12 to allow the threads 22 of the first fixation element 12 to engage the bone 52.

[0025] After the pilot hole 54 is formed, the first fixation element 12 may be rotatably driven (e.g., screwed) into the bone 52 (for example using a driver) as generally illustrated in **FIG. 4.** Again, it should be noted that the first fixation element 12 may be secured to the bone 52 without a pilot hole 54. The depth of the first fixation element 12 within the bone 52 may be set by rotating the first fixation element 12 until the first fixation element 12 is in the desired position. By adjusting the depth of the first fixation element 12 within the bone 52, the fixation system 10 may be used in a wider variety of applications. For example, adjusting the depth of the first fixation element 12 may compensate for different amounts of bone preparation (e.g., removal of bone at the end).

[0026] After the first fixation element 12 is secured in the first bone 52, a first tapered sidewall 42 of the interconnect 16 may be co-axially received in the opening 34 of the cavity 28 of the first fixation element 12, for example, as generally illustrated in **FIGS. 5** and **6**. As seen, the sidewall 42 of the interconnect 16 may be inserted into the cavity 28 of the first fixation element 12 until the shoulder 46 abuts against the proximal end 24 of the first fixation element 12. Optionally, an alignment device 55 may be used to locate where the second fixation element 14 should be secured to the second bone 56. For example, the alignment device 55 may include a pin configured to be received in the cavity 49 of the interconnect 16. The pin 55 may be secured within the cavity 49 and extend beyond the interconnect 16. The second bone 56 may then be placed into axial alignment with the pin 55. The pin 55 may include a pointed tip 58 which may pierce and/or mark the location on the second bone 56 where the second fixation element 14 should be secured.

[0027] Optionally, the pin 55 may be secured into the second bone 56, and a pilot hole may be formed in the second bone 56 using a cannulated drill bit advanced over the pin 55.

[0028] After the location of the second fixation element 14 has been determined, the second fixation element 14 may be may be rotatably driven (e.g., screwed) into the bone 56 (for example using a driver) as generally illustrated in FIG. 7. Again, it

should be noted that the second fixation element 14 may be secured to the bone 56 without a pilot hole. The depth of the second fixation element 14 within the bone 56 may be set by rotating the second fixation element 14 until the second fixation element 14 is in the desired position. By adjusting the depth of the second fixation element 14 within the bone 56, the fixation system 10 may be used in a wider variety of applications. For example, adjusting the depth of the second fixation element 14 may compensate for different amounts of bone preparation (e.g., removal of bone 56 at the end).

[0029] After the second fixation element 14 has been secured in the second bone 56, the second tapered sidewall 44 of the interconnect 16 may be co-axially received in the opening 34 of the cavity 28 of the second fixation element 14, for example, as generally illustrated in **FIG. 8.** As seen, the sidewall 44 of the interconnect 16 may be inserted into the cavity 28 of the second fixation element 14 until the shoulder 46 abuts against the proximal end 24 of the second fixation element 14.

[0030] It may be appreciated that the depth of first and second fixation elements 12, 14 may be set independent of each other and independent of the interconnect 16. More specifically, while the depth of the first and second fixation elements 12, 14 determines the separation distance between the first and second bones 52, 56, the first and second fixation elements 12, 14 and the interconnect 16 are not limited to a specific orientation relative to each other. As such, the separation distance between the first and second bones 52, 56 may be infinitely adjustable.

[0031] It should be appreciated that the various steps in the method described herein do not necessarily have to be performed in any specific order. For example, the first and the second fixation elements 12, 14 may be secured in the bones prior to the interconnect 16 being coupled with either of the fixation elements 12, 14.

[0032] Turning now to FIGS. 9a and 9b, an exploded view (FIG. 9a) and assembled view (FIG. 9b) of another embodiment of a fixation system 100 is generally illustrated. The fixation system 100 includes a first and a second fixation element 112, 114 as well as an interconnect 116. The first and second fixation elements 112, 114 may be similar to any fixation elements described herein. The interconnect 116 includes a first and a second generally cylindrical region 138, 140 each having a tapered external surface/sidewall 142, 144, respectively. The tapered sidewalls 142, 144 have a taper which generally corresponds to the tapered sidewalls 132 of the first and second fixation elements 112, 114, respectively, to form a frictional or

interference fit as generally illustrated in FIG. **9b** and as generally described herein. The interconnect 116 of FIGS. **9a** and **9b** does not have a shoulder.

[0033] With reference to FIGS. 10a and 10b, an exploded view (FIG. 10a) and assembled view (FIG. 10b) of yet another embodiment of a fixation system 200 is generally illustrated. The fixation system 200 includes a first and a second fixation element 212, 214 as well as an interconnect 216. While the interconnect 216 is illustrated without a shoulder, this is not a limitation of the present disclosure unless specifically claimed as such and the interconnect 216 may include any interconnect described herein. Optionally, the interconnect 216 may include a cannulated passage 217 extending along a longitudinal axis of the interconnect 216 between both ends. At least one of the fixation elements 212, 214 includes a cannulated passage 221. The cannulated passage 221 extends from the proximal end 224 (e.g., from the cavity 228) to the distal end 226. In practice, a guide pin may be inserted into the end of the bone, for example, along the longitudinal axis of the bone. A pilot hole may optionally be formed over a portion of the guide pin, for example using a cannulated drill bit. One or more of the cannulated fixation elements (e.g., cannulated fixation element 240) may be advanced over the guide pin such that the guide pin is received within the cannulated passage 221 and the fixation elements 212, 214 may be secured into the bone as described herein. Optionally, a cannulated interconnect 216 may also be advanced over the guide pin.

[0034] Again, while only one fixation element 214 is illustrated with cannulated passage 221, it should be understood that both fixation elements 212, 214 may include a cannulated passage 221. One advantage of having only one cannulated fixation element 214 is that a guide pin may be inserted into the cavity 228 of the first fixation element 212 and may abut against the distal end 229. The distal end 229 may therefore prevent the guide pin from moving beyond the first fixation element 212 when the second bone is urged against the guide pin.

[0035] Alternatively (or in addition), a guide pin may be used which includes a flange extending radially outwardly having a diameter greater than the diameter of the cavity 228. The flange may be position a distance away from an end of the guide pin such that a portion of the guide pin is received within the cavity 228 of the first fixation element 212 when the flange abuts against the proximal end 224 of the first fixation element. The flange may therefore prevent the guide pin from advancing though the first fixation element 212, even if the first fixation element 212 is cannulated.

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[0036] Turning now to FIGS. 11a-lid, various view of another embodiment of a fixation system 300 are generally illustrated. In particular, FIG. 11a is an exploded view, FIG. lib is an assembled view, FIG. 11c is an exploded cross-sectional view, and FIG. lid is a cross-sectional assembled view of the fixation system 300. The fixation system 300 includes a first and a second fixation element 312, 314 as well as an interconnect 316. The first and second fixation elements 312, 314 are similar to any of the fixation elements described herein. The interconnect 316 may include tapered surfaces 338, 340 which are separated by a flexible region 369. The tapered surfaces 338, 340 are configured to engage with the cavities 328 of the first and second fixation elements 312, 314 as described herein. The flexible region 369 is configured to allow the first and second fixation elements to move (e.g., bend) with respect to each other such that the two bones secured together by the fixation system 300 (when assembled) can move. For example, at least a portion of the interconnect 316 (e.g., at least the flexible region 369) may include a superelasticity and/or shape memory material such as, but not limited to, nickel titanium alloys nitinol (e.g., an alloy of nickel and titanium).

[0037] The dimensions of the flexible region 369 may be selected to allow the bending characteristics of the interconnected 316 to be adjusted. For example, the cross-sectional dimensions, shape, and/or length of the flexible region 369 may be adjusted to increase the range of motion (e.g., bending) of the fixation system 300, the amount of force necessary to bend the fixation system 300, and/or the direction(s) in which the fixation system may bend. For example, FIGS. 12a-12d generally illustrates one embodiment of a fixation system 400 including a first and a second fixation element 412, 414 and an interconnect 416 having a flexible region 469 configured to allow the fixation system 400 to bend in a generally only one direction (e.g., generally only in a single plane). For example, at least a portion of the flexible region 469 may have a generally rectangular cross-section having a length running along the longitudinal axis of the interconnect 416 and a width and height generally perpendicular thereto. The dimensions of the width or the height may be selected to provide directional movement and stability of the interconnect 416 such that the interconnect 416 will generally only bend in one direct as a result of the forces in which the fixation system 400 will experience in a normal or typical application (e.g., the forces that the fixation system 400 would likely experience when installed in a foot, hand, or the like).

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[0038] While the fixation system 400 is illustrated having a generally rectangular cross-section, this is not a limitation of the present disclosure unless specifically claimed as such. For example, at least a portion of the flexible region 469 may have a generally oval cross-section, one or more longitudinal and/or transverse ribs, grooves, or the like.

[0039] A benefit of the fixation systems 300, 400 is that they may allow for some degree of flexibility when used to couple to adjacent bones which originally were coupled together by way of a joint. In the fixation systems 300, 400, the interconnects 316, 416 may have a separation length (i.e., distance between the first and second fixation elements when assembled) which is greater than the separation length of the other embodiments described herein. The larger separation length may facilitate bending of the fixation systems when assembled. The fixation systems may have a diameter of approximately 0.5 to 4 mm, an overall length of between approximately 5 to 20 mm, and may bend up to an angle between 10 degrees to 60 degrees.

[0040] Turning now to **FIG. 13**, yet another embodiment of a fixation system 500 consistent with the present disclosure is generally illustrated. The fixation system 500 includes a first and a second fixation element 512, 514 and an interconnect 516. At least one of the fixation elements 512, 514 includes a generally cylindrical protrusion 598 extending outwardly from the proximal end 524. The generally cylindrical protrusion 598 has a tapered external surface 599. The interconnect 516 includes at least one tapered generally cylindrical cavity 528 having a tapered internal surface 530 configured to frictional engage the corresponding tapered external surfaces 599 of protrusions 599 of the corresponding fixation elements 512, 514. While the fixation system 500 is illustrated in which interconnect 516 includes a first and a second tapered generally cylindrical protrusion 598, it should be understood that either of the fixation elements 512, 514 may include a tapered cavity as described herein and the corresponding end of the interconnect 516 may have a tapered protrusion as described herein.

[0041] The fixations systems described herein may be used to couple any two bones. For example, a fixation system 600 consistent herewith may be used to couple two or more bones 602, 604 in a foot 606 as generally illustrated in FIG. 14. A fixation system 700 consistent herewith may also be used to couple to or more bones 702, 704 in a hand 706 as generally illustrated in FIG. 15. It should be understood, however,

that these are merely illustrative examples and that the fixation systems described herein are not limited to feet 606 and/or hands 706 unless specifically claimed as such.

[0042] It should be appreciated that various features of the different embodiments described herein may be combined together. For example, the interconnect may be eliminated such that the two fixation elements may be directly coupled to each other, for example, using a tapered interference connection as described herein.

[0043] According to one aspect, the present disclosure features a fixation system for coupling a first and a second portion of bone together. The fixation system includes a first fixation element, a second fixation element, and an interconnect. The first fixation element includes an external surface configured to engage the first portion of bone and a first tapered mating surface. The second fixation element includes an external surface configured to engage the second portion of bone and a second tapered mating surface. The interconnect includes a first and a second tapered surface disposed at generally opposite ends. The first and the second tapered surfaces of the first and the second element, respectively, to form frictional interference connections therebetween.

[0044] According to another aspect, the present disclosure features a fixation system for coupling a first and a second portion of bone together including a first fixation element, a second fixation element, and an interconnect. The first fixation element includes a first body having an external surface configured to engage the first portion of bone. The first body defines a first generally cylindrical protrusion having a tapered external surface. The second fixation element includes a second body having an external surface to engage the second portion of bone. The second generally cylindrical protrusion having a tapered external surface configured to engage the second portion of bone. The second body defines a first and a second tapered external surface. The interconnect includes a first and a second tapered generally cylindrical cavity having a tapered internal surface configured to frictionally engage the tapered external surfaces of the first and the second protrusions.

[0045] According to yet another aspect, the present disclosure features a fixation system for coupling a first and a second portion of bone together including a first fixation element, a second fixation element, and an interconnect. The first fixation element includes a first body having an external surface configured to engage the first portion of bone. The first body defines a first generally cylindrical cavity having a

tapered internal surface. The second fixation element includes a second body having an external surface configured to engage the second portion of bone. The second body defines a second generally cylindrical cavity having a tapered internal surface. The interconnect includes a first and a second tapered generally cylindrical protrusion having a tapered external surface configured to frictionally engage the tapered internal surfaces of the first and the second cavities.

[0046] While the principles of the present disclosure have been described herein, it is to be understood by those skilled in the art that this description is made only by way of example and not as a limitation as to the scope of the invention. The features and aspects described with reference to particular embodiments disclosed herein are susceptible to combination and/or application with various other embodiments described herein. Such combinations and/or applications of such described features and aspects to such other embodiments are contemplated herein. Other embodiments are contemplated within the scope of the present invention in addition to the exemplary embodiments shown and described herein. Modifications and substitutions by one of ordinary skill in the art are considered to be within the scope of the present invention, which is not to be limited except by the following claims.

[0047] All definitions, as defined and used herein, should be understood to control over dictionary definitions, definitions in documents incorporated by reference, and/or ordinary meanings of the defined terms.

[0048] The indefinite articles "a" and "an," as used herein in the specification and in the claims, unless clearly indicated to the contrary, should be understood to mean "at least one."

[0049] The phrase "and/or," as used herein in the specification and in the claims, should be understood to mean "either or both" of the elements so conjoined, i.e., elements that are conjunctively present in some cases and disjunctively present in other cases. Other elements may optionally be present other than the elements specifically identified by the "and/or" clause, whether related or unrelated to those elements specifically identified, unless clearly indicated to the contrary.

[0050] All references, patents and patent applications and publications that are cited or referred to in this application are incorporated in their entirety herein by reference.

[0001] While the principles of the present disclosure have been described herein, it is to be understood by those skilled in the art that this description is made only by way of example and not as a limitation as to the scope of the invention. The features and

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aspects described with reference to particular embodiments disclosed herein are susceptible to combination and/or application with various other embodiments described herein. Such combinations and/or applications of such described features and aspects to such other embodiments are contemplated herein. Other embodiments are contemplated within the scope of the present invention in addition to the exemplary embodiments shown and described herein. Modifications and substitutions by one of ordinary skill in the art are considered to be within the scope of the present invention, which is not to be limited except by the following claims.

[0002] The terms and expressions which have been employed herein are used as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding any equivalents of the features shown and described (or portions thereof), and it is recognized that various modifications are possible within the scope of the claims. Accordingly, the claims are intended to cover all such equivalents. Various features, aspects, and embodiments have been described herein. The features, aspects, and embodiments are susceptible to combination with one another as well as to variation and modification, as will be understood by those having skill in the art. The present disclosure should, therefore, be considered to encompass such combinations, variations, and modifications.

[0051] Additional disclosure in the format of claims is set forth below:

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What is claimed is:

1. A fixation system for coupling a first and a second portion of bone together, said fixation system comprising:

a first fixation element having an external surface configured to engage said first portion of bone, said first fixation element including a first tapered mating surface;

a second fixation element having an external surface configured to engage said second portion of bone, said second fixation element including a second tapered mating surface; and

an interconnect comprising a first and a second tapered surface disposed at generally opposite ends, said first and said second tapered surfaces configured to frictionally engage said first and said second tapered mating surfaces of said first and said second element, respectively, to form frictional interference connections therebetween.

2. The fixation system of claim 1, wherein said first fixation element defines a first generally cylindrical element having said first tapered mating surface; and

wherein said interconnect includes a first tapered generally cylindrical portion having said first tapered surface configured to frictionally engage said first tapered mating surfaces of said first fixation element.

3. The fixation system of claim 2, wherein said second fixation element defines a second generally cylindrical element having said second tapered mating surface; and

wherein said interconnect includes a second tapered generally cylindrical portion having said second tapered surface configured to frictionally engage said second tapered mating surfaces of said second fixation element.

4. The fixation system of claim 2, wherein said first tapered generally cylindrical portion of said first fixation element defines a generally cylindrical cavity having an internal surface including said first tapered mating surface; and

wherein said first tapered generally cylindrical portion of said interconnect includes a first generally cylindrical protrusion having an external surface including said first tapered surface. 5. The fixation system of claim 2, wherein said first tapered generally cylindrical portion defines a generally cylindrical protrusion having an external surface including said first tapered mating surface; and

wherein said first tapered generally cylindrical portion of said interconnect includes a first generally cylindrical cavity having an internal surface including said first tapered surface.

6. The fixation system of claim 1, further including a pin configured to extend outwardly from said first fixation element along a longitudinal axis of said first fixation element.

7. The fixation system of claim 1, further including a shoulder extending radially outwardly from at least a portion of said interconnect, said shoulder located between said first and said second tapered surfaces.

8. The fixation system of claim 1, wherein said interconnect further includes a cannulated passageway extending along a longitudinal axis of said interconnect between said generally opposite ends thereof.

9. The fixation system of claim 1, wherein said first fixation element further includes a cannulated passage extending between a proximal end to a distal end of said first fixation element.

10. The fixation system of claim 1, wherein at least a portion of said interconnect is configured to allow at least a portion of said interconnect to bend.

11. The fixation system of claim 10, wherein at least a portion of said interconnect comprises a shape memory material.

12. The fixation system of claim 10, wherein said interconnect is further configured to allow bending motion in generally only a single plane.

13. The fixation system of claim 10, wherein said interconnect is configured to reduce bending in at least one longitudinal plane.

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14. The fixation system of claim 1, wherein said external surface of said first fixation element includes an externally threaded portion configured to engage said first portion of bone.

15. The fixation system of claim 14, wherein said first fixation element is configured to engage with a driver to rotate said first fixation element into said first portion of bone.

16. The fixation system of claim 15, wherein said first fixation element includes at least one notch configured to engage with a driver to rotate said first fixation element.

17. The fixation system of claim 15, wherein said first fixation element includes at least one notch configured to engage with a driver to rotate said first fixation element.

18. The fixation system of claim 1, wherein said external surface of said first fixation element includes a keyed region configured to engage with a corresponding keyed region of said driver to rotate said first fixation element.

19. A fixation system for coupling a first and a second portion of bone together, said fixation system comprising:

a first fixation element comprising a first body having an external surface configured to engage said first portion of bone, said first body defining a first generally cylindrical protrusion having a tapered external surface;

a second fixation element comprising a second body having an external surface configured to engage said second portion of bone, said second body defining a second generally cylindrical protrusion having a tapered external surface; and

an interconnect comprising a first and a second tapered generally cylindrical cavity having a tapered internal surface configured to frictionally engage said tapered external surfaces of said first and said second protrusions.

20. A fixation system for coupling a first and a second portion of bone together, said fixation system comprising:

a first fixation element comprising a first body having an external surface configured to engage said first portion of bone, said first body defining a first generally cylindrical cavity having a tapered internal surface;

a second fixation element comprising a second body having an external surface configured to engage said second portion of bone, said second body defining a second generally cylindrical cavity having a tapered internal surface; and

an interconnect comprising a first and a second tapered generally cylindrical protrusion having a tapered external surface configured to frictionally engage said tapered internal surfaces of said first and said second cavities.







<u>1</u>

FIG. 2

















FIG. 10a



FIG. 10b

300

312



326





FIG. 11d











514

512

500



526

521

FIG. 13



FIG. 14



FIG. 15

INTERNATIONAL SEARCH REPORT

International application No. PCT/US 12/71 199

A. CLA SSIFICATION OF SUBJECT MATTER IPC(8) - A61 F 2/36 (201 3.01) USPC - 623/23. 15, 23. 19, 23.39 According to International Patent Classification (IPC) or to both national classification and IPC Is. 'FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC(8) - A61 F 2/36 (2013.01) USPC - 623/23.1 5, 23.19, 23.39 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched 606/63; 623/16.1 1, 623/' (Search term limited; see below) Electronic data base consulted during the international search (name ol' data base and, where practicable, search terms used) PubWest (PGPI3, USPT. EPAB, JPAB); Google Search Terms: Bone, first, second, middle, intermediate, segment, member, element, taper, driver, screwdriver, shape memory, nitinol				
C. DOCUMENTS CONSI DERED TO BE RELEVANT				
Category*	Citation of document, with indication, where ap	opropriate, of the relevant passages	Relevant to claim No.	
x	US 2004/01 93268 Λ1 (HAZENBROUCK) 30 September 2004 (30.09.2004) Entire document, especially Abstract, para[001 1]- para[0045] and FIGS. 4-15, 27.			
X - Y	US 2006/0167560 A1 (HECK et at.) 27 July 2006 (27.0 Abstract, para[0055], para(0060]- para[0068] and FIGS	1, 2, 4, 7, 9 and 20 		
X - Y	US 2003/0204267 A 1 (HAZENBROUCK et al.) 30 Octo especially Abstract, para[0006], para[0041]- para[0046] -20.	1, 10 and 12-13 11		
x	US 2004/0193267 A 1 (JONES et al.) 30 September 20 especially Abstract, para(0033]- para[0035] and FIGS. 1-3, 5-6 and 19	1-3, 5-6 and 19		
Y	US 6,610.095 B1 (POPE et al.) 26 August 2003 (26.08.2003) col 11, ln 14-37, FIG. 2AB		11	
Y	US 4,016.874 A (WIAFFEI et al.) 12 April 1977 (12.04.19 11.	977) Abstract, col 3, ln 53-59, FIGS. 1,	14-18	
Further	documents are listed in the continuation of Box C.			
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