(19) World Intellectual Property Organization

International Bureau





(10) International Publication Number

WO 2008/098250 A2

PC'

(43) International Publication Date 14 August 2008 (14.08.2008)

- (51) International Patent Classification: *A61F 2/36* (2006.01)
- (21) International Application Number:

PCT/US2008/053606

(22) International Filing Date:

11 February 2008 (11.02.2008)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/889,267

10 February 2007 (10.02.2007) US

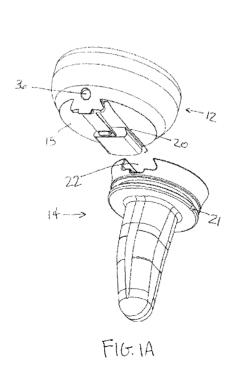
- (71) Applicant (for all designated States except US): SMALL BONE INNOVATIONS, INC. [US/US]; 505 Park Avenue, 14th Floor, New York, NY 10022 (US).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): LEIBEL, David, A. [US/US]; 32189 Helium Street, Princeton, MN 55371 (US).

- (74) Agents: GRIFFIN, Gail, H. et al.; Morgan Lewis & Bockius LLP, 1701 Market Street, Philadelphia, PA 19103 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

 without international search report and to be republished upon receipt of that report

(54) Title: RADIAL HEAD IMPLANT AND RELATED INSTRUMENT



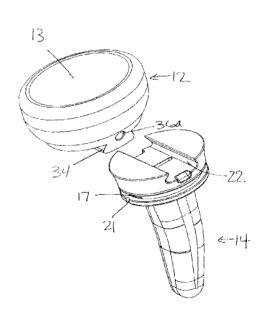


FIG. IB

(57) Abstract: A radial head implant including a head, a stem, and a locking mechanism, whereby the head laterally engages the stem, and an instalment for implanting and removing such implant is described.

TITLE

RADIAL HEAD IMPLANT AND RELATED INSTRUMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of provisional Application No. 60/889,267, filed 10 February 2007, which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE INVENTION

[0002] Like other joints and anatomical features of the human body, the elbow joint is complex in its make-up and function. Also like the other joints and anatomical features of the human body, the elbow joint is unique unto itself and requires specific consideration for its reconstruction or replacement. The complexity and uniqueness of this joint are best appreciated by considering the skeletal motions which are involved in its movement.

[0003] In the transition of the hand and forearm from pronation to supination the radius and ulna of the forearm transition from a crossed relationship to a side-by-side relationship. In this movement there is a relative rotation of the radius bone about the ulna. Also during the transition between pronation and supination there is some relative translational movement between the radius bone and the ulna. The consequence of this is that from a reference point on the ulna, the radius bone appears to move with a general motion that includes both translation and rotation. The head of the radius interacts with the capitellum and the radial notch of the ulna during pronation and supination, providing elbow and forearm stability during rotation and translation.

[0004] In addition to its importance as a component of forearm function, the radial head is an equally important component of normal elbow function. Indeed, elbow function involves bending, lifting and twisting movements, all of which require joint stability. Because motions in the human body require the interaction of various anatomical components, it is important that replacement of a component be precise in form, size, and orientation. While the head of the radius bone directly engages the capitellum of the humerus and the radial notch of the ulna, it also relates indirectly to other anatomical components of the arm. Specifically, ligaments surrounding the radial head are essential to elbow stability. Further, misalignment of the radius bone will cause poor radial-

capitellar joint contact, leading to subluxation, or poor alignment of the elbow. It follows that the wrist and shoulder joints are also affected by the alignment of the radius bone.

Independent of having a workable prosthesis for the head of the radius bone is underscored by the debilitating effects which commonly result when a joint becomes damaged due to fracture, arthritis, or osteochondrosis. It is well known that radial head resection, as seen in elbow injuries, results in persistent elbow instability. Additionally, forearm axial instability can result from radial head excision if the remaining stabilizers, i.e., the supporting ligaments, are compromised. Because this loss of stability affects the interdependent functions of the elbow and forearm, when the radial head is damaged, it is common to see further damage to other components of the radial-ulnar joint system, including, but not limited to, the complex system of supporting ligaments that encase the elbow joint. It has been well demonstrated that damage to any one of the components of the radial-ulnar joint system leads to pain, weakness, and loss of motion. It is, therefore, of great importance to the patient that damage to the radial head be remedied.

SUMMARY OF THE INVENTION

[0006] The present invention includes a radial head implant for replacement of a head portion of a radius bone. In an embodiment of the invention, the implant includes a head, a stem, and a locking mechanism. In another embodiment, the head is adapted to engage the stem. In another embodiment, the locking mechanism includes an arm, a locking tab and an end tab.

[0007] In one embodiment, the head is adapted to slideably engage the stem. In an embodiment of the invention, the head is adapted to lockingly engage the stem. In another embodiment of the invention, the implant head is adapted to unlock and disengage from the stem after engagement and locking.

[0008] In an embodiment of the invention, the stem has (1) a proximal end and a distal end, (2) a first portion extending distally from the proximal end substantially along a first axis, and (3) a second portion extending distally from the first portion substantially along a second axis to the distal end, the first axis and the second axis defining an angle therebetween, the stem being shaped to facilitate insertion of said stem into the medullary canal of the radius bone. In an embodiment of the invention, the angle is from about 0 degrees to about 25 degrees. In an embodiment of the invention,

the radius of curvature between the first portion and the second portion is in a range between about 0.5 inches and about 3 inches.

[0009] In an embodiment of the invention, the surface of the head includes a highly polished cobalt chrome to facilitate articulation of the radius bone. In another embodiment, the stem includes a roughened surface, for interaction with the medullary canal of the radius bone.

[0010] In an embodiment of the invention, the stem is tapered with a distally decreasing cross section to facilitate insertion of the stem into the medullary canal of the radius bone. In another embodiment, the stem includes a collar positioned on a first portion of said stem to limit insertion of said stem into the medullary canal of the radius bone.

[0011] In another embodiment of the present invention, the stem comprises a recessed channel adapted to engage said head. In one embodiment, the recessed channel is positioned along a third axis substantially perpendicular to the first axis of the stem. In an embodiment of the invention, the head includes a mating portion. In another embodiment, the recessed channel is adapted to engage the mating portion by way of a dovetail interaction between said mating portion and the recessed channel.

[0012] In an embodiment of the invention, a radial head implant for replacement of a head portion of a radius bone having a head and a stem is described. In one embodiment, the head has a locking mechanism adapted to engage the stem with the head. In another embodiment, the recessed channel is adapted to engage the locking mechanism.

[0013] In another embodiment of the invention, an instrument for implanting a radial head implant is described. In one embodiment, the instrument includes a hook mechanism, at least two handles, a lever, and a first mating portion. In one embodiment, the hook mechanism is adapted to engage a groove on the stem. In another embodiment, the first mating portion is adapted to engage a second mating portion on the head of the implant.

[0014] In an embodiment of the present invention, a method for engaging a head and stem of a radial implant is described. In one embodiment, the method includes engaging the hook mechanism with the groove on the stem. In another embodiment, the method includes engaging the first mating

portion with the second mating portion. In another embodiment, the method includes applying opposing pressure to the handles.

[0015] In an embodiment of the invention, a radial head implant for replacement of a head portion of a radius bone that includes a head, a stem, and a locking mechanism is described. In one embodiment, the head is adapted to engage the stem by way of a dovetail interaction between the head and the stem. In another embodiment, the head includes a mating portion and the stem includes a recessed channel. In one embodiment, the mating portion is adapted to engage the recessed channel by way of a dovetail interaction. In an embodiment of the invention, the mating portion includes an angle α , defining the angle between distal surface 15 of the head and a side of the mating portion. In another embodiment, the recessed channel includes an angle, β , defining an angle between the proximal side of the stem and a side of the recessed channel. In another embodiment, the angles α and β are substantially equal.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1, comprising Figures 1A and 1B, is an isometric view of a radial implant according to the present invention. Figures 1A illustrates a front view of engagement of the head and stem portions of a radial implant according to the present invention. Figure 1B illustrates a rear view of engagement of the head and stem portions of a radial implant according to the present invention.

[0017] Figure 2, comprising Figures 2A, 2B, and 2C, illustrates a cross sectional view of a radial implant according to the present invention. Figure 2A illustrates a front view of the radial implant. Cross section A-A, identified in Figure 2A is depicted in Figure 2B. Detail A, identified in Figure 2B is illustrated in Figure 2C.

[9018] Figure 3, comprising Figures 3A-3F, illustrates different views of a head portion of a radial implant according to the present invention. Figure 3A illustrates a top view of a head portion of a radial implant according to the present invention. Figure 3B is a side view of a head portion of a radial implant according to the present invention. Figure 3C is a side view (which is about 90 degrees from the view shown in Figure 3B) of a head portion of a radial implant according to the present invention. Figure 3D is a bottom view of a head portion of a radial implant according to the present invention. Figures 3E and 3F are isometric views of a head portion of a radial implant according to the present invention.

[0019] Figure 4, comprising Figures 4A-4C, illustrates different views of a stem portion of a radial implant according to the present invention. Figure 4A is a top view of a stem portion of a radial implant according to the present invention. Figure 4B is a side view of a stem portion of a radial implant according to the present invention. Figure 4C is a side view (which is about 90 degrees from the view shown in Figure 3B) of a stem portion of a radial implant according to the present invention.

- [0020] Figure 5 illustrates an isometric view of a stem portion of a radial implant according to the present invention.
- [0021] Figure 6, comprising Figures 6A-6D, illustrates different views of an instrument according to the present invention. Figure 6A is a rear isometric view of an instrument according to the present invention engaging the head and stem portions of a radial implant according to the present invention. Figure 6B is another rear isometric view of an instrument according to the present invention. Figure 6C is a slightly magnified view of the hook and lever mechanisms of an instrument according to the present invention. Figure 6D is a front isometric view of an instrument according to the present invention.
- [0022] Figure 7, comprising Figures 7A and 7B, is an isometric view of an embodiment of a radial implant according to the present invention. In Figure 7A, a front isometric view of engagement of the head and the stem portions of an embodiment of the radial implant is shown. Figure 7B is a rear isometric view of engagement of the head and the stem portions of an embodiment of the radial implant is shown.
- [0023] Figure 8, comprising Figures 8A-8C, illustrates different views of an embodiment of a radial implant according to the present invention. In Figure 8A, a front view of an embodiment of the radial implant is shown. In Figure 8B, a cross sectional view of the radial implant along the cutting plane line A-A identified in Figure 8A is shown. In Figure 8C, DETAIL B, identified in Figure 8B, is shown.
- [0024] Figure 9, comprising Figures 9A-9F, illustrates different views of an embodiment of a head portion of a radial implant according to the present invention. In Figure 9A, a top view of an embodiment of the head portion 12 is shown. In Figure 9B, a side view of an embodiment of the head portion is shown. In Figure 9C, a side view (which is about 90 degrees from the view shown in

Figure 9B) of an embodiment of the head portion is shown. In Figure 9D, a bottom view of an embodiment of the head portion is shown. In Figure 9E, a front isometric view of an embodiment of the head portion is shown. In Figure 9F, a rear isometric view (which is rotated 180 degrees from the view shown in Figure 9E) of an embodiment of the head portion is shown.

[0025] Figure 10, comprising Figures 10A-10C, illustrates different views of an embodiment of a stem portion of a radial implant according to the present invention. In Figure 10A, a top view of an embodiment of the stem portion is shown. In Figure 10B, a side view of an embodiment of the stem portion is shown. In Figure 10C, a side view (that is rotated 90° from the view shown in Figure 10B) of an embodiment of the stem portion is shown.

[0026] Figure 11 illustrates an isometric view of an embodiment of a stem portion of a radial implant according to the present invention.

DETAILED DESCRIPTION

[0027] Listing of Reference Numerals

- 10 radial head implant
- 12 head portion
- 13 proximal surface of head portion
- 14 stem portion
- 15 distal surface of head portion
- 16 first stem portion
- 17 groove
- 18 second stem portion
- 19 collar
- 20 mounting portion
- 21 orientation marker
- 22 recessed channel
- 24 -- end notch

- 25 locking mechanism
- 26 end tab
- 28 arm
- 30 locking tab
- 32 locking tab notch
- 34 mating portion
- 36, 36a female mating dimple of head 12
- 38 instrument
- 40 fixed instrument handle
- 42 movable instrument handle
- 44 sliding lever
- 46 hook mechanism
- 48 male mating portion of lever 44
- 100 first axis
- 101 second axis

[0028] Detailed Description

[0029] The present invention relates to a radial head implant 10 having a head portion 12 and a stem portion 14, head 12 adapted to engage stem 14 through a mounting portion 20. For purposes of this disclosure, and specifically for relative directional references between components of the present invention, head 12 is considered to be proximal to stem 14. Accordingly, stem 14 is considered to be distal to head 12.

[0030] Referring to Figures 1 to 5 and 7 to 11, implant 10 comprises a head 12 and a stem 14. In an embodiment of the invention, head 12 is adapted to articulate with the capitellum of a humerus bone. In an embodiment of the invention, head 12 is substantially rounded in shape.

[0031] Referring to Figures 3 and 4 and 9 and 10, in an embodiment of the present invention, head 12 has a proximal surface 13 that is configured to articulate with the capitellum of a humerus bone.

In an embodiment of the invention, proximal surface 13 includes a substantially concave recess to articulate with the capitellum of a humerus bone. In an embodiment of the invention, head 12 also includes a distal surface 15 that includes a mounting portion 20 adapted to engage stem 14 of implant 10. In an embodiment of the invention, head 12 includes a female mating dimple 36, 36a on either side of head 12, substantially 180 degrees from each other, and along the same axis with mounting portion 20, as more fully discussed below.

In an embodiment of the invention, mounting portion 20 is adapted to engage a recessed 100321 channel 22 of stem 14. In another embodiment, mounting portion 20 of head 12 is adapted to slideably engage recessed channel 22 of stem 14. In an embodiment of the present invention, mounting portion 20 includes a mating portion 34. In an embodiment of the invention, mating portion 34 is adapted to slideably engage recessed channel 22 along a lateral axis that is substantially 90 degrees from the long axis of implant 10. In an embodiment of the invention, as shown in Figure 3C, the right and left side portions of mating portion 34 are integral with distal surface 15 of head 12 at an angle, α . In another embodiment of the invention the angle, α , is equal to or less than 90 degrees. In another embodiment of the invention, as shown in Figure 3C, the angle, α , is preferably less than 90 degrees. In an embodiment of the invention, the angle, α , can be the same or different for the right and left side portions of mating portion 34. In an embodiment of the invention, viewed from the side, as in Figure 4B, the right and left side portions of recessed channel 22 are integral with the proximal side of stem 14 at an angle, β , that is less than or equal to 90 degrees. In another embodiment of the invention, when mating portion 34 and recessed channel 22 are engaged, α and β are substantially equal. In an embodiment of the invention, the angle, β, can be the same or different for the right and left side portions of recessed channel 22. In an embodiment of the invention, the distal side of mating portion 34 is shaped to slideably engage and conform with recessed channel 22.

[0033] In an embodiment of the invention, the mating interaction between recessed channel 22 and mating portion 34 is a dovetail interaction. In an embodiment of the present invention, mounting portion 20 of head 12 comprises a locking mechanism 25, adapted to lockingly engage head 12 with stem 14. In one embodiment of the present invention, locking mechanism 25 comprises an arm 28 and an end tab 26. In an embodiment of the invention, arm 28 is stiff, but slightly flexible or springy. In another embodiment, arm 28 includes a locking tab 30. In an embodiment of the invention, locking tab 30 is adapted to engage a locking tab notch 32 of stem 14.

In another embodiment of the invention, end tab 26 is adapted to engage an end notch 24. In one embodiment, stem 14 includes two end notches 24, (see Figures 1-5). In one embodiment stem 14 includes one end notch 24, (see Figures 7-10). In another embodiment of the invention, when head 12 and stem 14 are fully engaged and locked, end tab 26 engages end notch 24, locking tab 30 engages locking tab notch 32, and head 12 and stem 14 are locked into place.

[0034] Referring to Figures 4, 5, 10 and 11, in an embodiment of the present invention, stem 14 of implant 10 is substantially perpendicular to recessed channel 22. In an embodiment of the invention, stem 14 is substantially the same width from top to bottom. In another embodiment, stem 14 is tapered. In another embodiment of the present invention, stem 14 is curved in shape and is generally arcuate. In an embodiment of the present invention, the configuration of stem 14 is intended to structurally mimic the shape of the medullary canal of a radius bone.

In one embodiment, stem 14 includes a first stem portion 16 and a second stem portion 18, [0035] and a collar 19, which is integral with first stem portion 16. In an embodiment of the invention, collar 19 is positioned to limit insertion of stem 14 into the medullary canal of a radius bone. In another embodiment, the proximal side of collar 19 of stem 14 is integral with recessed channel 22, and at least one end notch 24. In another embodiment, the proximal side of collar 19 includes locking tab notch 32, which, in one embodiment of the invention, is substantially parallel to an end notch 24 along recessed channel 22, and which is adapted to engage locking tab 30 of head 12. In an embodiment of the invention, locking tab notch 32 is located in the center of recessed channel 22. In an embodiment of the invention, collar 19 includes an orientation marker 21, which aids in positioning stem 14 in the medullary canal. In an embodiment of the invention, orientation marker 21 is positioned opposite the biceps tuberosity protrusion. In an embodiment of the invention, recessed channel 22 is positioned along an axis that is substantially parallel to orientation marker 21. In this embodiment, only one end notch 24 is required and head 12 can slideably engage stem 14 from either side; thus this embodiment of implant 10 is useful for both right and left radius bones. In another embodiment, recessed channel 22 is positioned along an axis that is perpendicular to orientation marker 21. This embodiment requires two end notches 24 and will require a right and a left version of implant 10. In another embodiment, collar 19 includes a groove 17, which is adapted to engage an instrument 38 according to the present invention.

[0036] In an embodiment of the present invention, first stem portion 16 extends distally from the distal side of collar 19 substantially along a first axis 100. In another embodiment of the present invention, second stem portion 18 extends distally from first stem portion 16 substantially along a second axis 101. In an embodiment of the present invention, the first axis 100 and the second axis 101 define an angle, θ . In one embodiment, the angle θ ranges from about 0 degrees to about 25 degrees. In another embodiment, the angle θ ranges from about 5 degrees to about 25 degrees. In another embodiment, the angle θ ranges from about 5 degrees to about 15 degrees. In an embodiment of the present invention, the curve of stem 14 that is established by the angle, θ , can be achieved using a radius of curvature that is in a range of from about 0.5 inch to about 3 inches. In another embodiment of the present invention, the curve of stem 14 that is established by the angle, $\theta_{\rm c}$ can be achieved using a radius of curvature that is in a range of from about 0.5 inch to 3 inches or from about 1 inch to about 2.5 inches. In another embodiment, the curve of stem 14 that is established by the angle, θ , can be achieved using a radius of curvature that is in a range of from about 1.5 inches to about 2 inches. In an embodiment of the present invention, recessed channel 22 is positioned along a third axis that is substantially perpendicular to the first axis 100 of stem 14.

[0037] In another embodiment of the present invention, the cross section of stem 14 decreases (for example, as a taper) as it extends distally from head 12. In an embodiment of the invention, the taper of stem 14 facilitates insertion of stem 14 into the medullary canal of the radius bone and aids to anchor implant 10 to the radius bone. In another embodiment, the cross section of stem 14 remains constant as it extends distally from head 12. In an embodiment of the present invention, stem 14 is substantially identical to the stem portion of the radial implant disclosed in U.S. Patent No. 6,709,459, which is herein incorporated by reference in its entirety. In another embodiment, stem 14 is substantially identical to the stem portion of the radial implant disclosed in U.S. Patent No. 6,656,225, which is herein incorporated by reference it its entirety.

[0038] In an embodiment of the invention, stem 14 is cemented, press fit, and/or impacted into the intramedulary canal according to methods known by those skilled in the art. In an embodiment of the invention, a cement, for example, methyl methacrylate, is used.

[0039] In an embodiment of the present invention, radial implant 10 includes a roughened or textured surface on part or all of implant 10 that interacts with the medullary canal of the radius bone to aid in securing stem 14 to the radius bone and to allow for bone ingrowth. In an embodiment of

the present invention, stem 14 may be coated with a material such as titanium, cobalt-chrome beads, or hydroxyapatite.

[0040] In an embodiment of the present invention, radial implant 10 is comprised of any medically acceptable, biocompatible implant material. In one embodiment, radial implant 10 is comprised of cobalt chrome. In one embodiment, the cobalt chrome is highly polished. In another embodiment, radial implant 10 is comprised of titanium. In another embodiment, radial implant 10 is comprised of durable, biocompatible plastic or polymer material. In another embodiment, radial implant 10 is comprised of ceramic material.

[0041] The present invention also relates to an instrument for implanting or removing the lateral radial head implant. Referring to Figure 6, in an embodiment of the invention, instrument 38 includes a fixed handle 40, a movable handle, 42, a sliding lever 44, and a hook mechanism 46. In an embodiment of the invention, sliding lever 44 further includes a male mating portion 48 to engage female mating portion 36, 36a of head 12.

The present invention is also directed to methods for using and implanting radial implant [0042] 10. In an embodiment of the present invention, implant 10 is assembled by engaging head 10 with stem 14. In an embodiment of the invention, recessed channel 22 is adapted to engage head 12 with stem 14. In an embodiment of the present invention, when head 12 engages stem 14, mating portion 34 slides into recessed channel 22 of stem 14. In an embodiment of the invention, mating portion 34 slides into recessed channel 22 of stem 14 by way of a dovetail mating mechanism. In an embodiment of the invention, mating portion 34 slides into recessed channel 22 from either the right or left side of stem 14, depending on which (i.e., the right or the left) radial head is being replaced. In another embodiment of the invention recessed channel 22 includes a single end notch 24 and recessed channel 22 is rotated 90 degrees relative to orientation marker 21. Accordingly, in this embodiment of the invention, when head 12 fully engages stem 14, mating portion 34 slides into position in recessed channel 22, locking tab 30 snaps into notch 32, and end tab 26 engages the single end notch 24 on stem 14. In another embodiment of the invention, recessed channel 22 includes two end notches 24. Accordingly, in this embodiment of the invention, when head 12 fully engages stem 14, mating portion 34 slides into position in recessed channel 22, locking tab 30 snaps into notch 32, and end tab 26 engages one of end notches 24 on stem 14. In an embodiment of the

invention, end notch 24 engages with end tab 26 as mating portion 34 slideably engages recessed channel 22.

[0043] In an embodiment of the invention, the proximal surface of end notch 24 is angled upward such that locking mechanism 25, in particular arm 28, upon engagement of end notch 24, moves to a depressed state as head 12 slides into recessed channel 22. In one embodiment, head 12 slides into recessed channel 22. In another embodiment of the invention, head 12 slides into recessed channel 22 from one end of recessed channel 22. In an embodiment of the invention, when locking tab 30 reaches notch 32, locking tab 30 and arm 28 spring into an extended state and locking tab 30 locks into place at notch 32. In another embodiment of the invention, end tab 26 is angled downward and is adapted to mate with end notch 24 when head 12 and stem 14 are fully engaged.

[0044] In an embodiment of the invention, instrument 38 is used as an insertion tool to aid in inserting stem 14 into the medullary canal of the radius bone. In an embodiment of the invention, hook mechanism 46 engages groove 17 of stem 14. In an embodiment of the invention, stem 14, engaged with instrument 38, is implanted into a patient. In an embodiment of the invention, once stem 14 is implanted, head 12 is implanted by aligning male mating portion 48 of sliding lever 44 with female mating portion 36 of head 12 and applying opposing manual or mechanical pressure to fixed handle 40 and movable handle 42 (i.e., squeezing together) such that male mating portion 48 of sliding lever 44 engages female mating portion 36 of head 12. In an embodiment of the invention, head 12 slideably engages stem 14 until locking tab 32 on head 12 engages notch 30 of stem 14 and locks into place. In another embodiment of the invention, stem 14 is implanted prior to engagement with hook mechanism 44.

[0045] In an embodiment of the present invention, head 12 is adapted to unlock and disengage from stem 14. In an embodiment of the invention, head 12 is disengaged from stem 14 using instrument 38. In an embodiment of the invention, instrument 38 is rotated 180 degrees from its implant position (shown in Figure 6A). In an embodiment of the invention, hook mechanism 44 engages groove 17 of stem 14. In an embodiment of the invention, head 12 is disengaged from stem 14 by aligning male mating portion 48 of sliding lever 44 with female mating portion 36a of head 12 and applying opposing manual or mechanical pressure to fixed handle 40 and movable handle 42 (i.e., squeezing together) such that male mating portion 48 of instrument 38 engages female mating

portion 36a of head 12. In an embodiment of the invention, the pressure to fixed handle 40 and movable handle 42 disengages locking tab 30 from notch 32 and mounting portion 20 of head 12 slides out of recessed channel 22 and off of stem 14. In an embodiment of the invention, the pressure applied to fixed handle 40 and movable handle 42 must be great enough to overcome the normal kinematic forces generally encountered at the elbow joint. In another embodiment of the invention, the pressure applied to fixed handle 40 and movable handle 42 must be great enough to overcome up to twice the normal kinematic forces generally encountered at the elbow joint. In another embodiment of the invention, the pressure applied to fixed handle 40 and movable handle 42 must be great enough to overcome up to five times the normal kinematic forces generally encountered at the elbow joint.

[0046] It should be understood that the invention is not to be limited to the specific conditions or details described herein. Throughout the specification, any and all references to a publicly available document, including but not limited to a U.S. patent, are specifically incorporated by reference.

[0047] It will be apparent to those skilled in the art that various modifications and variations can be made in the methods and compositions of the present invention without departing from the spirit or scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of the present invention provided they come within the scope of the appended claims and their equivalents.

CLAIMS

WHAT IS CLAIMED IS:

 A radial head implant for replacement of a head portion of a radius bone comprising a head, a stem, and a locking mechanism, wherein said head is adapted to engage said stem, and wherein said locking mechanism comprises an arm, a locking tab and an end tab.

- 2. The radial head implant of claim 1, wherein said head is also adapted to disengage said stem.
- The radial head implant of claim 1, wherein said head is adapted to slideably engage said stem.
- 4. The radial head implant of claim 1, wherein said stem has (1) a proximal end and a distal end, (2) a first portion extending distally from said proximal end and substantially along a first axis, and (3) a second portion extending distally from said first portion and substantially along a second axis to said distal end, said first axis and said second axis defining an angle therebetween, said stem being shaped to facilitate insertion of said stem into the medullary canal of the radius hone.
- The radial head implant of claim 4, wherein said angle is from about 0 degrees to about 25 degrees.
- The radial head implant of claim 4, wherein said angle is from about 5 degrees to about 25 degrees.
- 7. The radial head implant of claim 4, wherein a radius of curvature therebetween said first portion and said second portion includes is in a range between about 0.5 inches and about 3 inches.
- 8. The radial head implant of claim 1, wherein said head comprises a surface comprising a highly polished cobalt chrome.
- The radial implant of claim 1, wherein said stem is tapered with a distally decreasing cross section to facilitate insertion of said stem into the medullary canal of the radius bone.
- 10. The radial implant of claim 1, wherein the stem comprises a textured surface.

11. The radial head implant of claim 1, wherein said stem further comprises a collar positioned on a first portion of said stem.

- 12. The radial head implant of claim 4, wherein said stem further comprises a recessed channel adapted to engage said head.
- 13. The radial head implant of claim 12, wherein said recessed channel is positioned along a third axis substantially perpendicular to said first axis of said stem.
- 14. The radial head implant of claim 12, wherein said head comprises a mating portion adapted to engage said recessed channel.
- 15. The radial head implant of claim 14, wherein said recessed channel is adapted to engage said mating portion by way of a dovetail interaction between said mating portion and said recessed channel.
- 16. A radial head implant for replacement of a head portion of a radius bone comprising a head and a stem,

wherein said head comprises a locking mechanism adapted to engage said stem with said head;

wherein, said stem comprises a recessed channel; and

wherein said recessed channel is adapted to engage said locking mechanism.

- 17. An instrument for implanting a radial head implant comprising a head and a stem, said instrument comprising:
 - (a) a hook mechanism;
 - (b) at least two handles;
 - (c) a lever, and
 - (d) a first mating portion,

wherein said hook mechanism is adapted to engage a groove on said stem, and further wherein said first mating portion is adapted to engage a second mating portion on said head of said implant.

18. A method for engaging a head and stem of a radial implant using the instrument of claim 17, said method comprising:

- (a) engaging said hook mechanism with said groove;
- (b) engaging said first mating portion with said second mating portion; and
- (c) applying opposing pressure to said at least two handles,

whereby said head engages said stem.

- 19. The radial head implant of claim 16, wherein said head is adapted to slideably engage said recessed channel of stem.
- 20. The radial head implant of claim 19, wherein said head further comprises a mating portion, wherein said mating portion is adapted to engage said recessed channel by way of a dovetail interaction.



