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(54) **POWERED OSTEOTOME TREPANATION TOOL**

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(58) **Field of Classification Search**

CPC **A61B 17/1757**

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,722,977 A 3/1998 Wilhelmy

6,007,496 A 12/1999 Brannon

(Continued)

FOREIGN PATENT DOCUMENTS

CN 210009092 U 2/2020

OTHER PUBLICATIONS

PCT Notification of Transmittal of the International Search Report and the Written Opinion of the International Searching Authority, or the Declaration issued to counterpart Application No. PCT/US2021/046492 dated Dec. 9, 2021.

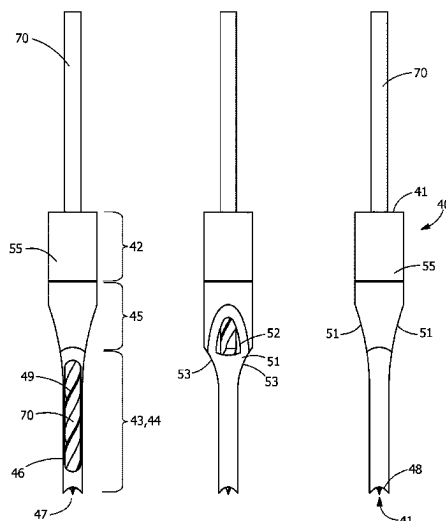
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(57) **ABSTRACT**

A surgical bone cutting system includes a trajectory guide and an osteotome or trepanation tool with a generally square cutting tip that creates a corridor through bone, for example, in the context of spine, through a facet joint or other vertebral structure and to the disc space between two vertebrae for any of a variety of surgical procedures, including but not limited to disc prep and cage insertion. The osteotome fits into the trajectory guide to contact bone and effect creating a bony corridor. In some embodiments, the trajectory guide includes a cylindrical allograft collection chamber, and the trajectory guide and osteotome fit into standard tubular retractors and are agnostic with respect to receiving standard drill bits or a powered auger insertable through a center through channel.

20 Claims, 5 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

7,670,328	B2 *	3/2010	Miller	A61B 17/1622 606/167
7,803,159	B2	9/2010	Perez-Cruet et al.	
8,118,813	B2	2/2012	Perez-Cruet et al.	
8,571,638	B2	10/2013	Shoham	
8,915,921	B2	12/2014	Ralph et al.	
9,642,633	B2	5/2017	Frey et al.	
9,826,986	B2	11/2017	Donner et al.	
10,806,470	B2	10/2020	Lipari et al.	
2004/0002711	A1 *	1/2004	Berry	A61B 17/1757 606/79
2004/0191897	A1 *	9/2004	Muschler	A61B 17/32002 435/325
2004/0193170	A1 *	9/2004	Kemppainen	A61F 2/4601 606/92
2007/0118136	A1	5/2007	Ek	
2007/0191852	A1	8/2007	Shimko et al.	
2008/0081951	A1	4/2008	Frasier et al.	
2008/0125856	A1 *	5/2008	Perez-Cruet	A61B 17/1671 623/1.23
2009/0118742	A1	5/2009	Hartmann et al.	

* cited by examiner

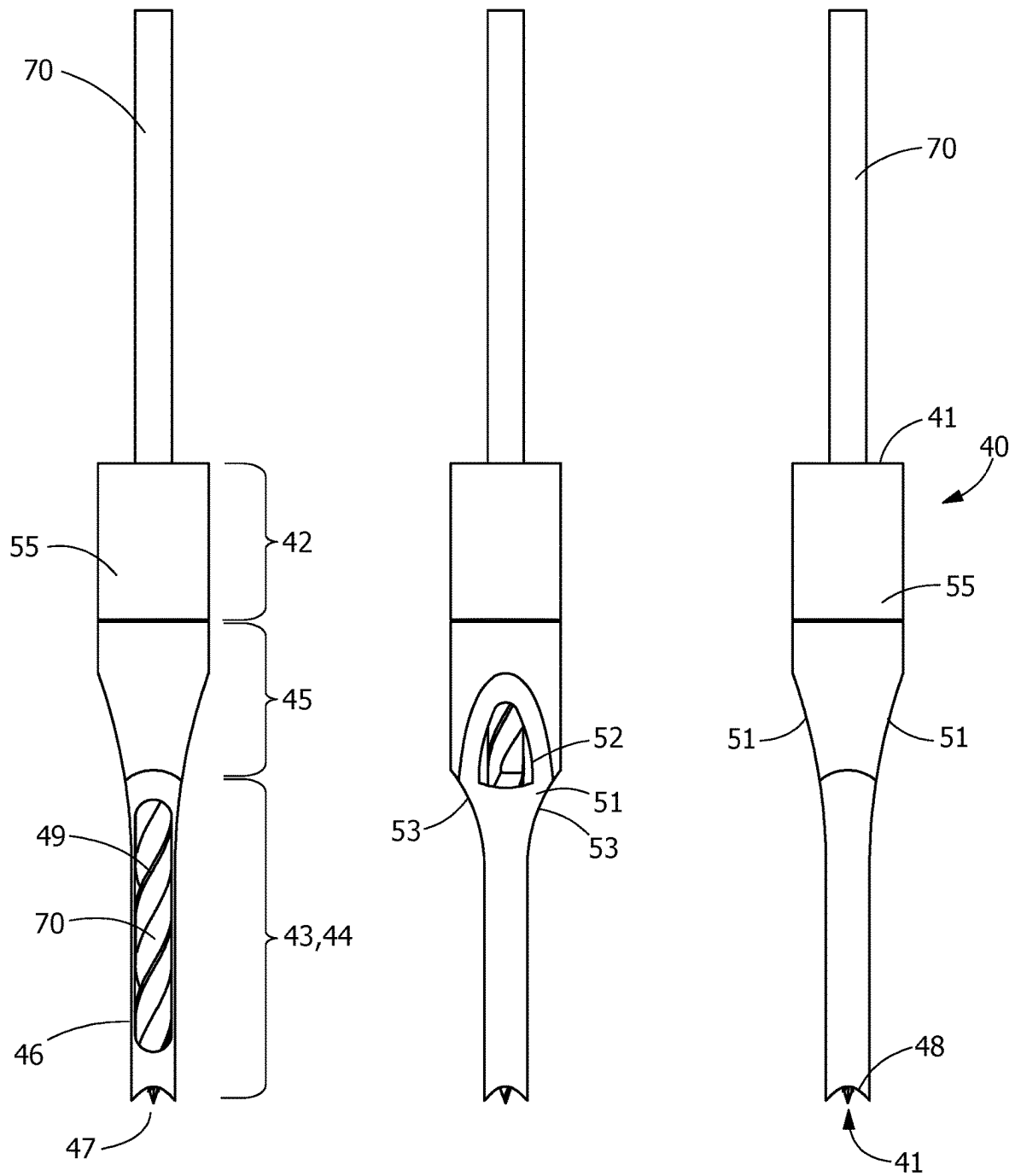


FIG. 1

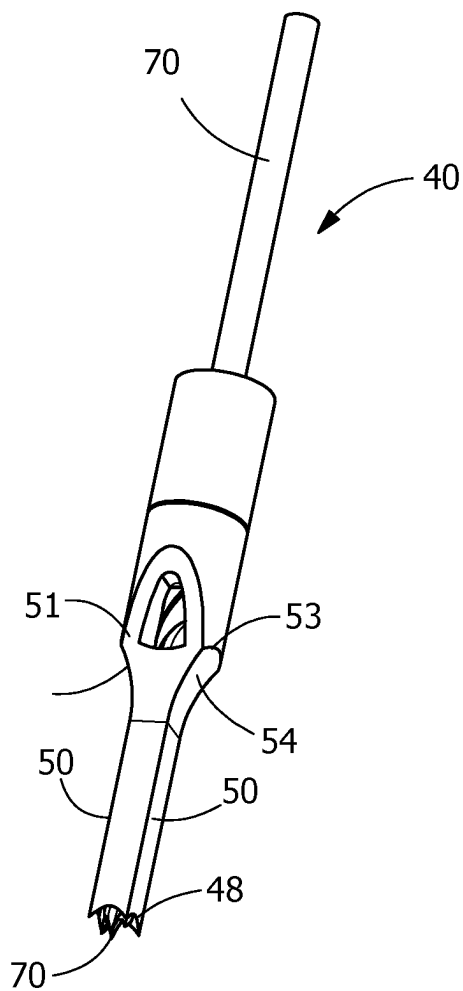


FIG. 2

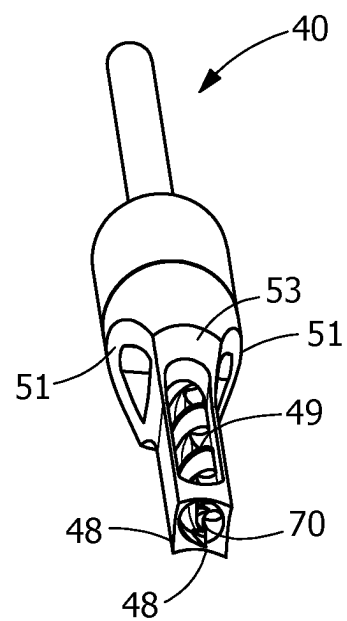


FIG. 3

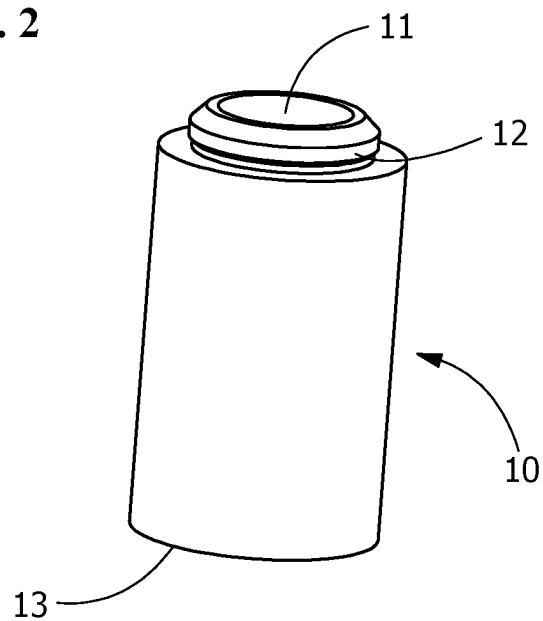


FIG. 4

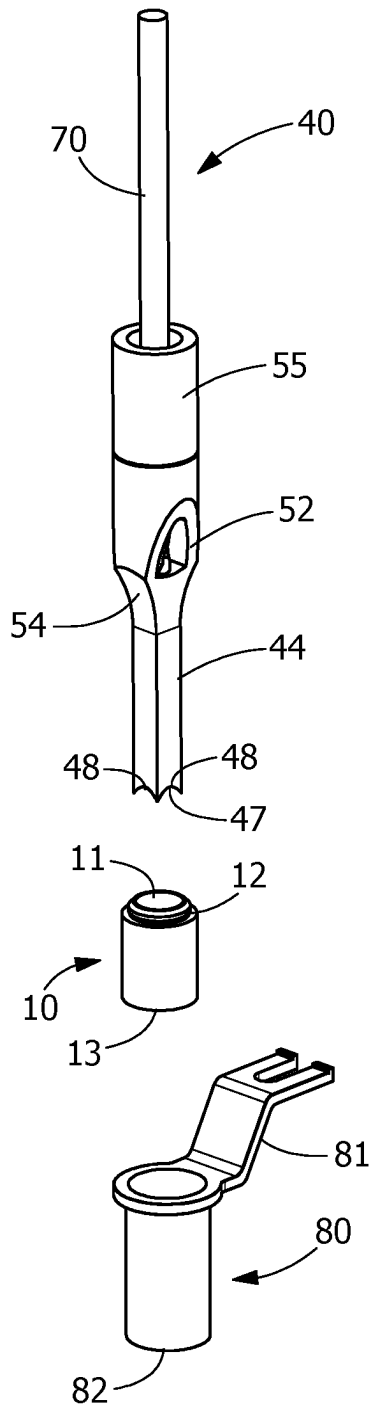


FIG. 5

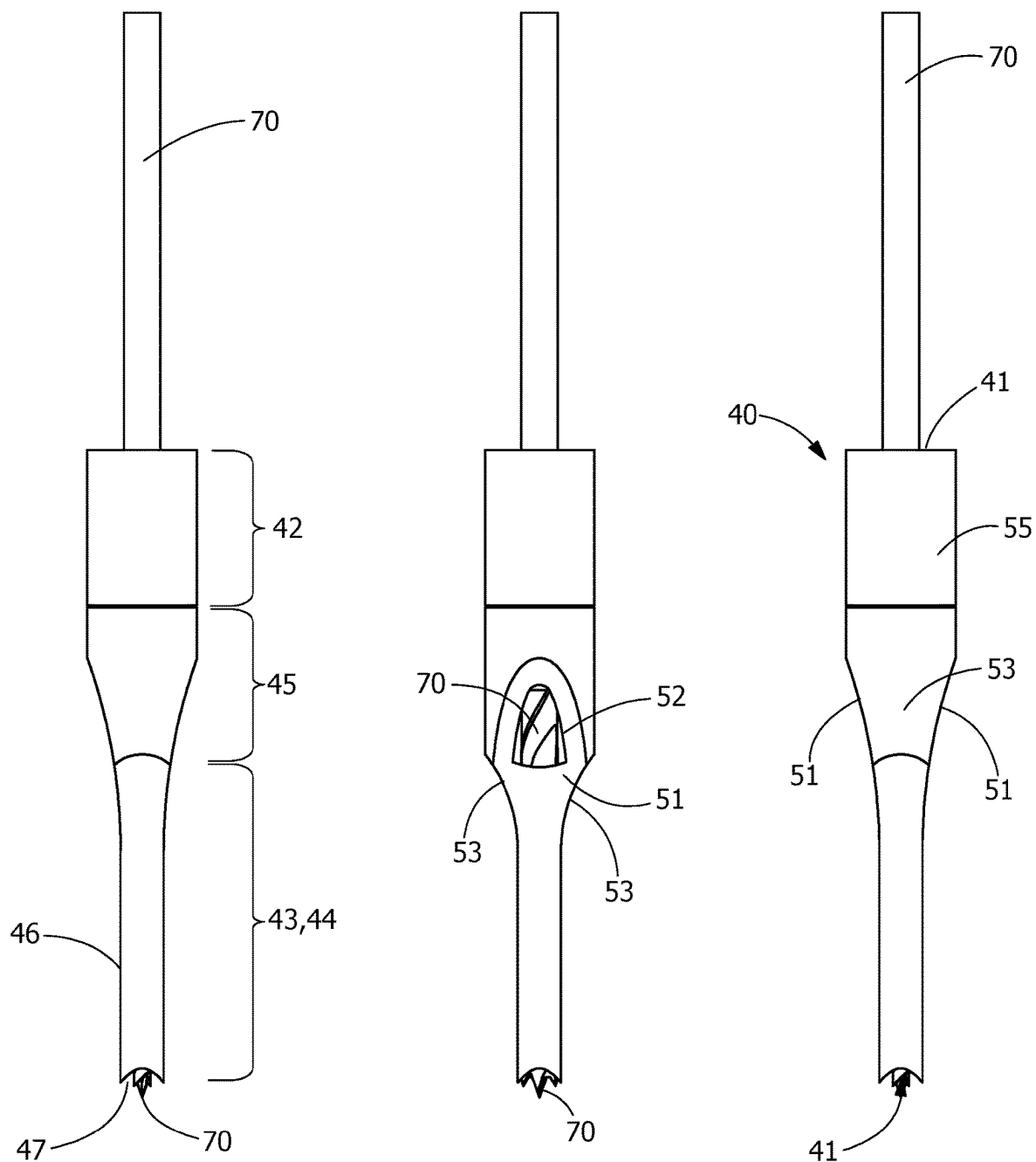


FIG. 6

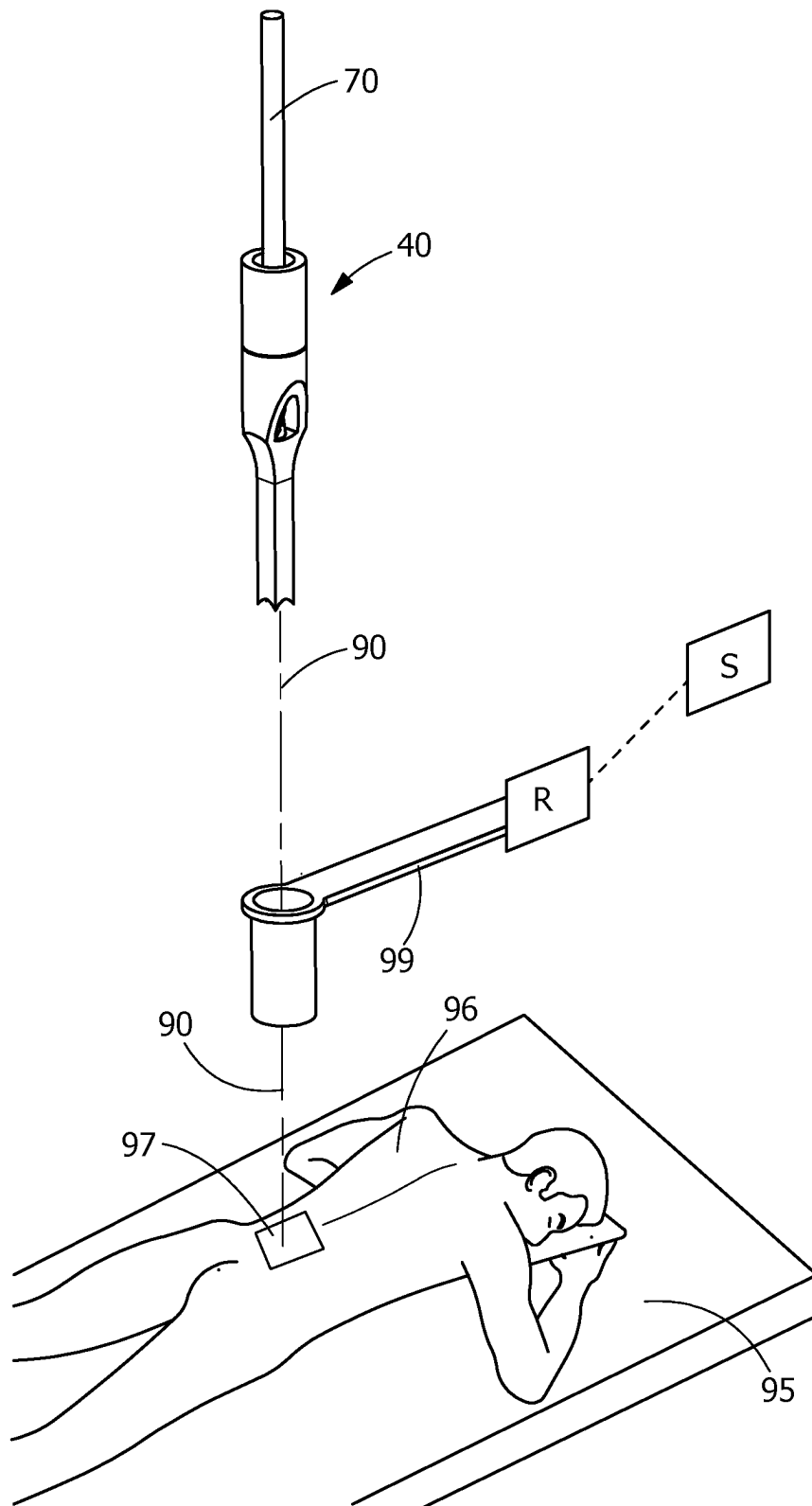


FIG. 7

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**POWERED OSTEOTOME TREPANATION
TOOL****RELATED APPLICATION**

The present application claims priority to U.S. Provisional Application No. 63/103,670 titled POWERED OSTEOTOME TREPANATION, which was filed on Aug. 18, 2020, the entirety of which is incorporated herein by reference.

FIELD OF THE INVENTION

The present disclosure is generally directed to instruments and related methods for bone and/or tissue removal. More particularly, the present disclosure is directed to handheld resected bone and/or tissue removal instruments and related methods for establishing a marked site on a bone and for removing a resected bone portion from a patient.

BACKGROUND OF THE INVENTION

A bone or tissue may be resected (i.e., the excision of a portion of the bone) in any number of ways for any number of reasons. For example, adjacent portions of two or more bones or tissue forming a joint therebetween may be resected, and the bones may be reduced to promote fusion of the bones. As another example, during an arthrodesis procedure in the spine to obtain access to the disc base. In a transforaminal lumbar interbody fusion procedure, for example, the superior and inferior articular facets are removed promote fusion between the disc space of the rostral and caudal spinal segment.

A bone may be resected using a device that cuts through the bone to separate a portion therefrom, and subsequent removal of the portion from the patient. This tissue is relatively difficult to remove from the resected bone portion, and thus makes removal of the resected bone portion difficult. A Kerrison rongeur, curette, burr, bone scalpel blade, osteotome, or other device is typically used to resect such tissue. The resected bone portion may thereby include some of such tissue connected thereto after resection.

Typical methods of removing a resected bone portion include the manual use of a tool, such as a rongeur, curette, osteotome and/or hemostat, to physically engage the portion and extract the portion from the patient. However, removal of a resected bone portion may be relatively difficult. For example, the resected bone portion may be positioned in a relatively tight, flat joint space which restricts access to the resected bone portion. As another example, the resected bone portion may be attached to at least one tendon, ligament or other soft tissue that is relatively difficult to resect or otherwise makes removal of the resected bone portion challenging.

Therefore, bone and/or tissue removal instruments and related methods that fit into tight spaces or joints, adequately remove soft tissue from resected bone or tissue portions, and securely engage resected bone are desirable.

BRIEF DESCRIPTION OF THE DRAWINGS

Features and advantages of the general inventive concepts will become apparent from the following description made with reference to the accompanying drawings, including drawings represented herein in the attached set of figures, of which the following is a brief description:

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FIG. 1 shows first, second and third side views of a first embodiment of an osteotome of the surgical bone cutting system;

FIG. 2 shows a perspective view from the second side view of the first embodiment of an osteotome of the surgical bone cutting system shown in FIG. 1;

FIG. 3 shows a bottom perspective view from the first side view of the first embodiment of an osteotome of the surgical bone cutting system shown in FIG. 1;

FIG. 4 shows a first embodiment of a trajectory guide of an osteotome of the surgical bone cutting system;

FIG. 5 shows a first embodiment of surgical bone cutting system including the first embodiment of an osteotome as shown in FIG. 1 and the first embodiment of a trajectory guide as shown in FIG. 4 and a prior art cylindrical surgical retractor, all depicted in an exploded view relative to an assembly thereof;

FIG. 6 shows first, second and third side views of a second embodiment of an osteotome of the surgical bone cutting system; and

FIG. 7 shows a second embodiment of surgical bone cutting system including the second embodiment of an osteotome as shown in FIG. 6 and a second embodiment of a trajectory guide, all depicted in an exploded view relative to an assembly thereof.

**REFERENCE NUMBERS USED IN THE
SPECIFICATION AND DRAWINGS**

The following table provides a key to the specific features mentioned in the specification which are numbered in the text or otherwise correspond to the indicated numbers in the table.

Referenced Feature	Ref #
surgical bone cutting system	100
trajectory guide	10
Hollow chamber	11
proximal and distal openings	12, 13
inner wall of the trajectory guide	15
osteotome	40
through channel	41
proximal portion	42
distal portion	43
cutting jig	44
central portion	45
guide shaft	46
distal cutting tip	47
concave radiused cutting edges	48
elongate slot aperture	49
opposing walls of the guide shaft	50
first pair of opposing sides	51
elongate aperture that tapers towards the guide shaft	52
Second pair of opposing sides	53
concave radiused taper	54
outer wall of the osteotome	55
drill bit	70
generally cylindrical surgical retractor	80
proximal handle	81
distal retractor end	82
a support substrate	95
Surgical subject	96
locking arm	99
robotic arm	99
target trajectory	90
robot	R
alignment/navigation system	S

Features and advantages of the general inventive concepts will become apparent from the following description made with reference to the accompanying drawings, including drawings represented herein in the attached set of figures, of which the following is a brief description.

SUMMARY OF THE INVENTION

This disclosure describes exemplary embodiments in accordance with the general inventive concepts and is not intended to limit the scope of the invention in any way. Indeed, the invention as described in the specification is broader than and unlimited by the exemplary embodiments set forth herein, and the terms used herein have their full ordinary meaning.

In some embodiments, the instant disclosure provides a first embodiment of a surgical bone cutting system that includes a trajectory guide that includes opposing proximal and distal openings and has a generally cylindrical shape, and an osteotome having a through channel suitable for receiving a drill bit or auger inserted therethrough, wherein the osteotome also includes a proximal portion, a distal portion that includes a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig including a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edges suitable for penetrating bone. In some embodiments, the trajectory guide and osteotome are configured to be arranged by passage of at least a portion of the distal portion of the osteotome through the proximal opening of the trajectory guide. In some embodiments, the surgical bone cutting system also includes a bone drill or auger comprising a bit suitable for penetrating bone. The bone drill or auger may be manually or electrically powered. In some examples, the bone drill may be ultrasonic or harmonic.

In some embodiments, the trajectory guide defines a generally hollow bone collection chamber between its proximal and distal openings, and the trajectory guide is sized and shaped for insertion within a generally cylindrical surgical retractor that comprises a proximal handle and a distal retractor end for contacting bone.

In some embodiments, the instant disclosure provides a second embodiment of a surgical bone cutting system that includes a trajectory guide including opposing proximal and distal openings and an osteotome having a through channel, and including a proximal portion, a distal portion including a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig including a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edges suitable for penetrating bone. In some embodiments, the trajectory guide and osteotome are configured to be arranged by passage at least the distal portion of the osteotome through the proximal opening of the trajectory guide, the osteotome have a maximum outer diameter that is less than an inner diameter of the trajectory guide to effectively control the trajectory of the inserted osteotome along a trajectory established by the trajectory guide when it is secured to the locking arm and the locking arm is fixed relative to the support substrate.

In some embodiments, the surgical bone cutting system also includes a bone drill or auger comprising a bit suitable

for penetrating bone, a support substrate, and a locking arm, the support substrate configured to retain a surgical subject in a secured and fixed position, the locking arm configured to retain the trajectory guide in a secured and fixed position relative to the support substrate, the surgical subject, or both,

In some embodiments, the locking arm is a robotic arm, and the surgical bone cutting system further includes an alignment and navigational system and a robot that is controlled by the navigational system to align the trajectory guide when connected to a robotic arm of the robot within a three dimensional space based on predetermined coordinates, wherein the three dimensional space is defined by coordinates and includes at least a portion of the support substrate, at least a portion of the surgical subject, or both.

In some embodiments, the instant disclosure provides a first method for excising bone from a clinical subject. In some embodiments, the method includes the step of providing a surgical bone cutting system that includes a trajectory guide including opposing proximal and distal openings and having a generally cylindrical shape, and an osteotome having a through channel suitable for receiving a bit suitable for penetrating bone inserted therethrough, and including a proximal portion, a distal portion including a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig including a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edges suitable for penetrating bone. In some embodiments, the method includes providing a bone drill or auger and a bit suitable for penetrating bone suitable for drilling bone.

In some embodiments, the method also includes the steps of establishing access to a surgical site adjacent a bone of a surgical subject; positioning and fixing the trajectory guide in a selected position with respect to the surgical site; and directing at least a portion of the distal portion of the osteotome through the proximal opening of the trajectory guide and securing the osteotome into engagement with bone in the surgical site.

In some embodiments, the step of establishing access to the surgical site includes securing a cylindrical retractor to the surgical subject, wherein the trajectory guide is sized and shaped for insertion within the cylindrical surgical retractor and defines a generally hollow bone collection chamber between its proximal and distal openings.

In some embodiments, the method for excising bone further includes the steps of mechanically driving at least a portion of the distal cutting tip into bone followed by passing the bone drill or auger within the through channel of the osteotome and into contact with bone and activating the drill or auger to remove bone tissue.

In some embodiments, the instant disclosure provides a second method for excising bone from a clinical subject using a predetermined trajectory for access to the surgical site, for example, employing coordinates for a target trajectory relative to the surgical site within a three dimensional space, wherein the three dimensional space is defined by coordinates that include at least a portion of the support substrate, at least a portion of the surgical subject, or both, the method including affixing the trajectory guide to a locking or robotic arm, and directing motion of the robotic arm to position the trajectory guide into alignment with the target trajectory.

In some embodiments, the osteotome has a maximum outer diameter that is less than an inner diameter of the trajectory guide. In some embodiments, the surgical bone

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cutting system further includes a support substrate; and a locking arm, the support substrate configured to retain the surgical subject in a secured and fixed position, the locking arm configured to retain the trajectory guide in a secured and fixed position relative to the support substrate, the surgical subject, or both.

In some embodiments, the method for excising bone further includes, after the step of establishing access to the surgical site, securing the trajectory guide to the locking arm and fixing the locking arm relative to the support substrate; and passing at least the distal portion of the osteotome through the proximal opening of the trajectory guide whereby interference between an outer wall of the osteotome and an inner wall of the trajectory guide effectively controls the trajectory of the inserted osteotome along a trajectory established by the trajectory guide.

In some embodiments, the locking arm is a robotic arm, the surgical bone cutting system further including an alignment and navigational system that comprises a robot that is controlled by the navigational system.

In some embodiments, the method for excising bone further includes providing coordinates for a target trajectory relative to the surgical site within a three dimensional space, wherein the three dimensional space is defined by coordinates and includes at least a portion of the support substrate, at least a portion of the surgical subject, or both, and the method further includes the steps of affixing the trajectory guide to the robotic arm, and directing motion of the robotic arm to position the trajectory guide into alignment with the target trajectory.

In various embodiments, the step of establishing access to the surgical site may include selecting a surgical site within a human spine wherein the selected surgical site is adjacent bone, for example, a facet joint, and the method for excising bone further includes a step selected from the group consisting of (1) mechanically driving at least a portion of the distal cutting tip into bone followed by removing the osteotome from the trajectory guide, (2) mechanically driving at least a portion of the distal cutting tip into bone followed by passing the bone drill or auger within the through channel of the osteotome and into contact with bone and activating the drill or auger to remove bone tissue, and (3) a combination thereof.

In another aspect, the present disclosure provides a powered osteotome device which, when combined with a system for navigation or stabilization guide, facilitates bone resection. In some embodiments, the instrument includes a first elongate member, a second elongate member. The first elongate member includes a cutting chisel edge defining the corridor for bone removal. The second elongate member is rotatably coupled to the first elongate to safely remove bone along the guide jig provided by the first member. The second head portion includes an interior surface with a front cutting tooth defining a free end of the second head portion, a substantially flat bone or irregular engagement surface, and gripping teeth extending between the front cutting tooth and the bone engagement surface.

In another aspect, the present disclosure provides for a method of removing a resected bone portion. The powered osteotome method includes integration with computer-assisted surgery and robotics. Combination with ultrasonic aspirator and use with electronic or pneumatic drilling devices.

In another aspect, the present disclosure provides a surgical instrument. The surgical instrument includes a first elongate member including guide jig and stabilization arm for trephination to the planned surgical target. The target

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may represent the disc space in the spine. The second rotating member fits within the first member to facilitate bone removal and collection.

In some embodiments, the invention can provide a bony corridor to the disc space front cutting tooth a distance within the range of 5 mm to 20 mm. In some such embodiments, the instrument further includes a biasing mechanism that biases the first and second member away from vital structures such as but not limited to nerve roots. Handle portions or stabilization guide attached to the operating table.

In some embodiments, the movable second member rotation point is formed via a stabilization guide and/or wire extending into the bone or facet joint.

In another aspect, the present disclosure provides for a method of removing and collecting resected bone or tissue portion from a body.

In some embodiments, the first head portion includes a substantially smooth interior tissue engagement surface to engage the bone without skiving or migration

In some embodiments, the resected bone may be used as morselized allograft for the arthrodesis procedure.

These and other objects, features and advantages of this disclosure will become apparent from the following detailed description of the various aspects of the disclosure taken in conjunction with the accompanying drawings.

DETAILED DESCRIPTION

This description describes exemplary embodiments in accordance with the general inventive concepts and is not intended to limit the scope of the invention in any way. Indeed, the invention as described in the specification is broader than and unlimited by the exemplary embodiments set forth herein, and the terms used herein have their full ordinary meaning.

The general inventive concepts will now be described with occasional reference to the exemplary embodiments of the invention. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art encompassing the general inventive concepts. The terminology set forth in this detailed description is for describing particular embodiments only and is not intended to be limiting of the general inventive concepts.

As used herein, the singular forms "a," "an," and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise.

Unless otherwise indicated, all numbers expressing quantities, properties, and so forth as used in the specification and claims are to be understood as being modified in all instances by the term "about." Accordingly, unless otherwise indicated, the numerical properties set forth in the specification and claims are approximations that may vary depending on the suitable properties desired in embodiments of the present invention. Notwithstanding that the numerical ranges and parameters setting forth the broad scope of the general inventive concepts are approximations, the numerical values set forth in the specific examples are reported as precisely as possible. Any numerical values, however, inherently contain certain errors necessarily resulting from error found in their respective measurements.

The term "proximal" as used in connection with any object refers to the portion of the object that is closest to the operator of the object (or some other stated reference point), and the term "distal" refers to the portion of the object that is farthest from the operator of the object (or some other

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stated reference point). The term “operator” means and refers to any professional or paraprofessional who delivers clinical care to a medical patient, particularly in connection with the delivery of care. A “clinical subject” refers to a human or other animal who is the subject of treatment with a bone fixation or reduction device in accordance with the disclosure. With respect to any references herein that may be made relative to a clinical subject, the term “medial” indicates a direction toward the centerline axis (e.g., the spine) of the clinical subject, and the term “lateral” indicates a direction toward a side of the clinical subject. The term “system” refers to any combination of two or more of objects, devices, or components. And the term “method” refers to any one of methods of using a device or system, and surgical methods or techniques employing a device or system.

Referring now to the drawings as variously depicted in FIG. 1-FIG. 7, the present invention includes a surgical bone cutting system **100** that is useful for penetrating and/or removing bone tissue from a clinical subject. In some embodiments, the bone cutting system **100** and methods are useful for spinal applications, for example, surgeries performed on the facet joints of the spine. Surgeries on the facet joints are often performed to reduce pain by relieving pressure and in some instances improving the stability of the motion segment. In such instances, fusion of adjacent vertebrae may be performed when a significant portion of a facet is removed. Other examples of surgery that may be performed using the disclosure system, in either open or using a minimally invasive approach and/or endoscopically, include decompression, reduction, or facetectomy. Though this disclosure includes description of embodiments of the invention used for facet joint surgery, it will be appreciated that the use of the system is not limiting, and it may be employed for other applications through the anatomy of clinical subject.

Referring now to FIGS. 1-5, the drawings, respectively, show: first, second and third side views of a first embodiment of an osteotome of the surgical bone cutting system, a perspective view from the second side view of the first embodiment of an osteotome of the surgical bone cutting system shown in FIG. 1; a bottom perspective view from the first side view of the first embodiment of an osteotome of the surgical bone cutting system shown in FIG. 1; a first embodiment of a trajectory guide of an osteotome of the surgical bone cutting system; and a first embodiment of surgical bone cutting system including the first embodiment of an osteotome as shown in FIG. 1 and the first embodiment of a trajectory guide as shown in FIG. 4 and a prior art cylindrical surgical retractor, all depicted in an exploded view relative to an assembly thereof.

Referring now to FIG. 5, the invention provides a surgical bone cutting system **100** that includes a trajectory guide **10** and an osteotome **40** or trepanation tool with a generally square cutting tip **47** that creates a corridor through bone, for example, in the context of spine, through a facet joint or other vertebral structure and to the disc space between two vertebrae for any of a variety of surgical procedures, including but not limited to disc prep and cage insertion. It will be appreciated that in various embodiments, the cutting tip **47** may be square in cross-section as depicted in the embodiments of the drawings herein, while in other embodiments it may have another polyhedral type of cross-sectional shape that is other than square in cross section, or it may be generally circular or elliptical in cross section. Further, in various embodiments, the guide shaft **46** may be square in cross-section as depicted in the embodiments of the draw-

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ings herein, while in other embodiments it may have another polyhedral type of cross-sectional shape that is other than square in cross section, or it may be generally circular or elliptical in cross section. Further still, in various embodiments, the proximal and central portions **42**, **45** of the osteotome **40** may be circular in cross-section (i.e., cylindrical) along all or a portion of their lengths, as depicted in the embodiments of the drawings herein, while in other embodiments any of these features may have another type of cross-sectional shape that is other than circular in cross section, for example polyhedral, or may be generally circular or elliptical in cross section.

Referring again to FIG. 5, the osteotome **40** fits into the trajectory guide **10** to contact bone and effect creating a bony corridor. In some embodiments, the trajectory guide **10** includes a cylindrical allograft collection chamber, and the trajectory guide **10** and osteotome **40** fit into standard tubular retractors and are agnostic with respect to receiving standard drill bits or a powered auger insertable through a center through channel **41**.

Referring now to FIG. 4 and FIG. 5, the instant disclosure provides a surgical bone cutting system **100** that includes a trajectory guide **10**. The trajectory guide **10** includes opposing proximal and distal openings **12**, **13** and has a generally cylindrical shape. In some embodiments, the trajectory guide **10** defines a generally hollow bone collection chamber **11** between its proximal and distal openings **12**, **13**, and the trajectory guide **10** is sized and shaped for insertion within a generally cylindrical surgical retractor **80** that comprises a proximal handle **81** and a distal retractor end **82** for contacting bone, as shown in FIG. 5. In some embodiments, the trajectory guide **10** proximal opening has a shape and dimension that corresponds with the cross-sectional shape and dimension of the distal cutting tip **47** of the osteotome **40**.

Referring now to FIGS. 1, 2, 3 and 5, the surgical bone cutting system **100** also includes an osteotome **40** having a generally cylindrical shape and a through channel **41** suitable for receiving a bit **70** inserted therethrough, and a proximal portion **42**, a distal portion **43** that includes a cutting jig **44**, and a central portion **45** between the proximal portion **42** and the distal portion **43**, the cutting jig **44** including a guide shaft **46** and a distal cutting tip **47**, the guide shaft **46** being tapered relative to at least the proximal portion **42**, and the distal cutting tip **47** having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edge **48** suitable for penetrating bone. In some embodiments, the guide shaft **46** includes at least one elongate slot aperture **49**. In some embodiments, each of the guide shaft **46** and the distal cutting tip **47** has a square cross-sectional shape, and the at least one elongate slot aperture **49** is present in at least one of four opposing walls of the guide shaft **50**. As depicted in FIGS. 1, 2, 3 and 5, the guide shaft **46** has four walls, one of which includes an elongate slot aperture, and three of which do not have any apertures. It will be appreciated that in various embodiments, whether cylindrical or square in cross-section, the guide shaft **46** may have two or more elongate slot apertures **49** or other openings to facilitate the collection of bone tissue. In the referenced drawings, the guide shaft **46** has a generally square cross-sectional shape that includes four walls, all of which are solid.

In some embodiments, the guide shaft **46** of the osteotome **40** is tapered relative to the central portion **45**. In some embodiments, the central portion **45** is generally cylindrical, the central portion **45** including a first pair of opposing sides **51** one or both of the first pair of opposing sides **51** including

an elongate aperture that tapers towards the guide shaft **52**, the central portion **45** also including a second pair of opposing sides **53** each including concave radiused taper **54**. As shown in the drawings, the guide shaft **46** and the distal cutting tip **47** each has a generally square cross-sectional shape.

In some embodiments, as shown, for example, in FIGS. **6** and **7**, the guide shaft **46** does not have any apertures. In the referenced drawings, the guide shaft **46** may have a generally square cross-sectional shape that includes four walls, all of which are solid. In some embodiments, at least a portion of a solid walled guide shaft **46** may have a cross-sectional shape that is not square, for example, cylindrical or triangular.

Referring again to FIG. **5**, the trajectory guide **10** and osteotome **40** are configured to be arranged by passage of at least a portion of the distal portion **43** of the osteotome **40** through the proximal opening of the trajectory guide **10**. In some embodiments, the surgical bone cutting system **100** also includes a bone drill or auger comprising a bit **70** suitable for penetrating bone. In some embodiments, as shown variously in the drawings, the proximal portion **42** of the osteotome **40** has a generally cylindrical shape.

According to the first embodiment of the surgical bone cutting system **100** as described above, the surgical bone cutting system **100** is particularly useful for enabling the collection of bone and other biological material that is removed from the surgical site during use of the surgical bone cutting system **100**, the collection of the material being accomplished using the embodiment of the trajectory guide **10** as shown in FIG. **4** and FIG. **5**, wherein the openings **11**, **13** are sized to limit the passage of material from within the hollow bone collection chamber **11**. In use, the action of the bit **70** penetrating bone drives excised material upwards whereby it can pass through the at least one elongate slot aperture **49** and collect within the collection chamber **11**.

Referring now to FIG. **6** and FIG. **7**, the drawings, respectively, show first, second and third side views of a second embodiment of an osteotome **40** of the surgical bone cutting system **100**, and a second embodiment of the surgical bone cutting system **100** according to the disclosure, as more fully described herein below, the second embodiment of the surgical bone cutting system **100** including the second embodiment of an osteotome as shown in FIG. **6** and a second embodiment of a trajectory guide, all depicted in an exploded view relative to an assembly thereof.

Referring now to FIG. **7**, in some embodiments, the instant disclosure provides a surgical bone cutting system **100** that includes a trajectory guide **10** including opposing proximal and distal openings **12**, **13** and an osteotome **40** having a generally cylindrical shape and a through channel **41**, and including a proximal portion **42**, a distal portion **43** including a cutting jig **44**, and a central portion **45** between the proximal portion **42** and the distal portion **43**, the cutting jig **44** including a guide shaft **46** and a distal cutting tip **47**, the guide shaft **46** being tapered relative to at least the proximal portion **42**, and the distal cutting tip **47** having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edges **48** suitable for penetrating bone.

In some embodiments, the trajectory guide **10** and osteotome **40** are configured to be arranged by passage at least the distal portion **43** of the osteotome **40** through the proximal opening of the trajectory guide **10**, the osteotome **40** have a maximum outer diameter that is less than an inner diameter of the trajectory guide **10** to effectively control the trajectory of the inserted osteotome **40** along a trajectory established

by the trajectory guide **10** when it is secured to the locking arm **99** and the locking arm **99** is fixed relative to the support substrate **95**.

In some embodiments, the surgical bone cutting system **100** also includes a bone drill or auger comprising a bit **70** suitable for drilling bone, and a support substrate **95** for supporting a clinical subject **96**, and a locking arm **99** for retaining the trajectory guide **10**. Generally, the support substrate **95** is configured to retain a surgical subject **96** in a secured and fixed position, and the locking arm **99** configured to retain the trajectory guide **10** in a secured and fixed position relative to the support substrate **95**, the surgical subject **96**, or both.

In some embodiments, the locking arm **99** is a robotic arm **99** as shown in FIG. **7**, and the surgical bone cutting system **100** further includes an alignment and navigational system that comprises a robot (R) that is controlled by the alignment and navigational system (S) to align the trajectory guide **10** to a target trajectory **90** when connected to the robotic arm **99** within a three dimensional space based on predetermined coordinates, wherein the three dimensional space is defined coordinates that include at least a portion of the support substrate **95**, at least a portion of the surgical subject **96**, or both.

According to the second embodiment of the surgical bone cutting system **100** as described above, the surgical bone cutting system **100** is particularly useful for enabling precise alignment of the osteotome **40** along a predetermined trajectory (a target trajectory **90**) that is established within a coordinate system in three-dimensional space that includes the clinical subject. The trajectory guide **10** is fixed in relation to the clinical subject to precisely orient the through channel of the trajectory guide **10** along the predetermined trajectory and to retain and fix the osteotome **40** along the target trajectory **90** by restricting the motion of the osteotome **40** to movement substantially along the target trajectory **90** (i.e., the outer surface of the osteotome and inner wall of the trajectory guide are tightly toleranced). The surgical bone cutting system **100** thereby ensures that the passage of the osteotome **40** into contact with bone in the surgical site **97** is consistent with a clinically appropriate path and critical biological features in the clinical subject **96** are avoided.

METHODS

Referring now to FIGS. **5** and **7**, the disclosure provides a surgical bone cutting system **100** for use according to an inventive method for excising bone from a clinical subject. Referring now to the surgical bone cutting system as depicted in FIG. **5**, the disclosure provides a method that includes the step of providing a surgical bone cutting system **100** that includes a trajectory guide **10** including opposing proximal and distal openings **12**, **13** and having a generally cylindrical shape and an osteotome **40** having a generally cylindrical shape and a through channel **41** suitable for receiving a bit **70** inserted therethrough, and including a proximal portion **42**, a distal portion **43** including a cutting jig **44**, and a central portion **45** between the proximal portion **42** and the distal portion **43**, the cutting jig **44** including a guide shaft **46** and a distal cutting tip **47**, the guide shaft **46** being tapered relative to at least the proximal portion **42**, and the distal cutting tip **47** having a square or rectangular cross-sectional shape and including opposing pairs of concave radiused cutting edge **48** suitable for penetrating bone. In some embodiments, the method includes providing a bone drill or auger and a bit **70** suitable for drilling bone.

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In some embodiments, the method also includes the steps of establishing access to a surgical site **97** adjacent a bone of a surgical subject **96**; positioning and fixing the trajectory guide **10** in a selected position with respect to the surgical site **97**; and directing at least a portion of the distal portion **43** of the osteotome **40** through the proximal opening of the trajectory guide **10** and securing the osteotome **40** into engagement with bone in the surgical site **97**.

In some embodiments, the access to the surgical site **97** includes securing to the surgical subject **96** one or more instruments selected from the group consisting of a surgical wire, a dilator, a retractor, and a combination thereof.

In some embodiments, the step of establishing access to the surgical site **97** includes securing a cylindrical retractor **80** to the surgical subject **96**, and wherein the trajectory guide **10** is sized and shaped for insertion within the cylindrical surgical retractor **80** and defines a generally hollow bone collection chamber **11** between its proximal and distal openings **12**, **13**.

In some embodiments, the method for excising bone further including the steps of mechanically driving at least a portion of the distal cutting tip **47** into bone followed by passing the bone drill or auger within the through channel **41** of the osteotome **40** and into contact with bone and activating the drill or auger to remove bone tissue.

In some embodiments, the method for excising bone further including collecting bone within the collection chamber **11**.

In some embodiments, the instant disclosure provides a method for excising bone from a clinical subject using a predetermined trajectory for access to the surgical site **97**, for example, employing coordinates for a target trajectory **90** relative to the surgical site **97** within a three dimensional space, wherein the three dimensional space is defined by coordinates that include at least a portion of the support substrate **95**, at least a portion of the surgical subject **96**, or both, the method including affixing the trajectory guide **10** to a robotic arm **99**, and directing motion of the robotic arm **99** to position the trajectory guide **10** into alignment with the target trajectory **90**.

In some embodiments, the osteotome **40** has a maximum outer diameter that is less than an inner diameter of the trajectory guide **10**. In some embodiments, the surgical bone cutting system **100** further includes a support substrate **95**; and a locking arm **99**, the support substrate **95** configured to retain the surgical subject **96** in a secured and fixed position, the locking arm **99** configured to retain the trajectory guide **10** in a secured and fixed position relative to the support substrate **95**, the surgical subject **96**, or both.

In some embodiments, the method for excising bone further includes, after the step of establishing access to the surgical site **97**, securing the trajectory guide **10** to the locking arm **99** and fixing the locking arm **99** relative to the support substrate **95**; and passing at least the distal portion **43** of the osteotome **40** through the proximal opening of the trajectory guide **10** whereby interference between an outer wall of the osteotome **55** and an inner wall of the trajectory guide **15** effectively controls the trajectory of the inserted osteotome **40** along a trajectory established by the trajectory guide **10**.

In some embodiments, the locking arm **99** is a robotic arm **99**, the surgical bone cutting system **100** further including an alignment and navigational system that comprises a robot (**R**) that is controlled by the navigational system.

In some embodiments, the method for excising bone further includes providing coordinates for a target trajectory **90** relative to the surgical site **97** within a three dimensional

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space, wherein the three dimensional space is defined by coordinates that include at least a portion of the support substrate **95**, at least a portion of the surgical subject **96**, or both, affixing the trajectory guide **10** to the robotic arm **99**, and directing motion of the robotic arm **99** to position the trajectory guide **10** into alignment with the target trajectory **90**.

In some embodiments, the step of establishing access to the surgical site **97** includes selecting a surgical site **97** within a human spine and wherein the selected surgical site **97** is adjacent bone that is a facet joint, the method for excising bone further including one or more of the steps of mechanically driving at least a portion of the distal cutting tip **47** of the osteotome **40** into bone followed by removing the osteotome **40** from the trajectory guide **10**, and mechanically driving at least a portion of the distal cutting tip **47** into bone followed by passing the bone drill or auger within the through channel **41** of the osteotome **40** and into contact with bone and activating the drill or auger to remove bone tissue. In some particular embodiments, the method includes specifically mechanically driving at least a portion of the distal cutting tip **47** of the osteotome **40** into bone followed by removing the osteotome **40** from the trajectory guide **10**, followed by insertion of one or more other surgical instruments into the surgical site **97** to manipulate bone or soft tissue therein.

Any one of the steps according to the embodiments of the inventive methods as described herein may be repeated, including the steps of introducing and removing the osteotome **40** from the surgical site **97**, in any order or combination, to effect bone penetration and/or removal.

While various inventive aspects, concepts, and features of the general inventive concepts are described and illustrated herein in the context of various exemplary embodiments, these various aspects, concepts, and features may be used in many alternative embodiments, either individually or in various combinations and sub-combinations thereof. Unless expressly excluded herein, all such combinations and sub-combinations are intended to be within the scope of the general inventive concepts. Still further, while various alternative embodiments as to the various aspects, concepts, and features of the inventions (such as alternative materials, structures, configurations, methods, devices and components, alternatives as to form, fit and function, and so on) may be described herein, such descriptions are not intended to be a complete or exhaustive list of available alternative embodiments, whether presently known or later developed.

Those skilled in the art may readily adopt one or more of the inventive aspects, concepts, or features into additional embodiments and uses within the scope of the general inventive concepts even if such embodiments are not expressly disclosed herein. Additionally, even though some features, concepts or aspects of the inventions may be described herein as being a preferred arrangement or method, such description is not intended to suggest that such feature is required or necessary unless expressly so stated. Still further, exemplary, or representative values and ranges may be included to assist in understanding the present disclosure; however, such values and ranges are not to be construed in a limiting sense and are intended to be critical values or ranges only if so expressly stated. Moreover, while various aspects, features and concepts may be expressly identified herein as being inventive or forming part of an invention, such identification is not intended to be exclusive, but rather there may be inventive aspects, concepts and features that are fully described herein without being expressly identified as such or as part of a specific invention.

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Descriptions of exemplary methods or processes are not limited to inclusion of all steps as being required in all cases, nor is the order that the steps are presented to be construed as required or necessary unless expressly so stated. Further, while disclosed benefits, advantages, and solutions to problems have been described with reference to specific embodiments, these are not intended to be construed as essential or necessary to the invention.

What is claimed is:

1. A surgical bone cutting system, comprising:

i. a trajectory guide comprising opposing proximal and distal openings and having a generally cylindrical shape;

ii. an osteotome having a through channel suitable for receiving a bit suitable for penetrating bone inserted therethrough, and comprising a proximal portion, a distal portion comprising a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig comprising a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and comprising opposing pairs of concave radiused cutting edges suitable for penetrating bone; and

iii. a bone drill or auger comprising a bit suitable for penetrating bone,

wherein the trajectory guide and osteotome are configured to be arranged by passage of at least a portion of the distal portion of the osteotome through the proximal opening of the trajectory guide.

2. The surgical bone cutting system according to claim 1, wherein the proximal portion of the osteotome has a generally cylindrical shape.

3. The surgical bone cutting system according to claim 1, wherein the trajectory guide defines a generally hollow bone collection chamber between its proximal and distal openings, and wherein the trajectory guide is sized and shaped for insertion within a generally cylindrical surgical retractor that comprises a proximal handle and a distal retractor end for contacting bone.

4. The surgical bone cutting system according to claim 1, the guide shaft comprising at least one elongate slot aperture.

5. The surgical bone cutting system according to claim 4, wherein each of the guide shaft and the distal cutting tip has a square cross-sectional shape, and the at least one elongate slot aperture is present in least one of four opposing walls of the guide shaft.

6. The surgical bone cutting system according to claim 1, wherein the trajectory guide proximal opening has a shape and dimension that corresponds with the cross-sectional shape and dimension of the distal cutting tip of the osteotome.

7. The surgical bone cutting system according to claim 1, wherein the guide shaft of the osteotome is tapered relative to the central portion.

8. The surgical bone cutting system according to claim 1, wherein the central portion is generally cylindrical, the central portion comprising a first pair of opposing sides, one or both of the first pair of opposing sides comprising an elongate aperture that tapers towards the guide shaft, the central portion also comprising a second pair of opposing sides each comprising concave radiused taper.

9. A surgical bone cutting system, comprising:

i. a trajectory guide comprising opposing proximal and distal openings;

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ii. an osteotome having a through channel, and comprising a proximal portion, a distal portion comprising a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig comprising a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and comprising opposing pairs of concave radiused cutting edges suitable for penetrating bone;

iii. a bone drill or auger comprising a bit suitable for penetrating bone, and

iv. a support substrate and a locking arm, the support substrate configured to retain a surgical subject in a secured and fixed position, the locking arm configured to retain the trajectory guide in a secured and fixed position relative to the support substrate, the surgical subject, or both,

wherein the trajectory guide and osteotome are configured to be arranged by passage at least the distal portion of the osteotome through the proximal opening of the trajectory guide, the osteotome have a maximum outer diameter that is less than an inner diameter of the trajectory guide to effectively control the trajectory of the inserted osteotome along a trajectory established by the trajectory guide when it is secured to the locking arm and the locking arm is fixed relative to the support substrate.

10. The surgical bone cutting system according to claim 1, wherein the locking arm is a robotic arm, the surgical bone cutting system further comprising an alignment and navigational system that comprises a robot that is controlled by the navigational system to align the trajectory guide when connected to the robotic arm within a three dimensional space based on predetermined coordinates, wherein the three dimensional space is defined coordinates that include at least a portion of the support substrate, at least a portion of the surgical subject, or both.

11. A method for excising bone from a clinical subject, the method comprising:

a. providing a surgical bone cutting system that includes

i. a trajectory guide comprising opposing proximal and distal openings and having a generally cylindrical shape;

ii. an osteotome having a through channel suitable for receiving a bit suitable for penetrating bone inserted therethrough, and comprising a proximal portion, a distal portion comprising a cutting jig, and a central portion between the proximal portion and the distal portion, the cutting jig comprising a guide shaft and a distal cutting tip, the guide shaft being tapered relative to at least the proximal portion, and the distal cutting tip having a square or rectangular cross-sectional shape and comprising opposing pairs of concave radiused cutting edges suitable for penetrating bone; and

iii. a bone drill or auger and a bit suitable for penetrating bone

b. establishing access to a surgical site adjacent a bone of a surgical subject;

c. positioning and fixing the trajectory guide in a selected position with respect to the surgical site;

d. directing at least a portion of the distal portion of the osteotome through the proximal opening of the trajectory guide and securing the osteotome into engagement with bone in the surgical site.

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12. The method for excising bone according to claim 11, wherein the access to the surgical site includes securing to the surgical subject one or more instruments selected from the group consisting of a surgical wire, a dilator, a retractor, and a combination thereof.

13. The method for excising bone according to claim 12, wherein the step of establishing access to the surgical site includes securing a cylindrical retractor to the surgical subject, and wherein the trajectory guide is sized and shaped for insertion within the cylindrical surgical retractor and defines a generally hollow bone collection chamber between its proximal and distal openings.

14. The method for excising bone according to claim 13, the method for excising bone further comprising the steps of mechanically driving at least a portion of the distal cutting tip into bone followed by passing the bone drill or auger within the through channel of the osteotome and into contact with bone and activating the drill or auger to remove bone tissue.

15. The method for excising bone according to claim 14, the method for excising bone further comprising collecting bone within the collection chamber.

16. The method for excising bone according to claim 11, wherein the osteotome has a maximum outer diameter that is less than an inner diameter of the trajectory guide, the surgical bone cutting system further comprising;

iv. a support substrate; and

v. a locking arm, the support substrate configured to retain the surgical subject in a secured and fixed position, the locking arm configured to retain the trajectory guide in a secured and fixed position relative to the support substrate, the surgical subject, or both.

17. The method for excising bone according to claim 16, the method for excising bone further comprising, after the step of (c) establishing access to the surgical site, the steps comprising:

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securing the trajectory guide to the locking arm and fixing the locking arm relative to the support substrate; and passing at least the distal portion of the osteotome through the proximal opening of the trajectory guide whereby interference between an outer wall of the osteotome and an inner wall of the trajectory guide effectively controls the trajectory of the inserted osteotome along a trajectory established by the trajectory guide.

18. The method for excising bone according to claim 17, wherein the locking arm is a robotic arm, the surgical bone cutting system further comprising

vi. an alignment and navigational system that comprises a robot that is controlled by the navigational system.

19. The method for excising bone according to claim 18, the method for excising bone further comprising, providing coordinates for a target trajectory relative to the surgical site within a three dimensional space, wherein the three dimensional space is defined by coordinates that include at least a portion of the support substrate, at least a portion of the surgical subject, or both, affixing the trajectory guide to the robotic arm, and directing motion of the robotic arm to position the trajectory guide into alignment with the target trajectory.

20. The method for excising bone according to claim 19, wherein the step of establishing access to the surgical site includes selecting a surgical site within a human spine and wherein the selected surgical site is adjacent bone that is a facet joint, the method for excising bone further comprising the step selected from the group consisting of (1) mechanically driving at least a portion of the distal cutting tip into bone followed by removing the osteotome from the trajectory guide, (2) mechanically driving at least a portion of the distal cutting tip into bone followed by passing the bone drill or auger within the through channel of the osteotome and into contact with bone and activating the drill or auger to remove bone tissue, and (3) a combination thereof.

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