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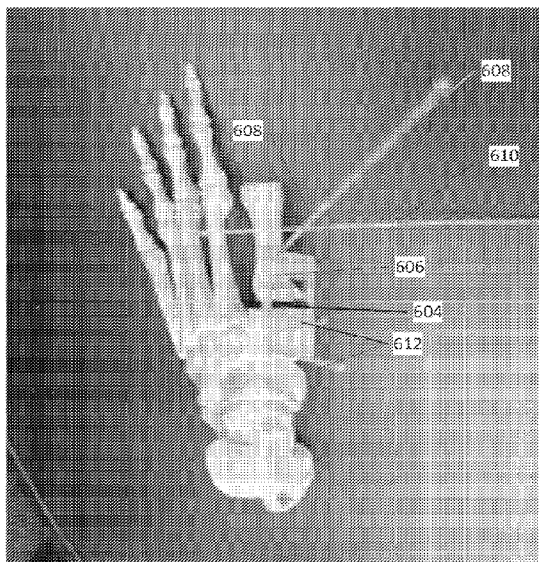


FIG. 6B

(57) Abstract: Disclosed herein is a system and method for providing a surgical appliance and, optionally, one or more fixation devices to assist in the performance of bunion correction surgery. The appliance and fixation devices are custom fabricated to fit a particular patient's physiology based on a model derived from imaging of the foot.



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## SYSTEM AND METHOD FOR PATIENT-SPECIFIC PLANNED BUNION CORRECTION

### **Related Applications**

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/391, 831, filed July 25, 2022, entitled “System and Method for Patient-Specific Planned Bunion Correction”, the contents of which are incorporated herein in their entirety.

### **Field of the Disclosure**

[0002] The present disclosure relates generally to the field of orthopedic surgical procedures and, more particularly, to orthopedic devices and implants used in bunion corrective surgery.

### **Background**

[0003] A bunion (hallux valgus) is a bony bump that forms on the joint at the base of the big toe. It occurs when the first metatarsal bone becomes displaced in one or more dimensions, causing the big toe to get pulled toward the smaller toes and forcing the joint between the hallux bone and the first metatarsal bone to be displaced laterally to form a protruding bump on the side of the foot.

[0004] Over time, the foot bones are squeezed into an unnatural formation, causing damaged anatomy that can result in unsightly disfigurement and pain that can range from a mild annoyance to serious discomfort. In some

cases, the bunion can lead to disability and the lack of ability to perform activities of daily living. Bunions can get worse as the patient ages. If left untreated, a bunion can cause arthritis or may cause the cartilage in the joint to deteriorate.

[0005] **FIG. 1** shows the right foot of a patient exhibiting a bunion. The bunion is characterized, in this case, by a 14° mechanical intertarsal angle (mIMA) 102, which is the angle between the first metatarsal 102 and the second metatarsal 108. The normal range for the mIMA is between 6° and 12°. In addition, the bunion is further characterized by a 35° hallux abductus angle (HAA) 104, which is an offset angle of the hallux bone 104 from a line running longitudinally through the first metatarsal 102. The normal range for the HAA is between 4° and 12°.

[0006] Bunion surgery may be performed to reduce the pain and correct the deformity caused by a bunion. The corrective surgery for bunion is known as a metatarsal osteotomy or bunionectomy and may involve cutting the bones and repositioning them with metal screws to straighten the big toe and reduce the bump on the side of the foot.

[0007] The corrective surgery may include a series of cuts made to the bones (and/or soft tissue) at the tarsometatarsal joint between the tarsal 106 and the first metatarsal 102 and/or at the metatarsophalangeal joint between the first metatarsal 102 and the hallux 104. In some instances, only one or the other of the cuts may be needed. Once the cuts at the joints are made, the bones are shifted into alignment, such that the mIMA and the HAA are within acceptable ranges, and the bones are thereafter

fixed in place with a fixation device, which may most commonly be screws or clamps between the adjacent bones held in place by screws.

[0008] One deficiency with the current state-of-the-art corrective surgery is the lack of a guide to guide the cutting of the bones, or the availability only of a generic guide based on anatomy samples from a large population of patients. Therefore, would be desirable, and the surgical outcome could be improved, if a customize guide and/or fixation devices could be provided which have been custom designed and fabricated based on the physiology of each particular patient.

#### **Summary of the Disclosure**

[0009] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended as an aid in determining the scope of the claimed subject matter.

[0010] In a first example, a method for fabricating a surgical appliance for performing bunion corrective surgery includes collecting imagery of a foot exhibiting the bunion anomaly, deriving a model of the foot based on the imagery and fabricating the appliance to custom fit the foot.

[0011] In the first example, or any other example disclosed therein, the method further includes creating a surgical plan using the model, the surgical plan including identifying areas of one or more bones that need to be removed

and identifying areas of connection on the one or more bones for the appliance, wherein the fabrication of the appliance is further based on the surgical plan.

[0012] In the first example, or any other example disclosed therein, the method further includes wherein the appliance covers the tarsometatarsal joint and further wherein the one or more bones include a medial cuneiform and a first metatarsal.

[0013] In the first example, or any other example disclosed therein, the method further includes wherein the appliance covers the metatarsophalangeal joint and further wherein the one or more bones include a first metatarsal and a hallux.

[0014] In the first example, or any other example disclosed therein, the method further includes wherein the appliance covers a tarsometatarsal joint and a metatarsophalangeal joint.

[0015] In the first example, or any other example disclosed therein, the method further includes wherein the imagery includes one or more x-rays.

[0016] In the first example, or any other example disclosed therein, the method further includes wherein the one or more x-rays are multi-planar, non-orthogonal x-rays.

[0017] In the first example, or any other example disclosed therein, the method further includes wherein the model of the foot is derived by denoting differences between the foot shown in the one or more x-rays and a statistical model of a foot.

[0018] In the first example, or any other example disclosed therein, the method further includes wherein the statistical model of the foot is an Atlas model.

[0019] In the first example, or any other example disclosed therein, the method further includes identifying areas of connection on the one or more bones for one or more fixation devices and fabricating the one or more fixation devices to custom fit the physiology of the foot.

[0020] In the first example, or any other example disclosed therein, the method further including wherein the cutting guide is composed of a hard or semi flexible plastic.

[0021] In the first example, or any other example disclosed therein, the method further includes wherein the cutting guide is manufactured using an additive or subtractive manufacturing process.

[0022] In a second example, a surgical appliance includes one or more holes defined in the appliance to guide the drilling of holes in a first bone to accept pins disposed in the drilled holes to hold the appliance to a first bone and a reduction area through which a pin is inserted into a second bone to allow rotation of the second bone with respect to the first bone, the reduction area including a locking area, wherein manipulating the pin through the reduction area imparts a rotation to the second bone and wherein placing the pin in the locking area holds the second bone in the rotated position.

[0023] In the second example, or any other example disclosed therein, the appliance further includes a cutting guide indicating areas of the first and second bones to be removed during the surgical procedure.

[0024] In the second example, or any other example disclosed therein, appliance further includes wherein the size, shape and location of the cutting area and reduction area are customized for a particular patient.

[0025] In the second example, or any other example disclosed therein, the appliance further includes wherein the first bone is a medial cuneiform and the second bone is a first metatarsal.

[0026] In a third example, a surgical appliance includes one or more holes defined in the appliance to guide the drilling of holes in a first bone to accept pins disposed in the drilled holes to hold the appliance to a first bone, and a reduction slot defined in the appliance through which a pin attached to a second bone extends, the slot defining a detent, wherein manipulating the pin through the slot imparts a rotation to the second bone and compresses the second bone against the first bone and wherein capturing the pin in the detent secures the second bone in the rotated and compressed position.

[0027] In the third example, or any other example disclosed therein, the appliance further includes a first cutting slot to guide removal of bone from the first bone and a second cutting slot to guide removal of bone from the second cuneiform.

[0028] In the third example, or any other example disclosed therein, the appliance further includes an oblique hole define in the appliance allowing

the placement of a screw extending through the second bone and into the first bone to secure the second bone in the rotated and compressed position with respect to the first bone.

[0029] In the third example, or any other example disclosed therein, the appliance further includes wherein an inside surface of the appliance is custom-shaped to conform to the first and second bones of a particular patient.

[0030] In the third example, or any other example disclosed therein, the appliance further includes wherein a location, size and shape of the first and second cutting slots and the reduction slot are customized for a particular patient.

[0031] In the third example, or any other example disclosed therein, the appliance further includes wherein the first bone is a medial cuneiform and the second bone is a first metatarsal.

[0032] In a fourth example, a surgical appliance includes a top portion sized and shaped to be positioned on the top of a foot and covering a portion of the second through fifth toes and a bottom portion to engage the soft tissue on the underside of the foot.

[0033] In the fourth example, or any other example disclosed therein, the appliance further includes wherein the top and bottom portions are separate pieces.

[0034] In the fourth example, or any other example disclosed therein, the appliance further includes wherein the top and bottom portions are connected by a flexible hinge portion.

[0035] In the fourth example, or any other example disclosed therein, the appliance further includes one or more markings to aid in the placement of the appliance with respect to various landmarks on the foot.

[0036] In the fourth example, or any other example disclosed therein, the appliance further includes wherein the appliance defines an Ab/adduction reference surface.

[0037] In the fourth example, or any other example disclosed therein, the appliance further includes wherein the appliance defines a flexion reference surface.

[0038] In the fourth example, or any other example disclosed therein, the appliance further includes wherein an inner surface of the top portion is custom-shaped for a particular patient.

[0039] In a fifth example, a method for performing bunion correction surgery on a foot includes affixing an appliance to a medial cuneiform using one or more pins, attaching a reduction pin to a metatarsal, removing portions of one or both of the metatarsal and the medial cuneiform, manipulating the reduction pin through a reduction area or slot defined in the appliance to rotate the metatarsal with respect to the medial cuneiform and locking the metatarsal in the rotated position by engaging the reduction pin in a locking detent define in the reduction area or slot.

[0040] In the fifth example, or any other example disclosed therein, the method further includes wherein manipulating the reduction pin through a

reduction area or slot also compresses the metatarsal against the medial cuneiform.

[0041] In the fifth example, or any other example disclosed therein, the method further includes securing the metatarsal in the rotated and compressed position by inserting a screw through an oblique hole define in the appliance, the screw extending through the metatarsal and into the medial cuneiform.

[0042] In the fifth example, or any other example disclosed therein, the method further includes removing the appliance, affixing an interior fusion plate and a superior fusion plate with screws to the medial cuneiform and metatarsal.

[0043] In the fifth example, or any other example disclosed therein, the method further includes removing the appliance from the one or more pins holding the cutting guide to the medial cuneiform and the additional one or more pins holding the appliance to the metatarsal and placing a compression device on the one or more pins and compressing the medial cuneiform and metatarsal together.

[0044] In the fifth example, or any other example disclosed therein, the method further includes affixing an interior fusion plate with screws to the first and second bones, removing the compression device and the one or more pins and affixing a superior fusion plate with screws to the first and second bones.

[0045] The disclosure provides many advantages over prior state of the art practice. The custom-fabricated surgical appliance provides a personalized

indication of areas of the bone to be removed, as opposed to prior art practices, in which a generic cutting guide may be used. This results in a better fit between the bones at the revised joints and a closer match to goals of the surgery expressed as physician preferences during the pre-surgery planning phase. The custom-fabricated fixation devices are sized and spaced in accordance with the patient's physiology to provide a better fit. These improvements lead to better outcomes for the patients and reduces the chance that revision surgery will be required at a later date.

[0046] Further features and advantages of at least some of the examples of the present disclosure, as well as the structure and operation of various examples of the present disclosure, are described in detail below with reference to the accompanying drawings.

#### **Brief Description of the Drawings**

[0047] By way of example, specific exemplary examples of the disclosed system and method will now be described, with reference to the accompanying drawings, in which:

[0048] **FIG. 1** is an exemplary x-ray image showing typical bunion deformities caused by abnormal mIMA and HAA.

[0049] **FIGS. 2A** and **2B** are exemplary x-ray images showing corrected mIMA and HAA.

[0050] **FIG. 3** is a flowchart showing the overall process of creating and using the guide in accordance with the disclosure.

[0001] **FIG. 4** illustrates a process of creating a model of the foot based on differences between the imagery and a statistical model of a foot.

[0002] **FIGS. 5A-5C** illustrate the surgical planning process.

[0003] **FIG. 6A-C** show a first exemplary surgical appliance in accordance with this disclosure.

[0004] **FIGS. 7A-B** show a second exemplary surgical appliance in accordance with this disclosure.

[0005] **FIG. 8A-F** show a third exemplary surgical appliance in accordance with this disclosure.

[0006] **FIG. 9** shows a method of use of the third exemplary surgical appliance.

[0007] **FIG. 10** shows a method of use of the third exemplary surgical appliance with a rotation device.

[0008] **FIG. 11** is a flowchart showing the process of using the custom fabricated surgical appliance to perform the bunion correction surgery.

### **Detailed Description**

[0051] Disclosed herein is a system and method for creating various designs of a customized surgical appliances (e.g., cutting guides) and/or one or more fixation devices for use during bunion correction surgery. In some examples, the surgical appliances may be prepared for use to correct abnormalities in one or both of the mIMA or HAA. In a first example, two cutting guides may be prepared, one for correction of the mIMA and the other for correction of the HAA. In some examples, the guides may have

holes to guide drilling of holes in the bones, which may be used to affix the cutting guide to the bone using surgical pins and which may thereafter be used to connect permanent fixation devices to the bones. In a second example, the surgical appliance may include cutting guides and a means to hold and fix the metatarsal bone in a desired position. In a third example, the surgical appliance may include a means of establishing a base position of the foot and holding the 2<sup>nd</sup>- 5<sup>th</sup> metatarsals in place which the first metatarsal is positioned and fixed in a desired position.

[0052] **FIGS. 2A** and **2B** show the desired corrections undertaken during the bunion correction surgery. **FIG. 2A** shows correction of the HAA in which the hallux bone is moved into a normal alignment of between 4° and 12° with a longitudinal line running through the first metatarsal. In this case, as can be seen in **FIG. 2A**, the HAA has been corrected to 8°, well within the normal range. **FIG. 2B** shows correction of the mIMA in which the first metatarsal is moved into normal alignment with the second metatarsal such that the angle between the first and second metatarsals (mIMA) is between 6° and 12°. As shown in **FIG. 2B**, the mIMA has been corrected 9°, also well within the normal range.

[0053] **FIG. 3** shows process 300, in flowchart form, for creating the customized surgical appliance. At initial step 302, a potential candidate for the bunion correction surgery is identified. At step 304, imaging is performed on the patient's foot. In some examples, imaging may be x-ray, CT, MRI or any other form of imaging. In some examples wherein the imaging is 3D, the 3D model is able to be derived directly from the imaging.

[0054] However, in other examples, for example, when the imaging is x-ray, the 3D model of the foot will be derived from a comparison of the imaging to a statistical model of the foot, for example, an Atlas model. When x-ray imaging is used, a series of multi-plane, non-orthogonal x-ray images is collected and deviations from an average statistical model of the foot are noted. This is shown in **FIG. 4**, where the statistical model of the foot is shown in the left pane and the image of the patient's foot is shown in the right pane. Deviations of the patient's foot from the statistical model may be made by highlighting various landmarks and measurements on the imagery of the patient's foot. Based on this, a 3D model of the patient's foot can be derived based on the deviation of the patient's foot from the average statistical model. This provides a distinct advantage in that the 3D model may be derived based solely on two-dimensional x-ray images.

[0055] At step 306, the surgeon inputs patient information and surgical preferences. These may be based on personal preferences of the surgeon and/or an analysis of the imaging. For example, the surgeon may specify preferred angles for both the mIMA and the HAA as goals of the surgery. Other parameters of the surgery may also be expressed as preferences of the surgeon and input to the system. At step 308, the images and information input by the surgeon are transmitted to a surgical planning specialist. In some examples, the surgeon may perform the function of the surgical planning specialist.

[0056] At step 310, the specialist utilizes the data and a graphical user interface to plan the surgery and to create inputs for the process by which the

patient-specific implant (PSI) is fabricated. This process is shown in **FIGS. 5a-5c** for the tarsometatarsal joint. First, various landmarks on the images are identified. For example, with respect to the tarsometatarsal joint, as shown in **FIG. 5A**, the medial cuneiform area 504 and metatarsal fixation area 502 may be identified and measured. As shown in **FIG. 5B**, pre-plan fixation points 506 are identified and a patient specific cutting block may be identified to create a closing wedge bone cut 508, that is, a wedge of bone to be cut out that will allow the metatarsal bone 102 to align with the tarsal bone 106. Lastly, as shown in **FIG. 5C**, a template 510 for a fixation device may be created which provides a template for drill holes which will hold the final fixation device in place. As would be realized by one of skill in the art, templates 510 for more than one fixation device may be identified. A similar process (not shown) may be used for the metatarsophalangeal joint to align the HAA within the normal range<sup>3</sup>

[0057] At step 312 of the process shown in **FIG. 3**, the surgical plan is finalized and reviewed and sent to the surgeon for approval. At step 314, the surgeon reviews surgical plan and approves or rejects the plan. At step 316 the PSI data is transmitted to a manufacturing center, which will custom fabricate the cutting guide.

[0058] The cutting guide is fabricated at step 318. The cutting guide may be fabricated using any type of manufacturing process, for example, an additive or subtractive method of manufacture, an injection molding process, or any combination thereof. Preferably, the cutting guide may be composed of a hard or semi-flexible plastic material, for example,

polyethylene. Any manufacturing process or material is contemplated to be within the scope of the disclosure.

[0059] AT 320, the surgical appliance, as well as any custom-made fixation devices (not shown), are kitted with disposable surgical instruments and the kit is sterilized. At 322, the kit is sent to a surgery center and at 324, the surgical procedure may be completed using the kit. In another example of the disclosure, the custom-made surgical appliance may be sent to the surgical center as a standalone device.

[0060] A first exemplary surgical appliance 600 serves as a cutting guide for the tarsometatarsal joint and an aid for rotation of the metatarsal 102 and is shown in **FIGS. 6A-C**. Surgical appliance 600 may include a plurality of holes 602 which allow fixation of appliance 600 to the medial cuneiform 106. Surgical appliance 600 may be affixed to the medial cuneiform 106 using surgical pins 612, shown in **FIGS. 6B** and **6C**. Holes may be drilled into the medial cuneiform 106 using the holes 602 in appliance 600, and the pins may thereafter be inserted through the appliance 600 and into the medial cuneiform 106. Additional pins (not shown) may be placed into a lateral surface of the medial cuneiform 106 using guide holes 614 shown in **FIG. 6C**.

[0061] Cutting area 604 defines an area of the medial cuneiform 106 and/or the metatarsal 102 which will be removed during an osteotomy process. In preferred examples, the width, length and location of cutting area is customized for each patient, as described herein, dependent on imagery.

[0062] Pin 606, shown in **FIG. 6C**, is attached to metatarsal 106 and extends through a reduction area 608. Reduction area includes locking detent 610. Manipulation of pin 606 through reduction area 608 imparts a rotation to metatarsal 106 to provide the proper rotational correction. Once rotated, metatarsal 106 can be locked into the rotated position by securing pin 606 in locking detent 610. Additional pin 608 may be secured to metatarsal 106 through hole 603 to secure metatarsal 106 in the rotated position for further parts of the surgical procedure. Note that, in some examples, appliance 600 may be fabricated with a curved shape such as to extend from a top surface to a lateral surface of the medial cuneiform 106 and the metatarsal bone 102.

[0063] A second exemplary surgical appliance 700 is shown in **FIGS. 7(A,B)**. As illustrated, appliance 700 may include a body 701 having various features defined therein. As illustrated, in some examples, the body 701 may include one or more holes for accepting pins 702 to affix the body 701 to a stable surface of the foot, for example, medial cuneiform 106. In addition, the body 701 may include a slot 704, which may serve as a cutting slot to form the base of the first metatarsal 102 and a slot 706, which may serve as a cutting slot to form the head of the medial cuneiform 106, although this is but one configuration and the body may include more or less slots. Slots 708(A,B) are provided to guide the movement of pin 710, attached to the metatarsal 102, to provide for the rotation and compression of metatarsal 102 with respect to the medial cuneiform 106. In some examples, the slots 708(A,B) may include a general J-shaped slot, although

this is but one configuration and the slot may have alternate configurations such as, for example, straight, arcuate, or the like. In use, pin 710 may be locked into detent 712 after being rotated and compressed to the desired position. The body 701 may further include an oblique hole 714 which may be used to guide the placement of a screw which may be driven through metatarsal 102 and into medial cuneiform 106 to hold metatarsal 102 and medial cuneiform 106 in a desired position relative to each other. In various examples, appliance 700 may be formed using an additive manufacturing process which is customized, based on imagery, to a particular patient, although this is one configuration and the appliance may be manufactured by any suitable process now known or hereafter developed.

[0064] In use, an inner surface of body 701 may be shaped to match the outer contours of metatarsal 102 a medial cuneiform 106. Thus arranged, the appliance 700 may be affixed to any stable surface of the foot but, in preferred examples, is affixed to the medial cuneiform 106 using pins 702. Pin 710 is affixed to metatarsal 102. During the osteotomy process, the head of the medial cuneiform 106 is cut using cutting slot 706 and the base of the metatarsal 102 is cut using slot 704. Once the medial cuneiform 106 and metatarsal 102 have been resected, metatarsal 102 is rotated with respect to and compressed against medial cuneiform 106 by manipulating pin 710 through slots 708(A,B) and capturing pin 710 in detent 712, as shown in **FIG. 7B**. A screw inserted through oblique slot

714 is holds the medial cuneiform 106 and metatarsal 102 in place until permanent plates and screws can be placed.

[0065] A third exemplary surgical appliance 800 is shown in **FIGS. 8A-F**. Appliance 800 serves the purpose of stabilizing the bones of the foot such that metatarsal 102 can be placed with respect to the other metatarsals of the foot.

[0066] Appliance 800 includes a body 801 and a cutaway portion 803 which allows for manipulation of the first metatarsal 102 when the appliance is in place on the foot of the patient. In various examples, appliance 800 may be formed using an additive manufacturing process which is customized, based on imagery, to a particular patient, although this is one configuration and the appliance may be manufactured by any suitable process now known or hereafter developed. Note that appliance 800 is shown transparently in **FIGS 8A-F** solely for the purpose of explanation of the device.

[0067] As illustrated, in some examples, an inner surface of the upper portion of the body 801 is shaped to match the outer contours of the patient's foot. Thus arranged, in use, appliance 800 is placed on the foot using one or more of a number of landmarks defined on the patient's foot to properly align appliance 800, including for example, the tarsal sinus ("A"), the tubercle of the 5<sup>th</sup> metatarsal ("B"), the prominence of the 5<sup>th</sup> metatarsal ("C") and the tarsal boss ("D"), as shown in **FIG. 8A**. Other landmarks may also be used. As shown in **FIG. 8B**, appliance 800 may include one or more etched lines, alignment markings, landmarks, etc. formed on an outer

surface of body 801 of appliance 800. In use, the etched lines may be aligned with one or more of the landmarks of the foot, ensuring the appliance 800 is properly positioned on the foot. For example, etch line 802 is aligned with one of the 2<sup>nd</sup> through 5<sup>th</sup> metatarsals, etch line 804 is aligned with the ankle and/or second ray and etch line 806 is aligned with the tarsal boss ("D"). In other examples, etch lines corresponding to other alignment landmarks may be provided. Appliance 800 may also optionally be provided with a hook 808, which is curved to allow placement over the tip of the patient's second toe, for antero-posterior positioning.

[0068] The body 801 of appliance 800, in one example, is provided in two parts, one configured for placement on the top of the foot and one configured for placement on the bottom of the foot. Appliance 800 is secured to the foot using a clamp (not shown) engaging flat surfaces 822 and 816 as shown in **FIG. 8F**. In another example, the top and bottom portions of appliance 800 are connected via hinge 810, shown in **FIG. 8B**, which is compressed when appliance 800 is secured around the foot.

[0069] In some examples, appliance 800 is equipped with an Ab/adduction reference surface 812, as shown in **FIG. 8C**. Surface 812 provides a reference for placement of metatarsal 102, for example, wherein the longitudinal axis of metatarsal 102 is parallel to reference surface 812. In other examples, appliance 800 is also equipped with flexion reference surface 814, as shown in **FIG. 8D**, which provides a reference for placement of metatarsal 102, for example, wherein the longitudinal axis

of metatarsal 102 is parallel to flexion reference surface 814. Appliance 800 may also be provided with an optional stance reference plane 816.

[0070] A cross-section of appliance 800 is shown in **FIG. 8E**, showing the inside surface 820 of the top portion of appliance 800, which is customized to fit the foot of the patient, in a manner discussed earlier based on imagery. Because the lower portion of appliance 800 is in contact with the soft tissue of the bottom of the foot, the inside surface of the bottom portion will typically not need to be customized.

[0071] **FIGS. 9A-C** show one possible use of appliance 800. **FIG. 9A**, the suture endpoint is captured so that as the suture is tightened, it pulls metatarsal 102 into the corrected orientation. In **FIG. 9B**, the endpoint of pin 902 is rotated until it aligns with an intermetatarsal target point to ensure pin 902 is in the planned position/orientation (the arrows highlight the fact that the weight-bearing surfaces may be at different heights from the floor). **FIG. 9C** shows the suture attachment with a spacer between the 1<sup>st</sup> and 2<sup>nd</sup> metatarsals. The suture allows more mobility than rigid fixation to adjacent bones. It allows pin holes that are axially misaligned for axial compression.

[0072] **FIG. 10** show the use of appliance 800 with another surgical applicant that is used to rotate and place metatarsal 102. In the deformed state 102, lax or unstable soft tissues are released and conventional cutting guides, such as surgical appliances 600, 700, are used to prep the bones for arthrodesis. Metatarsal 102 is twisted into planned position 1004. The

pins can also form a permanent fixation between the 1<sup>st</sup> and 2<sup>nd</sup> metatarsals.

[0073] **FIG. 11** is a flow chart showing an exemplary process 1100 for using either of surgical appliances 600, 700 previously described, or any other surgical appliance. At step 1102, the appliance 600, 700 is fitted to medial cuneiform 106. Appliance 600, 700 should be aligned with the area from which bone needs to be removed from either or both of the medial cuneiform 106 and metatarsal 102, such as to allow metatarsal 102 to be position-corrected to create an mIMA within the normal range and as close as possible to the preference expressed by the physician during the pre-surgery planning process. At step 1104, the appliance 600, 700 is affixed to the medial cuneiform 106. At step 1106, the inferior plate holes are drilled in the medial cuneiform 106 and at step 1108, appliance 600, 700 is pinned to first metatarsal 102. At step 1110, the tarsometatarsal joint is open to partially or fully release the adductor hallucis muscle. The metatarsal 102 is rotated into the desired position at 1112. Using appliance 600, reduction pin 606 is rotated through reduction window 608 and locking pin 606 into the desired position using locking portion 610 defined in reduction window 608. For appliance 700, metatarsal 102 is moved to the desired position by rotating pin 710 through slot 708 and locking pin 710 into detent 712. At step 1114, the metatarsal 102 is further fixed to the cutting guide with a second pin 808 disposed through the distal hole in cutting guide 600 or through oblique hole 714 in appliance 700.

[0074] In step 1116, the first metatarsal may be provisionally fixed to the second metatarsal with at least one wire or pin 610 to stabilize the first metatarsal during the cutting process or attached to cuneiform 102. At step 118, an arthrotomy is performed to remove portions of either or both of the medial cuneiform 106 and metatarsal 102. At step 1120, appliance 600, 700 is removed. At step 1122, when using appliance 600, a compression device is placed in position using pins 602, 606 and 608 and, at step 1124, the metatarsal 102 and cuneiform are compressed together. When using appliance 700, metatarsal 102 is compressed against cuneiform 106 when pin 710 is locked into detent 712.

[0075] At step 1126, an inferior fusion plate (not shown) is placed with the screws going into medial cuneiform 106 and metatarsal bone 102. At step 1128, the compression device and pins are removed and, at step 1130, the superior fusion plate (not shown) is placed with the screws going into cuneiform 106 and metatarsal 102, preferably into the holes vacated by pins 602, 606 and 608. The inferior and superior fusion plates may be custom fabricated to fit the user's physiology using the same process used to fabricate appliance 600.

[0076] At step 1132, the surgical procedure is completed and the wound is closed. Although not explicitly stated herein, the surgical procedure may also include a correction of the HAA. The correction of the HAA may be accomplished using either a separate cutting guide or a cutting guide custom configured to cover both the tarsometatarsal joint and the metatarsophalangeal joint, based on the patient's physiology. The

procedure for the metatarsophalangeal joint should be identical or very similar to that for the tarsometatarsal joint just discussed.

[0077] Various examples of a system and method have been described herein to fabricate and use a tool for performing binding correction surgery. As would be realized by one of skill in the art, the present disclosure has been explained in terms of a cutting guide for binding correction surgery. However, the system and method are equally applicable to other joints of the body. As would be further realized by one of skill in the art, many variations on the system and method are possible and are contemplated to be within the scope of the present disclosure. Further, the present disclosure is not meant to be limited for use with a specific additive manufacturing machine, but instead is intended to be used with any additive manufacturing machine.

[0078] While particular configurations and manufacturing processes have been described herein, one of ordinary skill in the art would understand that the devices may be manufactured from any suitable material now known or hereafter developed. For example, the device may be manufactured from any suitable medical grade material including any suitable medical grade metal, plastic, or combinations thereof. For example, the device may be manufactured from plastic and include metal-reinforced pin holes or slots. In addition, and/or alternatively, the devices may be manufactured from any suitable manufacturing process including, for example, three-dimensional printing, additive manufacturing, of the like.

For example, the devices may be manufactured additively or subtractively (e.g., using stock material and drilling/reaming holes, slots, etc.).

[0079] The foregoing discussion has been presented for purposes of illustration and description and is not intended to limit the disclosure to the form or forms disclosed herein. For example, various features of the disclosure are grouped together in one or more examples or configurations for the purpose of streamlining the disclosure. However, it should be understood that various features of the certain examples or configurations of the disclosure may be combined in alternate examples, or configurations. Any example or feature of any section, portion, or any other component shown or particularly described in relation to various examples of similar sections, portions, or components herein may be interchangeably applied to any other similar example or feature shown or described herein. Additionally, components with the same name may be the same or different, and one of ordinary skill in the art would understand each component could be modified in a similar fashion or substituted to perform the same function.

[0080] Moreover, the following claims are hereby incorporated into this Detailed Description by reference, with each claim standing on its own as a separate example of the present disclosure.

[0081] As used herein, an element or step recited in the singular and proceeded with the word “a” or “an” should be understood as not excluding plural elements or steps, unless such exclusion is explicitly recited. Furthermore, references to “one example” of the present disclosure are not intended to

be interpreted as excluding the existence of additional examples that also incorporate the recited features.

[0082] The phrases “at least one”, “one or more”, and “and/or”, as used herein, are open-ended expressions that are both conjunctive and disjunctive in operation. The terms “a” (or “an”), “one or more” and “at least one” can be used interchangeably herein. All directional references (e.g., proximal, distal, upper, lower, upward, downward, left, right, lateral, longitudinal, front, back, top, bottom, above, below, vertical, horizontal, radial, axial, clockwise, and counterclockwise) are only used for identification purposes to aid the reader’s understanding of the present disclosure, and do not create limitations, particularly as to the position, orientation, or use of this disclosure. Connection references (e.g., engaged, attached, coupled, connected, and joined) are to be construed broadly and may include intermediate members between a collection of elements and relative to movement between elements unless otherwise indicated. As such, connection references do not necessarily infer that any two elements are directly connected and in fixed relation to each other. All rotational references describe relative movement between the various elements. Identification references (e.g., primary, secondary, first, second, third, fourth, etc.) are not intended to connote importance or priority but are used to distinguish one feature from another. The drawings are for purposes of illustration only and the dimensions, positions, order and relative to sizes reflected in the drawings attached hereto may vary.

**Claims**

1. A method for fabricating a surgical appliance for performing bunion corrective surgery comprising:
  - collecting imagery of a foot exhibiting the bunion anomaly;
  - deriving a model of the foot based on the imagery; and
  - fabricating the appliance to custom fit the foot.
2. The method of claim 1, further comprising:
  - creating a surgical plan using the model, the surgical plan comprising:
    - identifying areas of one or more bones that need to be removed; and
    - identifying areas of connection on the one or more bones for the appliance;
  - wherein the fabrication of the appliance is further based on the surgical plan.
3. The method of claim 2, wherein the appliance covers the tarsometatarsal joint and further wherein the one or more bones comprise a medial cuneiform and a first metatarsal.
4. The method of claim 2, wherein the appliance covers the metatarsophalangeal joint and further wherein the one or more bones comprise a first metatarsal and a hallux.

5. The method of claim 2, wherein the appliance covers a tarsometatarsal joint and a metatarsophalangeal joint.
6. The method of claim 1, wherein the imagery comprises one or more x-rays.
7. The method of claim 1, wherein the one or more x-rays are multi-planar, non-orthogonal x-rays.
8. The method of claim 1, wherein the model of the foot is derived by denoting differences between the foot shown in the one or more x-rays and a statistical model of a foot.
9. The method of claim 8, wherein the statistical model of the foot is an Atlas model.
10. The method of claim 2, further comprising:
  - identifying areas of connection on the one or more bones for one or more fixation devices; and
  - fabricating the one or more fixation devices to custom fit the physiology of the foot.
11. The method of claim 1, wherein the cutting guide is composed of a hard or semi flexible plastic.

12. The method of claim 1, wherein the cutting guide is manufactured using an additive or subtractive manufacturing process.

13. A surgical appliance comprising:

one or more holes defined in the appliance to guide the drilling of holes in a first bone to accept pins disposed in the drilled holes to hold the appliance to a first bone;

a reduction area through which a pin is inserted into a second bone to allow rotation of the second bone with respect to the first bone, the reduction area including a locking area;

wherein manipulating the pin through the reduction area imparts a rotation to the second bone; and

wherein placing the pin in the locking area holds the second bone in the rotated position.

14. The appliance of claim 13 further comprising:

a cutting guide indicating areas of the first and second bones to be removed during the surgical procedure.

15. The appliance of claim 13 wherein the size, shape and location of the cutting area and reduction area are customized for a particular patient.

16. The appliance of claim 13 wherein the first bone is a medial cuneiform and the second bone is a first metatarsal.

17. A surgical appliance comprising:

one or more holes defined in the appliance to guide the drilling of holes in a first bone to accept pins disposed in the drilled holes to hold the appliance to a first bone;

a reduction slot defined in the appliance through which a pin attached to a second bone extends, the slot defining a detent;

wherein manipulating the pin through the slot imparts a rotation to the second bone and compresses the second bone against the first bone; and

wherein capturing the pin in the detent secures the second bone in the rotated and compressed position.

18. The appliance of claim 17 further comprising:

a first cutting slot to guide removal of bone from the first bone; and

a second cutting slot to guide removal of bone from the second cuneiform.

19. The appliance of claim 18 further comprising:

an oblique hole define in the appliance allowing the placement of a screw extending through the second bone and into the first bone to secure the second bone in

the rotated and compressed position with respect to the first bone.

20. The appliance of claim 17 wherein an inside surface of the appliance is custom-shaped to conform to the first and second bones of a particular patient.
21. The appliance of claim 17 wherein a location, size and shape of the first and second cutting slots and the reduction slot are customized for a particular patient.
22. The appliance of claim 17 wherein the first bone is a medial cuneiform and the second bone is a first metatarsal.
23. A surgical appliance comprising:
  - a top portion sized and shaped to be positioned on the top of a foot and covering a portion of the second through fifth toes; and
  - a bottom portion to engage the soft tissue on the underside of the foot.
24. The appliance of claim 23 wherein the top and bottom portions are separate pieces.
25. The appliance of claim 23 wherein the top and bottom portions are connected by a flexible hinge portion.
26. The appliance of claim 23 further comprising:

one or more markings to aid in the placement of the appliance with respect to various landmarks on the foot.

27. The appliance of claim 23 wherein the appliance defines an Ab/adduction reference surface.

28. The appliance of claim 23 wherein the appliance defines a flexion reference surface.

29. The appliance of claim 23 wherein an inner surface of the top portion is custom-shaped for a particular patient.

30. A method for performing bunion correction surgery on a foot comprising:

affixing an appliance to a medial cuneiform using one or more pins;

attaching a reduction pin to a metatarsal;

removing portions of one or both of the metatarsal and the medial cuneiform;

manipulating the reduction pin through a reduction area or slot defined in the appliance to rotate the metatarsal with respect to the medial cuneiform; and

locking the metatarsal in the rotated position by engaging the reduction pin in a locking detent define in the reduction area or slot.

31. The method of claim 30 wherein manipulating the reduction pin through a reduction area or slot also compresses the metatarsal against the medial cuneiform.

32. The method of claim 31 further comprising:

securing the metatarsal in the rotated and compressed position by inserting a screw through an oblique hole define in the appliance, the screw extending through the metatarsal and into the medial cuneiform.

33. The method of claim 32, further comprising:

removing the appliance;

affixing an interior fusion plate and a superior fusion plate with screws to the medial cuneiform and metatarsal.

34. The method of claim 30, further comprising:

removing the appliance from the one or more pins holding the cutting guide to the medial cuneiform and the additional one or more pins holding the appliance to the metatarsal; and

placing a compression device on the one or more pins and compressing the medial cuneiform and metatarsal together.

35. The method of claim 33, further comprising:

affixing an interior fusion plate with screws to the first and second bones; and

removing the compression device and the one or more pins; and

affixing a superior fusion plate with screws to the first and second bones.

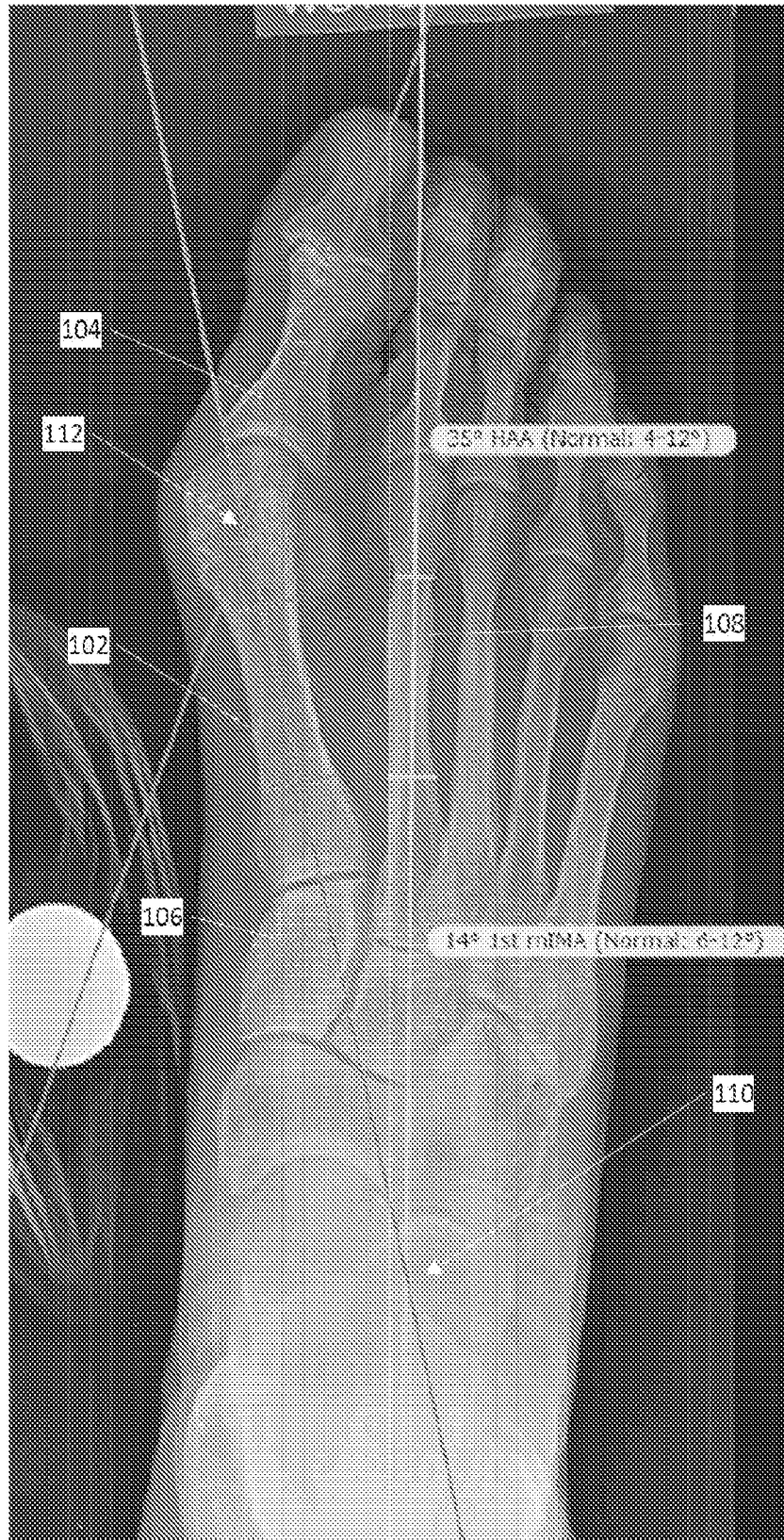


FIG. 1

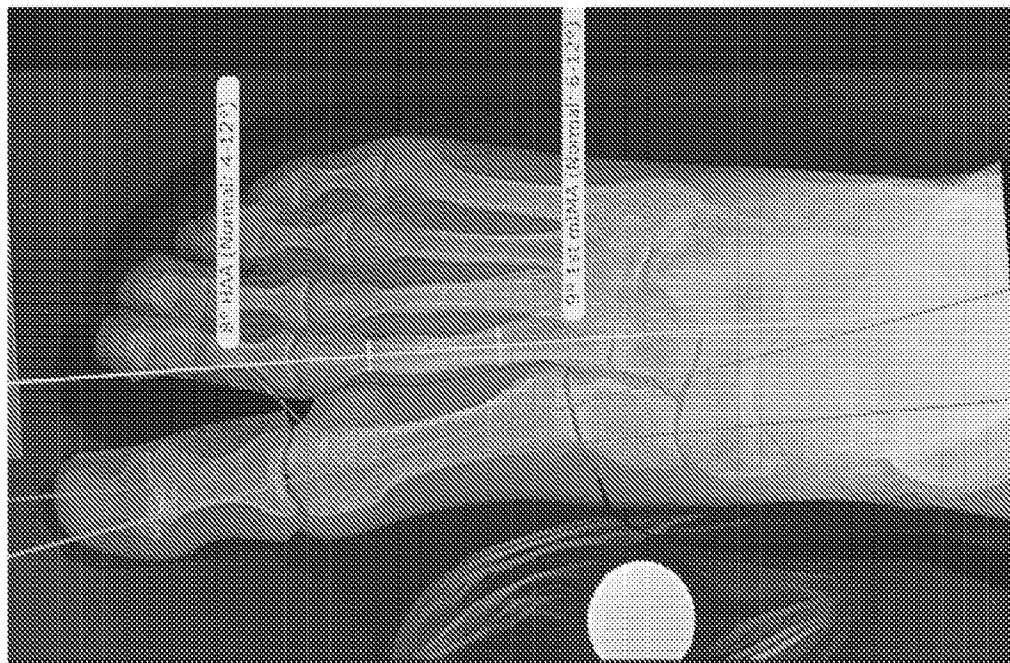


FIG. 2B

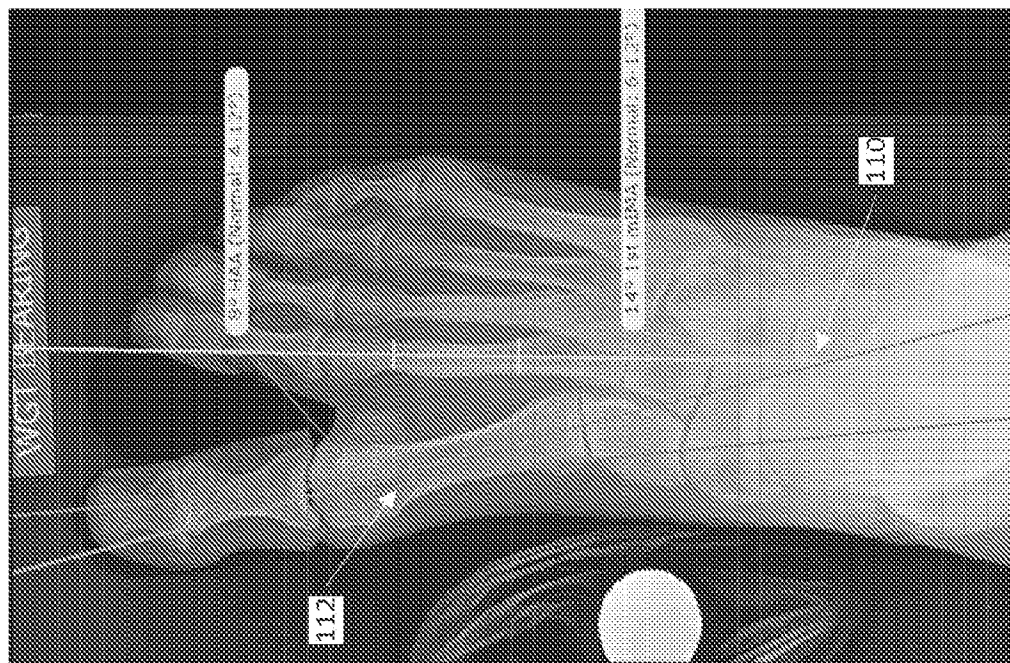
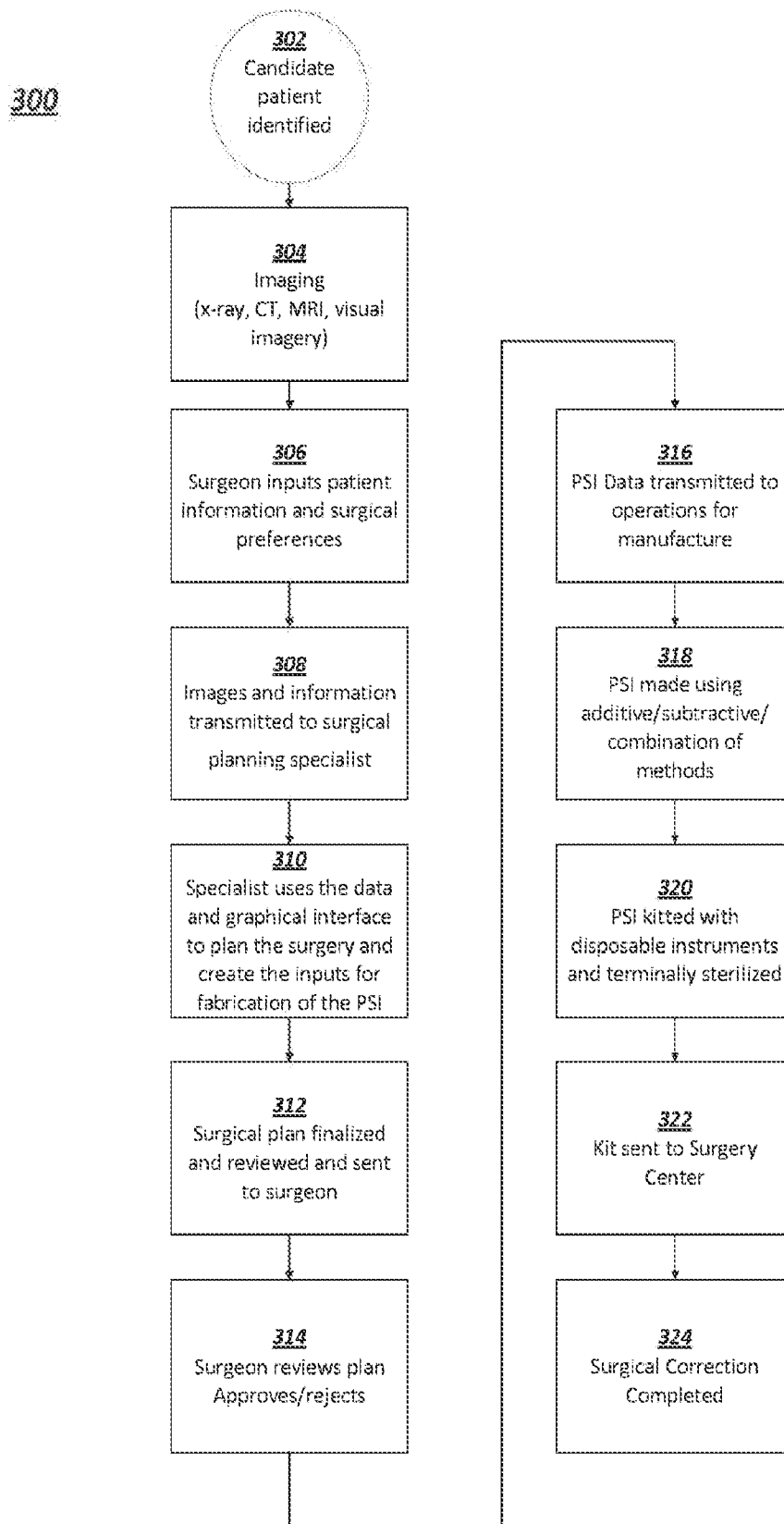


FIG. 2A

**FIG. 3**

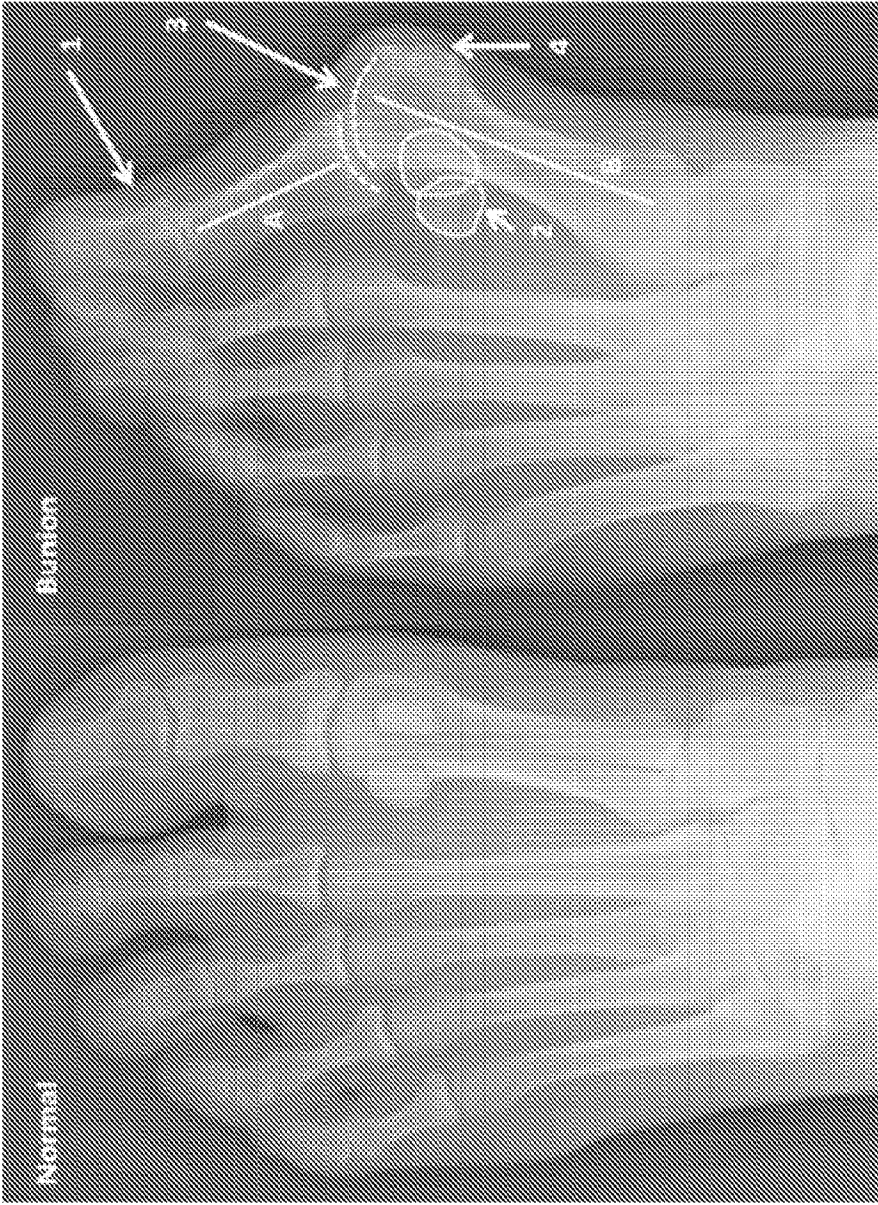


FIG. 4

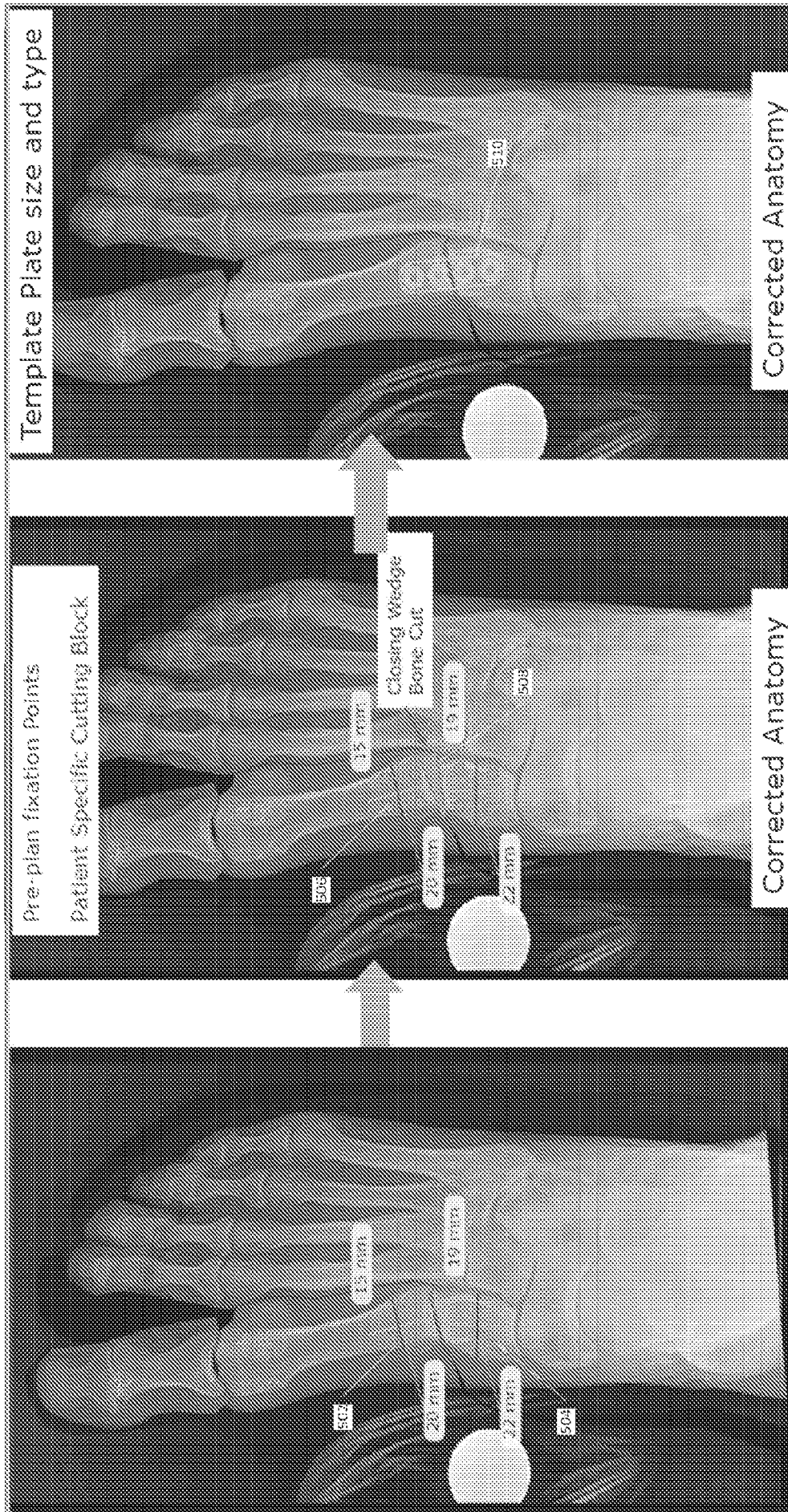
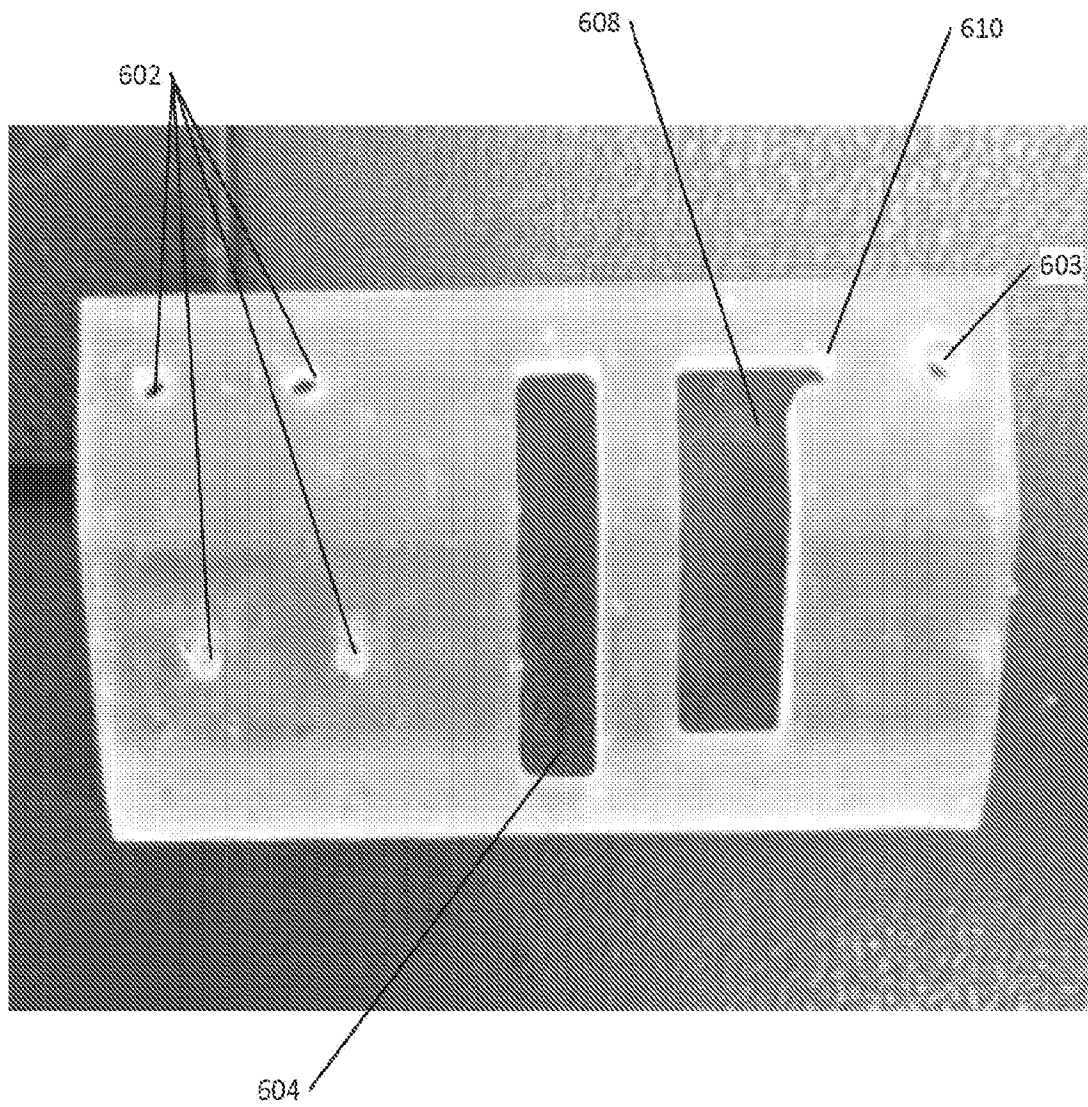


FIG. 5A

FIG. 5B

FIG. 5C

600*FIG. 6A*

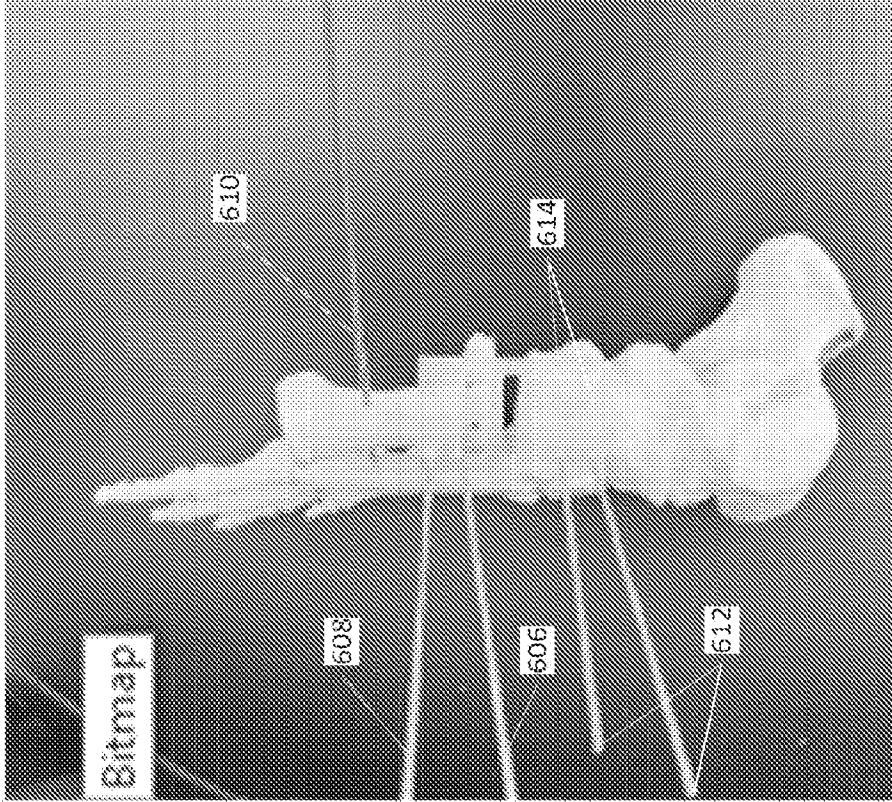


FIG. 6C

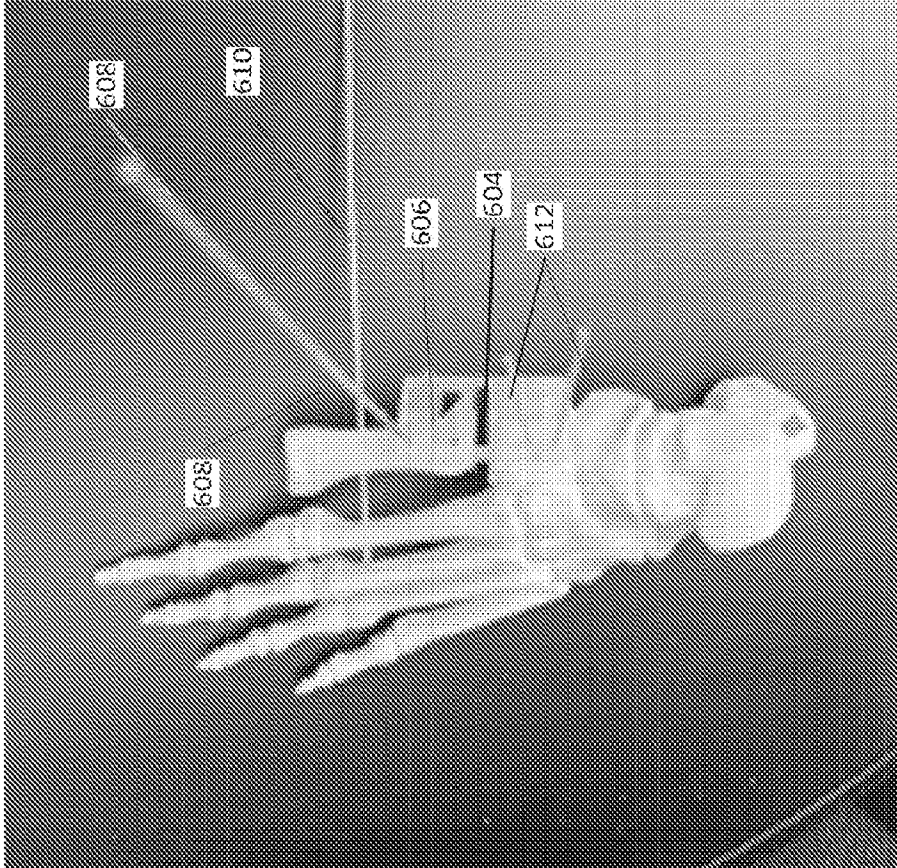


FIG. 6B

700

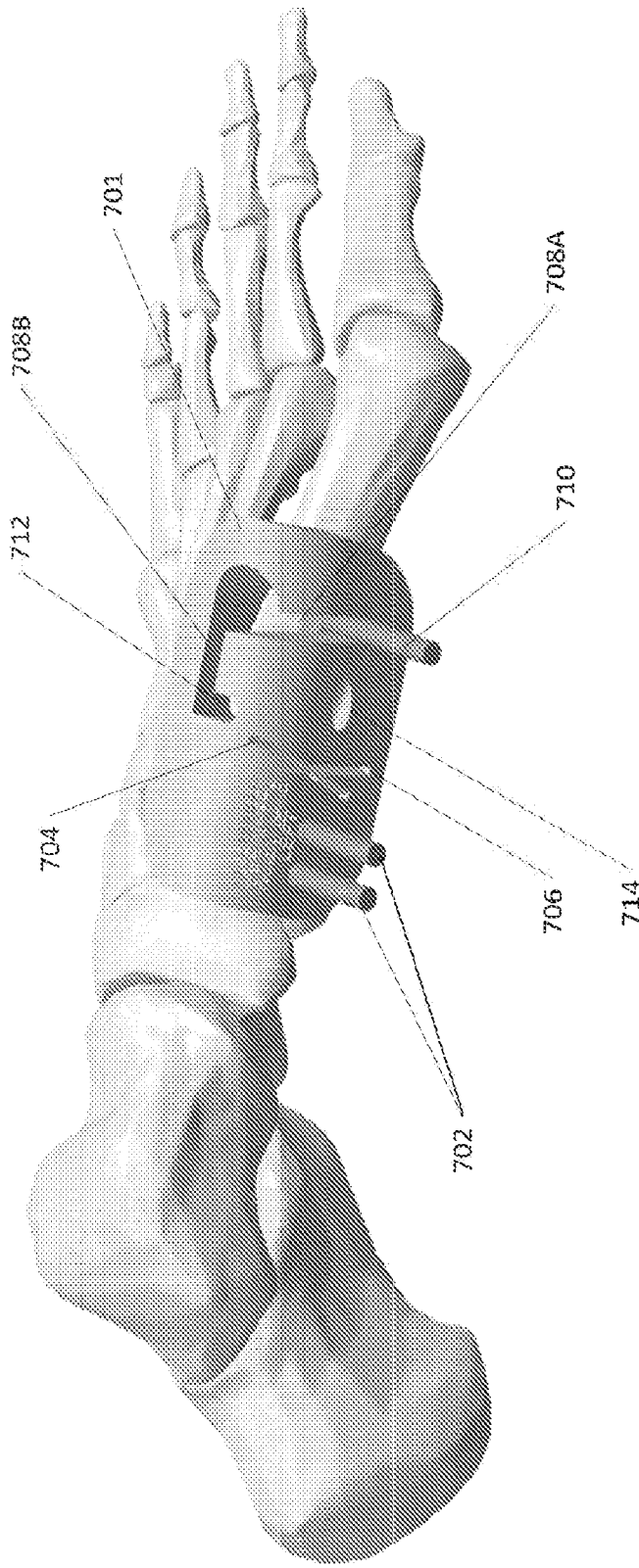


FIG. 7A

700

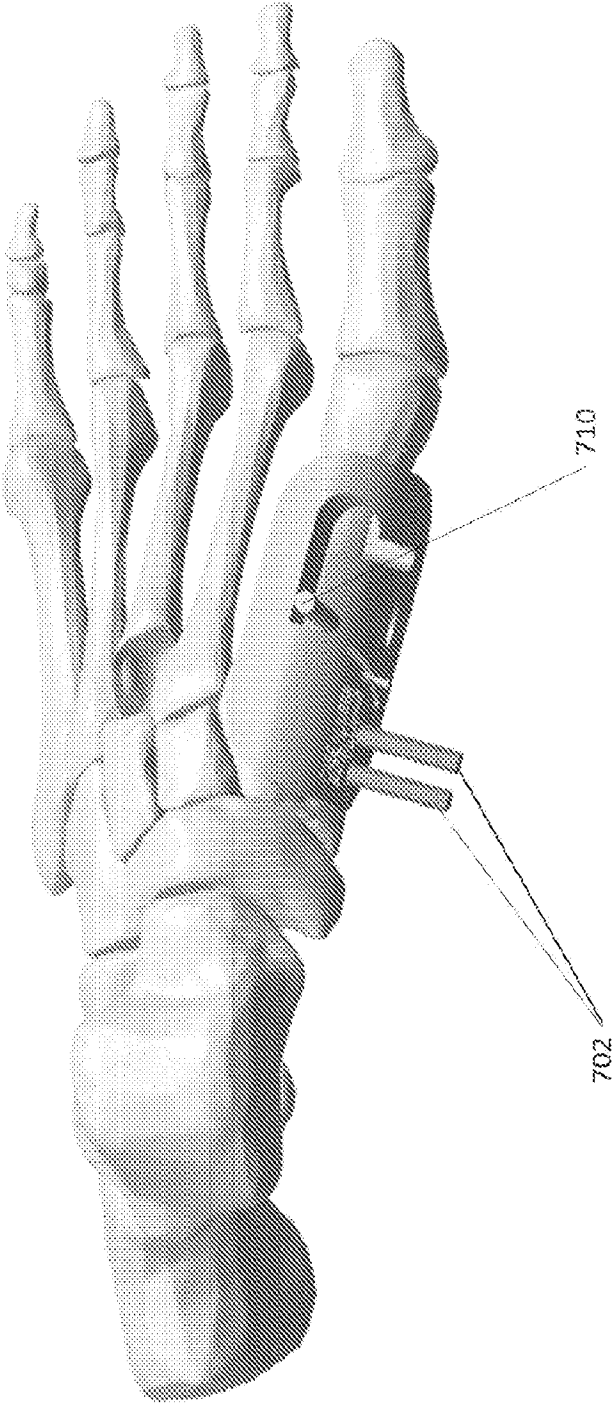


FIG. 7B

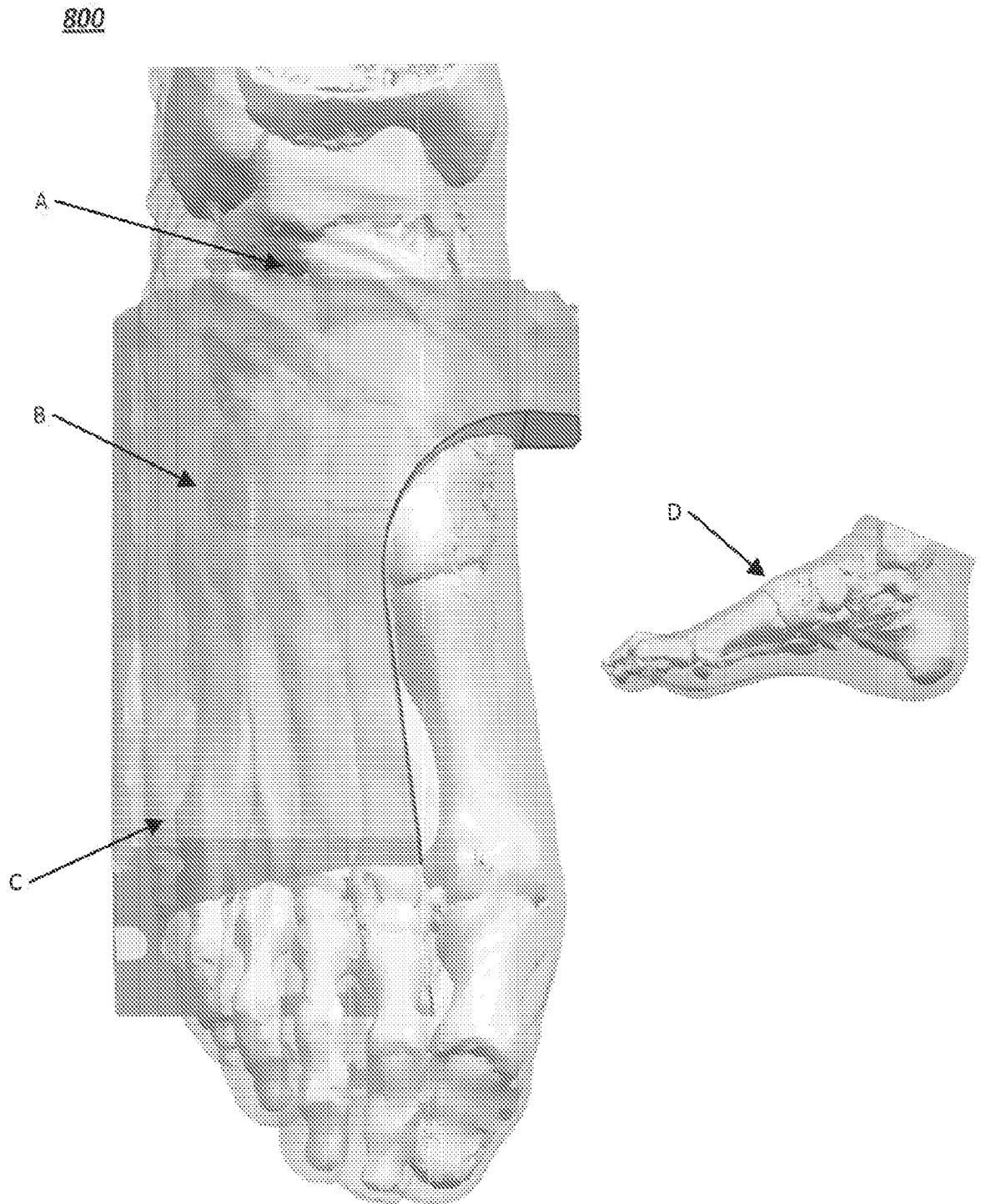
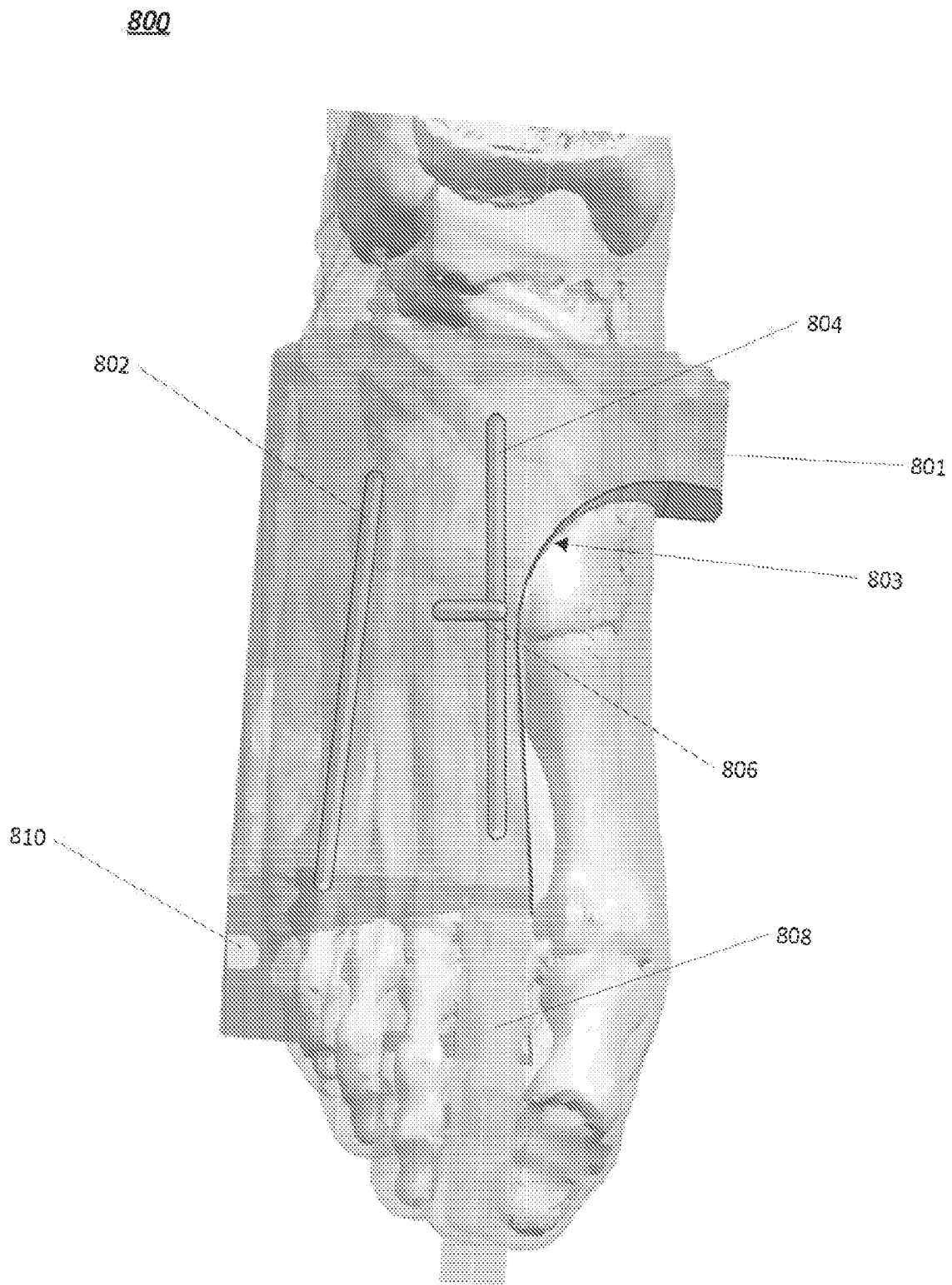
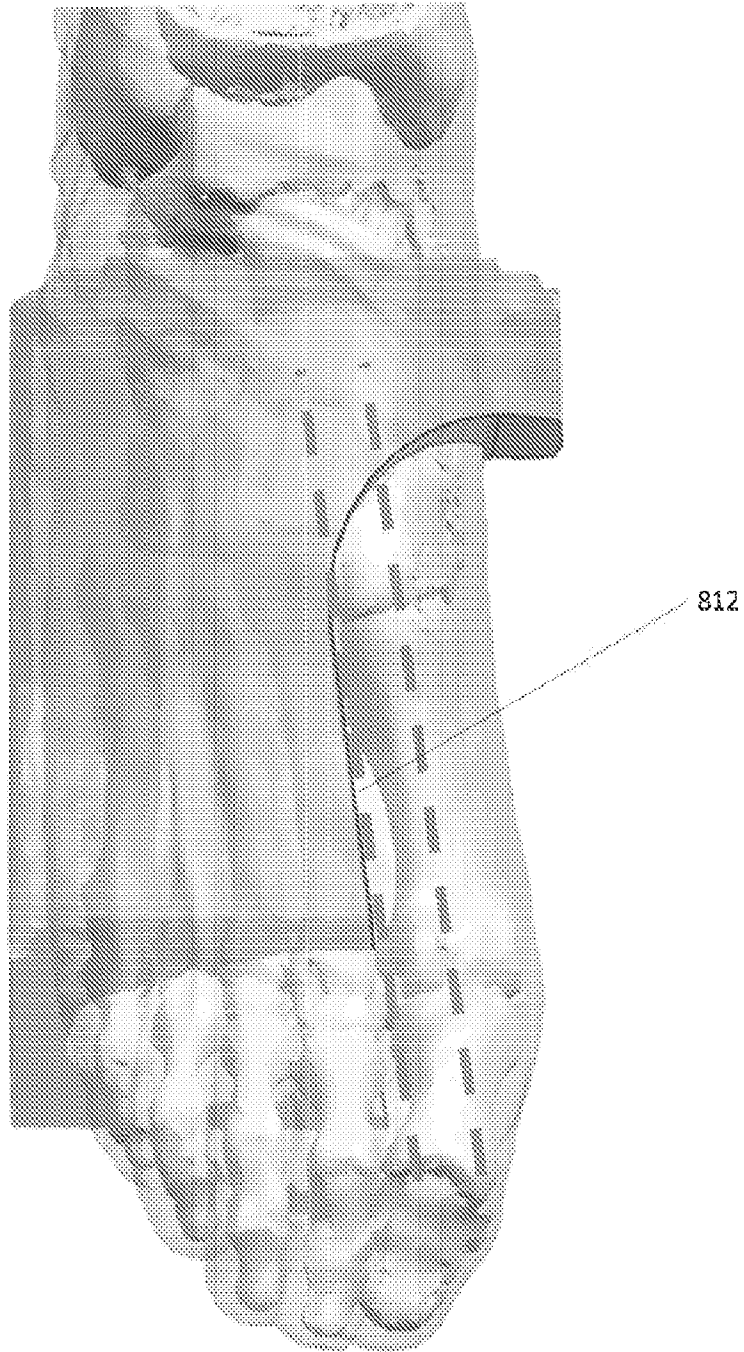


FIG. 8A

*FIG. 8B*

800*FIG. 8C*

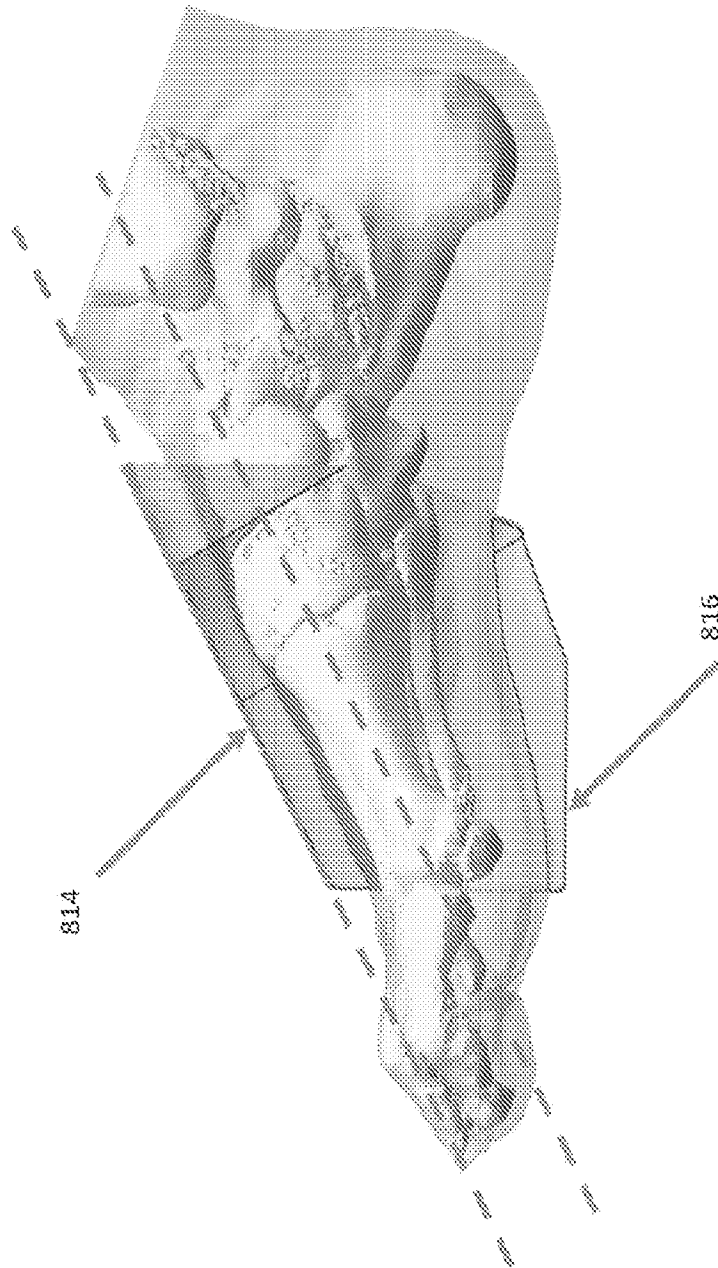


FIG. 8D

800

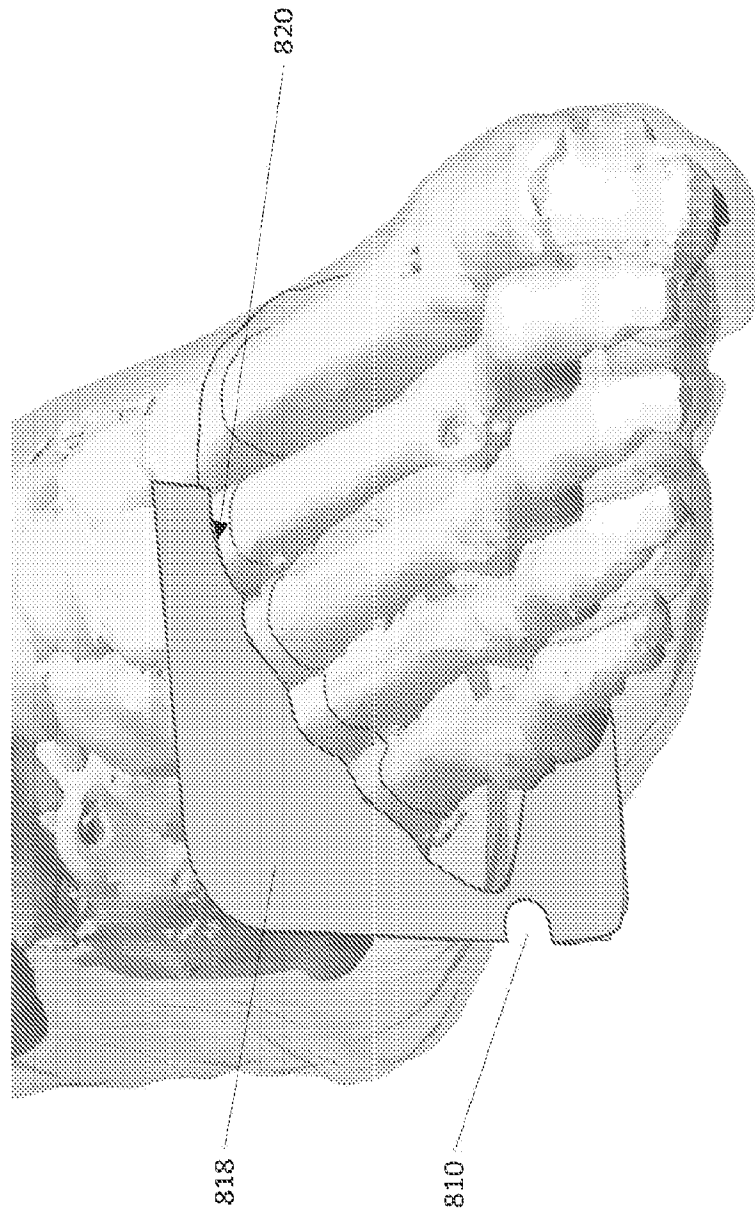


FIG. 8E

800

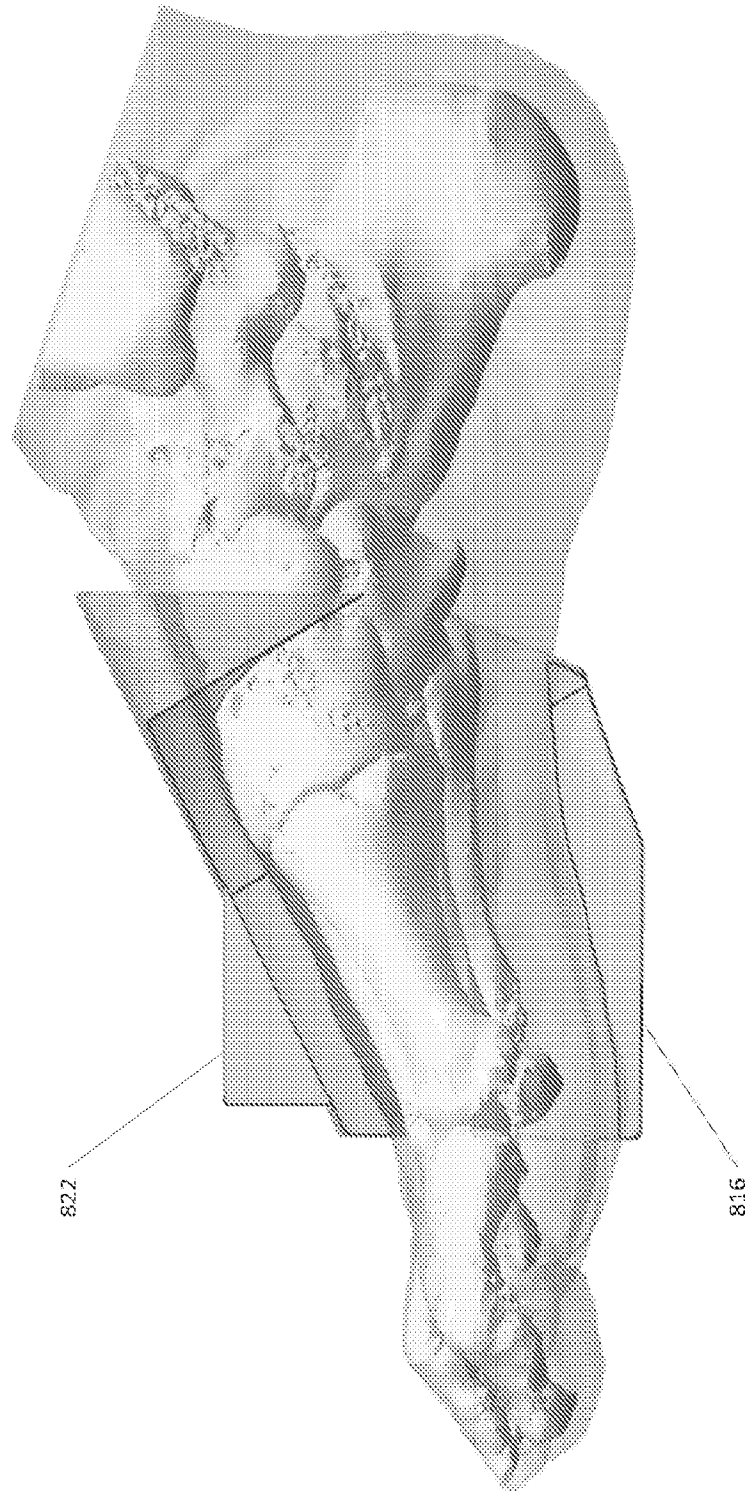
800

FIG. 8F

FIG. 9A

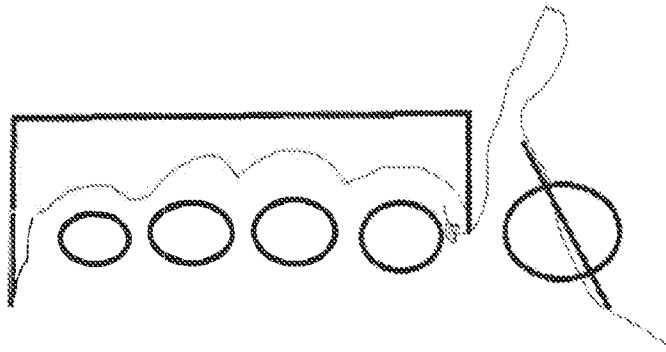


FIG. 9B

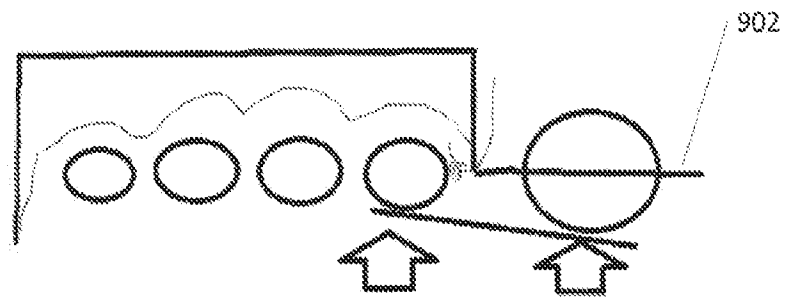
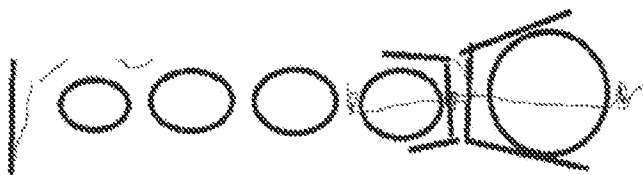
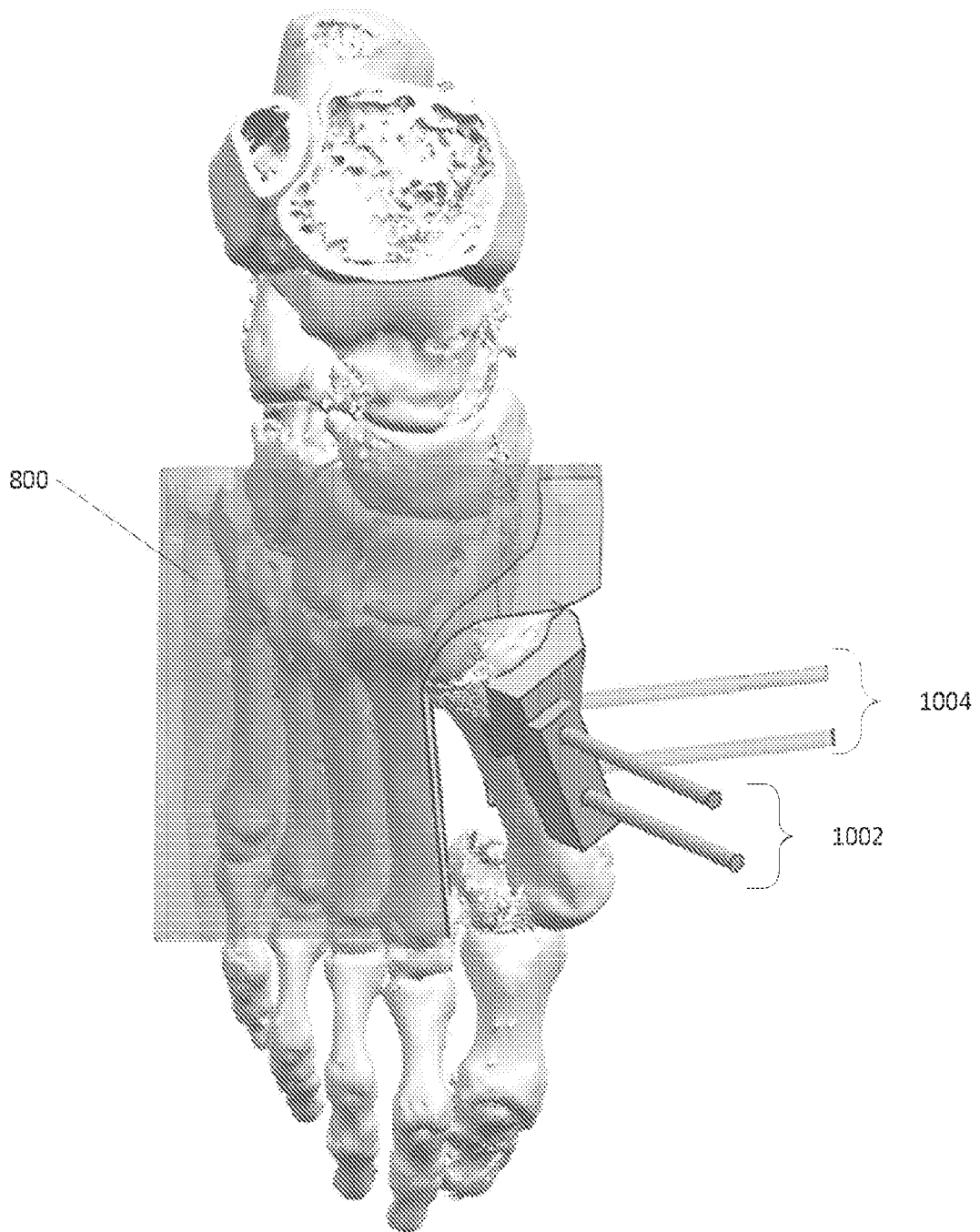
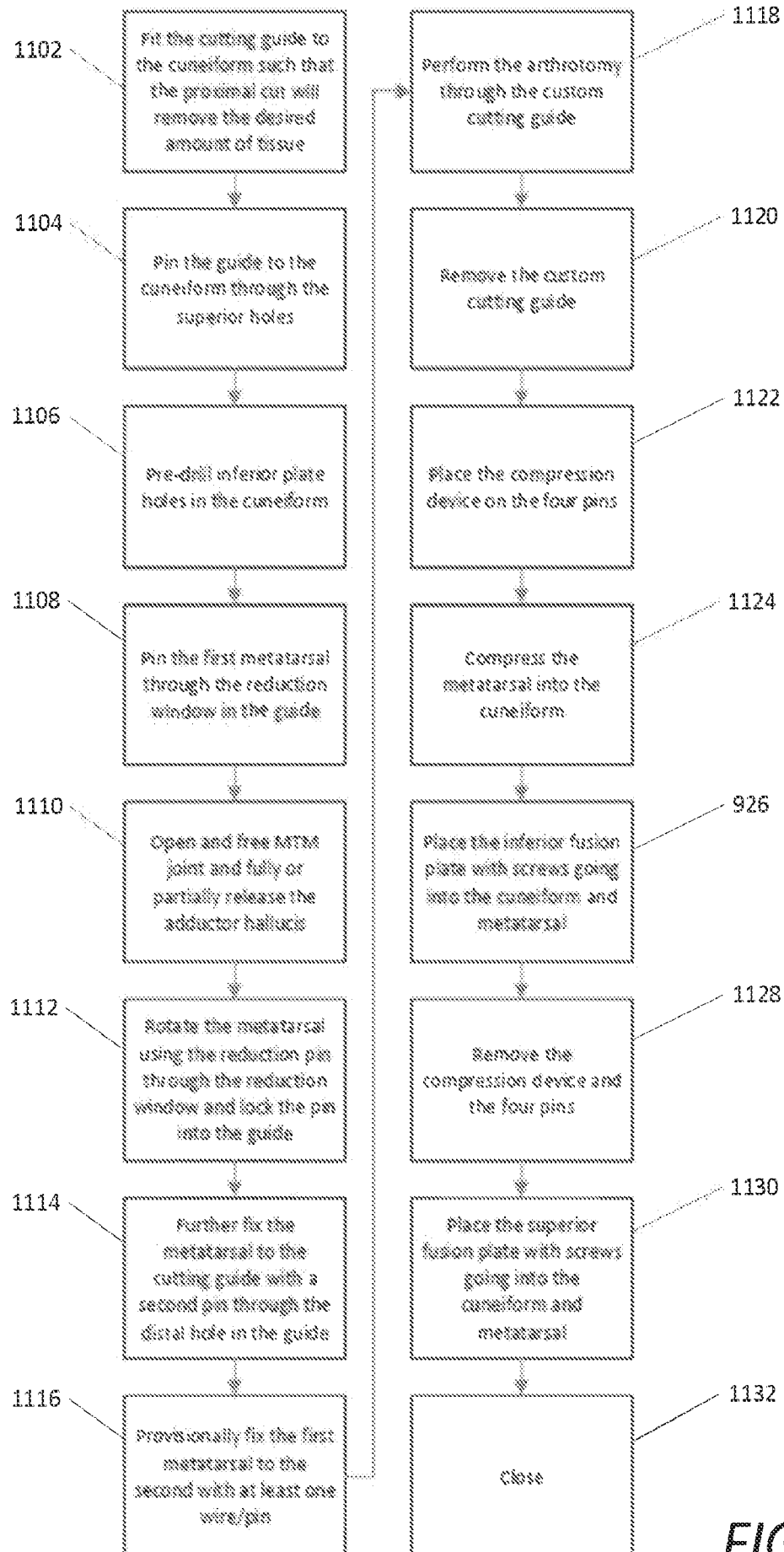


FIG. 9C



*FIG. 10*

**1100****FIG. 11**

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2023/028500

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/15 A61B17/17  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages                                                      | Relevant to claim No. |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X         | US 2022/211387 A1 (PERLER ADAM D [US] ET AL) 7 July 2022 (2022-07-07)                                                                   | 1-7,<br>10-12         |
| A         | figures 1A-3D<br>-----                                                                                                                  | 8, 9                  |
| X         | AU 2020 320 865 A1 (CROSSROADS EXTREMITY SYSTEMS LLC [US])<br>3 March 2022 (2022-03-03)<br>paragraph [0154] - paragraph [0156]<br>----- | 1                     |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

15 October 2023

Date of mailing of the international search report

14/12/2023

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040,  
Fax: (+31-70) 340-3016

Authorized officer

Fernández Arillo, J

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2023/028500

## Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 30-35  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Pursuant to Rule 39.1(iv) PCT, the subject-matter of claims 30-35 has not been searched, since it is directed to a method for treatment of the human body by surgery (they all contain the step of "removing portions of one or both of the metatarsal and the medial cuneiform" defined in claim 30).**
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

**see additional sheet**

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:  
**1-12**

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-12

A method for fabricating a surgical appliance for performing bunion corrective surgery comprising:collecting imagery of a foot exhibiting the bunion anomaly;deriving a model of the foot based on the imagery; andfabricating the appliance to custom fit the foot.

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2. claims: 13-22

A surgical appliance comprising: one or more holes defined in the appliance to guide the drilling of holes in a first bone to accept pins disposed in the drilled holes to hold the appliance to a first bone;a reduction area through which a pin is inserted into a second bone to allow rotation of the second bone with respect to the first bone, the reduction area including a locking area;wherein manipulating the pin through the reduction area imparts a rotation to the second bone; and wherein placing the pin in the locking area holds the second bone in the rotated position.

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3. claims: 23-29

A surgical appliance comprising:a top portion sized and shaped to be positioned on the top of a foot and covering a portion of the second through fifth toes; anda bottom portion to engage the soft tissue on the underside of the foot.

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2023/028500

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|-------------------------------------------|---------------------|----------------------------|---------------------|
| US 2022211387 A1                          | 07-07-2022          | NONE                       |                     |
| AU 2020320865 A1                          | 03-03-2022          | AU 2020320865 A1           | 03-03-2022          |
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|                                           |                     | EP 4003192 A1              | 01-06-2022          |
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|                                           |                     | US 2022249143 A1           | 11-08-2022          |
|                                           |                     | US 2023149045 A1           | 18-05-2023          |
|                                           |                     | WO 2021021640 A1           | 04-02-2021          |