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Inventor(s)	Kumar; Anup et al.

Reference Devices and Methods of Use For External Fixation Frames

Abstract

A reference assembly connected to a support ring of an external fixation frame. The reference assembly includes a mount device. The mount device includes a mount body, a static member, and a dynamic member. The static member is fixedly secured to and extends from the mount body and is configured to be received within a first hole of the support ring of the external fixation frame. The dynamic member is slidably connected to the mount body and is configured to be received within a second hole of the support ring. The reference assembly also includes a reference device that is connectable to the mount body. The reference device includes reference body and a plurality of reference objects disposed within the reference body. The reference objects are each made from a radiopaque material, and the reference body is made from a radiolucent material.

Inventors: **Kumar; Anup (Gurgaon, IN), Singhal; Soniya (Bareilly, IN), Gupta; Anmol (Bengaluru, IN), Saha; Indrajit (Mumbai, IN), Ali; Rustam (Bokaro Steel City, IN), Bhatia; Purvi (Faridabad, IN), Lehmann; Philippe (Lamboing, CH)**

Applicant: **Stryker European Operations Limited** (CARRIGTWOHILL, IE)

Family ID: **1000008490089**

Assignee: **Stryker European Operations Limited (CARRIGTWOHILL, IE)**

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATIONS [0001] This application claims the benefit of the filing date of U.S. Provisional Patent Application No. 63/552,218, filed Feb. 12, 2024, the disclosure of which is hereby incorporated herein by reference

BACKGROUND

[0002] Various orthopedic procedures, such as bone deformity correction, fracture reduction, limb lengthening, and the like, often require the implementation of an external fixation frame. An external fixation frame is typically positioned over the target limb, secured to underlying bone segments, and incrementally adjusted for manipulation, lengthening, angulation, rotation, and/or translation of the bone segments. Such adjustments need to be made precisely and are often made on a frequent basis (e.g., daily or weekly) during the patient's recovery.

[0003] Radiographic images are often utilized to determine proper placement and orientation of an external fixation frame relative to the bone, to develop a correction plan for future frame adjustments, and to ensure the adjustments being made are adequate. For example, two-dimensional medial-lateral (“M-L”) and anterior-posterior (“A-P”) radiographic images may be obtained to help determine the positioning of various fixation frame components (e.g., support rings) relative to bone segments and relative to each other. From there, a correction plan may be developed instructing the various incremental adjustments that need to be made to the external fixation frame's components to achieve the desired clinical results. However, during this process, many sources of error may be introduced, not least of which being the use of two-dimensional image inputs of indeterminate scale and orientation to obtain precise three-dimensional outputs. Therefore, further improvements are desirable.

BRIEF SUMMARY OF THE DISCLOSURE

[0004] In one aspect of the present disclosure, a reference assembly may be connected to a support ring of an external fixation frame. The reference assembly may include a mount device that may have a mount body, a static member, and a dynamic member. The static member may be fixedly secured to and may extend from the mount body and may be configured to be received within a first hole of the support ring of the external fixation frame. The dynamic member may be slidably connected to the mount body and may be configured to be received within a second hole of the support ring. The reference assembly may also include a reference device that may be connectable to the mount body. The reference device may have a reference body and a plurality of reference objects disposed within the reference body. The reference objects may each be made from a radiopaque material, and the reference body may be made from a radiolucent material.

[0005] Additionally, the reference objects may include a first reference object that may have a first cross-sectional dimension, and a second reference object that may have a second cross-sectional dimension. The first cross-sectional dimension being greater than the second cross-sectional dimension. The reference objects may each be spherical.

[0006] Furthermore, the reference body may include a base and a plurality of reference columns extending from the base. Each reference column may include at least a first reference object and a second reference object. The first reference object may have a larger cross-sectional dimension than the second reference object. The first reference object of each reference column may also be positioned further from the base than the second reference object. Each reference column may further include a third and fourth reference object. The third and fourth reference objects may each have a cross-sectional dimension equal to the cross-sectional dimension of the second reference object. The first, second, third, and fourth reference objects of each reference column may each be spherical. The reference body may include four reference columns, and the reference objects of each reference column may be arranged colinearly. Further, the first reference objects of the reference columns may be coplanar, and the fourth reference objects of the reference columns may also be coplanar. However, the second reference objects of the reference columns may be longitudinally staggered relative to one another.

[0007] In addition, each reference column may include a longitudinal opening and a reference insert removably disposed therein. The reference insert may include the first and second reference objects. The longitudinal opening of each reference column may include a threaded portion, and each reference column may include a threaded portion correspondingly engageable with the threaded portion of the longitudinal opening of the respective reference column.

[0008] Continuing with this aspect, the mount body may include a slot, and the dynamic member may be slidably disposed within the slot. The slot may be at least partially defined by opposing rails, and the dynamic member may include a head having a first head portion, a second head portion, and a circumferential groove disposed between the first head portion and the second head portion. The rails may be disposed within the groove of the head when the dynamic member is received within the slot. Also, the mount body may include a chamfer surface that at least partially defines the slot, and the head may include a corresponding chamfer surface that engages the chamfer surface of the mount body.

[0009] In some examples, the dynamic member may include a threaded shaft. In other examples, the dynamic member may have a first shaft portion, a second shaft portion, and an O-ring disposed between the first shaft portion and the second shaft portion. In further examples, the dynamic member may include a radially expandable shaft. Such radially expandable shaft may include a plurality of legs which may have a first and second configuration. In the first configuration, the plurality of legs may be in a relaxed state, and, in the second configuration, the plurality of legs may be in an expanded state. The radially expandable shaft may include a plunger at least partially disposed within a cavity defined by the plurality of legs. The plunger may be axially moveable from a first position in which the legs may be in the relaxed state to a second position in which the plunger pushes the legs radially outwardly to the expanded state. The plunger may include a threaded shaft, and the dynamic member may include a head threadedly connected to the threaded shaft such that rotating the head in a first direction may move the plunger from the first position to the second position, and rotating the head in a second direction may move the plunger from the second position back to the first position.

[0010] Furthermore, the reference device may include a reference body and a connection member that may extend from the reference body. The connection member may define a recess configured to receive an end of the mount body. The reference assembly may also include a connector that may have a threaded shaft. The connection member may include a through-hole, and the reference body may include a threaded opening. The through-hole and the threaded opening may be configured to receive the threaded shaft of the connector to secure the reference device to the mount device. The recess may be defined at least by a pair of chamfer surfaces of the connection member, and the mount body may include a corresponding pair of chamfer surfaces configured to engage the chamfer surfaces of the connection member. The threaded opening of the mount body may be disposed between the pair of chamfer surfaces thereof.

[0011] In a further aspect of the present disclosure, an external fixation frame may include first and second support rings. The first support ring may have a first inner row of holes and a second outer row of holes. The external fixation frame may also include one or more struts connected to and extending between the first and second support rings. Each strut may have an adjustable length. Additionally, the external fixation frame may include a reference assembly that may include a

mount device and a reference device. The mount device may have a mount body, a static member, and a dynamic member. The static member may be receivable within a hole of the second outer row of holes. The dynamic member may be moveable relative to the mount body and may be receivable within a hole of the first inner row of holes. The reference device may be connectable to the mount body and may have a plurality of reference objects that may each be radiopaque.
[0012] In a further aspect of the present disclosure, an external fixation frame may include first and second support rings. The first support ring may have a first inner row of holes and a second outer row of holes. The external fixation frame may also include one or more struts connected to and extending between the first and second support rings. Each strut may have an adjustable length. Additionally, the external fixation frame may include a reference assembly that may include a mount device and a reference device. The mount device may be connectable to the first inner row of holes and second outer row of holes. The reference device may be connectable to the mount body and may have a plurality of reference columns. Each reference column may have a first reference object and a second reference object. The first reference object may have a cross-sectional dimension greater than that of the second reference object, and the first and second reference objects may be radiopaque.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0013] FIG. **1** is a perspective view of an external fixation system according to an embodiment of the disclosure.
[0014] FIG. **2** is a perspective view of a reference assembly according to an embodiment of the disclosure and mounted to a support ring of the external fixation system of FIG. **1**.
[0015] FIG. **3**A is a perspective view of a reference device of the reference assembly of FIG. **2** according to an embodiment of the present disclosure.
[0016] FIG. **3**B is a transparent perspective view of the reference device of FIG. **3**A.
[0017] FIG. **3**C is another perspective view of the reference device of FIG. **3**A.
[0018] FIG. **3**D is schematic two-dimensional view of a reference object pattern of the reference device of FIG. **3**A.
[0019] FIG. **4**A is perspective view of a connection device of the reference assembly of FIG. **3**A according to an embodiment of the disclosure.
[0020] FIG. **4**B is a cross-sectional view of the connection device of FIG. **4**A taken along a midline of a dynamic member thereof.
[0021] FIG. **5**A is an exploded view of FIG. **2**.
[0022] FIG. **5**B is a partial transparent bottom view of the reference assembly of FIG. **3**A.
[0023] FIG. **5**C is a partial bottom cross-sectional view of the reference assembly of FIG. **3**A taken through a mount body, a fastener, and a connection member of a reference body thereof.
[0024] FIG. **5**D is a partial cross-sectional view of the reference assembly of FIG. **3**A taken through the mount body, the fastener, and the connection member of the reference body and orthogonal to the cross-sectional view of FIG. **5**C.
[0025] FIG. **6**A is a partial perspective view of a connection device according to another embodiment of the disclosure.
[0026] FIG. **6**B is a cross-sectional view of the connection device of FIG. **6**A taken along a midline of a dynamic member thereof.
[0027] FIG. **7** is an elevational view of a connection device according to a further embodiment of the disclosure.
[0028] FIG. **8** is an exemplary configuration of a computing device which may be used to implement aspects of the disclosure.

[0029] FIG. **9** is a flow diagram describing an example of a method that may be used to implement aspects of the disclosure.

DETAILED DESCRIPTION

[0030] FIG. **1** depicts an external fixation frame **10** in an assembled condition according to one aspect of the disclosure. Generally, fixation frame **10** includes a first support ring **20** and a second support ring **30**, with a plurality of adjustable length telescopic struts **40** coupling the first rings **20** to the second ring **30**. Fixation frame **10** may be a hexapod frame such that it includes six telescopic struts **40**, such as the depicted struts **40***a-f*. However, some frames **10** may have less struts **40**, such as four struts **40**, for example.

[0031] First ring **20** may also be referred to as a proximal ring or a reference ring, while second ring **30** may also be referred to as a distal ring or a moving ring. First and second rings **20**, **30** each include an inner edge **21**, **31**, outer edge **23**, **33**, and a ring-diameter which extends between the outer edge **23**, **33** at two locations thereof and through a center axis CA of the ring **20**, **30**. In the depicted example of fixation frame **10**, first ring **20** and second ring **30** have the same ring-diameter. However, in some fixation frame examples, the ring diameters may differ.

[0032] First ring **20** and/or second ring **30** may include a plurality of extension tabs **50**. In the illustrated example, each ring **20** and **30** includes six extension tabs **50** spaced circumferentially around a perimeter thereof and extending radially outwardly from the outer edge **23**, **33**. Although rings **20** and **30** are depicted as having six extension tabs **50**, each ring **20**, **30** may have more or less extension tabs **50** (e.g., three tabs) depending on the particular components of fixation system **10** and/or the ring diameter. In addition to what is described directly below, extension tabs **50** may help increase the cross-sectional area of rings **20**, **30** and thus provide for increased stiffness of rings **20**, **30**.

[0033] With this configuration, each ring **20**, **30** may include a first inner circumferential row of holes **60** and a second outer circumferential row of holes **70**. As illustrated, the second outer circumferential row of holes **70** may include at least a first hole **70***a* and a second hole **70***b* and may only be positioned on the plurality of extension tabs **50** on the rings **20** and **30**. It should be understood that although the second outer circumferential row of holes **70** is shown in FIG. **1** as being positioned solely on extension tabs **50**, top ring **20** and/or bottom ring **30** may contain two complete rows of holes, for example with a completely circular (or nearly completely circular) geometry. The use of extension tabs **50**, compared to two full circumferential rows of holes, may help reduce overall bulk of rings **20**, **30** and also provide for intuitive strut placement for surgical personnel. The completely circular version of rings **20**, **30** with two full (or nearly full) rows of circumferential holes may be particularly suited for relatively small diameter rings, although indentations or other features may be introduced to provide an intuitive interface for strut placement by surgical personnel.

[0034] Further, in the illustrated embodiment, the first and second circumferential rows of holes **60** and **70** may be positioned so that the first row of holes **60** does not align radially with the second row of holes **70**. In other words, first and second row of holes **60**, **70** form hole pairs that may each have a staggered configuration relative to the central axis CA of ring **20**, **30**. For example, a first hole pair comprising a first hole **60***a* of the first row of holes **60** and a second hole **70***a* of the second row of holes **70** may be aligned along an axis A**1** that intersects a first plane P1 containing central axis CA of first ring **20** at an oblique angle Q and at a location offset from central axis CA, as shown in FIG. **1**. For some hole pairs, the oblique angle θ may be 45 degrees, for example. Also, as shown, the first plane P1 may be parallel with a second plane P2 that may be tangent with an apex or mid-point **51** of tab **50**. Thus, the staggered configuration of the first and second rows of holes **60**, **70** may be such that these rows of holes have hole pairs (e.g., a first pair **60***a*, **70***a* and a second pair **60***b*, **70***b*) that define a respective axis pointing away from the central axis CA. However, in some embodiments, at least one hole pair may intersect central axis CA and/or intersect first plane P1 at a perpendicular angle.

[0035] The additional hole options provided by the second row **70** may also be utilized for connecting other components, such as fixation pins (not shown) to couple the rings **20**, **30** to the respective bone fragments/segments. Still further, the staggered configuration of holes between the first and second rows **60**, **70** may also help prevent interference between components attached to nearby holes. For example, a strut **40***a-f* attached to the first hole **70***a* of the second row **70** and a fixation pin, wire, or other fixation member attached to the first hole **60***a* of the first row **60** may not radially interfere with each other because of the staggering. It should also be understood that the size and/or number of tabs **50** may increase or decrease depending on the diameter of the rings **20** and **30**, with greater diameter rings **20** and **30** having larger tabs **50** with more holes **70** compared to smaller diameter rings. For example, the illustrated tabs **50** include six holes **70**, and a smaller ring may include smaller tabs **50** with four holes each, for example. Additionally, larger diameter rings **20**, **30** may have more tabs **50** than smaller diameter rings **20**, **30**. For example, a larger diameter ring **20**, **30** may have six tabs **50**, while a smaller diameter ring **20**, **30** may have three tabs **50**.
[0036] As shown, each strut **40***a-f* may include a threaded portion **42** that may thread into or out of a tube portion **44**, for example by interaction with a quick release mechanism **46**, to decrease or increase the length, respectively, of the telescopic strut **40**. In other embodiments, struts **40***a-f* may include an electric motor (not shown) for automated linear actuation to lengthen or shorten struts **40***a-f*. An example of such motorized struts can be found disclosed in U.S. application Ser. No. 18/160,780, filed Jan. 27, 2023, the disclosure of which is incorporated by reference herein in its entirety.
[0037] Each end of each strut **40***a-f* may be coupled to first ring **20** and second ring **30** via a joint mechanism **80** and secured via a nut **82**. Joint mechanism may be a ball joint, a constrained hinge joint, or a universal joint, as illustrated. The use of universal joints on each end of the strut **40***a-f* provides for six degrees of freedom of motion of the external fixation system **10**. It should be understood that although the disclosure is generally described in the context of closed circular rings, the concepts described herein may apply with equal force to other types of rings, such as open rings and/or U-shaped rings.
[0038] In external fixation system **10**, telescopic struts **40***a-f* may be used to reduce fractures and correct deformities over time. Patients correct the deformities by incrementally adjusting struts **40***a-f* in accordance with a correction plan. In this regard, the lengths of the struts **40***a-f* may be adjusted over time to change the position and orientation of the two rings **20**, **30** with respect to one another, which in turn repositions and reorients the bone fragments, with a goal of correcting the bone deformity. The adjustment of the external fixator **10** should strictly comply with the predetermined correction plan to ensure the desired clinical results are achieved.
[0039] Computational applications exist in which two-dimensional radiographic images of fixation frame **10** mounted on a bone may be utilized to determine the relative position of fixation frame **10** to bone fragments of the bone and to develop a correction plan for adjusting fixation frame **10** over time. An exemplary computational application for planning and optimizing bone correction is disclosed in U.S. Pat. No. 8,654,150 ("the '150 Patent"), the disclosure of which is hereby incorporated by reference herein in its entirety. However, issues may arise at least due to a parallax effect between the 2D radiographic images and the 3D fixation frame. Thus, the scale and perspective of the 2D radiographic images may not be commensurate with the 3D fixation frame **10** resulting in inaccurate measurements. Thus, measurements obtained from these radiographic images may not accurately reflect the 3D positioning of rings **20** and **30** relative to each other and the underlying bone which may result in suboptimal correction plans and undesirable patient outcomes. These potential inaccuracies can be rectified by utilizing a reference device of known scale and 3D coordinates to calibrate the 2D radiographic images and to obtain accurate fixation frame parameters, such as ring offset measurements and relative pose and position of rings **20** and **30** relative to the bone. The following describes exemplary reference assemblies which may be

connected to ring **20** and/or **30**.

[0040] FIGS. **2**-**5**D depict a reference assembly **100** according to an embodiment of the disclosure. Reference assembly **100** generally includes a reference device **110**, a mount device **140**, and a fastener **180**.

[0041] FIGS. **3**A-**3**D depict reference device **110** which generally includes a reference body **112** and a connection member **114** extending from reference body **112**. Reference body or reference array **112**, as depicted, may include a base **120** and a plurality of reference columns **122** extending upwardly or superiorly from base. Each column **122** is interconnected at one end via base **114** and may also be interconnected via struts **124** at another end of columns **122** or somewhere else along their length, as shown in FIG. **3**A. Regardless of where columns **122** are interconnected, such columns are generally in a fixed relationship relative to one another. In this regard, columns **122** may be arranged in a polygonal pattern about a longitudinal axis A1 of reference body **112**. For example, in the embodiment depicted, reference body **122** may have four reference columns **122***a-d* arranged in a square-shaped pattern. As such, a first distance D1 (also referred to as a first width) measured between the first and second columns **122***a*, **122***b* and the third and fourth columns **122***c*, **122***d* may be equal to a distance D2 (also referred to as a second width) measured between the first and fourth columns **122***a*, **122***d* and the second and third columns **122***a*, **122***c*, as shown in FIG. **3**C. Widths D1 and D2 may be 15 mm to 30 mm, for example. More specifically, widths D1 and D2 may be 17.67 mm or 28.28 mm, for example. In other embodiments, widths D1 and D2 may differ such that columns **122***a-d* are arranged in a rectangular pattern. In other embodiments, more or less reference columns **122** may be provided. For example, three reference columns **122** may extend from base **120** and form an equilateral triangle. In another example, five reference columns **122** may be arranged in a pentagon pattern. In either arrangement, columns **122** may form the corners of a polygonal pattern such that the reference columns **122** in the pattern are parallel to one another.

[0042] Also, as shown in FIG. **3**C, each reference column **122***a-d* extends from base **120** a third distance D3 (also referred to as a column length) from base **120**. In this regard, the column length D3 for each column **122***a-d* may be the same. For example, each column **122***a-d* may have a length of 30 mm to 60 mm. More specifically, the column length D3 for each column **122***a-d* may be 36 mm or 56 mm, for example. However, in some embodiments, the column length D3 may differ for each reference column **122***a-d*. In even further embodiments, the length of some of columns **122***a-d* may be equal, while the lengths of other such columns **122***a-d* may differ. For example, first and third columns **122***a*, **122***c* may have the same length while differing from the lengths of the second and fourth columns **122***b*, **122***d*, which themselves may have the same length. The differing lengths may help visually identify each reference column **122***a-d*.

[0043] Each reference column **122***a-d* may include a plurality of reference objects, such as a first reference object **118***a* and a second reference object **118***b*, for example. Reference objects **118***a*, **118***b* may be made from a radiopaque material such that it absorbs X-rays and appears opaque in a radiographic or other medical image. Examples of such radiopaque materials include radiopaque metals (e.g., tantalum, tungsten, stainless steel, and zirconium), radiopaque ceramics (e.g., zirconia and alumina), and/or radiopaque polymers (e.g., polyoxymethylene or POM (aka Delrin® of Delrin USA LLC), barium sulfate and tantalum-loaded polymers). Reference objects **118***a*, **118***b* may alternatively be made from a radiolucent material such as a material that is entirely or partially transparent to radiation and/or mostly entirely or partially transparent in X-ray, fluoroscopy, and other imaging modalities. Examples of radiolucent it materials can include polymers (e.g., polytetrafluoroethylene or PTFE (aka Delrin® of Delrin USA LLC)), plastic, para-aramid synthetic fiber, resins (e.g., polyether imide), carbon fiber or carbon composite, wood, cellulose, and the like. Polymers can include polypropylene, polyethylene, polyether ether ketone, polyaryletherketone, acrylonitrile butadiene styrene, nylon, and the like. Radiolucency of reference objects **118***a*, **118***b* can be adjusted by combining material having varying densities within the reference objects **118***a*, **118***b*. For example, a reference object **118***a*, **118***b* can include a first material with a higher density than a second material of reference object **118***a*, **118***b*. This first material may absorb more radiation and be less radiolucent than the second material, which may have a lower density and may absorb less radiation and be more radiolucent. Reference body **112** may also be made from a radiopaque or radiolucent material as desired. For example, reference objects may be made from stainless steel, while reference body **112** may be made from PTFE or POM.

[0044] As shown in FIGS. **3**B and **3**D, each reference object **118***a*, **118***b* in each reference column **122***a-d* may be in the form of a sphere or bead. However, other shapes are contemplated, such as a cylinder, for example. Each spherical reference object **118***a*, **118***b* in each reference column **122***a-d* may have the same diameter. However, as best shown in FIG. **3**B, first reference object **118***a* may have a larger diameter than second reference object **118***b*. For example, first reference object **118***a* may have a diameter of 4 mm, and second reference object **118***b* may have a diameter of 2 mm. Each reference column **122***a-d* may have a plurality of reference objects **118***a* and/or **118***b*. For example, each reference column **122***a-d* may have four of first reference object **118***a*, four of second reference object **118***b*, or four of any combination of first and second reference objects **118***a*, **118***b*. While four reference objects **118***a*, **118***b* are preferable as they may provide an optimal balance between accuracy and compactness of reference body **112**, each reference column **122***a-d* may have more or less reference objects **118***a*, **118***b* (e.g., three or five of first and/or second reference objects **118***a*, **118***b*). Additionally, it is preferable that one of the four reference objects be the larger diameter first reference object **118***a*, while the remaining three reference objects be the smaller diameter second reference object **118***b*, as illustrated in FIGS. **3**B and **3**D. Although, other configurations are contemplated, such as two of first reference object **118***a* and two of second reference object **118***b*, for example. The size difference between the larger spherical object **118***a* and smaller spherical objects **118***b* may help determine an appropriate scale of a radiographic image containing the reference objects **118***a*, **118***b*. In other words, when a two-dimensional radiographic image of reference columns **122***a-d* is obtained, the scale of the image may not be known. However, knowing the diameters of first and second reference objects **118***a*, **118***b* and their relative size differences can help calibrate the scale of the radiographic image ensuring proper measurement of the other objects within the radiographic image (e.g., bone and fixation frame **10**).

[0045] Reference objects **118***a*, **118***b* are preferably colinearly arranged within their respective column **122***a-d* and at various longitudinal positions. In other words, first reference column **122***a* may have reference object positions A1-D1 distributed along longitudinal axis of column **122***a*, second reference column **122***b* may have reference object positions A2-D2 distributed along a longitudinal axis of second column **122***b*, third reference column **122***c* may have reference object positions A3-D3 distributed along a longitudinal axis of third column **122***c*, and fourth reference column **122***d* may have reference object positions A4-D4 along a longitudinal axis of fourth column **122***d*. It should be noted that the distances between each object position mentioned above is measured center-to-center of the object spheres **118***a*, **118***b* that occupy such positions. As shown in FIG. **3**D, the larger diameter first reference object **118***a* may occupy each of the first positions A1-A4, and second reference objects **118***b* may respectively occupy the remaining positions B1-B4, C1-C4, and D1-D4. Positions A1-A4 may be located furthest from base **120**, positions D1-D4 may be located closest to base **120**, and positions B1-B4 and C1-C4 may be located somewhere in-between. It is preferable that the larger diameter first reference object **118***a* be located at the first position A1-A4 as it may help identify and distinguish each reference column **122***a-d* in a radiographic image from the others. It is, however, contemplated that first reference object **118***a* may be located at the fourth position D1-D4, for example.

[0046] The reference objects **118***a* that occupy first positions A1-A4 may be arranged in the same plane which may be perpendicular to axis A2. In other words, first positions A1-A4 may be coplanar. Similarly, fourth positions D1-D4 may be coplanar. Thus, the respective distances between first positions A1-A4 and fourth positions D1-D4 may be the same. However, in some embodiments, these positions may be staggered between the columns **122***a-d*. Although first positions A1-A4 and fourth positions D1-D4 may be coplanar and equidistant, second positions B1-B4 and third positions C1-C4 may not. In other words, the distances between second positions B1-B4 and first positions A1-A4 may differ from reference column **122***a-d* to reference column **122***a-d* such that second positions B1-B4 are longitudinally staggered from column to column. Similarly, the distances between third positions C1-C4 and first positions A1-A4 may differ from reference column **122***a-d* to reference column **122***a-d* such that third positions C1-C4 are longitudinally staggered from column to column. However, in some embodiments, some of second positions B1-B4 or third positions C1-C4 may be coplanar (see e.g., FIG. **3**D reference columns **116***a* and **116***b*). In such embodiments third positions C1-C4 or second positions B1-B4 should then be staggered so that ultimately each column has a different longitudinal reference object pattern. This is depicted in FIG. **3**D in which, even though B1 and B2 are coplanar, C1 and C2 are staggered.

[0047] The relative and differing distances of reference object positions A1-A4, B1-B4, C1-C4, and D1-D4 for reference columns **122***a-d* may help identify and distinguish each reference column **122***a-d* from the others in a radiographic image which can then help identify the orientation of the image. This may be done mathematically. For example, each column **122***a-d* may have a cross-ratio distinct from the others. The cross-ratio may be defined as follows:

[00001]$\text{CrossRatio} = \frac{AC * BD}{BC * AD}$

[0048] AC is the distance between respective positions A1-A4 and C1-C4, BD is the distance between respective positions B1-B4 and D1-D4, BC is the distance between respective positions B1-B4 and C1-C4, and AD is the distance between respective positions A1-A4 and D1-D4. Thus, as exemplified in the tabulated example below in table **1**, the cross-ratio for each column **122***a-d* may differ which may allow a processor to automatically measure the distances between reference objects **118***a*, **118***b*, using pixel units, for example, and calculate the cross-ratios which may then be cross-referenced with the known cross-ratios of each column **122***a-d* for automatic identification. Locating the larger diameter first reference object **122***a* at the first positions A1-A4 may help the processor identify the first position A1-A4 so that the other positions can be measured therefrom.

TABLE-US-00001 TABLE 1 1.sup.st Column 2.sup.nd Column 3.sup.rd Column 4.sup.th Column (116a) (116b) (116c) (116d) A1B1 = A2B2 = A3B3 = A4B4 = 0.5 units 0.5 units 2.25 units 1.25 units B1C1 = B2C2 = B3C3 = B4C4 = 1 units 2 units 0.375 units 0.5 units C1D1 = C2D2 = C3D3 = C4D4 = 1.5 units 1.5 units 0.375 units 1.25 units A1C1 = A2C2 = A3C3 = A4C4 = 1.5 units 2.5 units 2.625 units 1.75 units B1D1 = B2D2 = B3D3 = B4D4 = 2.5 units 2.5 units 0.75 units 1.75 units A1D1 = A2D2 = A3D3 = A4D4 = 3 units 3 units 3 units 3 units Cross-Ratio = Cross-Ratio = Cross-Ratio = Cross-Ratio = 1.25 1.04 1.75 2.04

[0049] Reference objects **118***a*, **118***b* may be embedded in each reference column **122***a-d* in the desired longitudinal pattern. For example, a radiolucent polymer material forming reference body **112** may be injected molded about each reference object **118***a*, **118***b* in the desired longitudinal arrangement, as described above. However, as shown in FIG. **3**B, each reference column **122***a-d* may be comprised of a longitudinal opening **126** and a reference insert removably **116***a-d* disposed within the respective openings **126**. In this regard, reference body **112** may be made from a radiolucent metal or polymer and machined or otherwise manufactured to have openings **126**. Each reference insert **116***a-d* may include a plurality of transverse openings **117***a*, **117***b* configured to receive the reference objects **118***a*, **118***b* at the desired longitudinal intervals corresponding to the reference object positions A1-A4, B1-B4, C1-C4, and D1-D4, described above. For example, as shown, a fourth reference insert **116***d* may be in the form of a cylinder with a plurality of cylindrical transverse openings **117***a*, **117***b* extending therein at predetermined positions along a length thereof. Spherical reference objects **118***a*, **118***b* may be inserted into the respective transverse openings **117***a*, **117***b* and a curable material, such as an adhesive, or a set screw, for example, may be used to secure the reference objects **118***a*, **118***b* within their respective transverse openings **117***a*, **117***b*. Such transverse openings **117***a*, **117***b* may be configured for the specific reference object **118***a*, **118***b* placed therein. Thus, for example, a larger diameter transverse opening **117***a* corresponding to the larger diameter spherical reference object **118***a* may be formed at one end of the insert **116***d* while smaller diameter transverse openings **117***b* may be formed at other positions along the length of insert **116***d* for smaller diameter spherical reference objects **118***b*. Alternatively, each insert **116***a-d* itself may be injected molded with reference objects **118***a*, **118***b* embedded therein.

[0050] A first end of each reference insert **116***a-d* may include a tool feature configured to engage an insertion tool, such as a driver, and a second end of each insert may be a threaded end **128** for threaded engagement with a corresponding column opening **126** to secure reference inserts **116***a-d* to reference body **112**. Thus, each insert **116***a-d* may be threadedly connected to reference body **112**. However, other connection mechanisms are also contemplated, such as press-fit and snap-fit connection mechanisms, for example. The removable insert configuration depicted allows reference body **112** to be configured with a variety of different reference object patterns, as desirable.

[0051] Connection member **114** may extend from base **120** in a direction opposite reference columns **122***a-d* and may be configured to connect to mount device **140**. In this regard, connection member **114** may define a recess **136** configured to receive at least a portion of mount device **140** and a through-hole **132** in communication with recess **136** for receipt of at least a portion of connector **180**, as best shown in FIGS. **3**A, **5**C, and **5**D. As shown, recess **136** may be defined by a plurality of intersecting walls which engage and help constrain mount device **140** when disposed within recess **136**. In this regard, connection member **114** may include an upper wall **135***a*, a lower wall **135***b*, an end wall **130**, and first and second sidewalls **134***a*, **134***b*, as best shown in FIGS. **5**C and **5**D. Upper wall **135***a* may be comprised by base **120**, and lower wall **135***b* may be comprised by at least a portion of end wall **130**. Sidewalls **134***a*, **134***b* define parallel side surfaces **137***a*, **137***b*, and upper and lower walls **135***a*, **135***b* define opposing upper and lower surfaces **131***a*, **131***b*, as also shown in FIGS. **5**C and **5**D. Further, in the embodiment depicted, first and second chamfer surfaces **139***a*, **139***b* (also referred to as angled surfaces) may be defined by end wall **130** and intersect first and second side surfaces **137***a*, **137***b* of sidewalls **134***a*, **134***b*, as best shown in FIG. **5**C. Through-hole **132** extends through end wall **130** between chamfered surfaces **139***a*, **139***b*, as also shown in FIG. **5**C.

[0052] Recess **136** may also perform an indexing function to help arrange reference columns **122***a-d* in a desired orientation relative to mount device **140** so that, when reference device **110** is mounted to a ring **20**, **30** of fixation frame **10**, reference body **112** is positioned in an optimal orientation for radiographic imaging, as described further below. In this regard, first and second sidewalls **134***a*, **134***b* may be parallel to the first width D1 of reference body **112** extending between first and second columns **122***a*, **122***b* and third and fourth columns **122***c*, **122***d*. Additionally, upper and lower walls **135***a*, **135***b* may extend perpendicular to column length D3 and longitudinal axis A2.

[0053] FIGS. **4**A and **4**B depict a mount device **140** according to an embodiment of the disclosure. Mount device or connection device **140** generally includes a mount body **142** and a dynamic member **144** moveable relative to mount body **140**.

[0054] Mount body or baseplate **142** may be an elongate structure extending along a longitudinal axis A3 from a first end to a second end thereof. The first end may include a planar end surface **155** that may be oriented perpendicular to longitudinal axis A3 and a threaded hole **156** (see FIG. **5**D) extending through end surface **155**. The first end may also have chamfer surfaces **154***a*, **154***b* (also referred to as angled surfaces) that may intersect end surface **155** at an oblique angle. Such chamfer surfaces **154***a*, **154***b* may be optional. Mount body **142** may also have a square or rectangular cross-section such that it has planar and parallel upper and lower surfaces **152***a*, **152***b* and planar and parallel side surfaces **153***a*, **153***b*. Side surfaces **153***a*, **153***b* may intersect first and second chamfer surfaces **154***a*, **154***b*, respectively, while upper and lower surfaces **152***a*, **152***b* may intersect end surface **155** and first and second chamfer surfaces **154***a*, **154***b*, as best shown in FIG. **4**A. While the square or rectangular cross-sectional geometry of mount body **142** is preferable to help orient and constrain reference device **110** when connected thereto, other geometries may be provided. For example, upper and lower surfaces **152***a*, **152***b* and side surfaces **153***a*, **153***b* may be convex or concave and/or may be tapered such that they are not parallel. Additionally, the first end of mount body **142** may not have chamfer surfaces **154***a*, **154***b*, but may instead have one or more indentation or projection (not shown) that may key into or with a corresponding feature in reference device **110** when connected thereto to help constrain such engagement.

[0055] A locating pin or static member **150** may extend downward or inferior from lower surface **152***b* at a location between the first and second end of mount body **142**. Locating pin **150** may define an axis A4 which may be oriented perpendicular to longitudinal axis A3. Locating pin **150** may be immoveable or static relative to mount body **142** and may be configured to be received within a hole **60***a*, **60***b*, **70***a*, **70***b* in ring **20** or **30** of fixation frame **10**. In some embodiments, locating pin **150** may include a stabilizing feature (not shown) to help stabilize locating pin **150** within the respective hole **60***a*, **60***b*, **70***a*, **70***b* to help limit movement of locating pin **150** therein. Such stabilizing feature can include an O-ring or flexible legs for a snap-fit connection, for example.

[0056] The second end of mount body **142** may include a pair of arms **165** and a slot **160** defined between the arms **165**. Arms **165** (also referred to as prongs) may extend in the longitudinal direction and may be arranged parallel to each other and to longitudinal axis A3. Each arm **165** may include an inwardly extending rail **162** that may define an upper shoulder or abutment surface **163***a* and a lower shoulder or abutment surface **163***b*. Mount body **142** may also include a chamfer surface **161** extending along each of arms **165** at an upper side thereof, as best shown in FIG. **4**A. Chamfer surface **161** may intersect upper shoulder **163***a*, as shown in FIG. **4**B, and may also extend in a U-shaped path about slot **160**, as shown in FIG. **4**A. Slot or recess **160** may extend in a longitudinal direction along longitudinal axis A3 and may also extend through upper and lower surfaces **152***a*, **152***b* of mount body **142**. A fastener **164** may be connected to arms **165** and extend across slot **160** which may help retain dynamic member **144** within slot **160**, as discussed further below. However, in some embodiments, mount body **142** may encircle or enclose slot **160**. Arms **165** may be flexible such that fastener **164** can be used to flex arms **165** toward each other to narrow slot **160**, and to flex arms **165** away from each other to widen slot **160**.

[0057] Dynamic member or dynamic pin **144** may include a head **170** and a shaft **172** extending from head **170** along a longitudinal axis A5. As shown in FIG. **4**B, head **170** may include an upper head portion **170***a*, a lower head portion **170***b*, and a circumferential groove extending about axis A5 disposed between upper and lower head portions **170***a*, **170***b*. Upper head portion **170***a* may be constrained from falling through slot **160** by upper abutment surface **163***a* and may include a circumferential chamfer surface **171** correspondingly angled to slidingly engage chamfer surface **161** of mount body **142**. The corresponding chamfers **161** and **171** of mount body **142** and dynamic member **144** may help auto-align dynamic pin **144** within a hole in ring **20**, **30**. Lower head **170***b* portion may form a circumferential collar extending radially outwardly and may constrain head **170** from being lifted out of slot **160** in conjunction with lower abutment surface **163***b*. Circumferential groove **173** may be defined between upper and lower head portions **170***a* **170***b*. Such groove **173** may be configured to receive rails **162** of first and second arms **165**. Thus, when head **170** is received within slot **160**, axis A5 of dynamic member may be parallel to axis A4 of locating pin **150**, and head **170** may be slideable in the longitudinal direction along axis A3 closer to or further away from axis A4 of locating pin **150**. This allows mount device **140** to adapt to rings **20**, **30** of different sizes and/or ring holes **60***a*, **60***b*, **70***a*, **70***b* separated by different distances. Shaft **172** may be a threaded shaft configured to be slidingly received within a hole **60***a*, **60***b*, **70***a*, **70***b* in first or second ring **20**, **30**. A nut, such as nut **82** shown in FIG. **1**, may be threadedly engaged to threaded shaft **172** when disposed within a hole **60***a*, **60***b*, **70***a*, **70***b* in first or second ring **20**, **30** to secure dynamic member **144** member to ring **20**, **30**.

[0058] Fastener or connector **180** generally includes a head **181** and a shaft **182**. Head **181** may be a thumb knob that allows for manual operation. However, in some embodiments, head **181** may have a tool feature for engagement with a driver or wrench, for example. Shaft **182** may include a threaded end **183** (see FIG. **5**D) such that a portion of shaft **182** is unthreaded and another portion is threaded. However, shaft **182** may be threaded along a majority or entirety of its length.

[0059] FIGS. **5**A-**5**D depict the connection of reference assembly **100** to first ring **20** of fixation frame **10**. It should be understood though that such connection may also be applicable to second ring **20**. As shown, mount device **140** may be mounted or connected to first ring **20** by inserting locating pin **150** and dynamic member **144** into respective holes of the staggered rows **60**, **70** of ring **20**. More specifically, in the embodiment depicted, locating pin **150** may be inserted into a first hole **70***a* of second row of holes **70**, and dynamic member **144** may be inserted into a first hole **60***a* in first row of holes **60**, as shown in FIG. **5**A. As the dynamic member **144** and locating pin **156** are inserted into their respective holes **60***a*, **70***a*, dynamic member **144** may be moved longitudinally within slot **160** as necessary to ensure that shaft **172** of dynamic member **144** is properly aligned with first hole **60***a*. In this regard, reference assembly **100** is adapted to hole pairs of differing distances. It should be noted that, in this configuration of mount device **140** with respect to ring **20**, when reference device **110** is connected to mount device **140**, reference body **112** is positioned outside of the ring diameter of ring **20** rather than inside the ring diameter, as illustrated in FIGS. **2** and **5**A. This is preferable as the patient's limb is located within ring **20** and may obstruct reference assembly **100**. However, it is contemplated that locating pin **150** may be inserted into a hole in the inner ring of holes **60** (e.g., first or second hole **60**, **60***b*) and the dynamic member **144** may be inserted into a hole in the outer ring of holes **70** (e.g., first or second hole **70***a*, **70***b*) so that reference device **110** ends up positioned within the diameter of ring **20** when connected to mount device **140**. Nonetheless, once dynamic pin **144** is positioned within its corresponding hole, a nut, like nut **82** of FIG. **1**, may be threaded onto threaded shaft **172** to secure dynamic member **144** and mount body **142** to ring **20**. Chamfer surfaces **161**, **171** of mount body **142** and dynamic member head **170** may engage each other as the nut is tightened which may help auto-align threaded shaft **172** with the hole so that shaft **172** is coaxial with hole and so that axes A4 and A5 are parallel.

[0060] After mount device **140** is mounted to ring **20** or prior to mounting mount device **140** to ring **20**, reference device **110** is connected to the first end of mount body **142.** In this regard, the first end of mount body **142** may be inserted into recess **136** of connection member **114** of reference device **112** so that reference columns **122***a-d* extend upwardly therefrom. However, it is contemplated that reference device **110** may be connected to mount body **142** so that reference columns **122***a-d* extend downwardly. As the first end of mount body **142** is inserted into recess **136** of connection member **114**, upper surface **152***a* of mount body **142** engages upper surface **131***a* of connection member **114**, lower surface **152***b* of mount body **142** engages lower surface **131***b* of connection member **114**, side surfaces **153***a*, **153***b* of mount body **142** engage side surfaces **137***a*, **137***b* of connection member **114**, chamfer surfaces **154***a*, **154***b* of mount body **142** engage chamfer surfaces **139***a*, **139***b* of connection member **114**, and threaded opening **156** of mount body **142** is aligned with through-hole **132** of connection member **114**, as best shown in FIGS. **5B-5D**. Thereafter, threaded end **183** of connector **180** is inserted through through-hole **132** and into threaded engagement with threaded hole **156** of mount body **142** which draws mount body **142** into further engagement with chamfer surfaces **139***a*, **139***b* of connection member **114**.

[0061] This collection of surface engagement helps constrain reference device **110** from all rotational degrees of freedom relative to mount body **142** and indexes reference body **112** into a desired orientation relative to ring **20**. As mentioned above, first and second rows of holes **60**, **70** may have a staggered arrangement. Thus, when mount device **140** is connected to hole pairs of first and second rows **60**, **70**, the longitudinal axis A3 of mount body **142** may extend at the angle θ relative to plane P1. This may have the effect of rotating or orienting reference body **112** so that in a M-L plane and/or in an A-P plane, at least three reference columns are presented (one column may be obscured by another). This is preferable over an orientation in which only two columns **122** of columns **122***a-d* are presented in the A-P and/or M-L planes (two columns **122** may be obscured by the other columns **122**) which could occur if mount body **142** were to be positioned on ring **20** so that axis A3 intersects central axis CA perpendicular to plane P1. As such, it is preferable for reference body **112** to be oriented relative to ring so that A-P and M-L radiographic images thereof include at least three visible reference columns **122** of the four reference columns **122***a-d*. Thus, while the depicted embodiment is shown connected to first holes **60***a*, **70***a* of first and second rows of holes **60**, **70**, it should be understood that other hole pairs (e.g., holes **60***b* and **70***b*) may be selected depending on availability (other hole pairs may be occupied with other devices) provided that at least three reference columns **122** are apparent in the desired radiographic images. Additionally, the connection between mount body **142** and reference device **110** is such that longitudinal axis A2 of reference body **112** is parallel with central axis CA of ring.

[0062] FIGS. **6**A and **6**B depict a mount device **240** according to another embodiment of the disclosure. Mount device **240** is similar to mount device **140**. Thus, for ease of review, like elements are accorded like reference numerals to that of mount device **140** but within the 200-series of numbers. For instance, mount device **240** includes a mount body **242**, locating pin **250**, and a dynamic member **244**. However, mount body **242** and dynamic member **244** may differ from mount body **142** and dynamic member **144**, as described below.

[0063] Dynamic member **244** generally includes a head **270** and an expandable shaft **272** extending from head **270**. Head **270** may be a thumb knob such that it may be operated manually. Alternatively, or in addition to, head **270** may include a tool feature for engagement with a corresponding tool, such as a driver or a wrench. For example, an exterior of head **270** may include a plurality of angled surfaces (not shown) for engagement with a wrench. Head **270** may include a threaded hole **275** extending entirely therethrough or at least partially therein. A lower end or inferior end of head **270** may include a circumferential chamfer surface **271** configured to engage superior chamfer surface **261** of mount body **242** to help auto-align dynamic member **244** to a hole in ring **20** or **30**, as described above with respect to mount device **140**.

[0064] Expandable shaft **272** may include an outer member **280** and an inner member **290**. Inner member **290** may be moveable relative to outer member **280** such that movement of inner member **290** radially expands or radially contracts outer member **280**. As shown, outer member or sleeve **280** may include a sleeve body **282** and a plurality of legs **287** extending downwardly or inferiorly relative to sleeve body **282**. Outer member **280** may include two legs **287**, for example. However, in some embodiments more than two legs **287** may be provided, such as three legs **287**, for example. Legs **287** may be cantilevered to sleeve body **282** and may be flexible such that they are radially moveable from a relaxed position, as shown in FIG. **6**B, to a flexed position in which legs **287** are positioned radially outwardly from the relaxed position. Thus, legs **287** may be biased toward the relaxed position. Legs **287** may each include an inner surface **286** that may taper or be angled radially outwardly from a superior to inferior direction, as best shown in FIG. **6**B. Thus, such inner surfaces **286** of legs **287** may at least partially define a cavity **281** that has a larger cross-sectional dimension at an inferior end of legs **287** (i.e., free end of legs **287**) than at a superior end of legs **287** (i.e., end of legs **287** connected to sleeve body **282**). Sleeve body **282** may include a circumferential chamfer surface **284** at an upper end or superior end thereof. Such chamfer surface **284** may be configured to engage an inferior chamfer surface **273** of mount body **242**, as shown in FIG. **6**B. Such corresponding chamfer surfaces **273**, **284** may further assist in auto-alignment of dynamic member **244**.

[0065] Inner member or plunger **290** may include a plunger body **294** and a threaded shaft **292** extending from plunger body **294**. Plunger shaft **292** may be a threaded shaft that may extend through slot **260** of mount body **242** and threadedly engage threaded hole **275** of head **270**. Plunger body **294** may be disposed within cavity **281** of outer member **280** and may include a tapered outer surface **296** that may be correspondingly tapered with respect to inner surfaces **286** of legs **287** such that outer surface **296** of plunger body **294** tapers radially outwardly from a superior to inferior direction. A foot or guide projection **298** may extend radially outwardly from plunger body **294** and may be slidably disposed within a window or slot **283** of outer member **280** so as to help translationally guide plunger **290** and prevent its rotation relative to outer member **280**.

[0066] In operation, dynamic member **244** may slide within slot **260** to help align itself to a hole in ring **20**, **30**, as described above with respect to dynamic member **144**. Once dynamic member **244** is positioned within its respective ring hole, head **270** may be rotated in a first direction which may cause plunger body **294** to move upwardly within cavity **281** which may concurrently cause outer surface **296** of plunger body **294** to push on inner surfaces **286** of legs **287** thereby pushing legs **287** radially outwardly into engagement with ring **20**, **30**. Dynamic member **244** can then be removed by rotating head **270** in a second direction which may drive plunger body **294** downwardly allowing legs **297** to move radially inwardly to their relaxed state. In other words, expandable shaft **272** may have a first configuration and second configuration. In the first configuration, plunger body **294** may be positioned at an inferior end of cavity **281** such that legs **287** may be in their relaxed state. In the second configuration, plunger **294** may be positioned near a superior end of cavity **281** such that plunger body **294** may push against legs **287** radially outwardly to their flexed and expanded state. In the first configuration, expandable shaft **272** may be easily slid into and out of a hole of ring **20** or **30**. In the second configuration, expandable shaft **272** via legs **287** may bear against ring **20**, **30** to secure and stabilize expandable shaft **272** thereto. Although the embodiment depicted illustrates an example in which plunger **290** moves superiorly to expand legs **287** radially outwardly, it is contemplated that inner surfaces **286** of legs **287** and outer surface **296** of plunger body **294** may be oppositely configured such that driving plunger body **294** inferiorly or downwardly expands legs **287**. A compression spring **285** may be positioned between outer member **280** and plunger body **294** to help stabilize plunger body **294** as it is moved from the first configuration to the second configuration and to help provide tactile feedback and to assist moving plunger body **294** back to the first configuration.

[0067] FIG. **7** depicts a mount device **340** according to a further embodiment of the disclosure. Mount device **340** is similar to mount device **140**. Thus, for ease of review, like elements are accorded like reference numbers to that of mount device **140** but within the **300**-series of numbers. For instance, mount device **340** includes a mount body **342** and a dynamic member **344**. However, dynamic member **344** may differ from dynamic member **144**, as described below.

[0068] Dynamic member **344** generally includes a head **370** and a shaft **372**. Head **370** is similar to head **170** in that it includes a first head portion **370***a* and second head portion **370***b* configured to slide along opposing rails **362** of mount body **342**. Additionally, mount body **342** is similar to mount body **142** in that it includes a chamfer surface **371** and rails **362** that define upper and lower abutment surfaces **363***a*, **363***b*. However, shaft **372** differs from shaft **172** in that it may include a first shaft portion or upper portion **377***a*, a second shaft portion or lower portion **377***b*, and an O-ring **379** positioned within a circumferential groove between first portion **377***a* and second portion **377***b*. In the embodiment depicted, first portion **377***a* and second portion **377***b* are fixed relative to each other, and O-ring **379** has a diameter slightly greater than that of first and second shaft portions **377***a*, **377***b*. Thus, in operation, when shaft **372** is pushed into a hole in ring **20** or **30** of fixation frame **10**, O-ring **379** engages such hole and helps stabilize shaft **372** from movement therein via friction between O-ring **379** and ring **20**, **30**.

[0069] However, in other embodiments, second portion **377***b* may be moveable relative to first portion **377***a*, such as via a threaded member (not shown) extending through head **370** and first portion **377***a* to second portion **377***b*. In this regard, operating the threaded member may cause the second portion **377***b* to move toward first portion **377***a* to compress and outwardly expand O-ring **379**. Thus, in such embodiment, when shaft **372** is initially positioned within a hole in first or second ring **20**, **30**, shaft **372** may have some play within the hole which can be reduced or eliminated by moving second portion **377***b* relative to first portion **377***a* to selectively expand O-ring **379**.

[0070] FIG. **8** depicts an exemplary computing device **400** that may be utilized to implement aspects of the present disclosure. Computing device **400** may include one or more processors **410**, memory **420**, one or more input/output "I/O" devices **430**, and other components typically present in general purpose computing devices. The processor(s) **410** can be any conventional processor, such as a commercially available CPU. Alternatively, the processor **410** can be a dedicated component such as an application specific integrated circuit ("ASIC") or other hardware-based processor. Memory **420** can store information accessible by processor **410**, including instructions **422** that can be executed by processor **410**. Memory **420** can also include data **424** that can be retrieved, manipulated, or stored by processor **410**. Memory **420** can be of any non-transitory type capable of storing information accessible by processor **410**, such as a hard-drive, memory card, ROM, RAM, write-capable, and read-only memories. Instructions **422** can be any set of instructions to be executed directly, such as machine code, or indirectly, such as scripts, by processor **410**. In that regard, the terms "instructions," "application," "steps," and "programs" can be used interchangeably herein. The one or more I/O devices **430** can include user input devices (e.g., a mouse, keyboard, or touch screen) and one or more displays (e.g., monitor having a screen, a touch-screen, a projector, or other device that is operable to display information).

[0071] FIG. **9** depicts a method of obtaining fixation frame parameters for assessing position relative to bone and for generating a correction plan. The methods described herein may be implemented at least partially by a computational application of computing device **400**. Such computational application may be a modified version of the aforementioned computational application of the '150 Patent, for example, to perform the methods described herein.

[0072] At block **450**, reference assembly **100** may be connected to ring **20** of fixation frame **10**, as described in more detail above. In some embodiments, reference assembly **100** could also be connected to ring **30**. In even further embodiments, a first reference assembly **100** may be connected to first ring **20**, and a second reference assembly connected to ring **30**.

[0073] At block **451**, an M-L and/or A-P radiographic image of fixation frame **10**, reference assembly **100**, and the underlying bone may be obtained and uploaded to the computational application. As described in more detail above, the orientation of reference body **112** may be such that at least three reference columns **122***a-d* are presented in one or both of these planes.

[0074] At block **452**, processor **410** may detect reference objects **118***a*, **118***b* within the radiographic image and may determine their dimensions and 2D coordinates within the radiographic image with a distinction between the larger first reference objects **118***a* and smaller second reference objects **118***b*. Such dimensions and coordinates may be measured in pixel units. The detection of reference objects **118***a*, **118***b* in the radiographic image may include using an edge detection algorithm, such as Canny edge detection, for example. Additional image processing may be performed thereafter. For example, a Ramer-Douglas-Peucker algorithm may be utilized to help contour the items captured in the radiographic image. Once the requisite image pre-processing has been performed and the boundaries of the reference objects **118***a*, **118***b* identified, radius dimensions of each detected reference object and the 2D coordinates thereof may be determined by processor **410**.

[0075] Blocks **453** and **454** represent a correspondence algorithm in which each detectable reference column **122***a-d* is first identified and verified for further use in the method. In this regard, processor **410** may find a first reference object, preferably the large reference object **118***a*, in a column **122** and fit a line to identify each set of colinear reference objects **118***a*, **118***b*. The coordinates of the larger first reference objects **118***a*, as determined in block **452**, may assist in helping to define the first point in the colinear columns **122***a-d* via which the remaining reference objects **118***b* may be identified. Once an initial estimate of the reference objects **118***a*, **118***b* included in each detectable reference column **122***a-d* is made by processor **410**, the collinearity of reference objects **118***a*, **118***b* may be assessed using the cross-product of the reference object positions A1-A4, B1-B4, C1-C4, D1-D4 to verify that the reference objects **118***a*, **118***b* estimated for each reference column **122***a-d* are indeed a part of that reference column. If the cross-product is less than a threshold value, such as 0.05, for example, then further verification is performed. If the threshold value is exceeded, then the reference objects identified do not have the requisite co-linearity. As such, processor **410** may select other reference objects **118***a*, **118***b* for co-linear assessment or another radiographic image may be utilized. Should the cross-product be less than the threshold value, then the cross-ratios of the respective co-linear columns **122***a-d* are computed, as described in more detail above. If the computed cross-ratios are close to the actual cross-ratios for reference objects **118***a*, **118***b* of each respective reference column **122***a-d*, then the reference columns **122***a-d* in the radiographic image have been verified for collinearity, distinctness, and for accuracy so that they may then be used to establish correspondence between the 2D coordinates of the image and the 3D coordinates of reference device **110** and the other items in the radiographic image, such as fixation frame **10**.

[0076] As mentioned above, the first reference object **118***a* in each column **122***a-d* may be larger in cross-sectional dimension than the other reference objects **118***b*. This helps ensure the cross-ratio for any given column **122***a-d* is computed in the appropriate order for further analysis. For example, consider four reference objects **118** in a sequence A, B, C, and D which has a known cross-ratio. If processor **410** were to identify the reference objects A-D out of order (e.g., in the order of D, C, B, and A) and compute the cross-ratio accordingly, then the out-of-order cross-ratio would not match that of the reference objects **118** in the proper sequence. Locating the larger reference object **118***a* at a known location within a reference column **122***a-d*, preferably at one of the end positions, helps reduce error and provides a mode of self-verification. This also helps reduce computation and matching across the potential different ratio combinations to find the right match on a particular column **122**. Moreover, the relative sizes of the reference objects **118***a* and **118***b* may be used to scale the radiographic image upon initial detection by processor **410** so as to help in computing the distances in the image. This may be done by computing the pixel to mm (or other unit of measurement) ratio.

[0077] Thus, processor **410** may find the first and largest reference objects **118***a* in the radiographic image, scale the image, and fit a line to each reference object **118***a* to identify respective columns **122***a-d*. Using the reference objects **118***a*, **118***b* on the line, the cross-ratio for each column **112***a-dd* may be computed in a sequence starting from the largest reference object **118***a*. The cross-ratios of the columns **122***a-d* in the radiographic image may then be matched to the known cross-ratios of the reference columns **122***a-d* of reference device **110** to uniquely identify each reference column **122***a-d*. This may assist with further computations, such as a pose computation, as correspondence between the radiographic image and the 3D reference object may be needed to perform the computation. It is also contemplated that shadows in the radiographic image may provide additional information about the relative positions of reference objects **118***a*, **118***b*, aiding in the accuracy of calibration. This may involve examining variations in shadow positions and shapes, and hence, can be used to further refine orientation and translation parameters.

[0078] Once the reference columns **112***a-d* have been verified for collinearity, distinctness, and for accuracy, they may then be used to establish correspondence between the 2D coordinates of the image and the 3D coordinates of reference device **110** and the other items in the radiographic image, such as fixation frame **10**. In this regard, 3D coordinates for the reference objects **118***a*, **118***b* within reference device **110** should be known. Additionally, the coordinates of such reference objects **118***a*, **118***b* should be known relative to ring **20**, the dimensions of which may also be known. Thus, the 3D coordinates for reference assembly **110**, fixation frame **10**, and bone may be mapped to the 2D radiographic image based on the above assessment of reference device **110**.

[0079] At block **456**, once the correspondence between 3D and 2D coordinates is established, pose estimations may be determined, and pose transformations on the 2D image may be performed. This

may be achieved by applying a machine vision or camera calibration algorithm, such as the Tsai-Lenz calibration algorithm. Such algorithm may be used to determine a translational vector and rotation matrix that may be applied to image to effectively rotate and translate the radiographic image to take into account distortions and/or errors that may arise due to the perspective at which the radiographic image is taken of the 3D fixation frame **10**, reference device **110**, and bone.
[0080] At block **457**, processor **410** may then estimate fixation frame parameters in terms of relative pose and position of rings **20** and **30** with respect to the bone and predefined anatomical features thereof. In this regard, processor **410** may make certain predefined measurements, such as ring offset measurements. Such measurements may then be used by processor **410** to generate a correction plan, as described in further detail in the aforementioned '150 Patent.
[0081] Although the subject matter disclosed herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications exemplified by such embodiments. It is therefore to be understood that numerous modifications may be made to the exemplary embodiments and that other arrangements may be devised such as combining one or more features of one embodiment with another embodiment or features from a plurality of embodiments, as an example. Thus, the exemplary embodiments herein are not intended to be exhaustive or to limit the disclosed subject matter to those embodiments disclosed.

Claims

1. A reference assembly connectable to a support ring of an external fixation frame, comprising: a mount device having a mount body, a static member, and a dynamic member, the static member being fixedly secured to and extending from the mount body and being configured to be received within a first hole of the support ring of the external fixation frame, the dynamic member being slidably connected to the mount body and being configured to be received within a second hole of the support ring; and a reference device connectable to the mount body, the reference device having a reference body and a plurality of reference objects disposed within the reference body, the reference objects each being made from a radiopaque material, and the reference body being made from a radiolucent material.
2. The reference assembly of claim 1, wherein the reference objects include a first reference object having a first cross-sectional dimension, and a second reference object having a second cross-sectional dimension, the first cross-sectional dimension being greater than the second cross-sectional dimension.
3. The reference assembly of claim 2, wherein the reference objects are each spherical.
4. The reference assembly of claim 1, wherein the reference body includes a base and a plurality of reference columns extending from the base, each reference column including at least a first reference object and a second reference object, the first reference object having a larger cross-sectional dimension than the second reference object.
5. The reference assembly of claim 4, wherein the first reference object of each reference column is positioned further from the base than the second reference object.
6. The reference assembly of claim 5, wherein each reference column includes a third and fourth reference object, the third and fourth reference objects each having a cross-sectional dimension equal to the cross-sectional dimension of the second reference object.
7. The reference assembly of claim 6, wherein the first, second, third, and fourth reference objects of each reference column are spherical.
8. The reference assembly of claim 6, wherein the reference body includes four reference columns.
9. The reference assembly of claim 8, wherein the reference objects of each reference column are arranged colinearly.
10. The reference assembly of claim 6, wherein the first reference objects of the reference columns

are coplanar.

11. The reference assembly of claim 10, wherein the fourth reference objects of the reference columns are coplanar.

12. The reference assembly of claim 11, wherein the second reference objects of the reference columns are longitudinally staggered relative to one another.

13. The reference assembly of claim 4, wherein each reference column includes a longitudinal opening and a reference insert removably disposed therein, the reference insert including the first and second reference objects.

14. The reference assembly of claim 13, wherein the longitudinal opening of each reference column includes a threaded portion, and each reference column includes a threaded portion correspondingly engageable with the threaded portion of the longitudinal opening of the respective reference column.

15. The reference assembly of claim 1, wherein the mount body includes a slot, and the dynamic member is slidably disposed within the slot.

16. The reference assembly of claim 15, wherein the slot is at least partially defined by opposing rails, and the dynamic member includes a head having a first head portion, a second head portion, and a circumferential groove disposed between the first head portion and the second head portion, the rails being disposed within the groove of the head when the dynamic member is received within the slot.

17. The reference assembly of claim 16, wherein the mount body includes a chamfer surface at least partially defining the slot, and the head includes a corresponding chamfer surface engaging the chamfer surface of the mount body.

18. The reference assembly of claim 15, wherein the dynamic member includes a threaded shaft.

19. An external fixation frame, comprising: first and second support rings, the first support ring having a first inner row of holes and a second outer row of holes; one or more struts connected to and extending between the first and second support rings, each strut having an adjustable length; and a reference assembly having a mount device and a reference device, the mount device having a mount body, a static member, and a dynamic member, the static member being receivable within a hole of the second outer row of holes, the dynamic member being moveable relative to the mount body and being receivable within a hole of the first inner row of holes, and the reference device being connectable to the mount body and having a plurality of reference objects each being radiopaque.

20. An external fixation frame, comprising: first and second support rings, the first support ring having a first inner row of holes and a second outer row of holes; one or more struts connected to and extending between the first and second support rings, each strut having an adjustable length; and a reference assembly having a mount device and a reference device, the mount device being connectable to the first inner row of holes and second outer row of holes, the reference device being connectable to the mount body and having a plurality of reference columns, each reference column having a first reference object and a second reference object, the first reference object having a cross-sectional dimension greater than that of the second reference object, and the first and second reference objects being radiopaque.