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(54) **COMPUTER-ASSISTED CRANIOMAXILLOFACIAL SURGERY**

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(73) Assignee: **THE JOHNS HOPKINS UNIVERSITY**, Baltimore, MD (US)

(21) Appl. No.: **15/100,256**

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(86) PCT No.: **PCT/US2014/067656**

§ 371 (c)(1),
(2) Date: **May 27, 2016**

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Publication Classification

(51) **Int. Cl.**

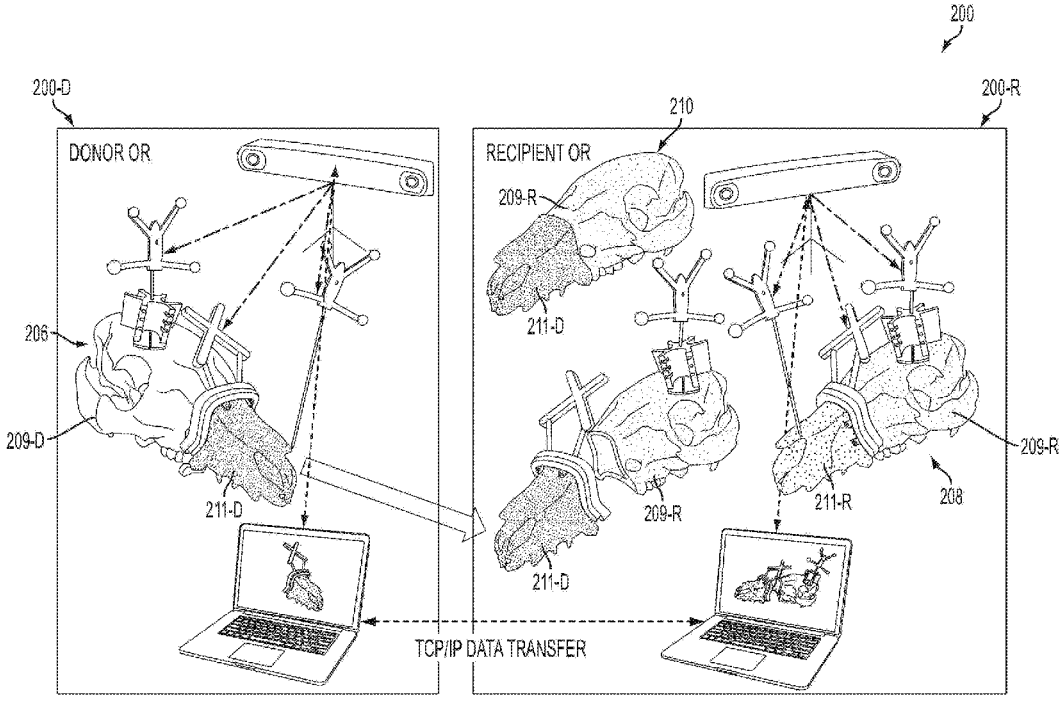
A61B 17/17	(2006.01)
A61B 34/10	(2006.01)
A61B 34/20	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 17/1739*** (2013.01); ***A61B 17/176*** (2013.01); ***A61B 34/20*** (2016.02); ***A61B 34/10*** (2016.02); *A61B 2034/105* (2016.02); *A61B 2034/108* (2016.02); *A61B 2034/2055* (2016.02); *A61B 2034/2051* (2016.02)

(57) **ABSTRACT**

A surgical system is provided. The system includes a reference unit, an implant and a detector. The reference unit includes a first trackable element. The implant includes a second trackable element. The detector is configured to provide at least one signal corresponding to a detected location of at least one of the first trackable element and the second trackable element.



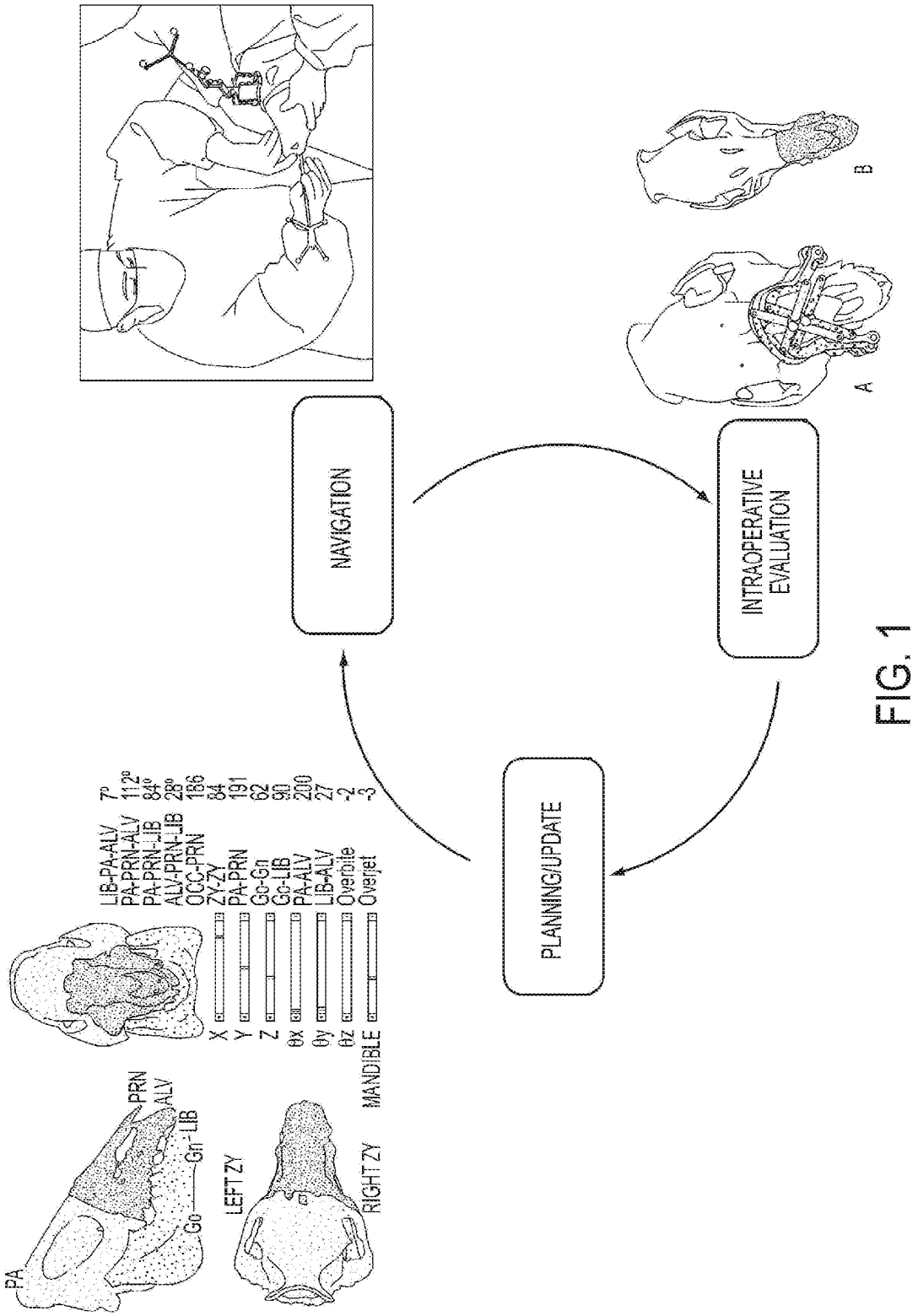

NAVIGATION
INTRAOPERATIVE EVALUATION
PLANNING/UPDATE
A
B
LIB-PA-ALV 7°
PA-PRN-ALV 112°
PA-PRN-LIB 84°
ALV-PRN-LIB 28°
OCC-PRN 186
ZY-ZY 84
PA-PRN 191
Go-Gn 62
Co-LIB 90
PA-ALV 200
LIB-ALV 27
Overbite -2
Overjet -3
X
Y
Z
θx
θy
θz
MANDIBLE
PA
PRN
ALV
Go
Gn
LIB
LEFT ZY
RIGHT ZY

FIG. 1

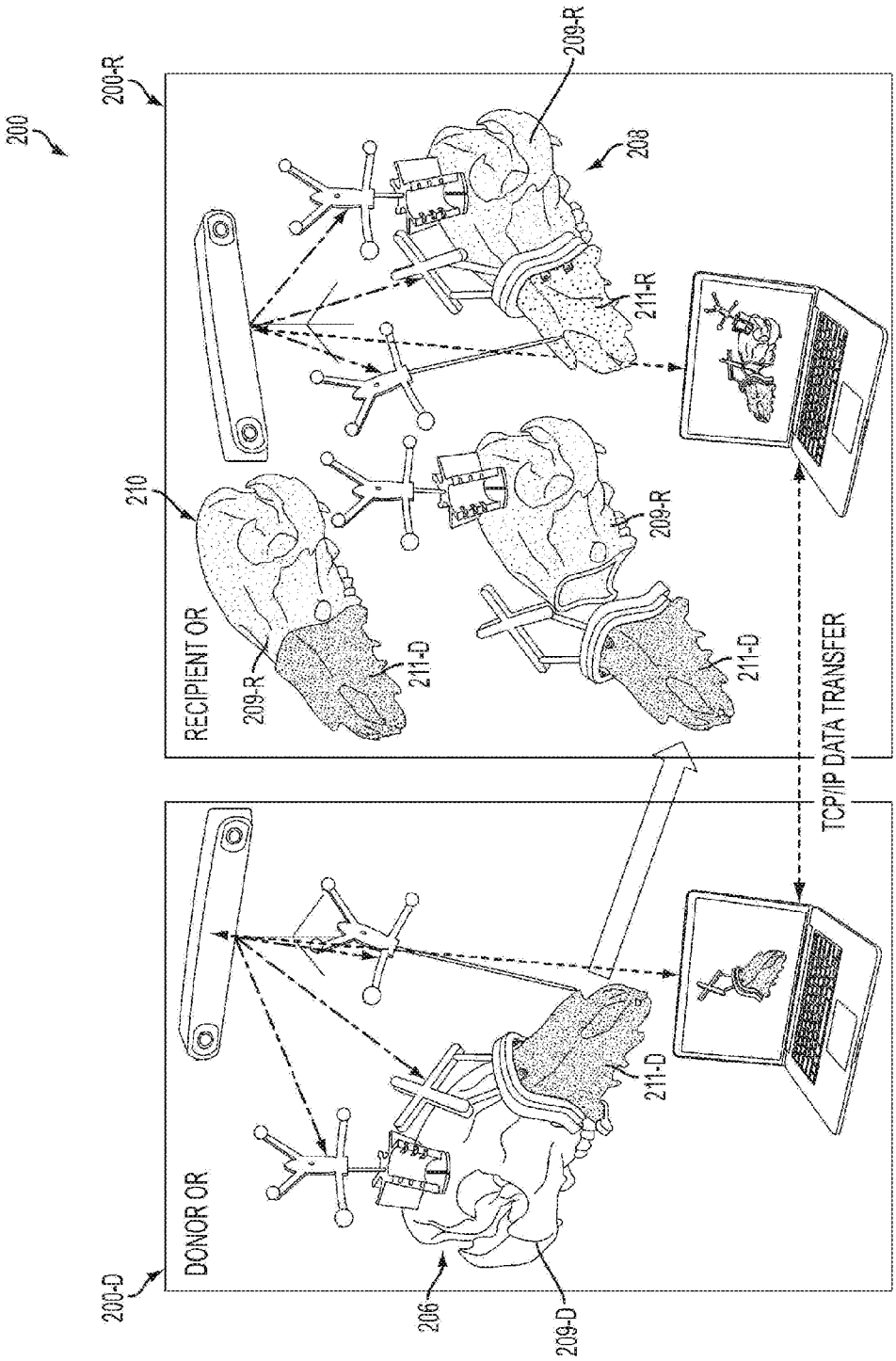

200
200-R
200-D
RECIPIENT OR
DONOR OR
210
208
209-R
209-D
211-R
211-D
206
TCP/IP DATA TRANSFER

FIG. 2A

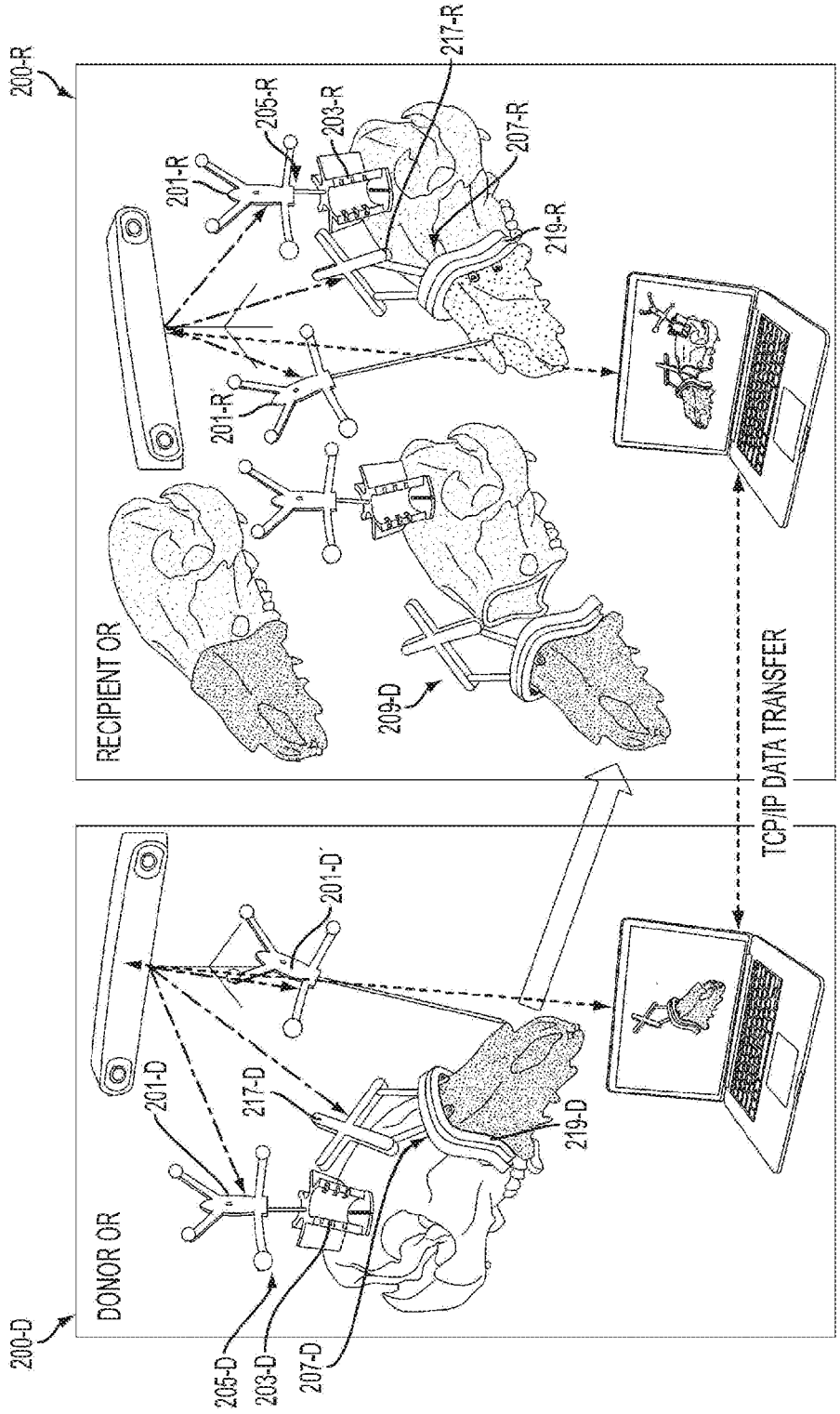

200-R
RECIPIENT OR
201-R
205-R
203-R
217-R
207-R
219-R
201-R'
209-D
TCP/IP DATA TRANSFER
200-D
DONOR OR
201-D
217-D
201-D'
219-D
205-D
203-D
207-D

FIG. 2B

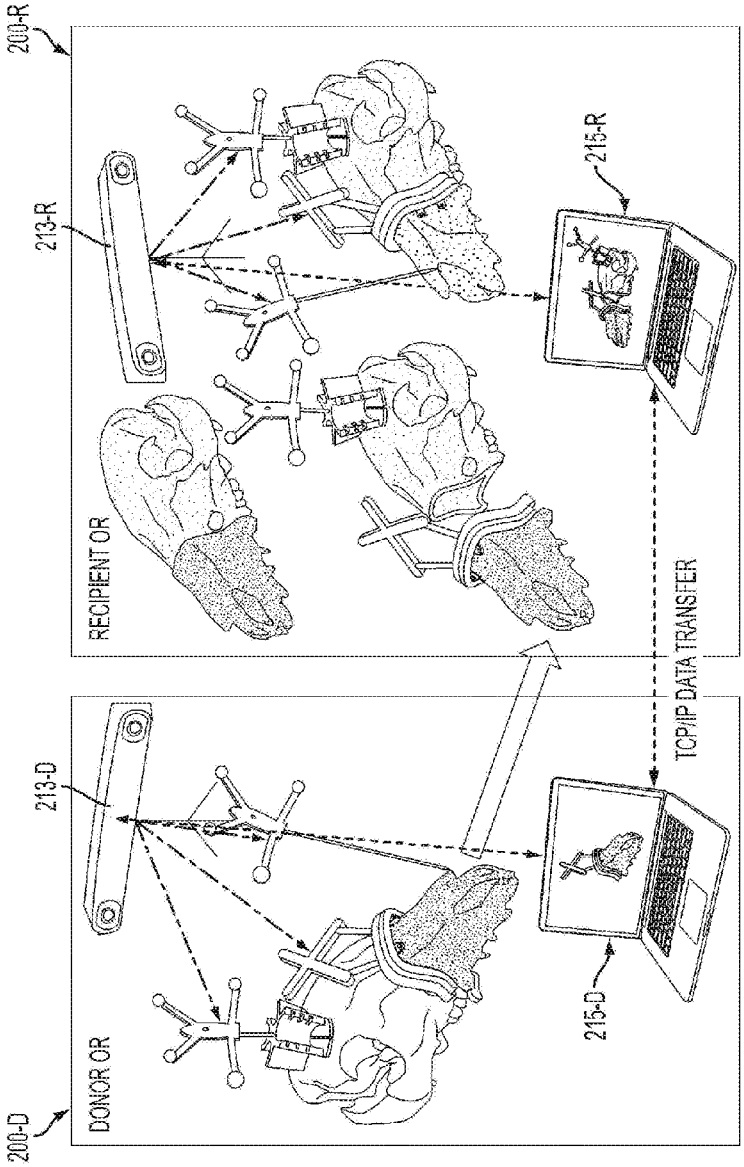


FIG. 2C

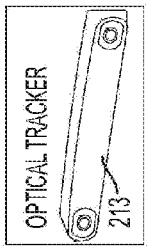


FIG. 2G

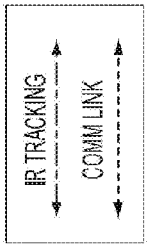


FIG. 2F

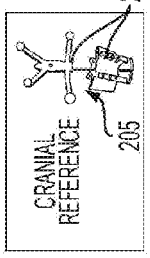


FIG. 2E

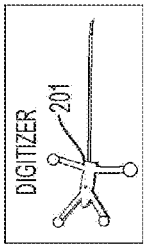


FIG. 2D

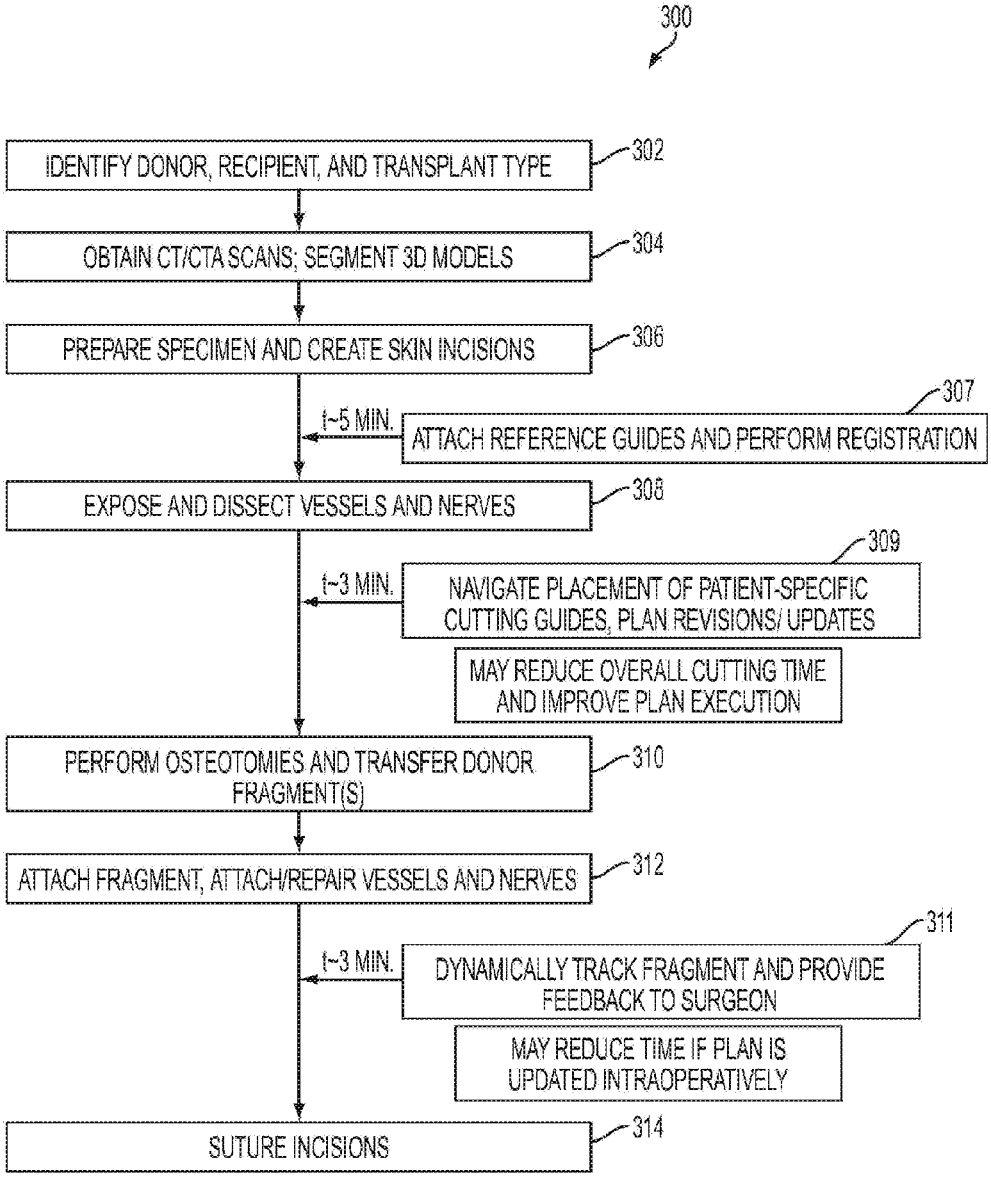

300
IDENTIFY DONOR, RECIPIENT, AND TRANSPLANT TYPE
302
OBTAIN CT/CTA SCANS; SEGMENT 3D MODELS
304
PREPARE SPECIMEN AND CREATE SKIN INCISIONS
306
307
t~5 MIN.
ATTACH REFERENCE GUIDES AND PERFORM REGISTRATION
EXPOSE AND DISSECT VESSELS AND NERVES
308
309
t~3 MIN.
NAVIGATE PLACEMENT OF PATIENT-SPECIFIC CUTTING GUIDES, PLAN REVISIONS/ UPDATES
MAY REDUCE OVERALL CUTTING TIME AND IMPROVE PLAN EXECUTION
PERFORM OSTEOTOMIES AND TRANSFER DONOR FRAGMENT(S)
310
ATTACH FRAGMENT, ATTACH/REPAIR VESSELS AND NERVES
312
311
t~3 MIN.
DYNAMICALLY TRACK FRAGMENT AND PROVIDE FEEDBACK TO SURGEON
MAY REDUCE TIME IF PLAN IS UPDATED INTRAOPERATIVELY
SUTURE INCISIONS
314

FIG. 3

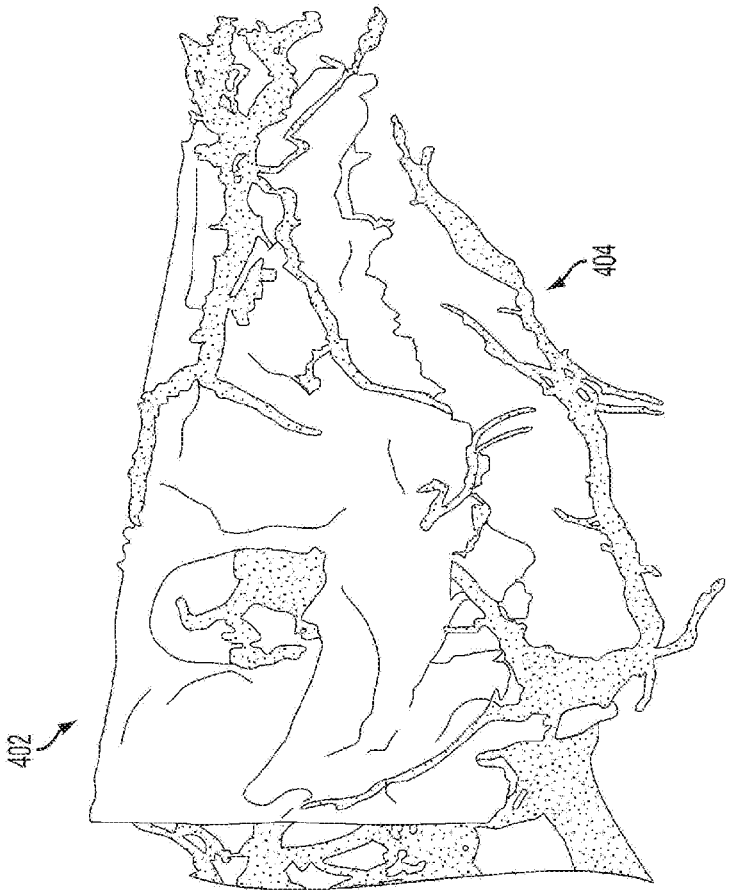


FIG. 4B

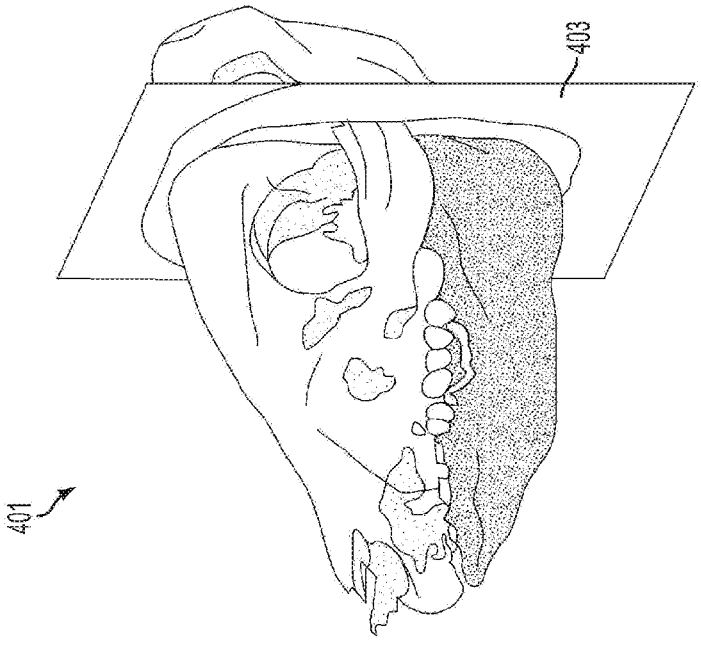


FIG. 4A

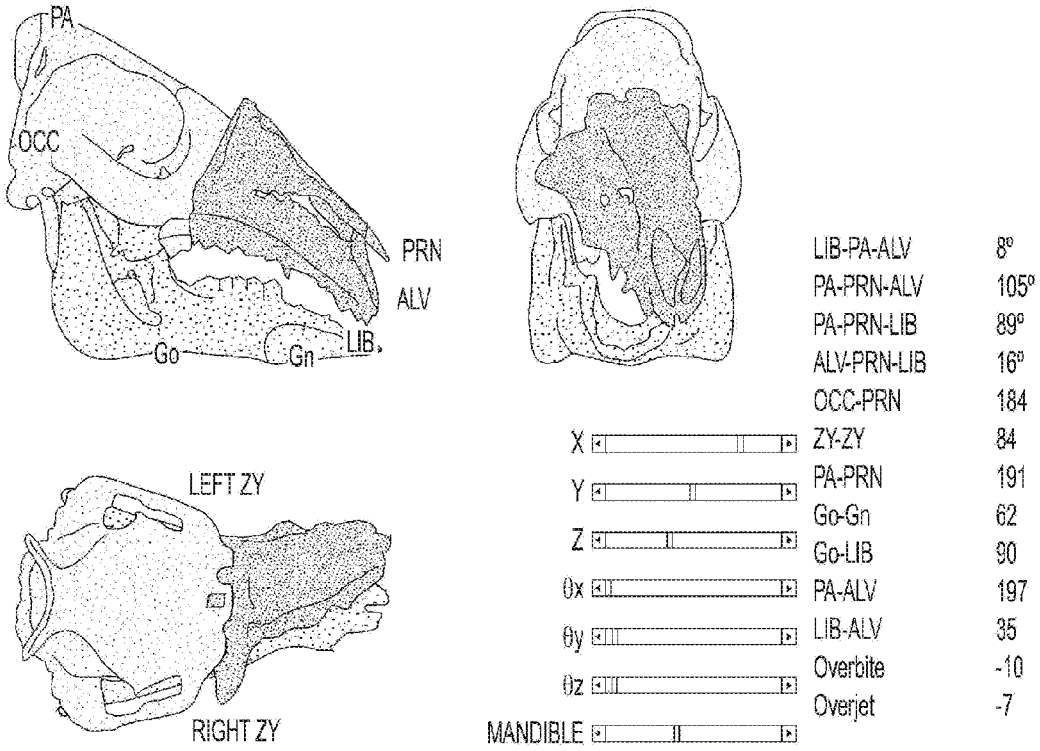

PA
OCC
PRN
ALV
Go
Gn
LIB
LEFT ZY
RIGHT ZY
X
Y
Z
θx
θy
θz
MANDIBLE
LIB-PA-ALV 8°
PA-PRN-ALV 105°
PA-PRN-LIB 89°
ALV-PRN-LIB 16°
OCC-PRN 184
ZY-ZY 84
PA-PRN 191
Go-Gn 62
Go-LIB 90
PA-ALV 197
LIB-ALV 35
Overbite -10
Overjet -7

FIG. 5A

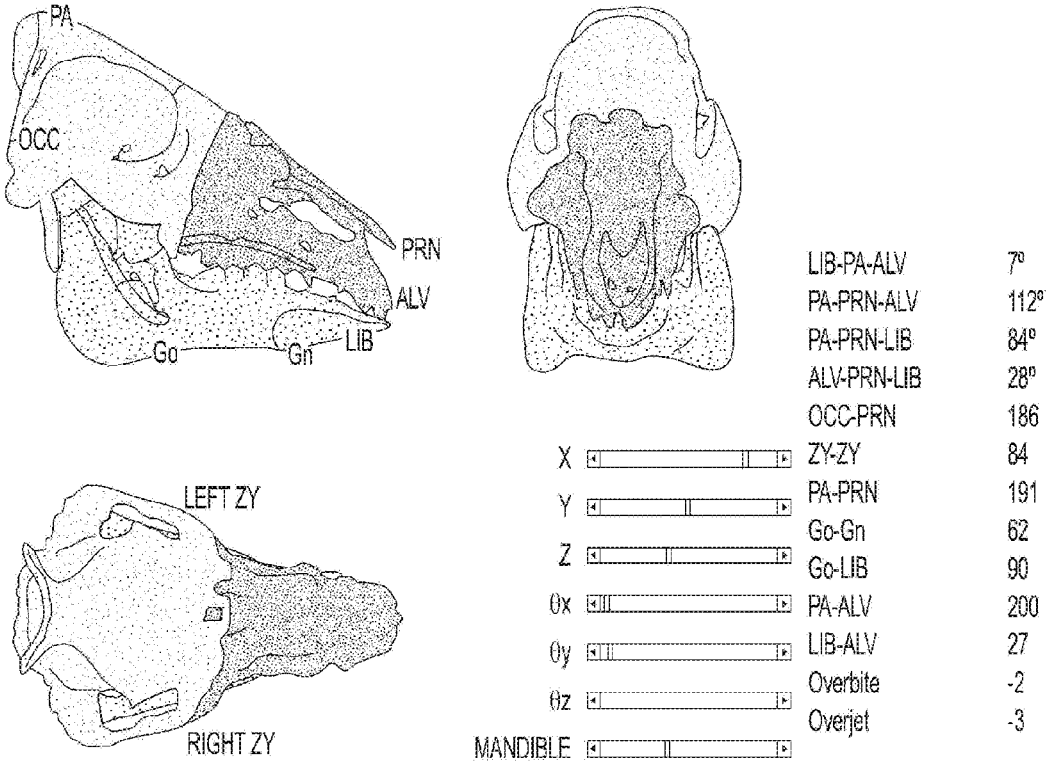

PA
OCC
PRN
ALV
Go
Gn
LIB
LEFT ZY
RIGHT ZY
X
Y
Z
θx
θy
θz
MANDIBLE
LIB-PA-ALV 7°
PA-PRN-ALV 112°
PA-PRN-LIB 84°
ALV-PRN-LIB 28°
OCC-PRN 186
ZY-ZY 84
PA-PRN 191
Go-Gn 62
Go-LIB 90
PA-ALV 200
LIB-ALV 27
Overbite -2
Overjet -3

FIG. 5B

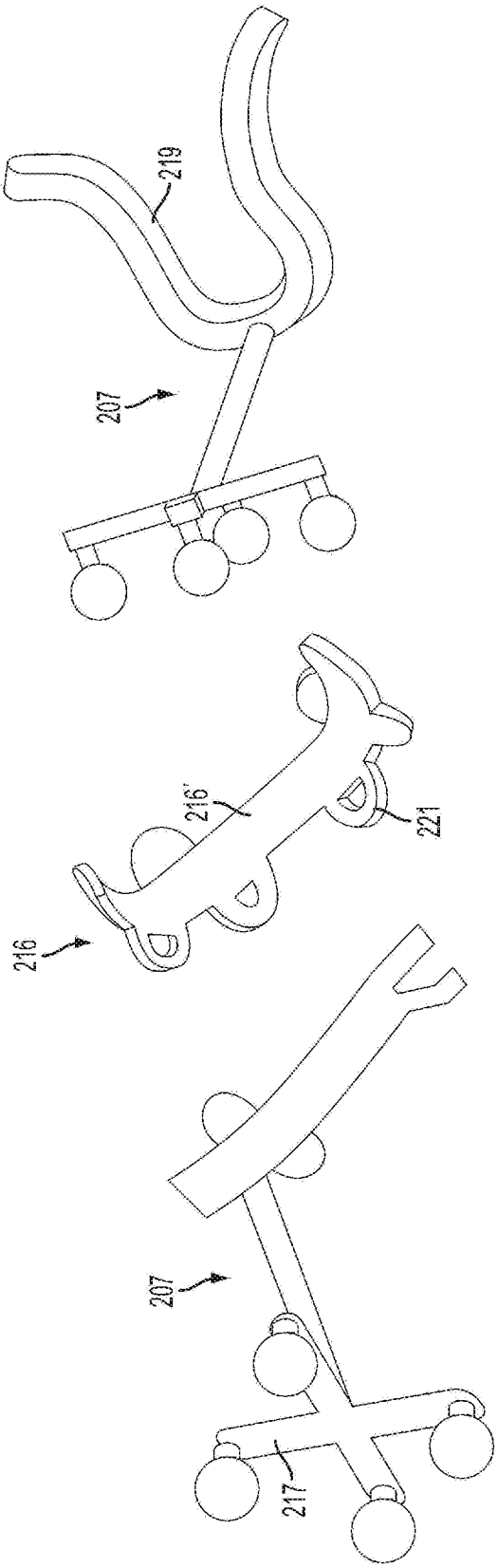


FIG. 6

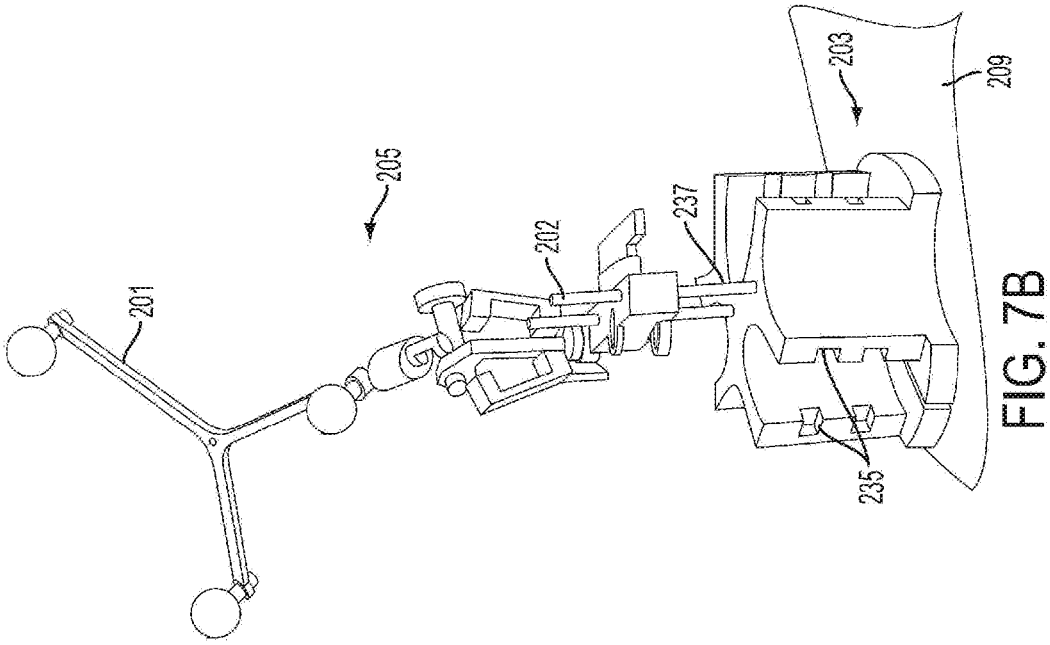


FIG. 7B

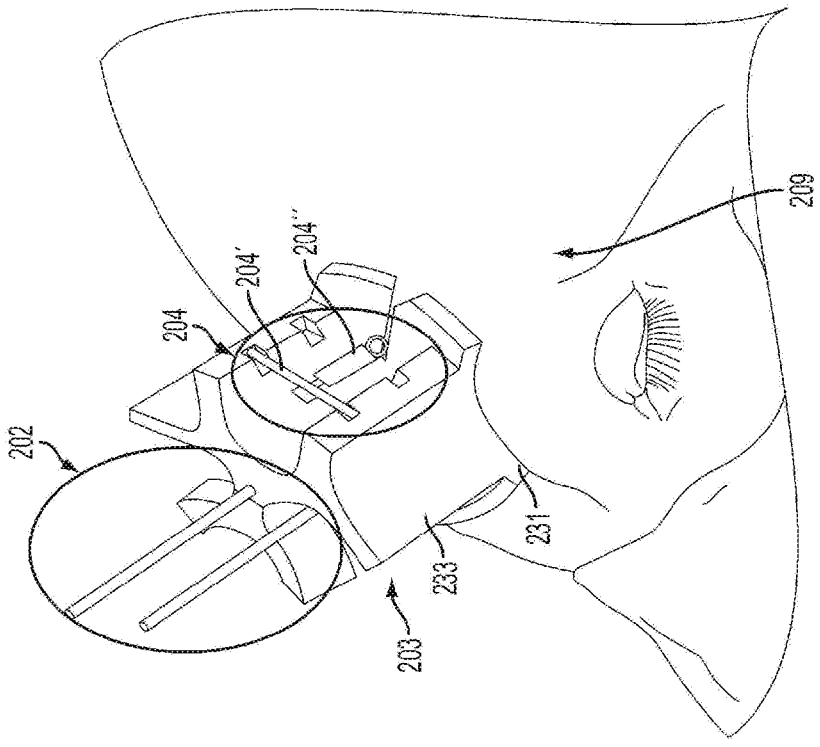


FIG. 7A

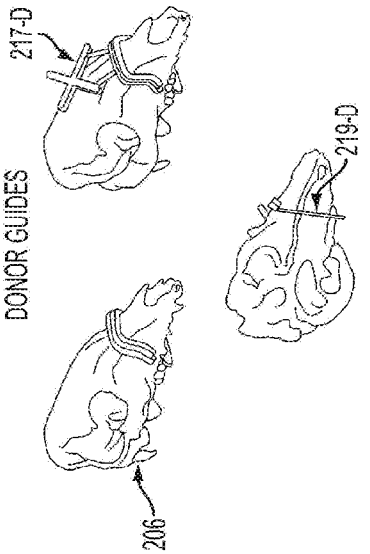


FIG. 8A

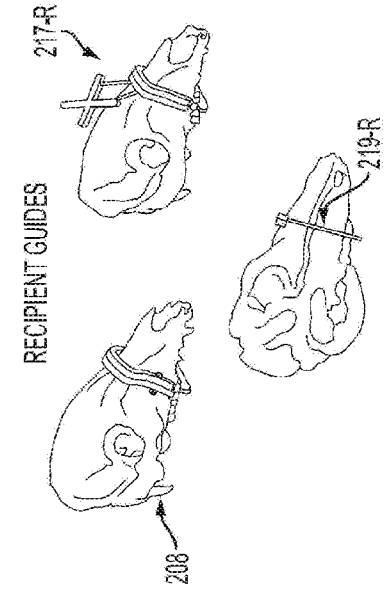


FIG. 8B

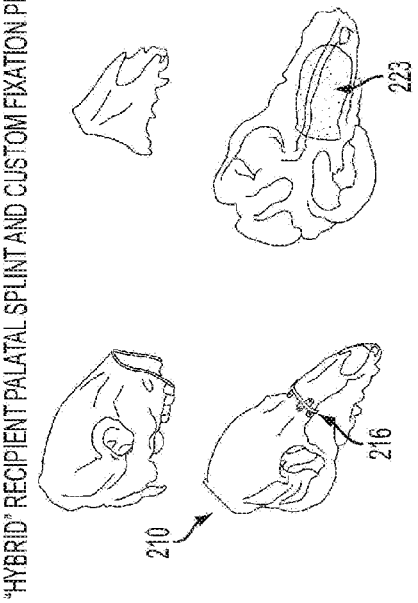


FIG. 8C

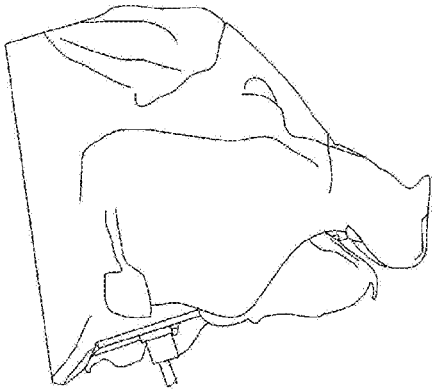


FIG. 9A

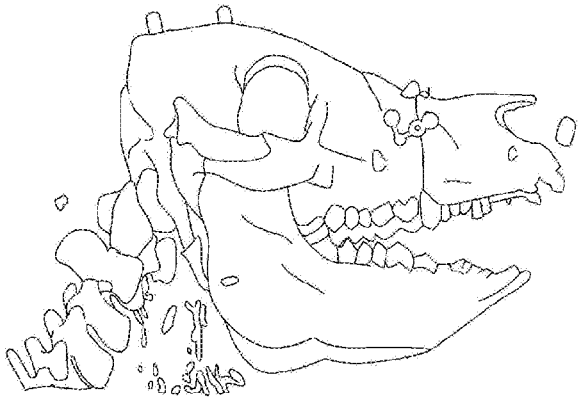


FIG. 9B

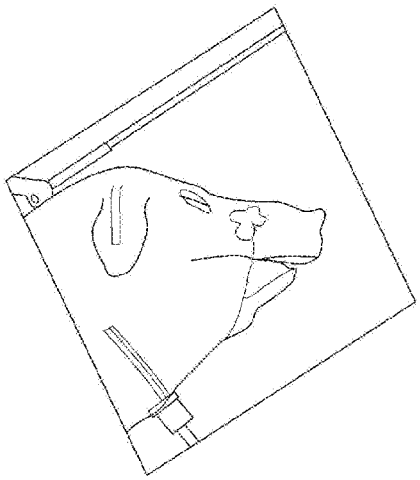


FIG. 9C

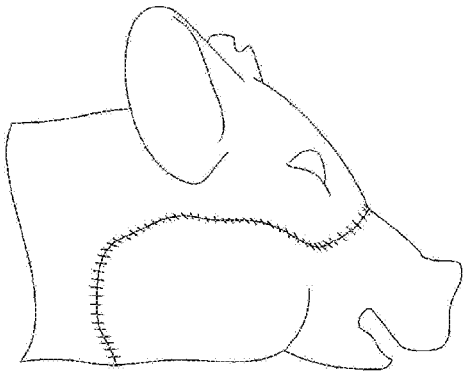


FIG. 9D

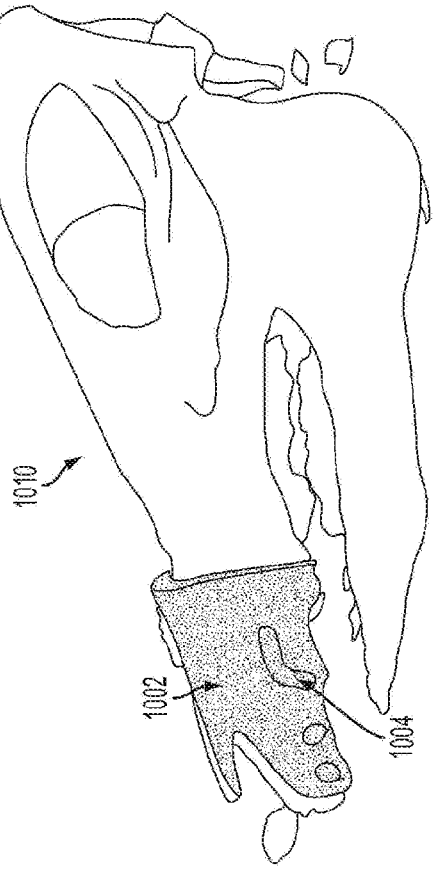


FIG. 10B

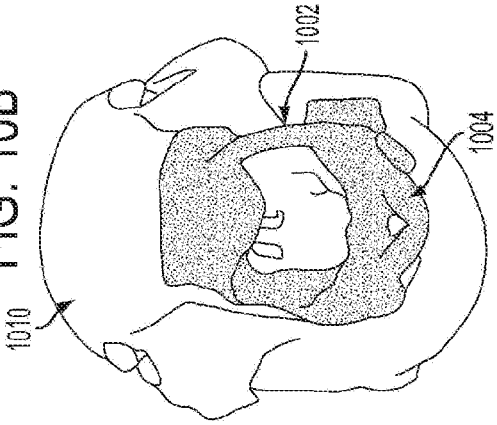


FIG. 10C

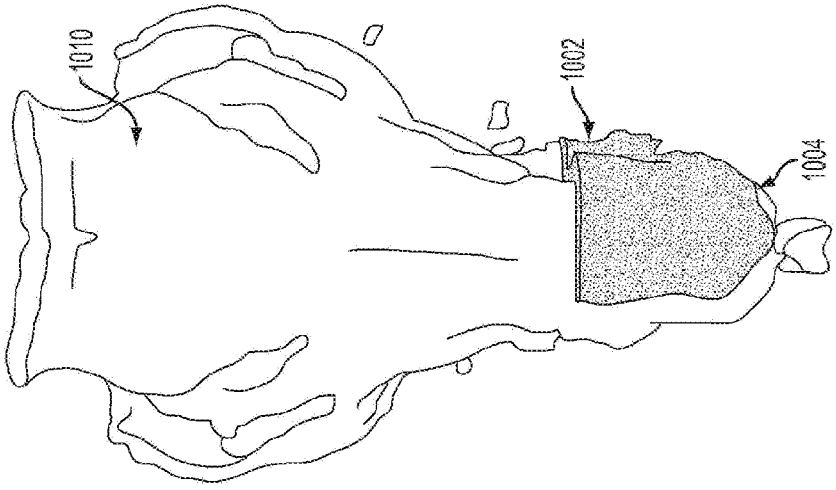


FIG. 10A

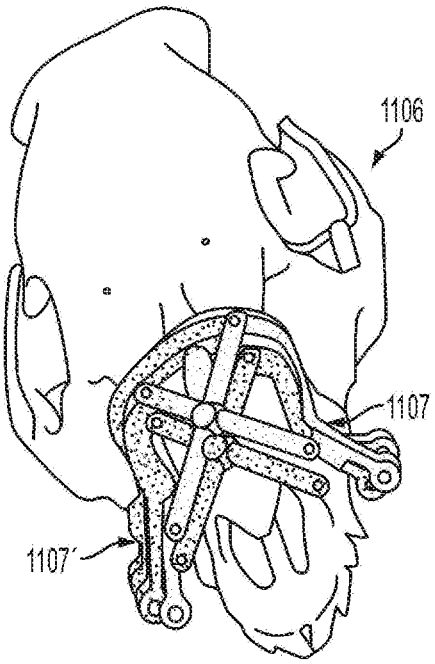


FIG. 11A

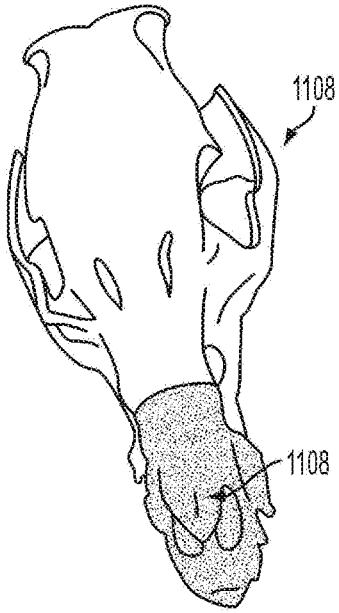


FIG. 11B

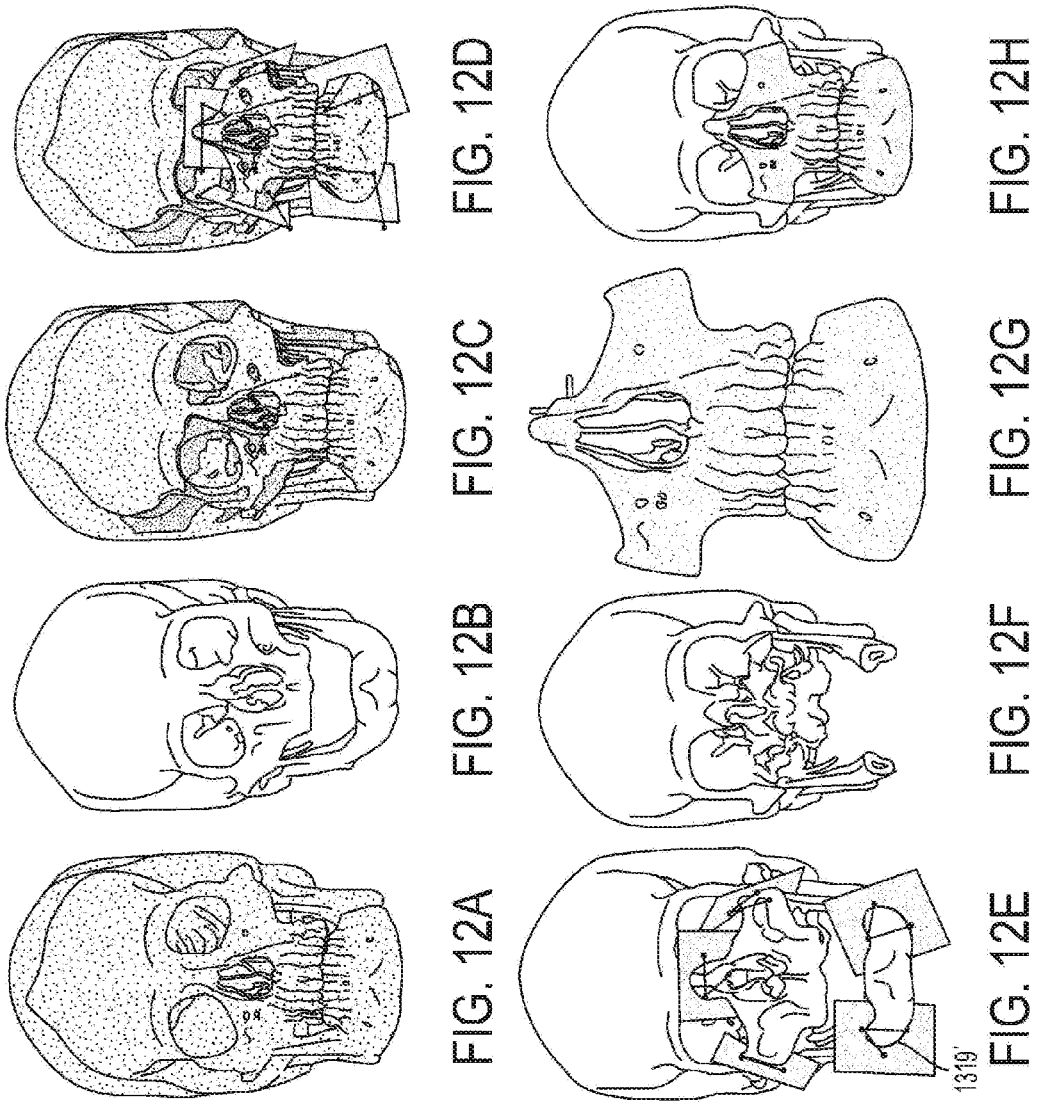


FIG. 12A FIG. 12B FIG. 12C FIG. 12D

FIG. 12E FIG. 12F FIG. 12G FIG. 12H

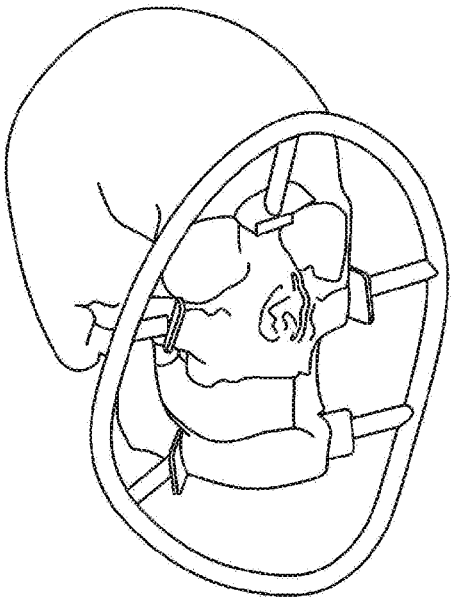


FIG. 13A

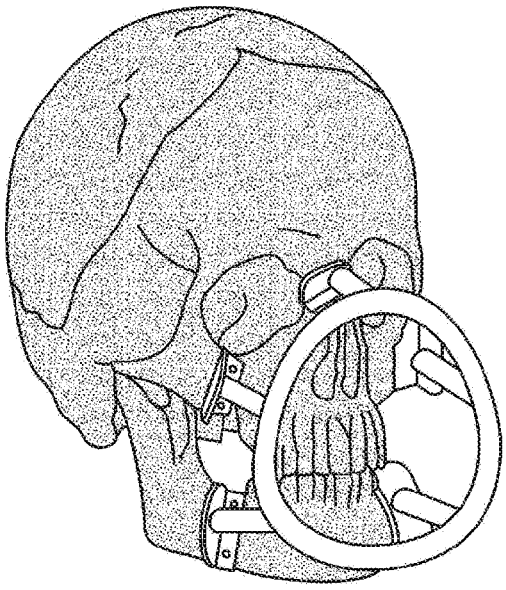


FIG. 13B

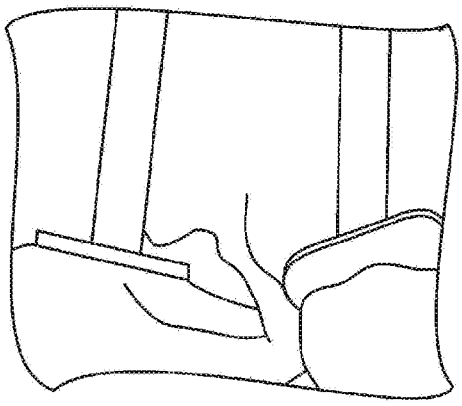


FIG. 13C

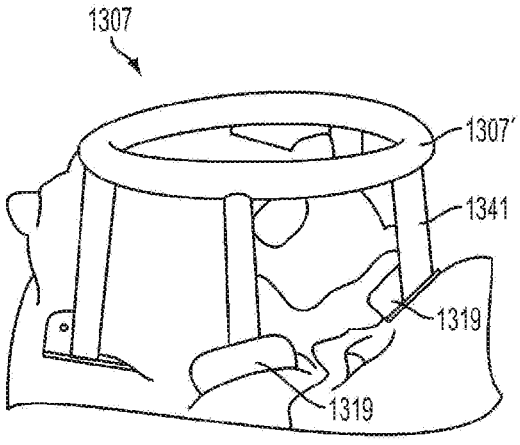


FIG. 13D

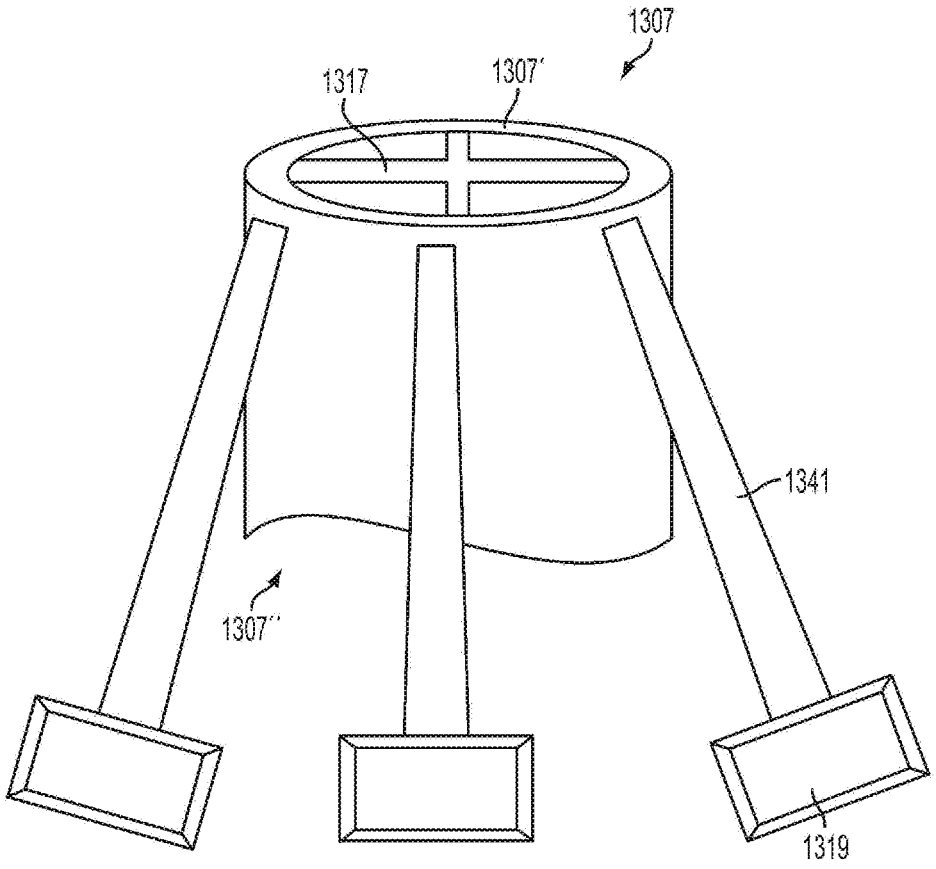


FIG. 14A

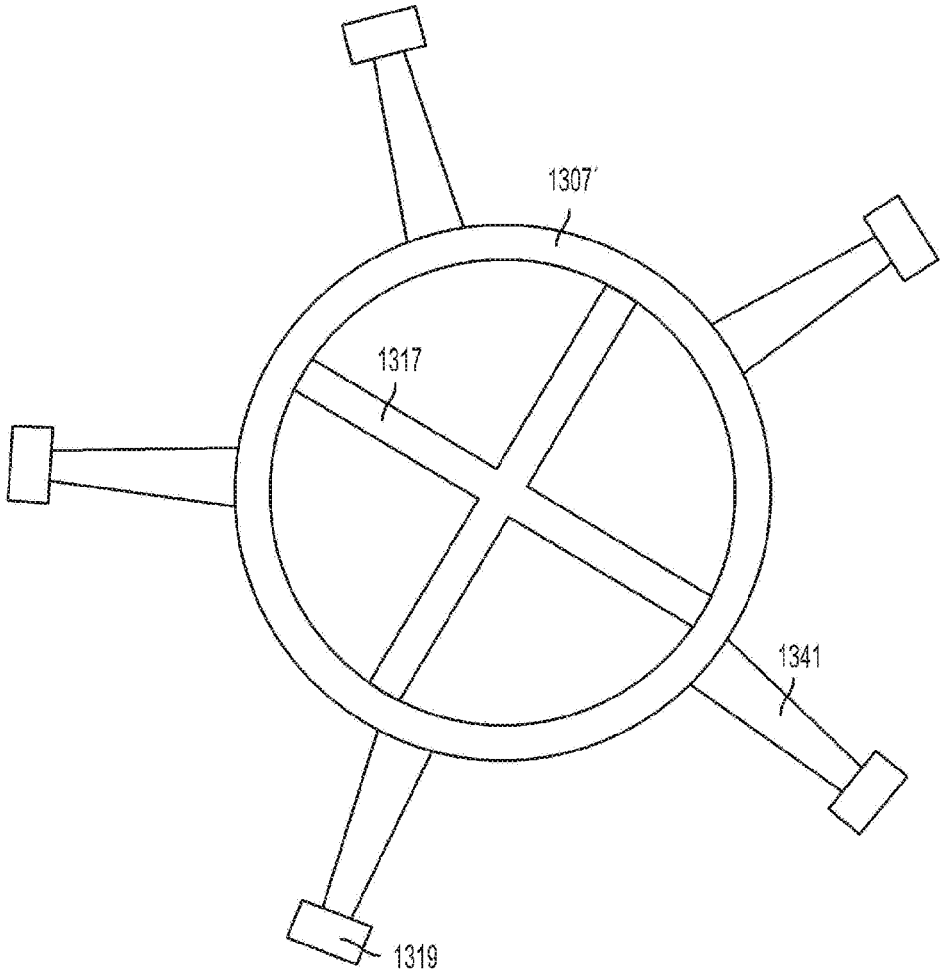


FIG. 14B

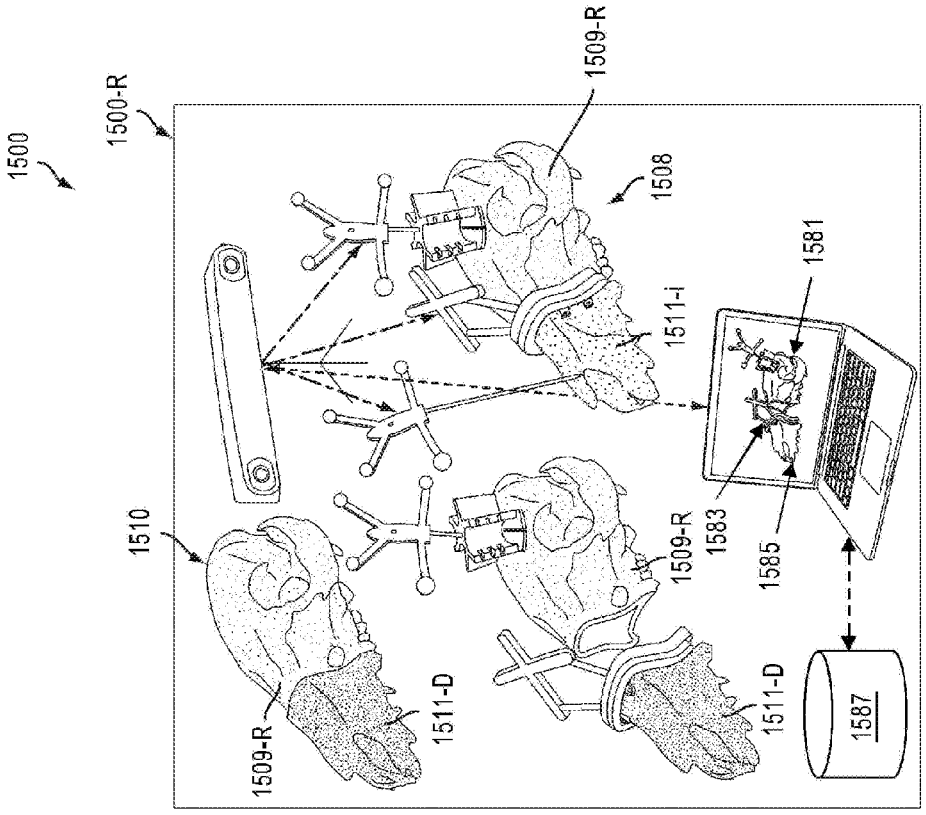

1500
1500-R
1509-R
1508
1511-i
1581
1510
1509-R
1583
1585
1509-R
1511-D
1511-D
1587

FIG. 15A

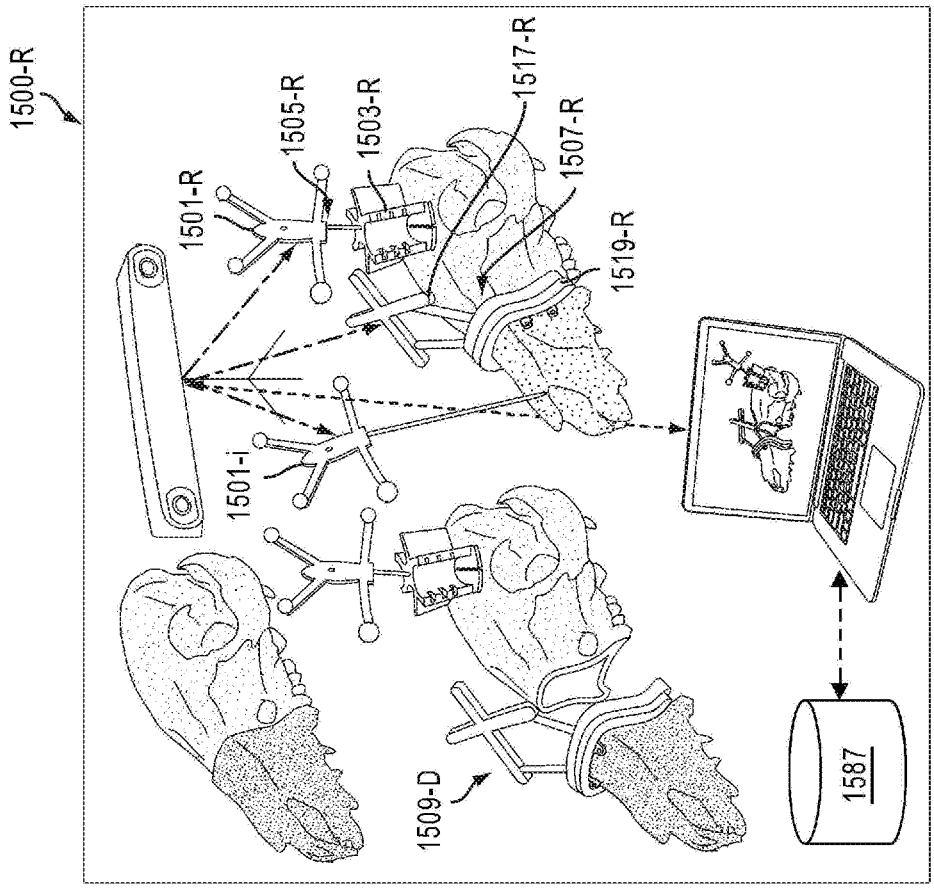


FIG. 15B

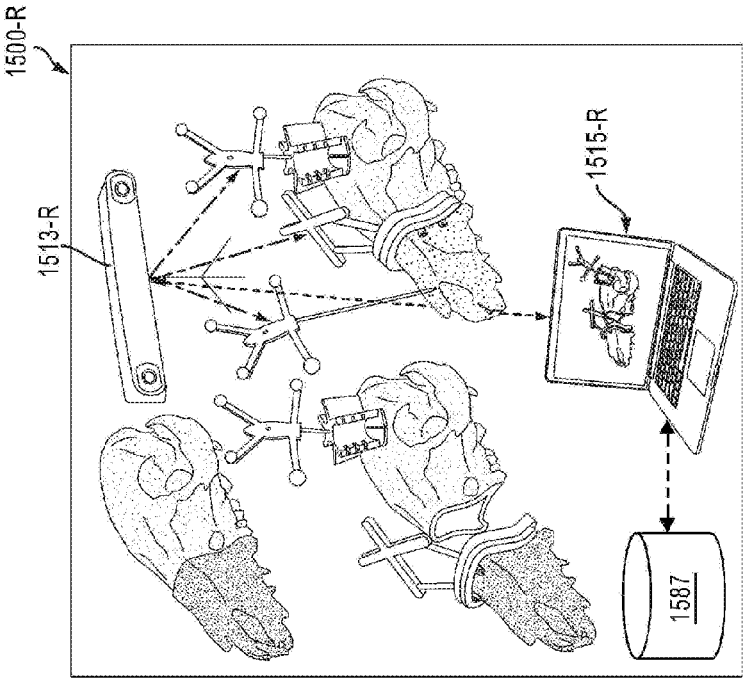


FIG. 15C

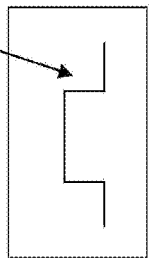


FIG. 15H

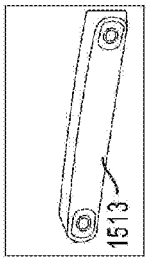


FIG. 15G

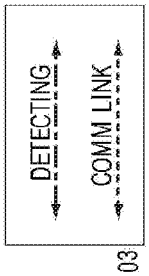


FIG. 15F

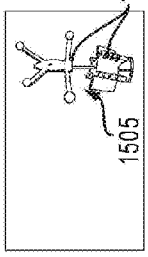


FIG. 15E

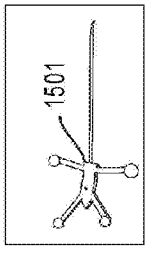


FIG. 15D

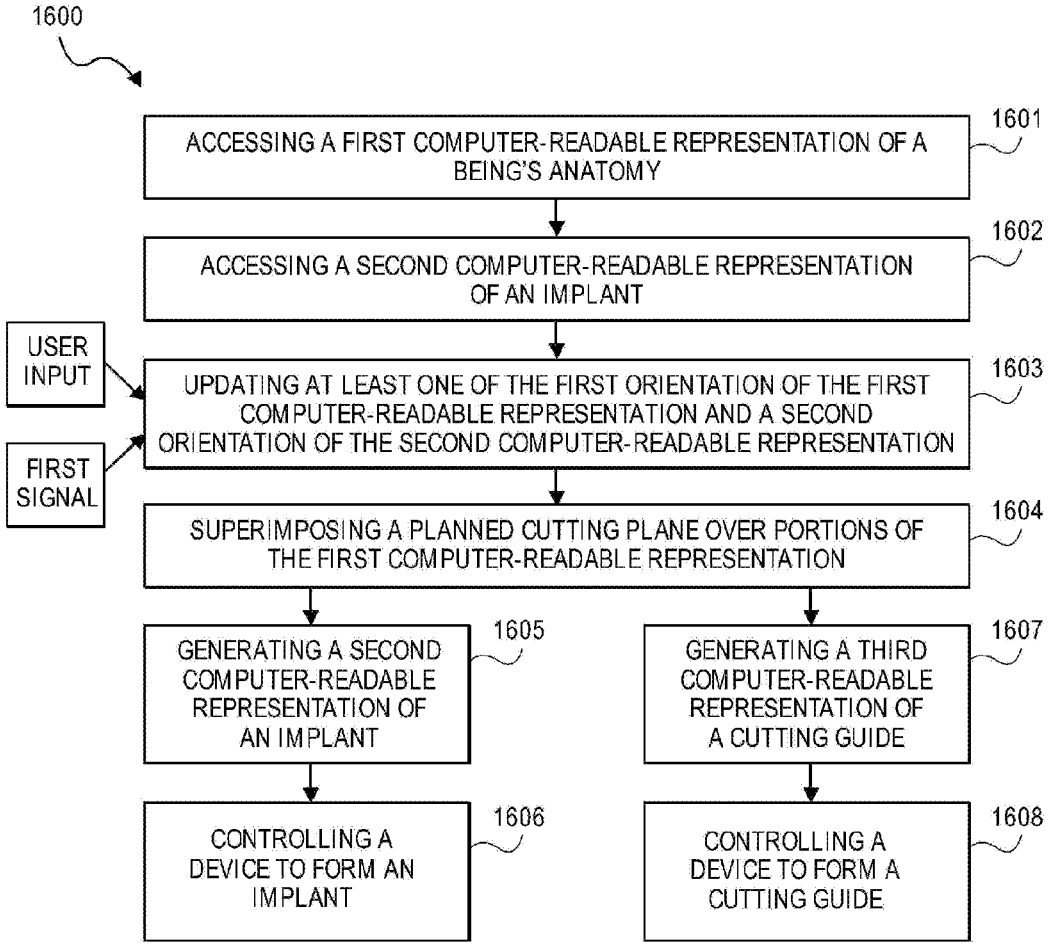

1600
ACCESSING A FIRST COMPUTER-READABLE REPRESENTATION OF A BEING'S ANATOMY
1601
ACCESSING A SECOND COMPUTER-READABLE REPRESENTATION OF AN IMPLANT
1602
USER INPUT
FIRST SIGNAL
UPDATING AT LEAST ONE OF THE FIRST ORIENTATION OF THE FIRST COMPUTER-READABLE REPRESENTATION AND A SECOND ORIENTATION OF THE SECOND COMPUTER-READABLE REPRESENTATION
1603
SUPERIMPOSING A PLANNED CUTTING PLANE OVER PORTIONS OF THE FIRST COMPUTER-READABLE REPRESENTATION
1604
GENERATING A SECOND COMPUTER-READABLE REPRESENTATION OF AN IMPLANT
1605
GENERATING A THIRD COMPUTER-READABLE REPRESENTATION OF A CUTTING GUIDE
1607
CONTROLLING A DEVICE TO FORM AN IMPLANT
1606
CONTROLLING A DEVICE TO FORM A CUTTING GUIDE
1608

FIG. 16

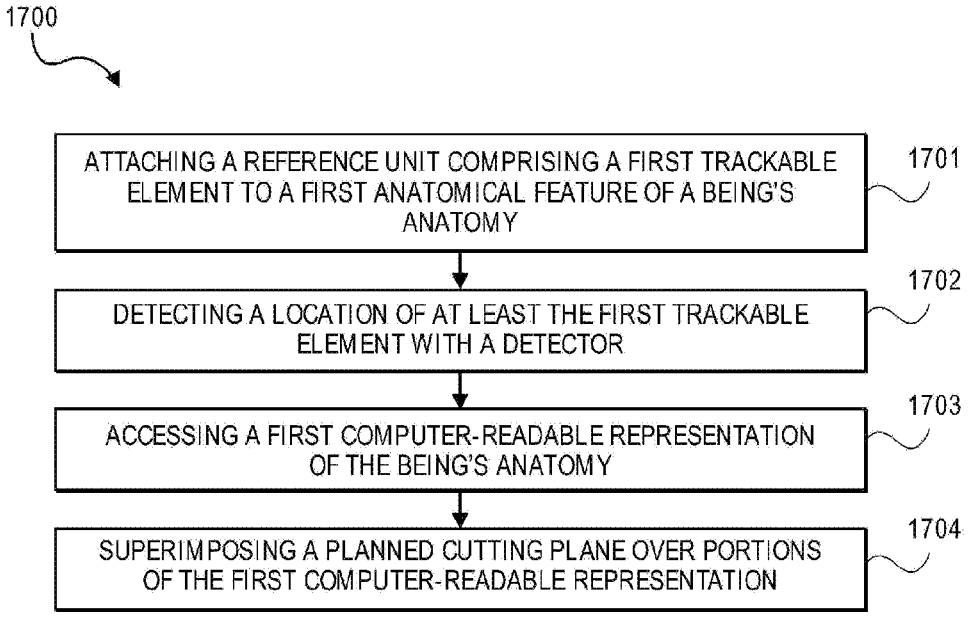

1700
ATTACHING A REFERENCE UNIT COMPRISING A FIRST TRACKABLE ELEMENT TO A FIRST ANATOMICAL FEATURE OF A BEING'S ANATOMY
1701
DETECTING A LOCATION OF AT LEAST THE FIRST TRACKABLE ELEMENT WITH A DETECTOR
1702
ACCESSING A FIRST COMPUTER-READABLE REPRESENTATION OF THE BEING'S ANATOMY
1703
SUPERIMPOSING A PLANNED CUTTING PLANE OVER PORTIONS OF THE FIRST COMPUTER-READABLE REPRESENTATION
1704

FIG. 17

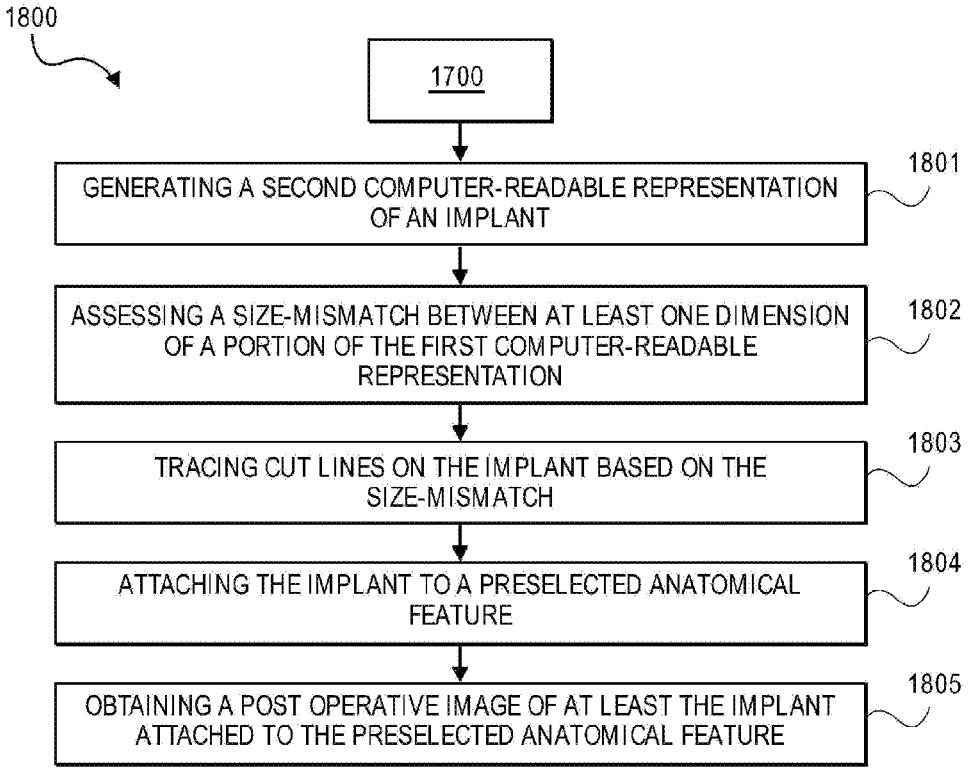

1800
1700
GENERATING A SECOND COMPUTER-READABLE REPRESENTATION OF AN IMPLANT
1801
ASSESSING A SIZE-MISMATCH BETWEEN AT LEAST ONE DIMENSION OF A PORTION OF THE FIRST COMPUTER-READABLE REPRESENTATION
1802
TRACING CUT LINES ON THE IMPLANT BASED ON THE SIZE-MISMATCH
1803
ATTACHING THE IMPLANT TO A PRESELECTED ANATOMICAL FEATURE
1804
OBTAINING A POST OPERATIVE IMAGE OF AT LEAST THE IMPLANT ATTACHED TO THE PRESELECTED ANATOMICAL FEATURE
1805

FIG. 18

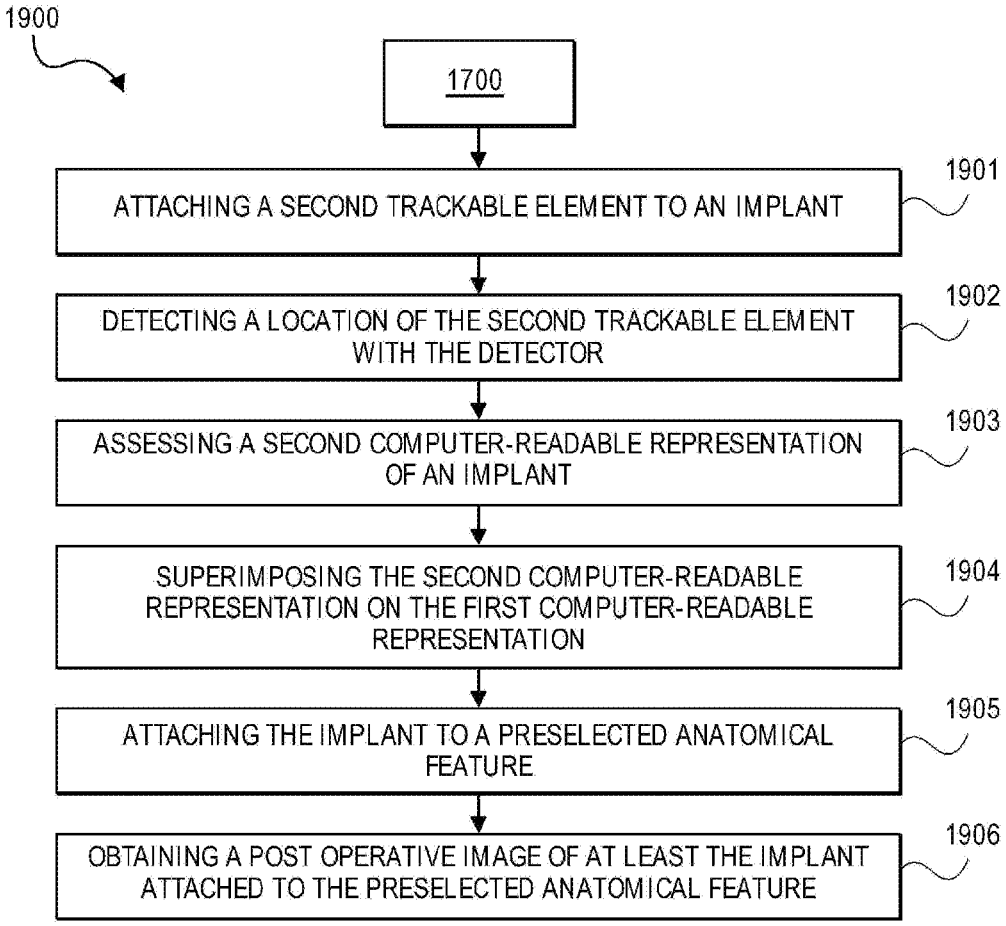

1900
1700
ATTACHING A SECOND TRACKABLE ELEMENT TO AN IMPLANT
1901
DETECTING A LOCATION OF THE SECOND TRACKABLE ELEMENT WITH THE DETECTOR
1902
ASSESSING A SECOND COMPUTER-READABLE REPRESENTATION OF AN IMPLANT
1903
SUPERIMPOSING THE SECOND COMPUTER-READABLE REPRESENTATION ON THE FIRST COMPUTER-READABLE REPRESENTATION
1904
ATTACHING THE IMPLANT TO A PRESELECTED ANATOMICAL FEATURE
1905
OBTAINING A POST OPERATIVE IMAGE OF AT LEAST THE IMPLANT ATTACHED TO THE PRESELECTED ANATOMICAL FEATURE
1906

FIG. 19

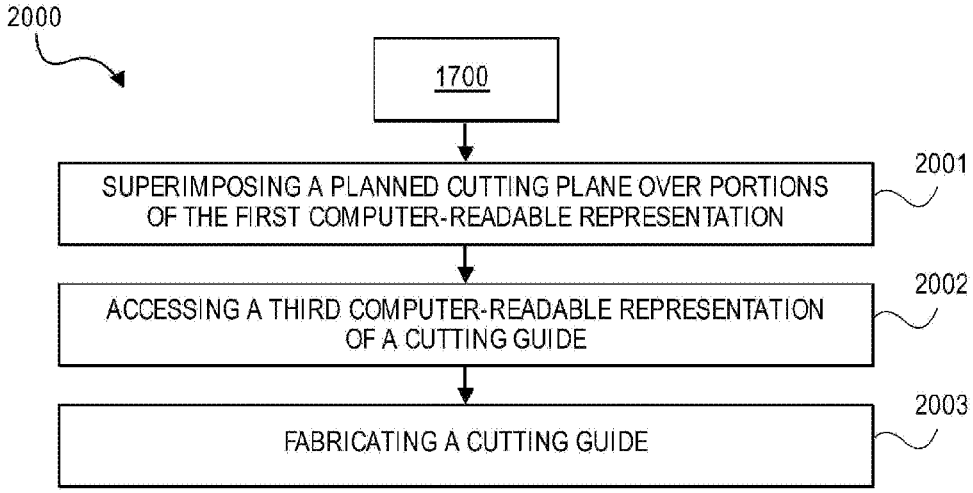

2000
1700
SUPERIMPOSING A PLANNED CUTTING PLANE OVER PORTIONS OF THE FIRST COMPUTER-READABLE REPRESENTATION
2001
ACCESSING A THIRD COMPUTER-READABLE REPRESENTATION OF A CUTTING GUIDE
2002
FABRICATING A CUTTING GUIDE
2003

FIG. 20

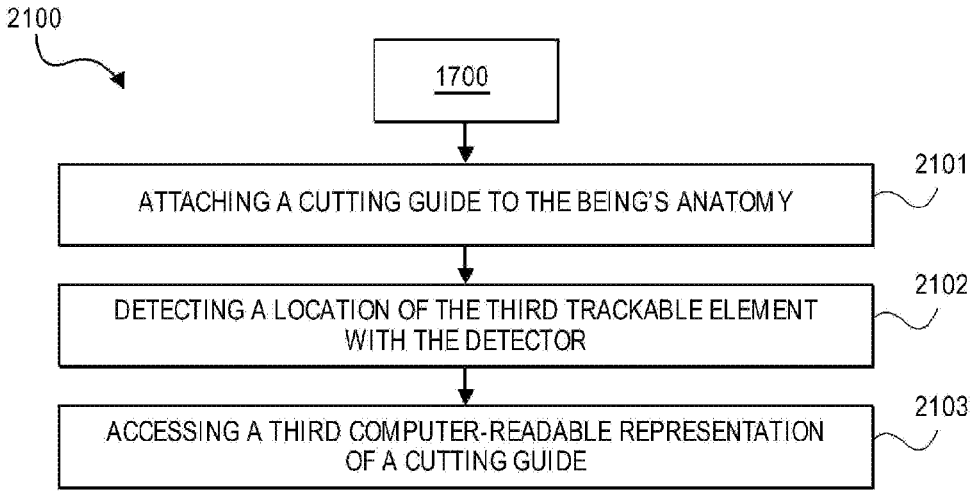

2100
1700
ATTACHING A CUTTING GUIDE TO THE BEING'S ANATOMY
2101
DETECTING A LOCATION OF THE THIRD TRACKABLE ELEMENT WITH THE DETECTOR
2102
ACCESSING A THIRD COMPUTER-READABLE REPRESENTATION OF A CUTTING GUIDE
2103

FIG. 21

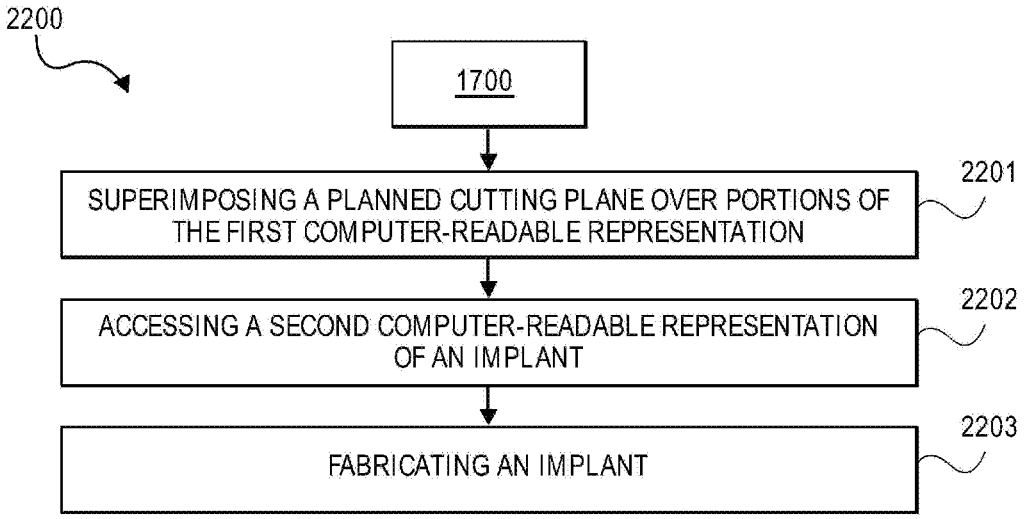

2200
1700
SUPERIMPOSING A PLANNED CUTTING PLANE OVER PORTIONS OF THE FIRST COMPUTER-READABLE REPRESENTATION
2201
ACCESSING A SECOND COMPUTER-READABLE REPRESENTATION OF AN IMPLANT
2202
FABRICATING AN IMPLANT
2203

FIG. 22

COMPUTER-ASSISTED CRANIOMAXILLOFACIAL SURGERY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Patent Application Ser. No. 61/910,204, filed Nov. 29, 2013; 61/940,196, filed Feb. 14, 2014; and 62/049,866, filed Sep. 12, 2014, each of which is hereby incorporated by reference in its entirety.

GOVERNMENT SUPPORT STATEMENT

[0002] This invention was made with government support under NCATS Grant No. UL1TR000424-06 awarded by the National Institutes of Health. The government has certain rights in the invention.

FIELD OF THE INVENTION

[0003] This invention relates generally to the field of surgery, particularly craniomaxillofacial surgery, and specifically to the field of computer-assisted craniomaxillofacial surgery and all related orthognathic, neurosurgical and head/face/neck surgical procedures and associated methods, tools, and systems.

BACKGROUND OF THE INVENTION

[0004] Craniomaxillofacial surgery, in adults and pediatric patients alike, accompanies many obstacles related to skeletal, aesthetic, and dental discrepancies following trauma disfigurement, oncological resection/reconstruction, and/or correction of congenital/acquired deformity. Use of computer technology to improve accuracy and precision of craniomaxillofacial surgical procedures has been described for nearly 30 years, since the increasing availability of computed topography (CT) prompted the development of a CT-based surgical simulation plan for osteotomies.

[0005] Two broad approaches to computer-assisted surgery (CAS) have gained popularity: 1) pre-operative computer surgical planning and the use of three-dimensional computer manufactured surgical guides (3D CAD/CAM) to cut and reposition bone and soft tissue, and 2) utilizing intraoperative feedback relative to preoperative imaging for the surgeon to provide more objective data on what is happening beyond the "eyeball test." However, none are meant for real-time placement feedback in areas where guide placement is more challenging, such as the three-dimensional facial skeleton. Also, there are no single platforms built to provide BOTH planning AND navigation—with seamless integration. Additionally, standard off-the-shelf vendor computer-assisted surgery systems may not provide custom features to mitigate problems associated with the increased complexity of this particular procedure. Furthermore, there are currently no validated methods for optimizing outcomes related to facial (e.g., soft tissue), skeletal (e.g., hard tissue), and occlusal (e.g., dental) inconsistencies—a major hurdle to achieving this specialty's full potential.

[0006] One known system includes pre-operative planning and cutting guides by way of computer manufactured stereolithographic models for complex craniomaxillofacial surgery. However, such a system uses standard off-the-shelf vendor systems and does not include necessary features to mitigate the increased complexity of this particular field.

[0007] Additionally, known CAS paradigms for craniomaxillofacial surgery provide little capacity for intraoperative plan updates. This feature becomes especially important since, in some circumstances, it may be necessary to revise and update the preoperative plans intraoperatively due to shifting of bones, teeth and face.

[0008] What is needed in the art, therefore, is a single, fully-integrated platform, providing a computer-assisted surgery solution customized for pre-operative planning, intraoperative navigation, and dynamic, instantaneous feedback, for example, in the form of biomechanical simulation and real-time cephalometrics for craniomaxillofacial surgery that addresses common shortcomings of existing CAS systems and has the potential to improve outcomes across both the pediatric and adult-based patient population.

SUMMARY

[0009] In an embodiment, there is a computer-assisted surgical system. The system may include a reference unit, an implant and a detector. The reference unit may include a first trackable element. The implant may include a second trackable element. The detector may be configured to provide at least one signal corresponding to a detected location of at least one of the first trackable element and the second trackable element.

[0010] In another embodiment, there is a computer-assisted, surgical method. The method can include attaching a reference unit that includes a first trackable element to a first anatomical feature of a being's anatomy, detecting a location of at least the first trackable element with a detector, and accessing a first computer-readable reconstruction of the being's anatomy. The detector may be configured to provide at least one signal corresponding to a detected location of at least the first trackable element. The first computer-readable may include a first updatable orientation, wherein the first updatable orientation may be updated in response to the at least one signal.

[0011] Additional advantages of the embodiments will be set forth in part in the description which follows, and in part will be understood from the description, or may be learned by practice of the invention. The advantages will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

[0012] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed.

[0013] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate embodiments of the invention and together with the description, serve to explain the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. **1** is a flowchart of a surgical system and method that closes the loop between surgical planning, navigation, and enabling intraoperative updates to a surgical plan.

[0015] FIGS. **2**A-**2**C provide a schematic overview of a surgical system.

[0016] FIGS. **2**D-**2**G are graphical representations of some components and/or features of the surgical system of FIGS. **2**A-**2**C.

[0017] FIG. **3** is a flow chart depicting a procedure associated with use of the surgical system, for example, the surgical system of FIGS. **2**A-**2**C.

[0018] FIG. **4**A is a CT-scan of reconstructed images of a size-mismatched facial skeleton generated from segmentation software utilized for pre-operative planning.

[0019] FIG. **4**B shows a segmented arterial system of a craniomaxillofacial skeleton generated from CT angiography (CTA) data allowing 3D, intraoperative mapping.

[0020] FIGS. **5**A-**5**B show depictions of on-screen images provided by a surgical system, such as the surgical system of FIG. **2**A displaying real-time, dynamic cephalometrics and pertinent measurements applicable to humans. FIG. **5**A shows a donor's face-jaw-teeth alloflap in suboptimal position as compared to a recipient's cranium. FIG. **5**B shows appropriate face jaw-teeth positioning with immediate surgeon feedback and updated cephalometric data pertinent to a pre-clinical investigation. A surgeon may adjust the position of face-jaw-teeth segment upwards, downwards, forwards, or backwards based on this real-time cephalometric feedback, as this information helps to predict optimal form and function. For instance, placing the face-jaw-teeth segment forward may improve the patient's airway, but if moved too far forward, it may cause the patient to have a significant overjet (i.e. malocclusion) and abnormal appearance in a profile view.

[0021] FIG. **6** shows some pre-bent fixation plates with screw holes designed virtually to accommodate the donor-to-recipient skeletal mismatch areas and matching navigational cutting guides of a surgical system, for example, the surgical system of FIGS. **2**A-**2**C.

[0022] FIG. **7**A shows a kinematic reference mount of an embodiment as it is affixed onto a donor's cranium with intermaxillary screws. A permanent suture (not visible) attaches stabilizers, such as springs and/or cross bars, which allow easy removal and replacement during surgery.

[0023] FIG. **7**B shows a detachable rigid body with reflective markers attached to the reference body.

[0024] FIGS. **8**A-**8**C are illustrations of cutting guides of the embodiments with navigational capabilities. FIG. **8**A illustrates a donor face-jaw-teeth alloflap recovery, FIG. **8**B shows a recipient preparation prior to transplant, and FIG. **8**C illustrates a custom pre-bent fixation plate and palatal splint designed to achieve face-jaw-teeth alignment and skeletal inset.

[0025] FIGS. **9**A-**9**D are renderings showing exemplary surgical results.

[0026] FIGS. **10**A-**10**C are a top-view (bird's eye view), a left-sided profile view, and a frontal view, respectively, of images displayed by an imaging system of a surgical system. The images depict a recipient skeleton and include real-time assessment of planned versus actual face-jaw-teeth positions.

[0027] FIGS. **11**A-**11**B are "on screen" images displayed by an imaging sub-system of a surgical system. The images depict an ideal location of a cutting guide versus an actual position and an actual inset position of a donor alloflap for aesthetic, dental, and skeletal relation in size-mismatched donors due to anterior translation of cutting guide.

[0028] FIG. **12** illustrates a virtual osteotomy and planned cut plane placement on virtual representations of a skeletal feature.

[0029] FIGS. **13**A-**13**D illustrate a virtual placement of a cutting guide alongside (FIGS. **13**A-**13**B) and illustrated representations of an actual placement (FIGS. **13**C-**13**D).

[0030] FIG. **14**A illustrates a perspective view of a variation of a cutting guide, for example, a variation of the cutting guide of FIG. **13**.

[0031] FIG. **14**B illustrates a top view of a variation of a cutting guide, for example, a variation of the cutting guide of FIG. **13**.

[0032] FIGS. **15**A-**15**C provide schematic overviews of a surgical system of an embodiment.

[0033] FIGS. **15**D-**15**H are graphical representations of some components and/or features of the surgical system of FIGS. **15**A-**15**C.

[0034] FIG. **16** is a flow chart depicting instructions that may be executed by a processor.

[0035] FIGS. **17**-**22** are each flow charts depicting embodiments of a surgical method.

DESCRIPTION OF THE EMBODIMENTS

[0036] Reference will now be made in detail to the present embodiments, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[0037] Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the invention are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical value, however, inherently contains certain errors necessarily resulting from the standard deviation found in their respective testing measurements. Moreover, all ranges disclosed herein are to be understood to encompass any and all sub-ranges subsumed therein. For example, a range of "less than 10" can include any and all sub-ranges between (and including) the minimum value of zero and the maximum value of 10, that is, any and all sub-ranges having a minimum value of equal to or greater than zero and a maximum value of equal to or less than 10, e.g., **1** to **5**. In certain cases, the numerical values as stated for the parameter can take on negative values. In this case, the example value of range stated as "less that 10" can assume negative values, e.g. −1, −2, −3, −10, −20, −30, etc.

[0038] The following embodiments are described for illustrative purposes only with reference to the figures. Those of skill in the art will appreciate that the following description is exemplary in nature, and that various modifications to the parameters set forth herein could be made without departing from the scope of the present invention. It is intended that the specification and examples be considered as examples only. The various embodiments are not necessarily mutually exclusive, as some embodiments can be combined with one or more other embodiments to form new embodiments.

[0039] Disclosed are embodiments of a computer-assisted surgery system that provides for large animal and human pre-operative planning, intraoperative navigation which includes trackable surgical cutting guides, real-time biomechanical simulation with visual feedback following bone cuts and various jaw-teeth segment movements for predicting post-operative function (i.e. mastication), and instantaneous visual feedback of objective cephalometric measurements/angles as needed for a variety of reconstructive and aesthetic instances of craniomaxillofacial and orthognathic surgery. Such a system can be referred to as a computer-

assisted planning and execution (C.A.P.E.) system and can be exploited in complex craniomaxillofacial surgery like Le Fort-based, face-jaw-teeth transplantation, for example, and any type of orthognathic surgical procedure affecting one's dental alignment.

[0040] The fundamental paradigm for computer-assisted surgery (CAS) involves developing a surgical plan, registering the plan and instruments with respect to the patient, and carrying out the procedure according to the plan. Embodiments described herein include features for workstation modules within a CAS paradigm. As shown in FIG. **1**, a surgical system of the embodiments can enable intraoperative evaluation of a surgical plan and can provide instrumentation for intraoperative plan updates/revisions when needed.

[0041] Embodiments can include a system with integrated planning and navigation modules, for example, a system for tracking donor and recipient surgical procedures simultaneously. In general, features of such a system can include: 1) two or more networked workstations concurrently used in planning and navigation of the two simultaneous surgeries for both donor and recipient irrespective of geographic proximity, 2) two or more trackers, such as electromagnetic trackers, optical trackers (e.g., Polaris, NDI Inc.), and the like, for tracking bone fragments, tools, and soft tissues, 3) one or more guides, reference kinematic markers, etc. as required for navigation. These features are described in further detail with respect to FIGS. **2**A-**2**G.

[0042] Preoperative planning can include the following tasks: a) segmentation and volumetric reconstruction of the donor and recipient facial anatomy; b) planning for patient-specific cutting guide placement; c) cephalometric analysis and biomechanical simulation of the hybrid skeleton's occlusion and masticatory function, respectively; d) fabrication of the hybrid cutting guides enabling both geometric ("snap-on" fit) and optical navigation; e) 3D mapping the vascular system on both recipient and donor facial anatomy; and f) plan updates, if necessary, based on the feedback from the intraoperative module. As used herein, "snap-on fit" or "snap-on" or "snap on" are used to describe the way an item, such as a cutting guide, attaches to a pre-determined area. That is, the cutting guide actually "snaps-on" to a certain pre-determined area along the patient being's anatomy, such as the facial skeleton, and in all other areas it doesn't fit properly since size and width varies throughout significantly with many convexities and concavities.

[0043] Intraoperative tasks of embodiments described herein can generally include: 1) registering the preoperative model reconstructed from the CT data to donor and recipient anatomy; 2) visualizing (e.g., using information from the tracker, such as an electromagnetic tracker, optical tracker, and the like) the instruments and cutting guides to help the surgeon navigate; 3) verifying the placement of cutting guides, and performing real-time cephalometric and biomechanical simulation for occlusion analysis, if, for any reason, the osteotomy sites need to be revised; 4) dynamically tracking the attachment of the donor fragment to the recipient and providing quantitative and qualitative (e.g., visual) feedback to the surgeon for the purpose of improving final outcomes related to form (i.e., overall facial aesthetics) and function (i.e., mastication, occlusion relation, airway patency). Such a procedure is described in further detail below with respect to FIG. **3**.

Preoperative Planning

[0044] In general, a method for performing a surgery includes a virtual surgical planning step that includes performing segmentation and 3D reconstruction of recipient and donor CT scans (e.g., Mimics 15.01, Materialise, Leuven Belgium). Virtual osteotomies can then be performed within the software to optimize the donor/recipient match. Patient-customized cutting guide templates can then be created (3-matic 7.01, Materialize, Leuven, Belgium). These templates can then be rapid-prototyped via an additive manufacturing modeling process, which can include, but is not limited to, stereolithography or 3D printing and the like. The surgical method and system for performing surgery are described in further detail below.

[0045] Referring to FIGS. **4**A and **4**B, during the initial planning stage, surgeons determine a virtual plan **401** based on the recipient's craniomaxillofacial deformity irrespective of the donor. From registered CT data, segmentation software generates volume data for specific key elements (e.g., the mandible, maxilla, and cranium) used for preoperative planning and visualization. The planning workstation automatically generates the expected cut geometry of the donor fragment **402** together with the recipient, thereby defining the predicted facial skeleton with accompanying hybrid occlusion. If available, blood vessels **404** are segmented from CT angiography scans as shown in FIG. **4**B. That is, in an embodiment, nerves (via known nerve foramens) and vessels (both arteries and veins) can be localized to provide a full anatomical "road map" to the surgeons for a more precise, time-saving anatomical dissection with perhaps decreased blood loss and smaller incisions. The planning module can also perform static cephalometric analysis and evaluation of face-jaw-teeth harmony via biomechanical simulation on varying constructions of the hybrid donor and recipient jaws, such as that shown in FIGS. **5**A-**5**B. Using this tool, the surgeon can evaluate different placements for the donor's face-jaw-teeth alloflap on the recipient's facial skeleton in relation to orbital volumes, airway patency, facial projection, and dental alignment. An automated cephalometric computation for the hybrid face indicates the validity of the planned surgery from both an aesthetic, functional and reconstructive standpoint based on various measurements of pertinent landmarks as shown, for example, in Tables 1A-B.

TABLE 1A

Pertinent landmarks for cephalometric analysis

SYMBOL	NAME and DEFINITION
Go	Gonion: a point mid-way between points defining angles of the mandible
Gn	Gnathion: most convex point located at the symphysis of the mandible
ALV	Alveolare: mid-line of alveolar process of the upper jaw, at incisor - alveolar junction
LIB	Lower Incisor Base: midline of anterior border of alveolar process of mandible at the incisor-alveolar junction
PA	Parietale: most superior aspect of skull in the midline, (formed by nuchal crest of occipital bone and parietal bone)
PRN	Pronasale: bony landmark representing anterior limit of nasal bone
ZY	Zygion: most lateral point of malar bone
OCC	Occipital region: midpoint between the occipital condyles

TABLE 1B

Cephalometric measurements and related units.

	Measure												
	ZY-ZY	PA-PRN	Go-Gn	Go-LIB	PA-ALV	LIB-ALV	Overbite	Overjet	OCC-PRN	LIB-PA-ALV	PA-PRN-ALV	PA-PRN-LIB	ALV-PRN-LIB
Units	mm	mm	mm	Mm	mm	mm	mm	mm	mm	deg	deg	deg	deg

[0046] To evaluate and predict cephalometric relationships both during planning and intra-operative environments, the system can use validated, translational landmarks between swine and human to thereby allow effective pre-clinical investigation. The cephalometric parameters defined by these landmarks can be automatically recalculated as the surgeon relocates the bone fragments using a workstation's graphical user interface.

[0047] Preoperative planning can also involve fabrication of custom guides **207** (as shown in FIG. **6**) and palatal splints **223** (as shown in FIG. **8**C). Planned cut planes **403** (as shown in FIG. **4**) can be used for defining the geometry of the cutting guides to thereby provide patient-specific cutting guides. These cutting guides can be designed according to the skeletal features through which the cutting plane intersects, such as an outer skeletal surface of a cross section defined by the cutting plane, and can be fabricated via stereolithography, or via any additive manufacture technology. In an embodiment, custom cutting guide templates can be separately designed and navigational registration elements can be added (Freeform Plus, 3D Systems, Rock Hill, S.C.). As discussed above, the surgical guides can be manufactured via additive manufacturing technology (AMT). The cutting guides can, therefore, be a 3D printing material such as a polymer, and can include an attachment surface **216** configured for attaching to a skeletal feature, and can have a "snap-on" fit to both donor and recipient. As described above, the attachment surface may include a contoured surface that corresponds to the contours of the skeletal feature within the planned cut planes. A navigation surface, such as a reference geometry **217** connected, built into, or attached to the guide structure directly or via attachment guides (not shown), enables dynamic intraoperative tracking of guides with respect to the patient's skeleton. Palatal splints ensure planned dento-skeletal alignment fixation following Le Fort-type facial transplants or any similar type of surgery. Fixation plates **216** can include a primary surface **216'** and a plurality of fixation surfaces **221**, such as eyelets, for screw placement to provide rigid immobilization at the irregular skeletal contour areas along various donor-to-recipient interfaces. Having pre-bent fixation plates decreases total operative times and helps to confirm accurate skeletal alignment by overcoming step-off deformities at bone-to-bone interfaces. Accordingly, at least one of the plurality of fixation surfaces can be located on one side of the primary surface and configured for attaching the fixation surface to a donor skeleton fragment, and at least one of another of the plurality of fixation surfaces is located on another side of the primary surface and configured for attaching the fixation surface to a recipient skeleton. The whole fixation plate or just portions of the fixation plate, such as the primary surface or fixation surfaces can be manufactured via additive manufacturing technology.

[0048] The cutting guide's navigation surface can include trackable objects, for example, on the reference geometry, such as infrared (IR) reflective coatings or IR emitters. For example, the trackable objects can include a plurality of integrated tracking spheres, each of which has an IR reflection surfaces.

Intraoperative Surgical Assistance

[0049] Individual navigation for both donor and recipient surgeries tracks the cutting guides with respect to planned positions. Surgeons can attach a reference unit, such as a kinematic reference mount to three intramedullary fixation (IMF) screws arranged in a triangular pattern on each the donor and recipient craniums as shown in FIG. **7**A-**7**B. Accordingly, in an embodiment, there is a reference unit **205** for providing real-time surgical navigation assistance. The reference unit for providing real-time surgical navigation assistance can include a kinematic mount **203**, at least one fixation rod **202**, at least one support **204**, and reference geometry **201**. The kinematic mount **203** can include a base with a plurality of recesses defined by sidewalls **233**, at least one pair of slots **235** defined by portions of the sidewalls, with each slot of the pair formed across the recess from the other slot, and at least one guide hole **237** extending through a length of the fixation plate. The at least one fixation rod **202** can extend through the at least one guide hole **237**. An end of the at least one support rod can be configured for attaching to a skeleton of a being **209**. The at least one support can be disposed in the pair of slots and can be configured to attach to the being. The reference geometry **201** can be attached to the at least one fixation rod.

[0050] The at least one support **204** can include at least one cross-bar **204'** with ends that are configured for placement in the slots **235**, and a spring **204"** attached at one end to the at least one cross-bar **204'** and attached at another end to the patient (e.g., a human-being). The spring attached at another end to the being can be attached via a suture (further described below). The reference unit **205** can further include a trackable object disposed on the reference geometry. The trackable object disposed on the reference geometry can include an IR reflective surface. The mount **203** can be made via additive manufacturing techniques and can therefore include a polymer. The at least one fixation rod can include a plurality of intramedullary fixation screws. The base can be configured for being detachably mounted on the skeleton of the being **209**. The intramedullary fixation screws can be arranged in a triangular pattern. Accordingly the guide-holes can be configured in a triangular pattern on the base.

[0051] Accordingly, the mount design permits flexibility in the placement of the IMF screws so that no template is necessary. A spring **204"** can attach to each IMF screw via suture threaded through, for example, the eyelets. These

springs hold the cranial mount **203** in place and allow easy removal and replacement of the cranial mount (e.g. during positional changes required for bone cuts and soft tissue dissections). This may provide detachability and use of Intramaxillary fixation (IMF) screws for stable attachment.

[0052] The reference geometry **201** (e.g., which can be purchased from Brainlab, Westchester, Ill., USA) attached to the kinematic mount **203** provides a static coordinate frame attached to the patient. The surgeon can digitize three bony landmarks (e.g., the inferior aspect of the orbits and antero-superior maxilla) to define a rough registration between the environment and virtual models. For example, three, consistent points can be selected which can be quick to find, easy to reproduce on numerous occasions, and would remain constant irrespective of the user and his/her experience with the systems of the embodiments. The surgeon can thereby collect several point sets from exposed bone using a digitization tool and uses an iterative closest point registration technique to refine the registration. As shown in FIG. **8**, once registered, the surgeon navigates the placement of the cutting guide **217** using the combination of "snap-on" geometric design and the tracking system coupled to visual feedback. This allows assessment of inaccuracies related to soft tissue interference, iatrogenic malpositioning, and anatomical changes since acquiring original CT scan data, and/or imperfections in cutting guide design or additive manufacturing process.

[0053] Self-drilling screws affix the cutting guide to the patient's skeleton to ensure osteotomies are performed along pre-defined planes, maximizing bony congruity. After dissecting the donor's maxillofacial fragment and preparing the recipient's anatomy, the surgical team transfers the facial alloflap. The system is configured to track the final three-dimensional placement of, for example, the Le Fort-based alloflap providing real-time visualization such as that shown in FIG. **5**A-**5**B. This provides real-time visualization of important structures such as new orbital volumes (vertical limit of inset), airway patency (posterior horizontal limit of inset), and facial projection (anterior horizontal limit of inset). Once confirmed, the surgeon fixates the donor alloflap to the recipient following conventional techniques with plates and screws.

[0054] Accordingly, returning to FIGS. **2**A-**2**G, there is a system **200** for tracking donor and recipient surgical procedures simultaneously. The system can include a donor sub-system **200**-D, a recipient sub-system **200**-R and a communications link (indicated by the horizontal dotted-line) such as a communication link that provides TCP/IP data transfer between the donor and recipient sub-systems. The donor sub-system can include a first computer workstation **215**-D, a first cranial reference module **205**-D, a first cutting guide **207**-D for attaching to a preselected location of a donor skeleton **206**, a first fragment reference module **201**-D', and a first tracker **213**-D. The first cutting guide **207**-D can include an attachment surface **219**-R configured for attaching to a skeletal feature, and a navigation surface **217**-D connected to the attachment surface and comprising a trackable reference geometry. The first tracker **213**-D may be configured to be in communication with the first computer workstation, for example, via a communications link. The first tracker can be configured to track, for example via IR optical tracking, a location of a portion of the first cranial reference module, a portion of the first cutting guide and a portion of the first fragment reference module. The recipient sub-system **200**-R can include a second computer workstation **215**-R, a second cranial reference module **205**-R, and a second tracker **213**-R. The second tracker **213**-R can be configured to be in communication with the second computer workstation, for example, via a communications link. The second tracker can be configured to track, for example, via IR optical tracking, a location of a portion of the second cranial reference module. The communications link can connect the first computer workstation and the second computer workstation such that the first computer workstation and second computer workstation are able to communicate.

[0055] The recipient sub-system **200**-R can further include a second fragment reference unit **201**-R. The second tracker **213**-R can further be configured to track a location of a portion of the second fragment unit.

[0056] The recipient sub-system **200**-R can further include a second cutting guide **219**-R for attaching to a preselected location of a recipient skeleton **208**. The second tracker **213**-R can further be configured to track a location of a portion of the second cutting guide.

[0057] Additionally, when a surgeon has removed the donor skeletal fragment from the donor, it can then be transferred for attachment onto the recipient. Accordingly, the second tracker **213**-R can be further configured to track a location of a portion of the first cutting guide **207**-D so that it can be matched relative a position of the second cranial reference module **205**-R.

[0058] The first cranial reference unit, the second cranial reference unit, or both the first and second cranial reference units can include a kinematic mount **205** as described above.

[0059] Using the system of FIGS. **2**A-**2**G, it is possible to execute a surgical method, such as the surgical method described in FIG. **3**. For example, in step **302** a donor, recipient and transplant type are identified. CT/CTA scans of both the donor and recipient are collected and 3D models are created in step **304**. The donor and recipients are prepared for surgery with the creation of skin incisions in step **306**. The method continues at **307** with attachment of reference guides and performing registration. For example, a first cranial reference unit can be attached to a donor skeleton, a first fragment reference unit can also be attached to the donor skeleton at a location that is different that of the first cranial reference unit. The locations of the first cranial reference unit and the first fragment reference unit can be tracked with a first tracker. 3D reconstructions of the donor skeleton can be constructed showing a first virtual cranial reference unit and first virtual fragment reference unit superimposed on the first 3D reconstruction at locations that correspond to relative positions of the first cranial reference unit and the first fragment reference unit.

[0060] A second cranial reference unit can be attached to a recipient skeleton. A second location of the second cranial reference unit can be tracked with a second tracker. A second 3D reconstruction of the recipient skeleton can be created with a second virtual cranial reference unit superimposed on the second 3D reconstruction at a location that corresponds to a location of the second cranial reference unit. At **308**, vessels and nerves are dissected and exposed. At this stage, navigation of the patient-specific cutting guides can occur, with plan revision and updates provided periodically. For example, a first cutting guide, such as a patient-specific cutting guide according to the descriptions provided above, can be attached onto the donor skeleton at a preselected

location such as that corresponding to a planned cut-plane. The location of the first cutting guide can be tracked with the first tracker. A first virtual cutting guide can be superimposed on the first 3D reconstruction at a location that corresponds to a location of the first cutting guide relative to the location of the first cranial reference unit or the location of the first fragment reference unit.

[0061] A first virtual fragment can be formed by segmenting the 3D reconstruction of the donor skeleton at a location adjacent to the first virtual cutting guide. The first virtual fragment can be superimposed on the second 3D reconstruction of the recipient skeleton.

[0062] At step **310**, a surgeon can perform an osteotomy on the donor skeleton to remove the first fragment but cutting the skeleton along a cutting path defined by the first cutting guide. Upon transferring the removed skeletal fragment from the donor, the first cutting guide can be tracked, by the second tracker, for example, when the fragment is brought near the recipient for attachment. The surgeon can then navigate placement of the cutting guide as it is dynamically tracked at step **311**, and will receive feedback from the system such as by referring to a first virtual fragment that is superimposed on the second 3D reconstruction to form a hybrid 3D reconstruction. At step **312**, the first fragment can then be attached to the recipient skeleton via known surgical methods and the incisions can be sutured in step **314**.

[0063] The step of superimposing the first virtual fragment on the second 3D reconstruction of the recipient skeleton can include performing an automated cephalometric computation for the hybrid reconstruction. In fact, the step of superimposing the first virtual fragment on the second 3D reconstruction can include providing a communications link between a first workstation on which the first 3D reconstruction is displayed and a second workstation on which the second 3D reconstruction is displayed, and initiating a data transfer protocol that causes the first workstation and the second workstation to send electronic signals through the communications link.

[0064] Surgical methods of the embodiments described above can also include attaching a second cutting guide at a preselected location on the recipient skeleton. The second cutting guide can also include features of the cutting guide described above.

[0065] For the surgical methods of embodiments described herein the donor skeleton can include a male skeleton or a female skeleton and the recipient skeleton can include a female skeleton. Alternatively, the donor skeleton can include a male or female skeleton and the recipient skeleton can include a male skeleton.

[0066] Surgical methods of the embodiments can further include steps for assessing a size-mismatch between the donor skeleton and the recipient skeleton by measuring a dorsal maxillary interface between the first fragment and recipient skeleton. In an embodiment, the surgical method can include selecting a location of the first fragment onto the recipient skeleton that minimizes dorsal step-off deformity at the area of osteosynthesis. In an embodiment, the first cutting guide, the second cutting guide, or both the first cutting guide and the second guide may be or include concentric cutting guides.

[0067] Surgical methods of embodiments can further include mapping the vascular system on the facial anatomy of both the recipient and the donor and superimposing corresponding virtual representations of the vascular system and the facial anatomy onto the first 3D representation, such as shown in FIG. **4**B

[0068] Surgical methods of embodiments can include a method for registration of a preoperative model, for example a model reconstructed from CT data, to donor and recipient anatomy. Such a method can include: creating a plurality of indentations on the donor skeleton, creating a plurality of virtual markers on the first 3D reconstruction of the donor skeleton corresponding to the locations of the indentations on the donor skeleton, placing a trackable object on at least one of the plurality of indentations, and determining whether a subsequent location of the virtual markers is within a predetermined tolerance relative to an actual subsequent location of the indentations.

EXAMPLES

Example 1

[0069] Live transplant surgeries (n=2) between four size-mismatched swine investigated whether or not an embodiment could actually assist a surgical team in planning and executing a desired surgical plan. As shown in FIGS. **9**A-**9**B, the first live surgery confirmed the proposed utility of overcoming soft and hard tissue discrepancies related to function and aesthetics. The final occlusal plane within the first recipient was ideal and consistent with the virtual plan as seen on lateral cephalogram as shown in FIG. **10**C. Pre-operative functional predictions of donor-to-recipient occlusion were realized based on cephalometric analyses as shown in FIG. **9**C performed both before and after surgery. Soft tissue inconsistencies of the larger-to-smaller swine scenario were also reduced following the predicted movements of face, jaw and teeth as shown in FIG. **10**D.

[0070] The second live surgery showed improved success as compared to its predecessor due to surgeon familiarity and technology modifications. System improvements and growing comfort of the surgeons led to reduced operative times for both donor and recipient surgeries. Overall the surgical time reduced from over 14 hours to less than 8 hours due to improved surgical workflow and increased comfort with a system of an embodiment.

[0071] Based on the results obtained in the live and plastic bone surgeries, the functions associated with setting up a system of an embodiment (attaching references, performing registration, attaching cutting guides) adds about 11 minutes to the total length of surgery.

[0072] The system also recorded information, such as rendering information which can be stored in a storage medium of a workstation, relating the donor fragment **1002** to the recipient **1010** qualitatively as shown by color mismatch **1004**, which matched the post-operative CT data as shown in FIG. **10**. The recipient cutting guide **1107'** was not placed as planned **1107** due to an unexpected collision between the cranial reference mount and the recipient cutting guide as shown in FIGS. **11**A-**11**B. In this case, there was anterior translation of the cutting guide (toward the tip of the swine's snout) by approximately 4 cm.

[0073] Overall, the donor **1106** and recipient craniums (n=4) **1108** were registered successfully to the reference bodies for both live surgeries. The model to patient registration error across the surgeries was 0.6 (+/−0.24) mm. The cutting guide designs of the embodiments proved highly useful in carrying out the planned bone cuts, which com-

pensated for size-mismatch discrepancies between donor and recipient. Marking spheres fixated to the guides allowed real-time movement tracking and "on-table" alloflap superimposition onto the recipient thereby allowing visualization of the final transplant result.

Example 2

[0074] Female and male donor heads (n=2), double-jaw, Le Fort III-based alloflaps were harvested using handheld osteotomes, a reciprocating saw, and a fine vibrating reciprocating saw. Both osteocutaneous alloflaps were harvested using a double-jaw, Le Fort III-based design (a craniomaxillofacial disjunction), with preservation of the pterygoid plates, incorporating all of the midfacial skeleton, complete anterior mandible with dentition, and overlying soft tissue components necessary for ideal reconstruction.

[0075] Prior to transplantation, both scenarios were completed virtually given the gender-specific challenges to allow custom guide fabrication as shown in panels A-H of FIG. **12**. Once assimilated, the donor orthognathic two-jaw units were placed into external maxilla-mandibular fixation (MMF) using screw-fixated cutting guides to retain occlusal relationships during the mock transplants as shown in panels A-D of FIG. **13**.

[0076] As shown in FIGS. **13**, **14**A-**14**B, an embodiment of a cutting guide **1307** can include a frame **1307'** with at least one attachment surface **1319**, for example 1 to 6 attachment surfaces, configured for attaching the cutting guide to a skeletal feature. The cutting guide can include a navigation surface **1317** (not shown in FIG. **13**) connected to the frame. The navigation surface can include a reference geometry that can be tracked by a tracker, for example, via IR optical tracking. The at least one attachment surface **1319** can include a contoured surface corresponding to contours of portions of the skeletal feature, for example, such as the contours of a skeletal feature that intersect a planned-cut plane as indicated by **1319'** in FIG. **12**. The at least one attachment surface **1319** can be detachably connected to a skeletal feature. The at least one attachment surface **1319** can be detachably connected to an attachment guide **1341**. The attachment guide **1341** can be detachably connected to a portion of the frame **1307'**. For example, attachment guides **1341** can be detachably connected via slots integrated into frame **1307'**, or held in place against frame **1307** with screws or the like. In another embodiment, attachment guides **1341** are formed as portions of frame **1307'** but can be removed. The frame can have a ring-like shape (as shown in FIG. **13**) or can have a cylinder-like shape (as shown in FIG. **14**A). Frame **1307'** having a cylinder like shape can have a bottom surface **1307"** that rests against a patient's soft tissue to provide support for the frame.

[0077] For example, during a surgical procedure, 3D reconstructions of portions of a donor skeleton are created. Planned cutting planes are selected and a cutting guide with attachment surfaces having a contoured surface corresponding to contours of portions of the skeletal feature, for example, such as the contours of a skeletal feature that intersect a planned-cut plane, is designed. The designed cutting guide is manufactured via, for example, an additive manufacturing process. The designed cutting guide with an integrated navigation surface is attached to the patient. For example, the cutting guide can be designed such that it has a snap-on fit over the skeletal feature, which can be further secured to the skeletal feature with set screws. A surgeon removes a donor skeletal fragment with the cutting guide attached to the fragment. The donor skeletal fragment is then attached to the recipient. As the donor skeletal fragment is attached to the recipient, the attachment surfaces are removed from the donor fragment. For example, each of the attachment guides **1341** with a corresponding attachment surface **1319** can be detached from the frame **1307'**. As this occurs, a cylindrical shaped frame **1307'** has a bottom surface **1307"** that rests against the soft tissue of the patient to provide stability for the remaining portions of the cutting guide and to hold the navigation surface **1317'** in place.

[0078] While the invention has been illustrated respect to one or more implementations, alterations and/or modifications can be made to the illustrated examples without departing from the spirit and scope of the appended claims. In addition, while a particular feature of the invention may have been disclosed with respect to only one of several implementations, such feature may be combined with one or more other features of the other implementations as may be desired and advantageous for any given or particular function. For example, the embodiments described herein can be used for navigation and modeling for osteotomy guidance during double-jaw face transplantation, single-jaw maxillofacial transplantation, and any other neurosurgical, ENT/head and neck surgery, or oral maxillofacial surgical procedure alike.

[0079] Embodiments described herein can include platforms for preoperative planning and intraoperative predictions related to soft tissue-skeletal-dental alignment with real-time tracking of cutting guides for two jaws (may be two jaws of same person in some cases) of varying width, height and projection. Additional safeguards, such as collection of confidence points, further enable intraoperative verification of the system accuracy. This, in addition to performing real-time plan verification via tracking and dynamic cephalometry, can considerably increase the robustness of the systems described herein. Moreover, systems of embodiments can include a modular system that allows additional functionality to be continually added.

[0080] Embodiments described herein can include an approach for resolving conflicts in case of position discrepancies between the placement of the guide and the guide position prompted by the navigation software. Such discrepancy may be due to either the guide (soft tissue interference, iatrogenic malpositioning, changes since the CT data was obtained or imperfections in cutting guide construction/printing), and/or the navigation system (e.g. registration error, or unintended movement of the kinematic markers). To resolve these source(s) of discrepancy, four indentations can be created on a bone fragment (confidence points) where a reference kinematic marker is attached. At any time during an operation, a surgeon can use a digitizer and compare the consistency of the reported coordinates of the indentations via navigation to their coordinates with respect to a virtual computer model.

[0081] Embodiments described herein can include a system that provides real-time dynamic cephalometrics and instantaneous masticatory muscle biomechanical simulation for planning and, real-time intraoperative predictions of function, and to ensure ideal outcomes in craniomaxillofacial surgery.

Additional Embodiments

Osseointegrated Dental and Craniofacial Implants

[0082] Patients with poor or missing dentitions may require dental implants to improve mastication. Similarly, patients with craniomaxillofacial defects may require either man-made (i.e. alloplastic) or tissue engineered custom implants for reconstruction and/or aesthetic improvement. A popular modality with increasing indications includes "osseointegrated dental implants" and "customized craniofacial implants (CCIs)". Osseointegrated dental implants can include, and may consist of, a two-piece permanent implant device, which is placed into either the maxilla or mandible skeleton with a power drill for placement and stability. A second piece, in the shape of a tooth is screwed onto the secure base. A CCI may be either supplied by a third-party vendor, printed with an additive or substractive manufacturing device, such as a 3D printer, that receives instructions generated provided by a system of the embodiments (e.g., the CAPE system), as described below, so that a custom implant is available to the surgeon and placed utilizing feedback from the CAPE system to achieve ideal positioning and alignment to the native anatomy. An embodiment of the CAPE system described above can be used to provide the dentist or surgeon real-time cephalometric feedback in an effort to restore ideal occlusion and predict optimized mastication with biomechanical predictions—as similar to maxillofacial transplantation. As such, the dentist or surgeon placing these items needs to know the bone stock quality of the jaw(s) and angle to place the framework. Also, the CAPE system can access computer-readable reconstructions of a being's anatomy, such as computer-readable files containing soft tissue and skeletal CT scan data, which may be uploaded ahead of time into a memory of a computer of the CAPE system), and which can be utilized to by a surgeon for predicting a patient's appearance during and after surgery even though they are in the supine position during surgery.

[0083] Osseointegrated Craniofacial Prosthetics

[0084] Patients with severe cranial or facial disfigurement may be poor surgical candidates due to overwhelming co-morbidities and/or because of an accompanying poor prognosis. Therefore, to help return these patients into society, some use craniofacial prosthetics as a way to restore "normalcy". Application of these three-dimensional prosthetics replacing absent craniofacial features and defects (i.e., skull, nasal, ocular, etc.) may either be hand-molded/painted by an anaplastologist or printed with 3D technology by a prosthetic craniofacial technician, outside vendor, or hospital's own 3D printer within the operating room. Either way, in an embodiment, the CAPE system described above can provide a one-stop solution for patients requiring alloplastic and/or tissue engineered reconstruction for craniomaxillofacial deformities. The craniofacial implants can be tracked in space as similar to a donor face-jaw-teeth segment described above. For example, pre-placement soft tissue prediction images and hard tissue prediction images of the prosthetic in ideal position may be fabricated and uploaded, and surgical plans may be optimized since these appliances are placed with osseointegrated devices as similar to dental implants described above—with rigid plates and screws. In an example, a virtual representation of an implant such as a displayed computer-readable reconstruction of an implant, may change appearance, for example, change to a different color on the display, in response to a signal provided by a detector and corresponding to a detected location of an actual implant's trackable element in relation to, for example, a reference unit attached to a being's anatomy, such as when the detected location is matched to a planned location for placement of the implant. As such, the surgeon placing the implant is provided with intra-operative visual feedback as to the a predetermined, such as an ideal, positioning of the implant in three-dimensional space by referring to a displayed virtual representation of the implant superimposed on the being's anatomy, and having an orientation which is updated in response to the detected location of the implant's trackable element.

[0085] Craniomaxillofacial Trauma Reconstruction

[0086] Patients suffering from acute or chronic facial disfigurement are often seen by a craniomaxillofacial surgeon. Both penetrating and/or blunt trauma may cause significant damage to the underlying facial skeleton. As such, in an embodiment, the CAPE system technology described herein allows the surgeon to assess and optimize bone fragment reduction and reconstruction with real-time feedback. In addition, fractures affecting the jaws can be aided by real-time cephalometrics in hopes to restore the patient back to their pre-trauma angle/measurements (as a way to assure proper occlusion). Navigation, as described above in an embodiment of the CAPE system, can be exceptionally helpful for orbit fractures around the eye or cranial fractures around the brain, since the nerve anatomy is delicate and consistent—which makes it applicable to the CAPE system. In summary, a surgeon (including the likes of a Plastic surgeon, ENT surgeon, oral/OMFS surgeon, oculoplastic surgeon, neurosurgeon) reducing craniofacial fractures needs to know the bone stock quality remaining, where plates/screws are best placed, and the optimal plan prior to entering the operating room.

[0087] Neurosurgical Procedures

[0088] Neurosurgeons frequently perform delicate craniotomies for access for brain surgery. Currently, there are several navigational systems available. However, none of the conventional systems include features described in the embodiments of the CAPE platform as described above. That is, the conventional systems lack the ability to assist both pre-operatively with planning and with intra-operative navigation for execution assistance. In addition, the current neurosurgery systems require the head to be placed in antiquated "bilateral skull clamp pins" during the entire surgery. This means that before each neurosurgery procedure starts, a big 3-piece clamp is crunched onto the skull of the patient to make sure the head does not move during surgery, particularly to allow for use of the conventional navigation systems. However, embodiments of the CAPE system, such as those described above, use a small, modified rigid cranial reference mount which removes the need for using a big, bulky clamp from the field and allows the surgeon to rotate the patient's head if and when needed. To a craniofacial plastic surgeon, who often is consulted to assist with simultaneous scalp reconstruction, elimination/removal of such pins from the surgical field is a huge advantage. For example, elimination of the pins makes scalp reconstruction in the setting of neurosurgery much safer since the pins aren't present to hold back mobilization and dissection of the nearby scalp, which is needed often for complex closure. It also, reduces the risk of surgical contamination since the current setup with pins is bulky and makes surgical draping and sterility much more difficult and

awkward. A small cranial mount as part of the CAPE system is a huge advancement for the field.

[0089] Congenital Deformity Correction

[0090] Unfortunately, newborns are commonly born with craniofacial deformities to either maternal exposure or genetic abnormalities. As such, they may have major development problems with their skeleton and the overlying structures (eyes, ears, nose) may therefore appear abnormal. In addition, newborns may suffer from craniosynostosis (premature fusing of their cranial sutures) which causes major shifts in the shape of their head at birth. In an embodiment, the CAPE system described above, can be utilized to address such congenital deformities, irrespective of etiology. For example, if a 16 year old needs to have major Le Fort surgery to move the central facial skeleton into better position forward to improve breathing, mastication, and appearance, use of the CAPE system technology for both pre- and intra-operatively provides a huge advancement for the field.

[0091] Head/Neck and Facial Reconstruction (ENT Surgery)

[0092] Head and neck surgeons in the specialty of Otolarygology (ENT) are frequently reconstructing facial skeletons. Reasons include post-tumor resection, facial trauma, aesthetic improvement, congenital causes and/or functional improvement (nose, mouth, eyes, etc). Therefore, this specialty would greatly benefit from use of the CAPE system technology described herein. For example, in an embodiment, use of the CAPE system can be used in a wide range of surgeries including such instances as post-trauma fracture reduction/fixation, free tissue transfer planning and execution (i.e., free flap reconstruction with microsurgical fibula flaps for large bone defects where the leg bone receives dental implants for jaw reconstruction), smaller jaw reconstruction cases with implant materials, and/or anterior skull base reconstructions with neurosurgery following tumor resection. This specialty is very diverse, and therefore the CAPE system's easy adaptability can help make it greatly valuable to this group of surgeons.

[0093] Orthognathic Surgery

[0094] Orthognathic surgery describes any of surgical procedure type moving the jaw and/or jaw-teeth segments. This is most commonly performed by either oral surgeons, oral-maxillofacial surgeons (OMFS), or plastic surgeons. It is done currently both in the hospital as an insurance case or in the outpatient setting for a fee-for-service. It may be indicated for enhanced mastication, improved aesthetics, and/or both reasons. Having the ability to plan and predict jaw movements based on biomechanical muscle (i.e., external) forces will be immensely valuable to this field. In an embodiment, surgeons can utilize the CAPE system described above to predict functional jaw movements both at time of surgery and after surgery (1, 5, 10, 20 years post-op). In addition, in an embodiment, a surgeon can utilize the CAPE system to provide real-time cephalometric feedback, which provides an advancement not seen in the conventional systems. In comparison, for the last several centuries, oral surgeons have used splints fabricated in the dental lab pre-operatively for assistance in the operating room to help confirm dental alignment as planned. This takes time (e.g., 4-6 hours to make by hand), effort, and money. In contrast to the conventional systems, surgeons utilizing the CAPE system can go to the operating room with pre-fabricated cutting guides and tracking instruments, cut the jaws where planned, and then match the teeth on the table based on real-time cephalometric feedback and biomechanical jaw simulation to predict post-operative mastication—unlike ever before. For example, use of the CAPE system will allow surgeons to know instantaneously if the aesthetic and functional angles/measurements are ideal and where they should be. In addition, the CAPE system is able to supply palatal cutting guides and pre-bent metal fixation plates (as opposed to the conventional methods that require hand bending each plate for proper shape). In summary, the CAPE system will be a "game-changer" for orthognathic surgery.

[0095] Computer-Assisted Cranioplasty

[0096] At least some embodiments described herein can be used for the immediate surgical repair of large cranial defects (>5 cm2). For example, embodiments described herein may be used for designing, forming and implanting customized craniofacial implants following benign/malignant skull neoplasm (tumor) resection (i.e. referred to as "single-stage implant cranioplasty"). Currently, it is challenging to reconstruct such patients with pre-fabricated implants using conventional methods since the actual size/shape of the defect site is unknown until the tumor is removed. Accordingly, use of a computer-assisted surgical system of an embodiment may significantly reduce the intraoperative time used for reshaping/resizing the customized implant. For example, embodiments provide visualization related to the tumor, the resulting skull defect, and the reshaped implant for exact positioning. In other words, in an embodiment, a Computer-Assisted Planning and Execution (CAPE) system that can be utilized for Le Fort-based, Face-Jaw-Teeth transplantation may also be used for improving both the pre-operative planning and intra-operative execution of single-stage implant cranioplasties. Cranioplasties may be performed to reconstruct large defects following stroke, trauma, aneurysmal bleeding, bone flap removal for infection, and oncological ablation. However, oncological defects are commonly reconstructed with "off-the-shelf" materials, as opposed to using a pre-fabricated customized implant—simply because the exact defect size/shape is unknown. With this in mind, embodiments described herein include a computer-assisted algorithm that may allow surgeons to reconstruct tumor defects with pre-customized cranial implants (CCIs) for an ideal result.

[0097] Nearly 250,000 primary brain tumors/skull-based neoplasms are diagnosed each year resulting in a range of 4500-5000 second-stage implant cranioplasties/year. Unfortunately, the common tumor defect cranioplasty is reconstructed with on-table manipulation of titanium mesh, liquid polymethylmethacrylate (PMMA), liquid hydroxyapatitie/bone cement (HA) or autologous split-thickness calvarial bone grafts (ref), which forces the surgeon to shape/mold these materials to an approximate size/shape. Expectingly, this results in some form of craniofacial asymmetry and a post-operative appearance which is suboptimal. Furthermore, the difficult shaping process may take several hours—which in turn increases anesthesia, total blood loss, risk for infection, morbidity, and all costs associated with longer operative times. Therefore, there is significant opportunity to extend this CAPE to thousands of patients.

[0098] In 2002, the advent of computer-aided design and manufacturing (CAD/CAM) was used for the first time to pre-emptively match the contralateral, non-operated skull for ideal contour and appearance, which provided for the use of CCIs. However, cranioplasties with such CCIs can only

be performed as "second stage" operations during which a clinician, such as a surgeon, ensures that the CCI fits perfectly into the skull defect. Recent developments have demonstrated the feasibility of CCIs for "single-stage cranioplasty", but this involves using a handheld bur to shave down the pre-fabricated implant artistically. However, challenges in both assessing and predicting each tumor-resection deformity pre-surgery still limits the applicability of CCIs in this patient population. For example, challenges such as 1) unknown exact tumor size, 2) unknown growth from time of pre-op CT scan-to-actual day of surgery, and 3) the unknown resection margins needed to minimize local recurrence. For these cases, the CCI would need to be reshaped/resized intraoperatively from a size slightly larger than expected—which is a process that may take several (2-4) hours. However, there are no established planning and execution systems available to assist these single-stage reconstructions. Accordingly, embodiments described herein may be used by surgeons in performing single-stage cranioplasty following oncological resection. In other words, embodiments include algorithms for real-time updates related to single-stage customized implant cranioplasty. For example, in an embodiment, there is a Computer-Assisted Planning and Execution (CAPE) system, which is a single, seamless platform capable of being used for both planning (pre-op use) and navigation (intra-op use) which overcomes the limitations of conventional systems that do either one or the other. In addition, embodiments include novel hardware such as trackable cutting guides and rigid cranial reference mount.

[0099] Computer-Assisted Surgical System

[0100] In an embodiment, there is a computer-assisted surgical system, such as the system **1500** depicted in FIGS. **15**A-**15**G. System **1500** may be similar to system **200** of FIGS. **2**A-**2**G, except that it may be utilized, for the pre-operative planning and intra-operative execution of a single-stage implant cranioplasty **1500**-R instead of transplantation. For example, in a single-stage implant cranioplasty, the anatomy of a being **1508**, which may be a human being, may include an anatomical feature **1511**-D, such as a diseased portion of the anatomy, that requires removal or replacement with an implant **1511**-*i*. During a surgical procedure, the anatomical feature **1511**-D may be separated from the being **1508** by cutting away from healthy portions **1509**-R of the being's anatomy. For example, a custom-made cutting guide **1507**-D may be used to provide a surgeon with slots that provide access for a cutting tool at preselecting cutting locations along the being's anatomy. After cutting sufficiently through the being's anatomy at the locations specified by the cutting guide, the anatomical feature is removed away from the being. Subsequently, an implant, such as a customized craniofacial implant **1511**-I, which may be fabricated via additive or subtractive manufacturing technology, may be attached near the healthy portions **1509**-R of the being's anatomy via an attachment **1519**-R.

[0101] System **1500** may include a reference unit **1505**-R, an implant **1511**-*i* and a detector **1513**-R. The reference unit **1505**-R may include a first trackable element **1501**-R. The implant may include a second trackable element **1501**-*i*. The implant may include an attachment **1519**-R which may include a contoured attachment surface **1507**-R. In addition to, or instead of trackable element **1501**-I, the attachment **1519**-R may also include one of a second trackable element **1517**-R. The detector may be configured to provide at least one signal **1591** corresponding to a detected location of at least one of the first trackable element and the second trackable element. Reference unit **1505**-R may include a cranial reference mount **1503**-R that may be attached to a location **1510** of a being's anatomy to provide a static frame of reference for tracking the location of first trackable element **1501**-R.

[0102] The system **1500** may further include a cutting guide **1507**-D having a third trackable element **1509**-D, and may be detected by the detector **1513**-R. Thus, the at least one signal **1591** may further correspond to a detected location of at the third trackable element **1509**-D of the cutting guide **1507**-D. The cutting guide **1507**-D may be a surgical guide assembly having an attachment device configured to be coupled to a bone. A cut location indicator may be coupled to the attachment device. The cut location indicator identifies a location where the bone is to be cut. An arm may be coupled to the attachment device, the cut location indicator, or both. A support structure may be coupled to the arm. The support structure is configured to have a tracking element coupled thereto.

[0103] The system **1500** may also include a computer **1515**-R, that receives the at least one signal **1591** from detector **1513**-R, and may also include an additive manufacturing device **1587**, which may be in communication with and controlled by the computer **1515**-R. The computer may be connected to a display on which computer-readable reconstructions of items, such as the implant and a being's anatomy, may be displayed. The at least one signal **1591** may be communicated between the detector and computer via a communications link, which may include data transmission wires and/or wireless transmissions either of which may be communicated through a network, such as a LAN or WAN network, including communication over an intranet or over the internet, including TCP/IP data transfer.

[0104] The detector **1513**-D may be an optical tracker, a magnetic tracker or both an optical tracker and a magnetic tracker. may be an optical tracker, a magnetic tracker or both an optical tracker and a magnetic tracker. Optical trackers typically emit and capture light in the invisible (infrared) electromagnetic spectrum. Trackable fiducials used with these systems can include passive (i.e., reflective) or active (i.e., those that actively emit infrared light) markers. Using specific geometries known to the camera, the pose of a reference can be tracked through the field of view. An example system is the NDI Polaris available from Northern Digital, Inc. (Ontario, Canada). Magnetic trackers rely on a magnetic field generator and (typically) a passive coil architecture. The field generator creates a time-varying field, which induces a current in the passive sensor. This current is measured and, through a calibration procedure, used to identify up to a 6-dof pose of the sensor. An example system is the NDI Aurora available from Northern Digital, Inc. (Ontario, Canada).

[0105] One or more of the first trackable element **1501**-R, the second trackable element **1501**-*i*, and the third trackable element **1509**-D, may be an IR reflector or an IR emitter, each of which may be detachably connected to an attachment surface. As an example, an IR reflector may be a detachably connected surface, such as a sphere. As an example, an IR emitter may be a light emitting diode configured to emit infrared light.

[0106] The implant may be fabricated during a surgical procedure by an additive or subtractive manufacturing

device, or may be a pre-fabricated implant such as, customized craniofacial implant (CCI) be an alloplastic implant. In an embodiment, the implant may include a polymer, metal, bioengineered material, or combinations thereof. For example, the implant may include titanium mesh, porous hydroxyapatite (HA), polymethylmethacrylate (PMMA), polyetheretherketone (PEEK) and/or combinations thereof.

[0107] The cutting guides described herein may be a surgical guide assembly having an attachment device configured to be coupled to a bone. A cut location indicator is coupled to the attachment device. The cut location indicator identifies a location where the bone is to be cut. An arm is coupled to the attachment device, the cut location indicator, or both. A support structure is coupled to the arm. The support structure is configured to have a tracking element coupled thereto.

[0108] System **1500** may also include at least one computer, such as computer **1515**-R. The at least one computer **1515**-R may be selected from a desktop computer, a network computer, a mainframe, a server, or a laptop. The at least one computer may be configured to access at least one computer readable reconstruction of at least one object, such as a being's anatomy, or at least portions of the being's anatomy, for example, a first computer readable reconstruction **1581** and a second computer readable reconstruction **1585**, and a third computer readable reconstruction. The computer readable reconstruction may include three-dimensional (3D) views, such as those created by scanning a patient via, for example, CT scan. At least one display may be connected to the at least one computer **1515**-R. The display may be configured to represent the computer readable reconstruction in a format visible to a user. The first computer may include at least one memory to store data and instructions, and at least one processor configured to access the at least one memory and to execute instructions, such as instructions **1600** included in the flow chart in FIG. **16**.

[0109] Instructions **1600** may include one or more of the steps included in the flowchart on FIG. **16**. For purposes of providing examples, some of the steps are described below with reference to components of system **1500** from FIGS. **15**A-**15**G. In an embodiment, first instructions **1600** include accessing a first computer-readable reconstruction of a being's anatomy at **1601** and accessing a second computer-readable reconstruction of the implant at **1602**. The first computer-readable reconstruction of the being's anatomy may include a first updatable orientation and the second computer-readable reconstruction of the implant may include a second updatable orientation. At **1603**, the instructions **1600** may also include updating at least one of the first orientation and the second orientation. In an example, step **1603** may be initiated by user input, for example, via user interaction with the computer, or by a signal, such as a signal provided by a detector, for example, signal **1591**. As described above, the first orientation and the second orientation may be updated, for example, on a display connected to the computer, in response to the at least one signal, for example, the at least one signal **1591**.

[0110] The instructions **1600** may also include superimposing a planned cutting plane over portions of the first computer-readable reconstruction at **1604**. Additional steps may include generating a second computer-readable reconstruction of the implant at **1605** and controlling an additive manufacturing device at **1606** to form an implant. In an example, the second computer-readable reconstruction of the implant generated at **1605** may include a geometry defined by at least one of: i) an interface between the planned cutting plane and the first computer-readable reconstruction, and ii) a selected portion of the computer-readable reconstruction, the selected portion comprising an anatomical feature of the being's anatomy, including but not limited to oncological defect sites, such as a benign/malignant skull neoplasm, large defects following stroke, trauma, aneurysmal bleeding, bone flap removal for infection, and oncological ablation. Additionally, the implant fabricated by the manufacturing device at **1606** may have dimensions defined by the geometry of the second computer-readable reconstruction.

[0111] The instructions **1600** may also include generating a third computer-readable reconstruction of a cutting guide at **1607** and controlling the additive manufacturing device to form a cutting guide at **1608**. In an example, the third computer-readable reconstruction of the cutting guide may include a geometry defined by an interface between the planned cutting plane and the first computer-readable reconstruction, and may also include a third updatable orientation. Additionally, the cutting guide fabricated by the manufacturing device at **1608** may include selected dimensions of the geometry of the third computer-readable reconstruction.

[0112] The device may be any manufacturing device that fabricates an object based on instructions, such as computer readable instructions, for example, instructions provided in digital data, including any device that utilizes additive or subtractive manufacturing technologies, such as those that fabricate an object from appropriately approved materials for medical use. Accordingly, the at least one device may be an additive manufacturing device, such as a 3D printer, or another kind of manufacturing device, including subtractive manufacturing device, such as a CNC machine. Examples of additive manufacturing technologies may include vat polymerization (e.g., PROJET® 6000, 7000, 8000 available from 3D Systems Corp., Rock Hill, S.C.), materials jetting (e.g., Objet 500 or Eden 250, each available from Stratasys, Ltd., Eden Prairie, Minn.), powder binding (e.g., PROJET® 460, 650 available from 3D Systems Corp., Rock Hill, S.C.), powder fusion (e.g., EBM® available from Arcam AB, Sweden), material extrusion (Fortus 250, 400, available from Stratasys, Ltd., Eden Prairie, Minn.), or any one denoted by the ASTM F42 committee on additive manufacturing. Accordingly, system **1500** may include a device (not shown) for manufacturing components, such as cutting guides, reference units and/or the trackable elements, and the device may be connected to at least one of the first computer and the second computer via the communications link described above. The instructions may also include generating a computer readable file that contains instructions for manufacturing the cutting guide and/or implant, for example a computer readable file that contains dimensions of a component, such as a cutting guide based on the geometry of the third computer-readable reconstruction.

[0113] The computer-readable reconstruction of the being's anatomy may be a computer-readable file created from a CT-scan. For example, the computer-readable representation may be a 3D reconstruction of a patient's anatomy.

[0114] During a surgical procedure, such as an implantation of an alloplastic, metal and/or bioengineered implant onto the anatomy of a patient being's anatomy, it is useful to track the location of the implant relative to the anatomy of the patient being before, during and/or after the implan-

tation. Accordingly, the signal—such as signal **1591** in the system **1500**—may correspond to a location of the first, second and/or third trackable element as detected by the detector **1513**. Thus, the instructions **1600** may also include updating the orientation of the first, second and/or third computer-readable reconstruction of the implant with an orientation that is updated based on the signal, which may correspond to a physical location of the first, second and/or third trackable element, respectively, as sensed by the detector.

[0115] Computer-Assisted Surgical Method

[0116] In an embodiment, there is also a computer-assisted surgical method. The method includes use of the CAPE system, which may provide a user an enhanced implant reconstruction experience, for example, providing a surgeon unprecedented, immediate visual feedback and allowing single-stage implant cranioplasty reconstruction for scenarios related to skull neoplasms, etc—in situations where the tumor defect is not known beforehand, but where a customized implant is needed requiring on-table modification via CAPE system guidance. Generally, the method can include the following: a) generating and/or accessing a computer-readable reconstruction of a patient's anatomy, such as via a preoperative CT scan that includes an anatomical feature, such as a defect, and constructing a 3D model of the anatomy; b) preselecting a resection area on the model; c) determining implant dimensions (can be a few millimeters greater than the size of the defect) and fabricate the implant with an additive and/or subtractive manufacturing device incorporated with the CAPE system; d) designing a trackable cutting guide based on the 3D model and fabricate with an additive and/or subtractive manufacturing device incorporated with the CAPE system; e) attaching a reference unit having a trackable element onto the patient's anatomy, such as at the patient's skull; f) registering the location of the trackable element/reference unit to the computer-readable reconstruction (preoperative CT scan); g) using the optically trackable cutting guide to perform bone cuts in the patient; h) using a detector to generate a signal in response to performing a trace of the defect boundaries, for example, if additional resection is required; i) superimposing information corresponding to signals generated by optical digitizer, such as signals in response to performing a trace of the defect boundaries, on the computer-readable reconstruction; j) registering the implant to the computer-readable reconstruction with the optical digitizer, for example, via tracking a location of a trackable element attached to the implant; k) tracing cut lines on the implant based on information obtained from the 3D model, such as a size mismatch between the implant and the defect; l) attaching the implant to the patient; m) obtaining a post-operative image of the patient and the attached implant, such as a CT scan.

[0117] The method may include any step or combination of steps included in the flow charts of FIG. **17-22** and described below. In an example shown in the flow-chart of FIG. **17**, a method **1700** can include attaching a reference unit that includes a first trackable element to a first anatomical feature of a being's anatomy at **1701**. The method may also include detecting a location of at least the first trackable element with a detector at **1702**, and accessing a first computer-readable reconstruction of the being's anatomy at **1703**. The detector may be detector **1513** as described above, and may be configured to provide at least one signal corresponding to a detected location of at least the first trackable element. The first computer-readable reconstruction may be first computer-readable reconstruction **1581** and may include a first updatable orientation. Accordingly, the first updatable orientation may be updated in response to user input and/or the at least one signal such as signal **1591** described above.

[0118] In an embodiment, a method **1800** may include all of the steps **1700** of FIG. **17**, and may also include any step or combination of steps included in the flow charts of FIGS. **18-22**. In an example shown in the flow chart of FIG. **18**, in addition to method **1700**, method **1800** may include generating a second computer-readable reconstruction of an implant at **1801**. The second computer-readable reconstruction may be second computer-readable reconstruction **1585** as described above, and may include a second updatable orientation, such as an orientation that may be updated in response to user input and/or the at least one signal, such as signal **1591** described above. The method **1800** may also include assessing a size-mismatch between at least one dimension of a portion of the first computer-readable reconstruction, for example, a portion corresponding to a selected anatomical feature of the being's anatomy, and at least one dimension of the second computer-readable reconstruction at **1802**. In an example, assessment of the size-mismatch may be performed via a cephalometric analysis, including a real-time cephalometric analysis. The method **1800** may also include tracing cut lines on the implant based on the size-mismatch. In an example, the cut lines may be traced on the implant such that an anatomical discrepancy at an area of removal or reconstruction of the anatomical feature is minimized. In an example, the anatomical discrepancy may be minimized based on a preselected tolerance, for example, in instructions provided for fabricating the implant, including instructions provided in computer-readable files, such as digital data, provided to an implant manufacturing device. The method **1800** may also include attaching the implant to a preselected anatomical feature at **1804**, such as to a patients anatomy surrounding oncological defect sites, such as a benign/malignant skull neoplasm, or large defect sites formed following stroke, trauma, aneurysmal bleeding, bone flap removal for infection, and oncological ablation. After implantation of the implant at **1804**, for example, the method can also include obtaining a post operative image of at least the implant attached to the preselected anatomical feature at **1805**. For example, a CT scan may be taken of the patient with implant attached.

[0119] In an embodiment, a method **1900** may include all of the steps **1700** in FIG. **17**, and may also include any step or combination of steps included in the flow charts of FIGS. **18-22**. In an example shown in the flowchart in FIG. **19**, in addition to method **1700**, method **1900** may include attaching a second trackable element to an implant at **1901**. For example, a second trackable element, such as second trackable element **1501-*i***, may be incorporated in the design of the implant as a detachably connected trackable element, or may be formed separate from the implant and attached to the implant. Method **1900** may also include detecting a location of the second trackable element with the detector at **1902**. Accordingly, the at least one signal may further corresponds to a detected location of the second trackable element. Method **1900** may also include accessing a second computer-readable reconstruction of the implant at **1903**. Similarly to the first computer-readable reconstruction, the sec-

ond computer-readable reconstruction may also include a second updatable orientation that may be updated in response to user input and/or the at least one signal. Additionally, method **1900** may include superimposing the second computer-readable reconstruction on the first computer-readable reconstruction at step **1904**, as well as attaching the implant to a preselected anatomical feature of the being's anatomy at **1905** and obtaining a postoperative image of at least the implant attached to the preselected anatomical feature at **1906**, as similarly described in steps **1804** and **1805** above, respectively.

[0120] In an embodiment, a method **2000** may include all of the steps **1700** in FIG. **17**, and may also include any step or combination of steps included in the flow charts of FIGS. **18-22**. In an example shown in the flowchart in FIG. **20**, in addition to method **1700**, method **2000** may include superimposing a planned cutting plane over portions of the first computer-readable reconstructions at **2001**. The planned cutting plane may be planned cutting plane **403** or the planned cut plane in FIG. **12** as described above, and the first computer-readable reconstruction may be the first computer-readable reconstruction **1581** as described above. The method **2000** may also include accessing a third computer-readable reconstruction of a cutting guide at **2002**. The third computer-readable reconstruction of the cutting guide may be the third computer-readable reconstruction **1583** in FIG. **15**A and described above. That is, the third computer-readable reconstruction may include a third updatable orientation and a geometry that corresponds to a bisecting interface between the planned cutting plane and the first computer-readable reconstruction, such as interface. The method **2000** may include fabricating a cutting guide at **2003**. The cutting guide may be cutting guide **1507**-D described above, and may include dimensions that correspond to the geometry of the third computer readable reconstruction. A third trackable element on the cutting guide. Additionally, a third trackable element may be provided on the cutting guide. For example, a third trackable element such as trackable element **1509**-D as described above, may be may be incorporated in the design of the cutting guide as a detachably connected trackable element, or may be formed separate from the cutting guide and attached to the cutting guide. It is noted that the at least one signal, such as signal **1591**, may also correspond to a detected location of the third trackable element, such as that detected by detector **1513**. It is also noted that the planned cutting plane may also include a fourth updatable orientation, such as an orientation that may be updated in response to user input.

[0121] In an embodiment, a method **2100** may include all of the steps **1700** in FIG. **17**, and may also include any step or combination of steps included in the flow charts of FIGS. **18-22**. In an example shown in the flow-chart in FIG. **21**, in addition to method **1700**, method **2100** may include attaching a cutting guide, such as cutting guide **1507**-D described above, to the being's anatomy. As described above, the cutting guide may include a third trackable element. Accordingly, the method **2100** may also include detecting a location of the third trackable element with the detector at **2102**, wherein the at least one signal further corresponds to a detected location of the third trackable element as also described above. The method **2100** may also include accessing a third computer-readable reconstruction of a cutting guide at **2103**. The third computer-readable reconstruction may include a third updatable orientation, wherein the third updatable orientation is updated in response to user input and/or the at least one signal.

[0122] In an embodiment, a method **2200** may include all of the steps **1700** in FIG. **17**, and may also include any step or combination of steps included in the flow charts of FIGS. **18-22**. In an example shown in the flowchart in FIG. **22**, in addition to method **1700**, method **2200** may include superimposing a planned cutting plane over portions of the first computer-readable representation at **2201**. In an example, the planned cutting plane may be superimposed to bisect the first computer-readable reconstruction to define at least one portion of the first-computer readable reconstruction corresponding to at least one diseased anatomical feature of the being's anatomy that is to be removed or replaced. Accordingly, the planned cutting plane may be planned cutting plane **403** or the planned cut plane in FIG. **12** as described above, and the first computer-readable reconstruction may be the first computer-readable reconstruction **1581** as described above. The method **2200** may also include accessing a second computer-readable representation of an implant at **2202** and fabricating an implant at **2203**. The second computer-readable reconstruction may be second computer-readable reconstruction **1585** as described above, and may include a second updatable orientation, such as an orientation that may be updated in response to user input and/or the at least one signal, such as signal **1591** described above. The implant may be implant **1511**-*i* described above, and may include dimensions that correspond to the geometry of the second computer readable reconstruction. Additionally, a second trackable element may be provided on the implant. For example, a second trackable element such as trackable element **1501**-*i* as described above, may be may be incorporated in the design of the implant as a detachably connected trackable element, or may be formed separate from the implant and attached to the implant. It is noted that the at least one signal, such as signal **1591**, may also correspond to a detected location of the second trackable element, such as that detected by detector **1513**. It is also noted that the planned cutting plane may also include a fourth updatable orientation, such as an orientation that may be updated in response to user input.

[0123] The described method may be utilized during a surgical procedure, such as a surgical implantation procedure or an implant-based cranioplasty. Accordingly, the implant may be a custom, 3D craniofacial implant made of either alloplastic materials or biologic tissue engineered cells as described above for implant **1511**-*i* and a being, such as a recipient being, on whom the surgical procedure is performed. In an example, the donor provides an anatomical feature and the recipient receives the anatomical feature. In an example, the donor being is a male being and the recipient is a female being. In an example, the donor being is a female being and the recipient is a male being. In an example, the donor and the recipient are the same sex. Although in some transplantations, the donor being and recipient being are two separate beings, the invention is not so limited. Accordingly, in an example the donor being and the recipient being may be i) the same being, or ii) different beings.

[0124] During a surgical procedure, such as an implantation of an alloplastic, metal and/or bioengineered implant onto the anatomy of a patient being's anatomy, it is useful to track the location of the implant relative to the anatomy of the patient being before, during and/or after the implan-

tation. Accordingly, the signal—such as signal **1591** in the system **1500**—may correspond to a location of the first, second and/or third trackable element as detected by the detector **1513**. Thus, the computer-assisted surgical method of the embodiments may include updating the orientation of the first, second and/or third computer-readable reconstruction of the implant with an orientation that is updated based on the signal, which may correspond to a physical location of the first, second and/or third trackable element, respectively, as sensed by the detector.

Example 3

Customized Craniofacial Implants (CCIs), and Surgical Planning

[0125] For implant design, patients underwent pre-operative fine cut (2 mm) CT scanning with three-dimensional reconstructions. The predicted skull resection was planned using mock surgery with stereolithographic (SLG) models to assess nearby critical structures and then discussed with the neurosurgeons involved with each case. Implant geometries were determined and CCIs were constructed according to the geometries. In all cases (7/7, 100%), the craniofacial surgeon chose to modify the implant's size/shape for ideal positioning. This included altering the orbital apex diameter for potential optic nerve edema following sphenoid wing resection (n=1 case) and circumferential overestimation (around 1 cm) to accommodate interim tumor growth.

Example 4

Operative Technique

[0126] The patient's head was pinned within either a Mayfield skull retractor or horseshoe. A pre-operative dose of antibiotic was administered intravenously prior to skin incision. Pedicled fasciocutaneous scalp and pericranial flaps were strategically designed and elevated in an effort to "sandwich" all implants with healthy, vascularized tissue. Next, the CCI was used as a template to draw out the planned tumor resection. Once the neoplasm was resected in en bloc fashion, the skull edges were inspected for inconsistencies and potential frontal sinus communication. Dural reconstruction was performed in instances where primary repair was not feasible. Resection margins were confirmed with intraoperative navigation by assessing CT bone characteristics. Following oncological ablation, a sterile back table was prepared for intraoperative modification of the implant. Excess implant material was marked and removed using a 5 mm egg contour burr. Once an ideal shape was achieved, the implant was pre-plated using standard plates and screws (Stryker, Inc. —Kalamazoo, Mich.). Coverage of the fixated implant was augmented by way of a regional pericranial flaps. The scalp was closed tension-free using wide subpericranial dissection and galeal scoring. Closed suction drains were placed to avoid unwanted dead space and fluid accumulation. In complex instances where the frontal sinus was invaded, we meticulously resected of all the mucosa extending down within the outflow tract, obliterated the cavity with autologous cancellous bone graft and vascularized pericranium, and performed cranialization with posterior table removal.

Example 5

Results

[0127] Seven immediate, single-stage cranioplasties following resection of malignant and benign skullbased neoplasms were performed successfully—using customized implants made of either PEEK, solid PMMA or Medpor (n=7 implants). Follow-up ranged between 1-16 months. Neoplasm specifics included four patients (4/7, 57%) with malignant pathology and 3 with benign (3/7, 43%). Five patients (5/7, 71%) underwent PEEK CCI reconstruction, one patient with solid PMMA CCI (1/7, 14%), and one with a porous polyethylene (Medpor) implant (1/7, 14%).

[0128] All cranial defects were greater than 5 centimeters squared (7/7, 100%) and tumor locations were widespread. These included an anterior sphenoid skull base intraosseous meningioma (1/7, 14%), two frontal bone-based intraosseous meningiomas (2/7, 28%), a recurrent fronto-parietal epithelioid hemangioendothelioma (1/7, 14%), a singular metastatic papillary thyroid carcinoma of the right pterion with dural invasion (1/7, 14%), a left temporal bone plasmacytoma which extended into the temporal fossa, and a high-grade pleomorphic sarcoma of frontal bone with dural invasion (1/7, 14%). Overall, the dura was violated in 6 of 7 cases (86%). One was repaired with simple interrupted sutures and reinforced with fibrin glue (Patient 1). Four cases required repair using a synthetic dural patch (1/6, 17%, Patient 6), pedicled pericranial flap (1/6, 17%, Patient 5), temporalis fascial graft (2/6, 33%, Patients 2, 3), tensor fascia lata graft (1/6, 17%, Patient 7), or vascularized pericranial flap (1/6, 17%, Patient 5). In addition, the PEEK implant for Patient 5 was further covered with a second pericranial flap and temporalis fascia flap. Of the 6 dural violations, 5 were due to tumor extension into the dura and 1 was due to a difficult dissection plane. Of note, two cases (2/7, 28%, Patients 5, 7) required rotational fasciocutaneous flaps based for complex scalp closure. synthetic dural patch (1/6, 17%, Patient 6), pedicled pericranial flap (1/6, 17%, Patient 5), temporalis fascial graft (2/6, 33%, Patients 2, 3), tensor fascia lata graft (1/6, 17%, Patient 7), or vascularized pericranial flap (1/6, 17%, Patient 5). In addition, the PEEK implant for Patient 5 was further covered with a second pericranial flap and temporalis fascia flap. Of the 6 dural violations, 5 were due to tumor extension into the dura and 1 was due to a difficult dissection plane. Of note, two cases (2/7, 28%, Patients 5, 7) required rotational fasciocutaneous flaps based for complex scalp closure.

[0129] In summary, all implants (7/7, 100%) required some form of contour modification. The additional operative time for this additional step ranged between 10-80 minutes. Overall, the implants were reduced in size by a range of 0.002-40.8% with a mean of 13.8% when compared to their original size. The reduction of size ranged from 3-3188 mm2, with a mean of 842 mm2.

[0130] The terms "couple," "coupled," "connect," "connection," "connected," "in connection with," and "connecting" refer to "in direct connection with" or "in connection with via one or more intermediate elements or members." Furthermore, to the extent that the terms "including", "includes", "having", "has", "with", or variants thereof are used in either the detailed description and the claims, such terms are intended to be inclusive in a manner similar to the term "comprising." As used herein, the phrase "at least one of" or "one or more of", for example, A, B, and C means any

of the following: either A, B, or C alone; or combinations of two, such as A and B, B and C, and A and C; or combinations of three A, B and C.

[0131] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

What is claimed is:

1. A computer-assisted surgical system, comprising:
a reference unit comprising a first trackable element;
an implant comprising a second trackable element; and
a detector configured to provide at least one signal corresponding to a detected location of at least one of the first trackable element and the second trackable element.

2. The system of claim **1**, wherein the detector comprises a magnetic detector or an optical detector.

3. The system of claim **1**, wherein at least one of the first trackable element and the second trackable element comprises an IR reflector or an IR emitter.

4. The system of claim **1**, further comprising a cutting guide comprising a third trackable element, wherein the at least one signal further corresponds to a detected location of the third trackable element, and wherein the third trackable element comprises an IR reflector or an IR emitter.

5. The system of claim **1**, further comprising a computer that receives the at least one signal, and an additive manufacturing device in communication with the computer.

6. The system of claim **1**, wherein the implant comprises a metal, a polymer, a bioengineered material, or combinations thereof.

7. The system of claim **1**, further comprising a computer in communication with the detector, wherein the computer comprises:
at least one memory to store data and instructions, and
at least one processor configured to access the at least one memory and to execute instructions, the instructions comprising:
accessing a first computer-readable reconstruction of a being's anatomy,
wherein the first computer-readable reconstruction of the being's anatomy comprises a first updatable orientation; and
accessing a second computer-readable reconstruction of the implant, wherein the second computer-readable reconstruction of the implant comprises a second updatable orientation.

8. The system of claim **7** wherein the instructions further include updating at least one of the first orientation and the second orientation in response to the at least one signal.

9. The system of claim **7**, further comprising an additive manufacturing device in communication with the computer, and wherein the instructions further comprise:
superimposing a planned cutting plane over portions of the first computer-readable reconstruction;
generating a third computer-readable reconstruction of a cutting guide, the third computer-readable reconstruction of the cutting guide comprising a geometry defined by an interface between the planned cutting plane and the first computer-readable reconstruction, and the third computer-readable reconstruction further comprising a third updatable orientation; and
controlling the additive manufacturing device to form a cutting guide comprising selected dimensions of the geometry of the third computer-readable reconstruction.

10. The system of claim **7**, wherein the instructions further comprise:
superimposing a planned cutting plane over portions of the first computer-readable reconstruction; and
generating the second computer-readable reconstruction of the implant, wherein the second computer-readable reconstruction of the implant comprises a geometry defined by at least one of: i) an interface between the planned cutting plane and the first computer-readable reconstruction, and ii) a selected portion of the computer-readable reconstruction, the selected portion comprising an anatomical feature of the being's anatomy.

11. The system of claim **10**, further comprising an additive manufacturing device in communication with the computer, and wherein the instructions further comprise:
controlling the additive manufacturing device to form an implant having dimensions defined by the geometry of the second computer-readable reconstruction.

12. The system of claim **11**, wherein the anatomical feature comprises a defect site and the implant is attachable at the defect site.

13. A computer-assisted, surgical method, comprising:
attaching a reference unit comprising a first trackable element to a first anatomical feature of a being's anatomy;
detecting a location of at least the first trackable element with a detector configured to provide at least one signal corresponding to a detected location of at least the first trackable element; and
accessing a first computer-readable reconstruction of the being's anatomy, the first computer-readable reconstruction comprising a first updatable orientation, wherein the first updatable orientation is updated in response to the at least one signal.

14. The method of claim **13**, further comprising:
generating a second computer-readable reconstruction of an implant, the second computer-readable reconstruction comprising a second updatable orientation;
assessing a size-mismatch between at least one dimension of a portion of the first computer-readable reconstruction corresponding to a selected anatomical feature of the being's anatomy and at least one dimension of the second computer-readable reconstruction; and
tracing cut lines on the implant based on the size-mismatch such that an anatomical discrepancy at an area of removal or reconstruction of the anatomical feature is minimized at a preselected tolerance.

15. The method of claim **14**, further comprising:
attaching the implant to a preselected anatomical feature; and
obtaining a postoperative image of at least the implant attached to the preselected anatomical feature.

16. The method of claim **13**, further comprising:
attaching a second trackable element to an implant;
detecting a location of the second trackable element with the detector, wherein the at least one signal further corresponds to a detected location of the second trackable element;

accessing a second computer-readable reconstruction of an implant, the second computer-readable reconstruction comprising a second updatable orientation, wherein the second updatable orientation is updated in response to the at least one signal; and

superimposing the second computer-readable reconstruction on the first computer-readable reconstruction.

17. The method of claim **16**, further comprising:

attaching the implant to a preselected anatomical feature of the being's anatomy; and

obtaining a postoperative image of at least the implant attached to the preselected anatomical feature.

18. The method of claim **13**, further comprising:

superimposing a planned cutting plane over portions of the first computer-readable reconstruction, wherein the planned cutting plane bisects the first computer-readable reconstruction to define at least one portion of the first-computer readable reconstruction corresponding to at least one diseased anatomical feature of the being's anatomy that is to be removed or replaced;

accessing a third computer-readable reconstruction of a cutting guide, wherein the third computer-readable reconstruction comprises a third updatable orientation and a geometry that corresponds to a bisecting interface between the planned cutting plane and the first computer-readable reconstruction;

fabricating a cutting guide comprising dimensions that correspond to the geometry of the third computer readable reconstruction; and providing a third trackable element on the cutting guide,

wherein the at least one signal further corresponds to a detected location of the third trackable element, and

wherein the planned cutting plane comprises a fourth updatable orientation.

19. The method of claim **13**, further comprising

attaching a cutting guide to the being's anatomy, wherein the cutting guide comprises a third trackable element;

detecting a location of the third trackable element with the detector, wherein the at least one signal further corresponds to a detected location of the third trackable element; and

accessing a third computer-readable reconstruction of a cutting guide, the third computer-readable reconstruction comprising a third updatable orientation,

wherein the third updatable orientation is updated in response to the at least one signal.

20. The method of claim **13**, further comprising:

superimposing a planned cutting plane over portions of the first computer-readable reconstruction, wherein the planned cutting plane bisects the first computer-readable reconstruction to define at least one portion of the first-computer readable reconstruction corresponding to at least one diseased anatomical feature of the being's anatomy that is to be removed or replaced;

accessing a second computer-readable reconstruction of an implant, wherein the second computer-readable reconstruction comprises a second updatable orientation and a geometry that corresponds to a bisecting interface between the planned cutting plane and the first computer-readable reconstruction;

fabricating an implant comprising dimensions that correspond to the geometry of the second computer-readable reconstruction, and

providing a second trackable element on the implant,

wherein the at least one signal further corresponds to a detected location of the second trackable element,

wherein the second updatable orientation is updated in response to the at least one signal, and wherein the planned cutting plane comprises a fourth updatable orientation.

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