United States Patent Application Publication	20250262063
Kind Code	A1
Publication Date	August 21, 2025
Inventor(s)	Kowalski; Matthew

SACROILIAC JOINT FUSION IMPLANTS

Abstract

Bone implants, assemblies, and methods thereof. The implants may include non-threaded triangular implants configured to promote fixation and fusion of the sacroiliac joint. The implants may have a triangular body configured to prevent or minimize rotational motion of the implant. The implants may include an inner core or an outer shell, which provides structural support for a lattice structure. The structural geometry may be generated through topology optimization software, such as finite element analysis, based on anatomical loading conditions for the implant.

Inventors: **Kowalski; Matthew (Eagleville, PA)**

Applicant: **GLOBUS MEDICAL, INC.** (AUDUBON, PA)

Family ID: **1000007786757**

Appl. No.: **18/444861**

Filed: **February 19, 2024**

Publication Classification

Int. Cl.: **A61F2/44** (20060101); **A61F2/30** (20060101)

U.S. Cl.:

CPC **A61F2/447** (20130101); **A61F2/30771** (20130101); **A61F2/30942** (20130101); A61F2002/30156 (20130101); A61F2002/30304 (20130101); A61F2002/30383 (20130101); A61F2002/30393 (20130101); A61F2002/30476 (20130101); A61F2002/30604 (20130101); A61F2002/30845 (20130101); A61F2002/3092 (20130101); A61F2002/3093 (20130101)

Background/Summary

FIELD OF THE INVENTION

[0001] The present disclosure relates to surgical devices, and more particularly, to implants and methods for fusing a sacroiliac joint.

BACKGROUND OF THE INVENTION

[0002] The sacroiliac joint (SI joint or SIJ) is the joint between the sacrum and the ilium bones of the pelvis. Limiting the rotational range of motion (RROM) in the sacroiliac joint has been of increasing interest to surgeons as evidence grows in support of the sacroiliac joint as a pain generator. The sacroiliac joint pain may stem from pregnancy (SIJ dysfunction), adjacent segment disease, trauma, anatomical variations such as excessive lumbar lordosis, osteoarthritic, inflammatory arthritis, etc. In many cases, the etiology may be treated with fusion of the sacroiliac joint.

[0003] Development in implants aim to ensure fixation and promote rapid fusion. Patients that receive sacroiliac joint fixation receive revision surgery 30.8% of the time compared to only 5.7% of patients that receive sacroiliac joint fusion. The revisions may be due to loosening of the screws, which lead to the reoccurrence of sacroiliac joint pain. As such, there currently exists a need to combine the clinical benefit of limiting the rotational range of motion, while being able to provide fixation and precise insertion methods of an implant to provide fusion.

SUMMARY OF THE INVENTION

[0004] To meet this and other needs, implants, assemblies, and methods are provided. In particular, the sacroiliac joint may be fixated and/or fused via a non-threaded implant. The implant may have a triangular body configured to prevent or minimize rotational motion of the implant and to promote fixation and fusion of the sacroiliac joint. The implant may include an inner core or an outer shell, which provides structural support for a lattice structure. The structural geometry may be generated through topology optimization software, such as finite element analysis, based on anatomical loading conditions for the implant. The geometry may be irregular, non-uniform, non-structured, or amorphous with unique patterns suited to each implant style. These implants may be used in bilateral, open, and percutaneous approaches to the spine and/or ilium and may be compatible with robotic and/or navigation systems.

[0005] According to one embodiment, a sacroiliac implant includes a dowel extending along a central longitudinal axis having a distal tip configured to facilitate insertion into bone and a proximal end configured to be engaged by an instrument. The dowel has a triangular cross-section with three faces and three vertices configured to limit rotational motion about the central longitudinal axis. The dowel includes a solid portion for providing structural integrity and a lattice portion for facilitating bone growth. The solid portion includes an amorphous geometry optimized based on anatomical loading conditions for the implant.

[0006] The sacroiliac implant may include one or more of the following features. The amorphous geometry for the solid portion may be developed by finite element analysis (FEA). The solid portion may include an inner core, for example, having an outer framework with three beams forming the three vertices of the dowel and an inner framework having the amorphous geometry. The amorphous geometry may define a plurality of irregular openings that vary in shape and size. The lattice portion may surround the inner framework and fills in the irregular openings. The distal tip may be a self-broaching tip with stepped cutting flutes in the form of concentric rings. The solid portion may include an outer shell, for example, having solid walls with non-uniform windows. The lattice portion may be a block sized and dimensioned to fit within the outer shell. The lattice portion may be securable to the outer shell with a spring latch.

[0007] According to one embodiment, a sacroiliac implant includes a structural core extending along a central longitudinal axis having a tapered nose configured to facilitate insertion into bone and a proximal end configured to be engaged by an instrument. The structural core has three fins extending outward from the central longitudinal axis. Three outer insert trays are receivable within

respective channels defined between adjacent fins of the structural core, thereby forming a triangular outer shape for the implant.
[0008] The sacroiliac implant may include one or more of the following features. The fins may be oriented at 120-degree intervals from each other. Each fin may have a base portion with tapered planar sides and a tip portion with a triangular tip. Each insert tray may include a multi-faceted inner surface configured to fit against the base portions of the fins. Each insert tray may include an outer surface defining a lattice structure. The lattice structure may include a porous scaffold configured to promote bone growth surrounded by a rim.
[0009] According to one embodiment, a method for stabilizing a sacroiliac joint includes (a) providing an implant having a triangular cross-section with three faces and three vertices, wherein the implant includes a solid portion for providing structural integrity and a lattice portion for facilitating bone growth, wherein the solid portion includes an amorphous geometry with irregular openings optimized based on anatomical loading conditions for the implant; (b) accessing an ilium of a patient; and (c) inserting the implant across the sacroiliac joint such that once the implant is fully seated, the implant prevents rotational motion of the implant. The method may include inserting multiple implants across the sacroiliac joint to better stabilize and prevent movement of the joint. The method may include accessing the sacroiliac joint with a robotic and navigational system.
[0010] Also provided are kits including implants of varying types and sizes, bone fasteners, spinal rods, k-wires, insertion tools, instruments, bone cement, biomaterials, and other components for performing the procedure(s).

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0011] A more complete understanding of the present invention, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings, wherein:
[0012] FIGS. **1**A-**1**B show perspective and front views, respectively, of a triangular sacroiliac implant having an inner core with projecting fins and outer insert trays with lattice according to one embodiment;
[0013] FIGS. **2**A-**2**B show the inner core and outer insert trays for the triangular sacroiliac implant of FIGS. **1**A-**1**B;
[0014] FIG. **3**A-**3**B show perspective and front views, respectively of a triangular sacroiliac implant having a main structural body with open channels and overlaying lattice walls according to one embodiment;
[0015] FIG. **4** shows a perspective view of the main structural body for the triangular sacroiliac implant of FIGS. **3**A-**3**B;
[0016] FIGS. **5**A-**5**B show a triangular sacroiliac implant with an outer cage and inner framework having an amorphous geometry filled with a lattice structure according to one embodiment;
[0017] FIG. **6** shows the inner structural framework for the implant of FIGS. **5**A-**5**B with the lattice structure omitted for clarity;
[0018] FIGS. **7**A-**7**B show forces applied to the implant to create an optimized generative topology for the inner framework according to one embodiment;
[0019] FIGS. **8**A-**8**C show perspective, front, and rear views, respectively, of a triangular sacroiliac implant with an outer cage and an inner generative topography framework according to one embodiment;
[0020] FIGS. **9**A-**9**B show perspective and side views, respectively, of a triangular sacroiliac implant with an outer cage having a self-cutting tip, an inner generative topography framework,

and a lattice structure according to one embodiment;
[0021] FIGS. **10**A-**10**B show an alternative self-broaching tip for the triangular sacroiliac implant of FIGS. **9**A-**9**B;
[0022] FIG. **11** shows a perspective view of a triangular sacroiliac implant with an outer shell filled with an inner lattice structure having a spring latch configured to secure the lattice to the outer shell according to one embodiment;
[0023] FIGS. **12**A-**12**B show the inner lattice structure with the spring latch, and the outer shell filled with the lattice structure with the tip omitted, respectively; and
[0024] FIGS. **13**A-**13**B show cross-sectional views of the spring latch secured to the outer shell, without and with lattice shown, respectively, according to one embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[0025] Implants, assemblies, and systems are configured to fixate and/or fuse the sacroiliac joint. The implants may be non-threaded with triangular bodies, which are configured to promote bone fixation and/or prophylactically fuse the sacroiliac joint. The bone implants may be used independently or may include the capability to integrate with long rod constructs, for example, with a tulip or other suitable attachment interface, to prophylactically fuse the sacroiliac joint.
[0026] These implants may be used in bilateral, open, and percutaneous approaches to the spine and/or ilium and may be compatible with robotic, imaging, and/or navigation systems. Further details of robotic and/or navigational systems can be found, for example, in U.S. Pat. Nos. 10,675,094, 9,782,229, and U.S. Patent Publication No. 2017/0239007, which are incorporated herein by reference in their entireties for all purposes.
[0027] Although described herein with reference to the sacroiliac joint, it will be appreciated that the devices described herein may be applied to other areas of the spine, other orthopedic locations in the body, and other medical procedures, such as trauma applications. Any of the implants described herein may be offered in a multitude of styles, sizes, and lengths, helping to ensure optimal patient fit.
[0028] The implants or components thereof may be comprised of titanium, stainless steel, cobalt chrome, cobalt-chrome-molybdenum, tungsten carbide, carbon composite, plastic or polymer—such as polyetheretherketone (PEEK), polyethylene, ultra-high molecular weight polyethylene (UHMWPE), resorbable polylactic acid (PLA), polyglycolic acid (PGA), allograft, autograft, or combinations of such materials or any other appropriate material that has sufficient strength to be secured to and hold bone, while also having sufficient biocompatibility to be implanted into a body. Although the above list of materials includes many typical materials out of which implants may be made, it should be understood that implants comprised of any appropriate material are contemplated.
[0029] Turning now to the figures, where like reference numbers may refer to like elements, FIGS. **1**A-**1**B shows an orthopedic fixation device, triangular dowel, or triangular implant **10** according to one embodiment. The implant **10** may include an inner or internal core **12**, which provides structural support for outer lattice insert trays **14**. The outer insert trays **14** may include a lattice structure **56** configured to promote bony growth and improve bone interface strength. The implant **10** extends from a proximal end **16** to a distal end **18** along a central longitudinal axis **20**. The distal end **18** may have a tapered nose **40** configured to enter the bone first, and the proximal end **16** may be configured to engage bone or be otherwise secured to a rod construct. The implant **10** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint. In addition, the implant **10** may be configured for ease of removal, if necessary.
[0030] With further emphasis on the front view of implant **10** shown in FIG. **1**B, the implant **10** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The assembled implant **10**, including inner core **12** with three outer insert trays **14** attached thereto, may have a general triangular prism shape including three outer surfaces or faces **24** and three angled corners or vertices **26**. The outer surfaces or faces **24** may be generally flat or planar

faces. The vertices **26** may be sharp or pointed or otherwise configured to engage bone. In one embodiment, the outer periphery of the implant **10** is an equilateral triangle with three equal planar faces **24** and three equal vertices **26** of the same angle. The outer triangular shape of the implant **10** is configured to provide rotational and axial fixation in the bone.

[0031] The internal core **12** is configured to hold three outer insert trays **14**, thereby resulting in the overall outer triangular shape of implant **10**. As best seen in FIG. **2**A, the internal core **12** may include a body with three wings or fins **30** extending outward from the central axis **20**. The fins **30** may extend outward from the central axis **20** and may be oriented at 120-degree intervals from each other, giving the core **12** a symmetrical, three-fold rotational symmetry. Each fin **30** may have a base portion **32** and a tip portion **34**. The base portion **32** may have flat, planar sides with a taper. For example, as the base portion **32** extends from the central axis **20** out toward the tip portion **34**, the base portion **32** may have a greater thickness near the base portion **32**, which narrows gradually toward the tip portion **34**. The fins **30** may have a solid construction or may define one or more windows to provide pathways for bony through-growth. In one embodiment, windows may be provided through the inner core **12**, for example, between each face of the external profile of the assembled implant **10** to promote fusion.

[0032] The tip portion **34** of each fin **30** may form a triangular tip with a tapered design that narrows to a point, thereby forming the vertices **26** of the outer triangular shape of the implant **10**. Opposite sides of each tip portion **34** may include an overhang **36** relative to the base portion **32**. The areas of overhang **36** may form the bottom of the triangular tip portion **34**. The areas of overhang **36** between adjacent fins **30** define a channel **38** configured to receive the insert tray **14**. In other words, three separate insert trays **14** are receivable within three respective channels **38** defined between adjacent fins **30**. Each channel **38** may further be defined by the walls of the base portion **32** of each fin **30**. As best seen in FIG. **1**B, the walls of the base portions **32** may define angled insets, for example, having a 120-degree angled recess for receiving the insert tray **14**. In this manner, the inner surface **50** of each insert tray **14** may be configured to contact the walls of the base portion **32** of the fins **30**. To prevent accidental disassembly of the insert trays **14** from the core **12**, the core channels **38** may be cut non-parallel to the face of the insert trays **16**. It will also be appreciated that one or more gaps may be formed between the insert tray **13** and fins **30** to allow for additional bony ingrowth, if desired.

[0033] The internal core **12** may form nose **40**, which tapers toward the distal end **18**, to facilitate insertion into bone. The nose **40** be blunt, pointed, or otherwise configured to engage bone. For example, a distal face **42** of each fin **30** may be tapered, angled, or beveled from the vertex **26** of the tip portion **34** toward the distal end **18** of the core **12**. The distal face **42** of each fin **30**, including base portion **32** and fin portion **34**, may resemble an arrow pointing toward the proximal end **16** of the core **12**. The core tip or nose **40** may have an angulation similar to a trocar tip to allow bony material to be pushed to the periphery of the outer profile of the implant **10**. The angled nose **40** may also prevent bony ingrowth on its tip to make potential removals easier, if needed.

[0034] The proximal end **16** of the core **12** may include one or more notches **42**. For example, angular notches **42** may be positioned along the central longitudinal axis **20** and on the tip portions **34** of each fin **30** at the proximal-most end **16**. These notches **42** may be configured to interface with an implant holder or insertion instrument, for example. The internal core **12** may define a central cannulation **44** along the central longitudinal axis **20** between the proximal and distal ends **16**, **18**. The central cannulation **44** may include a generally cylindrical bore extending through the body of the core **12**, for example, for guiding the implant **10** over a guide wire or k-wire.

[0035] With emphasis on FIG. **2**B, the insert trays **14** are shown in more detail. In this embodiment, the internal core **12** is configured to support three outer insert trays **14**, thereby resulting in the triangular shape of implant **10**. Each insert tray **14** includes an inner surface **50** and an outer surface **52**. The inner surface **50** may include a multi-faceted surface with two areas that bend to create an angle of 120 degrees between adjacent facets. For example, the inner surface **50** may be bifurcated

by a straight edge **54**, which extends along the bend between the two adjoining planes of the inner surface **50**. The straight edges **54** of each tray **14** may be parallel with the longitudinal axis **20** of the implant **10**. As best seen in FIG. **1**B, the inner surface **50** of the tray **14** may be configured to contact the bottom surface of channel **38** when the insert tray **14** is positioned within each respective channel **38** in the core **12**.

[0036] The outer surface **52** defines a lattice structure **56**, which provides a scaffold for bone healing and bone interdigitation. The lattice structure **56** may include a uniform or non-uniform lattice. The lattice structure **56** may include a porous scaffold structure, for example, including micropores. As the bone heals, the bone grows into the microporous structure further enhancing fixation. In some embodiments, the lattice structure **56** may have grid, honeycomb, hexagonal struts, or other patterns to promote bony in-growth. The lattice structure **56** may include a randomized or repeating pattern of open or interconnected pores. The lattice structure **56** may also vary in type, size, or porosity, for example, along the length of the implant **10**. The pores may be spherical, partially spherical, or of another suitable pore shape or configuration. The lattice structure **56** may have a suitable porosity (open volume), for example, greater than 50% open, greater than 60% open, greater than 70% open. In one embodiment, the lattice structure **56** may have a porosity in the range of about 50-80% to maximize the potential for bony in-growth. The lattice structure **56** may have pore sizes, for example, ranging from approximately 100 μm-2 mm, approximately 100 μm-1 mm, approximately 200-900 μm, or approximately 300-800 μm in diameter. Additional details on suitable porous structures are described, for example, in U.S. Pat. No. 10,524,926, which is incorporated by reference herein in its entirety for all purposes.

[0037] The insert trays **14** may have a solid or smooth area absent of lattice structure **56**, thereby adding structural integrity to the tray **14**. The lattice structure **56** may be surrounded by a solid edge, rim, or wall **58**. In other words, the outer perimeter of the tray **14** may form a solid wall **58** and the inner area may be filled with the lattice structure **56**. The thickness, depth, or volume of the lattice structure **56** may be provided to optimize bone growth. In addition, the thickness of the lattice structure **56** may be oversized for an increased press-fit of the implant **10**. The edges of the tray **14** may be straight and meet at sharp angles. The distal end **18** of each tray **14** may have a triangular shape with trapezoidal faces **60** that taper to a point or distal edge **62**. The proximal end **16** of each tray **14** may have a notch **64**, such as a square recess, which may be similar to notches **42**. The proximal notches **64** may be centrally located on the back of each tray **14** and configured to interface with an implant holder or insertion instrument, for example. As best seen in FIG. **1**A, the insert trays **14** may fit within channels **38** between fins **30** and extend from the distal end **16** of the implant **10** while revealing a portion of nose **40** of the core **12**. The insert trays **14** may include optional through-growth windows on the back side of the trays **14**, which mate with corresponding windows (not shown) in the core internal faces to further promote bony through-growth between each face of the external profile in the assembled implant **10**.

[0038] In one embodiment, the implant **10** may be created via a hybrid build with the internal core **12** manufactured using traditional methods rather than three-dimensional (3D) printing. The internal core **12** may be made, for example, by machining the core **12** from titanium. The core **12** provides the structural support for the insert trays **14**. Although titanium is exemplified, it will be appreciated that the core **12** may be made of a variety of materials, offering flexibility in material selection, to increase structural integrity of the implant **10**. The insert trays **14** may be created by additive manufacturing, such as three-dimensional (3D) printing. The additive manufacturing may include direct metal laser sintering (DMLS), powder bed fusion, vat photopolymerization, material jetting, lamination, extrusion, directed energy deposition, or any other suitable additive manufacturing process. Further, one or more surface treatments may be used to increase the frictional force between internal components and/or to enhance bone fusion.

[0039] After the components are built, the insert trays **14** may be assembled to the core **12**. The insert trays **14** may be inserted through the back of the core **12** prior to implantation or intra-

operatively. The trays **14** may be secured to the inner core **12** via a press-fit engagement, a threaded retention feature, or other suitable securing mechanism. The implant **10** may be implanted across the sacroiliac joint to fixate and fuse the joint. Once implanted in the sacroiliac joint, the trays **14** and core **12** provide anti-rotational features to help stabilize the implant **10**. The lattice structure **56** may help to promote bony ingrowth and improve bone interface strength over time.

[0040] Turning now to FIGS. **3**A-**3**B, an orthopedic fixation device, triangular dowel, or triangular implant **100** is shown according to one embodiment. Implant **100** includes an inner or internal core **112** with lattice insets or walls **114**. The internal core **112** acts as the internal structure, which supports the lattice walls **114**. The internal core **112** may have open channels **134**, which lay underneath the layer of lattice **156** to promote fusion. The lattice structure **156** may also help to promote bony growth and improve bone interface strength. The implant **100** extends from a proximal end **116** to a distal end **118** along a central longitudinal axis **120**. The distal end **118** may have a tapered nose **140** configured to enter the bone first, and the proximal end **116** may be configured to engage bone or be otherwise secured to a rod construct. The implant **100** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint.

[0041] With further emphasis on the front view of implant **100** shown in FIG. **3**B, the implant **100** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The implant **100** may have a general triangular prism shape including three outer surfaces or faces **124** and three angled corners or vertices **126**. The outer surfaces or faces **124** may be generally flat or planar faces. In this embodiment, the vertices **126** may be smoothed, rounded, or curved into a gentle arc. In one embodiment, the outer periphery of the implant **100** is an equilateral triangle with three equal planar faces **124** and three equal vertices **126** of the same angle. The outer triangular shape of the implant **100** is configured to provide rotational and axial fixation in the bone.

[0042] The internal core **112** is configured to hold three lattice walls **114**, thereby resulting in the outer triangular shape of implant **100**. As best seen in FIG. **4**, the internal core **112** may include a generally triangular body with three outer faces **130**. Each outer face **130** may define a recessed or inset area **132** configured to receive the lattice wall **114**. The inset area **132** may extend from the proximal end **116**, a distance toward the distal end **118**. The inset area **132** may resemble a U-shape or archway with two parallel sides with a semi-circle or arc connecting the parallel sides. The U-shape archway may form a blind recess near the nose **140** of the implant **100**. The inset area **132** may be open to the proximal end **116**, allowing access to the inset area **132**. In this manner, if constructed with a hybrid assembly, each lattice wall **114** may be slid into the inset area **132** from the rear of the implant **100**, thereby allowing for assembly of the implant **100**.

[0043] The internal core **112** may have a solid construction or may define one or more windows **134** to provide pathways for bony through-growth. In one embodiment, a plurality of windows **134** may be provided through each inset area **132**. Windows **134** from different sides or faces **130** may be in fluid communication with one another. The windows **134** may include cylindrical openings of different diameters. For example, a first set of circular windows **134** having larger diameters may be aligned centrally through inset area **132** and a second set of circular windows **134** having smaller dimeters may be arranged in pairs between the larger windows **134**. It will be appreciated that any suitable shape, size, and configuration of windows **134** may be provided to promote fusion.

[0044] The internal core **112** may form nose **140**, which tapers toward the distal end **118**, to facilitate insertion into bone. The nose **140** may be blunt, pointed, or otherwise configured to engage bone. For example, three distal faces **142** may be tapered, angled, or beveled from the vertex **126** of the implant **100** to the distal end **118** of the core **112**. Each face **142** may define a self-harvesting channel **136** to incorporate bony material left after drilling. Each self-harvesting channel **136** may be a circular or cylindrical opening cut non-perpendicular to the tapered distal

faces **142**. As best seen in FIG. **3**B, the self-harvesting channels **136** may be aligned parallel to the central longitudinal axis **120** of the implant **100**, which results in oval-shaped or elliptical openings on each of the distal faces **142**. The internal core **112** may define a central cannulation **144** along the central longitudinal axis **120** between the proximal and distal ends **116**, **118**. The central cannulation **144** may include a generally cylindrical bore extending through the body of the core **112**, for example, for guiding the implant **100** over a guide wire or k-wire. The windows **134** may be in fluid communication with the cannulation **144**.

[0045] The lattice insets **114** may include a wall or layer of lattice structure **156**, which provide a scaffold for bone healing and bone interdigitation. Each layer of lattice **156** may be sized and shaped to fit within the inset area **132** in the core **112**. For example, the lattice layer **156** may resemble a U-shape with two parallel sides and a semi-circle or arc connecting the parallel sides, which mimics the shape of the inset area **132**. Similar to lattice structure **56**, the lattice structure **156** may include uniform or non-uniform porous scaffold structure, for example, including micropores. The central body **112** and lattice **114** may be made as one 3D printed body or may be a hybrid assembly with the lattice portion **156** utilizing inserts similar to implant **10**. As the bone heals, the bone grows into the lattice structure **156** and the open channels **134** in the core **112** further enhancing fixation.

[0046] Turning now to FIGS. **5**A-**5**B, an orthopedic fixation device, triangular dowel, or triangular implant **200** is shown according to one embodiment. Implant **200** includes a structural core **212** surrounded with lattice **214**. The skeleton of the structural core **212** may be determined from computational analysis to predict the implant's behavior under load and boundary conditions. The structure of implant **200** is configured to maximize strength and osteoregenerative volumes. The surrounding lattice **214** helps to promote bony growth and improve bone interface strength. The implant **200** extends from a proximal end **216** to a distal end **218** along a central longitudinal axis **220**. The distal end **218** may have a triangular tip configured to enter the bone first, and the proximal end **216** may be configured to engage bone or be otherwise secured to a rod construct. The implant **200** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint.

[0047] Similar to implant **100**, the implant **200** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The implant **200** may have a general triangular prism shape including three outer surfaces or faces **224** and three angled corners or vertices **226**. The outer surfaces or faces **224** may be generally composed of or filled with the lattice structure **214**. The vertices **226** may be pointed or sharpened to facilitate insertion. In one embodiment, the outer periphery of the implant **200** is an equilateral triangle with three equal planar faces **224** and three equal vertices **226** of the same angle. The outer triangular shape of the implant **200** is configured to provide rotational and axial fixation in the bone. The structural core **212** may define a central cannulation **244** along the central longitudinal axis **220** between the proximal and distal ends **216**, **218**. The central cannulation **244** may include a generally cylindrical bore extending through the body of the core **212**, for example, for guiding the implant **200** over a guide wire or k-wire **246**.

[0048] As best seen in FIG. **6**, which omits the lattice structure for clarity, the structural core **212** may include an outer framework **230** and an inner framework **232**. The outer framework **230** may include an outer cage with three supports or beams **234**, which form the borders or edges of the vertices **226** of the triangle. The beams **234** may include thin straight strips of material, such as titanium, extending between a front end **236** and a rear end **238**. The front end **236** may include a beveled or triangular tip with cutting edges to ease impaction and prevent radial breaking of bone upon insertion. The beveled tip of the front end **236** allows bony material to be packed on the distal tip and trapped into the lattice **214**. The rear end **238** may have a triangular shape with each vertex connected to the respective beams **234**.

[0049] The inner framework **232** may include an irregular, non-uniform, non-structured, or

amorphous solid structure simulated or modeled from computational analysis, for example, using software on a computer. In one embodiment, the inner framework **232** may be developed and optimized using finite element analysis (FEA), solid mechanics simulations, dynamic analysis software, or other suitable engineering programs configured to model loads on a part and simulate the behavior of the part under specified conditions. In one embodiment, the structure of the inner framework **232** is generated using finite element analysis to predict the implant's behavior under load and boundary conditions. Finite element analysis may be software available on a computer, which may include at least a CPU (central processing unit), memory such as ROM (read only memory) and/or RAM (random access memory), communication means, input means such as a mouse or a keyboard, and output means such as a display. It will be appreciated that any suitable equipment and modeling software may be selected to optimize the structure of the inner framework **232**.

[0050] The finite element analysis may include modeling the implant, defining the material type and properties, and simulating loads or external forces acting on the body of the implant. As best seen in FIGS. **7**A-**7**B, a plurality of specified loads or forces on the implant **200** are depicted by arrows **240**. In FIG. **7**B, additional struts **242** are provided between the beams **234**, for example, as straight bracing and cross bracing with diagonal supports placed in an X-shaped manner. The load cases may be modeled for each indicated trajectory, implantation method, and/or worst-case load scenarios. The load cases may be applied as pressure, force, rotation moments, and/or bearing loads depending on the length of the implant **200** and its use. The loads may be applied in the direction of transferred forces at surfaces that align to typical patient anatomy for each trajectory available for a given implant length.

[0051] The finite element analysis may be used to model the inner framework **232** to maximize structural integrity and minimize structural volumes based on load cases expected. Based on the prior simulation and modeling, the inner framework **232** is created to define openings **233** of various shapes and sizes. The openings **233** may include a collection of holes and gaps that do not conform to a single shape or size standard. The openings **233** may be non-uniform and include a mix of irregularly shaped holes that vary in dimensions. The number, size, shape, and positioning of openings **233** may be optimized to maximize structural integrity while reducing the size or amount of material used in the construction of the framework **232**. Each implant length may have its own unique structural core **212** to maximize strength and porous volume. In other words, each implant length may have a different irregular, non-uniform, non-structured, or amorphous geometry based on the load modeling.

[0052] The structural core **212** may be surrounded and/or filled with lattice **214**, which may act as a scaffold for bone healing and bone interdigitation. Similar to lattice **56**, the lattice structure **214** may include a uniform or non-uniform porous scaffold structure. In this embodiment, the finite element analysis simulation may also be used to maximize porous volumes and optimize the percentage of lattice volume, thereby further enhancing fixation and fusion of the sacroiliac joint.

[0053] Turning now to FIGS. **8**A-**8**C, an orthopedic fixation device, triangular dowel, or triangular implant **300** is shown according to one embodiment. Implant **300** is similar to implant **200** and includes a structural core **312**, which may be modeled by computational analysis to predict the implant's behavior under load and boundary conditions. The openings **333** in the core **312** may be left open or may be optionally filled with lattice. The implant **300** extends from a proximal end **316** to a distal end **318** along a central longitudinal axis **320**. The distal end **318** may have a triangular tip configured to enter the bone first, and the proximal end **316** may be configured to engage bone or be otherwise secured to a rod construct. The implant **300** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint.

[0054] Similar to implant **200**, the implant **300** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The implant **300** may have a general triangular prism shape including three outer surfaces or faces **324** and three angled corners or vertices **326**.

The outer surfaces or faces **324** may be generally composed of the inner framework **332**. The vertices **326** may include the outer framework **330** with pointed or sharpened edges to facilitate insertion. In one embodiment, the outer periphery of the implant **300** is an equilateral triangle with three equal planar faces **324** and three equal vertices **326** of the same angle. The outer triangular shape of the implant **300** is configured to provide rotational and axial fixation in the bone. The structural core **312** may define a central cannulation **344** along the central longitudinal axis **320** between the proximal and distal ends **316**, **318**. The central cannulation **344** may include a generally cylindrical bore extending through the body of the core **312**, for example, for guiding the implant **300** over a guide wire or k-wire.

[0055] The structural core **312** may include outer framework **330** and inner framework **332**. The outer framework **330** may include an outer cage with three supports or beams **334** extending between a front end **336** and a rear end **338** of the implant **300**. The three supports or beams **334** form the borders or edges of the vertices **326** of the triangle. The beams **334** may include thin straight strips of material, such as titanium. The front end **336** may form a nose **340**, which tapers toward the distal end **318**, to facilitate insertion into bone. The nose **340** may include a beveled or triangular tip with cutting edges to ease impaction and prevent radial breaking of bone upon insertion. For example, three distal faces **342** may be tapered, angled, or beveled from the vertices **326** of the implant **300** to the distal end **318** of the core **312**.

[0056] Each distal face **342** may define a self-harvesting channel **343** to incorporate bony material left after drilling. Each self-harvesting channel **343** may be a non-circular opening cut through the tapered distal faces **342**. The channels **343** may facilitate self-harvesting of material into the open framework **312** of the implant **300**. The nose **340** may also be configured to push material toward the outer perimeter of the implant face. In other words, the tip's channels **343** may serve a dual purpose of self-harvesting and directing material to the outer perimeter of the implant **300**.

[0057] The rear end **338** of the implant **300** may have a thickened triangular shape with each vertex connected to the respective beams **334**. To ensure stability during the implantation process across the joint, grooves or channels **346** on the proximal end **316** of the implant **300** may be configured to mate with an implant holder, thereby preventing rotation. As best seen in FIG. **8**C, the channels **346** may include three straight channels **346** crossed over the center axis **320** and extending from the vertex **326** to the base of the opposite face **324**. It will be appreciated that other suitable configurations may be provided to interface with an instrument. The proximal end **316** of the implant **300** also provides stability and prevents rotation during implantation.

[0058] In the same manner as inner framework **232**, inner framework **332** may include an irregular, non-uniform, non-structured, or amorphous solid structure, which was previously simulated or modeled by computational analysis, for example, using finite element analysis (FEA). The inner framework **332** may be a single body that has been 3D printed using a symmetric generative topography framework, which ensures the structural integrity of the implant **300**. The inner framework **332** defines openings **333** of various sizes and shapes, which may be optimized to maximize structural integrity while reducing the size or amount of material used in the construction of the framework **332** based on load cases expected. Within the central region of the implant **300**, the openings **333** may remain open or may be optionally filled with lattice. The lattice may include uniform lattice or non-uniform lattice. If present, the lattice may further provide a scaffold for bone healing and bone interdigitation. Each implant length may have its own unique structural core **312** to maximize strength and porous volume.

[0059] Turning now to FIGS. **9**A-**9**B, an orthopedic fixation device, triangular dowel, or triangular implant **400** is shown according to one embodiment. Implant **400** includes a structural core **412** filled with lattice **414**. The skeleton of the structural core **412** may be determined from computational analysis to predict the implant's behavior under load and boundary conditions. The surrounding lattice **414** helps to promote bony growth and improve bone interface strength. The implant **400** extends from a proximal end **416** to a distal end **418** along a central longitudinal axis

420. The distal end **418** may have a self-broaching tip configured to enter the bone first, and the proximal end **416** may be configured to engage bone or be otherwise secured to a rod construct. The implant **400** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint.

[0060] The implant **400** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The implant **400** may have a general triangular prism shape including three outer surfaces or faces **424** and three angled corners or vertices **426**. The outer surfaces or faces **424** may be generally composed of the lattice structure **414**. The vertices **426** may be pointed or sharpened to facilitate insertion. In one embodiment, the outer periphery of the implant **400** is an equilateral triangle with three equal planar faces **424** and three equal vertices **426** of the same angle. The outer triangular shape of the implant **400** is configured to provide rotational and axial fixation in the bone. The structural core **412** may define a central cannulation **444** along the central longitudinal axis **420** between the proximal and distal ends **416**, **418**. The central cannulation **444** may include a generally cylindrical bore extending through the body of the core **412**, for example, for guiding the implant **400** over a guide wire or k-wire.

[0061] The structural core **412** may include an outer framework **430** and an inner framework **432**. The outer framework **430** may include an outer cage with three supports or beams **434** extending between a front end **436** and a rear end **438** of the implant **400**. The three supports or beams **434** form the borders or edges of the vertices **426** of the triangle. The beams **434** may include straight strips of material, such as titanium. The front end **436** may include a self-broaching tip with stepped cutting flutes or teeth **440**. As best seen in FIG. **9**B, the stepped cutting flutes **440** may include concentric rings **442** which step from a small diameter at the distal end **418** to a larger diameter as the rings **442** transition to beams **434** of the outer framework **430**. The rings **442** may be truncated as the front end **436** transitions from circular to triangular shapes. In an alternative embodiment shown in FIGS. **10**A-**10**B, the stepped cutting flutes **440** may include divergent flat cutting steps **446** with flutes on the flat sides. The divergent flat cutting steps **446** may be bifurcated to fan out and/or angle away from one another. The fluted areas **440** may be separated from one another by longitudinal channels or grooves **450** that run parallel to the length of the implant **400**. The grooves **450** may define smooth rounded or curved recesses configured to guide the bony material during insertion. In each tip configuration, the self-broaching and/or self-harvesting functionality minimizes surface area for implantation while providing additional surface area for bony on-growth. The stepped cutting flutes **440** may further help to promote fusion and reduce operative time.

[0062] The rear end **438** of the implant **400** may have a thickened triangular shape with each vertex connected to the respective beams **434**. The proximal end **416** may also include one or more fins **448**. For example, a pair of fins **448** may be located on each face **424** and along the vertices **426** of the implant **400**, thereby increasing the profile of the implant **400** at its proximal end **416**. Each fin **448** may have an angular shape with an enlarged proximal end. Each fin **448** may narrow in width and thickness as it extends distally seamlessly integrating into the beams **434**. The fins **448** may provide a tactile response to the surgeon, acting as additional resistance when the implant **400** is nearing the end of the implantation process. The fins **448** may also help to reduce the likelihood of implanting past the cortical section of bone, thereby contributing to enhanced surgical precision.

[0063] The inner framework **432** may include an irregular, non-uniform, non-structured, or amorphous solid structure, which was previously simulated or modeled by computational analysis, for example, using finite element analysis (FEA). The inner framework **432** may be a single body that has been 3D printed with a symmetric structural framework generated through topography optimization software based on anatomical loading conditions. In some instances, the inner framework **432** may mimic angled struts extending between the opposite beams **434**, which define irregular openings **433** therebetween. The irregular openings **433** may resemble triangular shapes but may be non-uniform in size or shape. The generative framework **432** may be complemented by

overlapping lattice framework **414** that intentionally does not completely fill the void within the volume containing the generative framework **434**. The area of lattice **414** near the distal end **418** may have a greater or more open porosity than the area of lattice **414** near the proximal end **416** of the implant **400**. In this manner, the self-harvesting tip **436** is able to channel more bony material into the central region of the implant without encountering obstructions. The lattice framework's non-uniform density may be configured to support and enhance the self-harvesting tip's functionality. The implant **400** combines broaching with implant insertion, streamlining operative procedures, and leveraging the force of implantation to self-harvest and pack internal channels, thereby promoting fusion.

[0064] Turning now to FIG. **11**, an orthopedic fixation device, triangular dowel, or triangular implant **500** is shown according to one embodiment. Unlike previous implants having an inner core, implant **500** has an outer cage or shell **512** filled with lattice **514**. The assembly **500** may include outer shell **512** with windows **530** created by generative topology optimization and internal 3D printed lattice **514** inserted into the shell **512**. The inner lattice **514** may be secured to the outer shell **512** with a spring latch **540** or other suitable connector. The implant **500** may be 3D printed as a single body. Alternatively, the implant **500** may have a hybrid structure where the lattice body **514** is 3D printed and the outer shell **512** is machined or 3D printed separately. Then, the inner lattice body **514** may be assembly to the outer shell **512**, for example, via spring latch **540**. The implant **500** extends from a proximal end **516** to a distal end **518** along a central longitudinal axis **520**. The distal end **518** may have a removable tip **532** configured to enter the bone first, and the proximal end **516** may be configured to engage bone or be otherwise secured to a rod construct. The implant **500** may be precisely inserted into bone to limit the rotational range of motion and prophylactically fuse the sacroiliac joint.

[0065] Similar to the other implants described herein, the implant **500** may define a polygonal outer shape, such as a three-sided polygon having a triangular cross-section. The outer shell **512** may have a general triangular prism shape including three outer surfaces or faces **524** and three angled corners or vertices **526**. The vertices **426** may be pointed or sharpened to facilitate insertion. In one embodiment, the outer periphery of the shell **512** is an equilateral triangle with three equal planar faces **524** and three equal vertices **526** of the same angle. The outer triangular shape of the implant **500** is configured to provide rotational and axial fixation in the bone.

[0066] The outer shell **512** may include solid walls with windows **530** defined therethrough. The outer shell **512** may include a series of windows **530** defined into each face **524** of the implant **500**. The layout of windows **530** may be based on previously simulated or modeled computational analysis, for example, using finite element analysis (FEA). The outer shell **512** may define non-uniform windows **530** including irregularly shaped holes of various sizes and shapes. The size, shape, placement, and spacing of the windows **530** may be optimized to maximize structural integrity while reducing the size or amount of material used in the construction of the shell **512** based on load cases expected. The outer shell **512** may be a single body that has been 3D printed or machined using conventional manufacturing. Each implant length may have its own unique outer shell **312** to maximize strength and open volume.

[0067] The distal end **518** of the outer shell **512** may include a removable tip **532**. The tip **532** may form a triangular tip with a tapered design that narrows toward the distal end **518**. The tip **532** may fit in corresponding opening **534** sized and dimensioned to receive the tip **532**. When the tip **532** is removed as shown in FIG. **12**B, the inner lattice **514** may be inserted into the front of the outer shell **512**. This mitigates the risk of postoperative disassembly and eliminates the need to remove mating material on the proximal end **516**, which is used for engagement with an implant holder. Once assembled, the tip **532** may be secured to the distal end **518** of the outer shell **512**. The proximal end **516** of the outer shell **512** may include one or more notches **536**. For example, angular notches **536** may be positioned along the central longitudinal axis **520** and at the corners of each face **524** at the proximal-most end **516**. These notches **536** may be configured to interface

with an implant holder or insertion instrument, for example.
[0068] As best seen in FIG. **12**A, the inner lattice **514** may include a lattice body or block sized and dimensioned to fit within the outer shell **512**. The lattice body **514** may have a tapered or narrowed nose **538** to fit in the tip **532** of the outer shell **512**. As described for the other embodiments, the lattice structure **514** may include a uniform or non-uniform 3D printed lattice, which acts as a scaffold for bone healing and bone interdigitation.
[0069] The inner lattice **514** may include a spring latch mechanism **540** configured to secure the inner lattice **514** in the outer shell **512**. The spring latch **540** is configured to fit snugly into one of the open sections on the outer shell **512**. The spring latch **540** may be located on an outside portion of the lattice **514**. As best seen in FIGS. **13**A-**13**B, the spring latch **540** may include a spring tab **542** defined by a spring cut **544**. The spring cut **544** defines the size, shape, and degree of flexibility of the tab **542**. The spring cut **544** partially surrounds the tab **542** isolating it on three sides while leaving the tab **542** attached to the main body. The free end **546** of the tab **542** can flex or move outward acting like a spring. When inserted into the outer shell **512**, the free end **546** of spring latch **540** engages a corresponding opening **540** in the outer shell **512**, thereby securing the inner lattice **514** to the outer shell **512**. The spring latch **540** is configured to avoid protrusion to the perimeter of the assembly, thereby preventing inadvertent depression of the latch **540**. The spring latch **540** ensures a secure and reliable mating interface between the outer shell **512** and the inner lattice **514**, contributing to the overall stability and safety of the implant **500**. Although a spring latch **540** is exemplified in this embodiment, it will be appreciated that other suitable securing mechanism may be used to retain the inner lattice **514** in the outer shell **512**.
[0070] Some of the implants described herein may combine the clinical benefit of limiting the rotational range of motion, while being able to provide fixation and precise insertion methods of the implant. Some of the implant structures may be generated through topology optimization software based on anatomical loading conditions to maximize potential fusion area without compromising structural strength. The implants may include lattice structures to promote bony on-growth and through-growth. The hybrid and 3D printed assemblies may provide structural integrity with optimized space for the lattice framework to increase bone interface strength. The implants may include various tip styles, such as trocar tips, self-broaching tips, and self-harvesting tips to reduce operative time.
[0071] A method for stabilizing a sacroiliac joint may include (a) providing one or more implants of types described herein; (b) accessing an ilium and/or a sacrum of a patient through a lateral approach or a posterior approach (e.g., lateral to medial or medial to lateral); and (c) inserting the implant across the sacroiliac joint, thereby providing fixation and promoting fusion of the two bones. Multiple implants may be inserted across the joint to better stabilize and prevent movement of the sacroiliac joint. The anatomy of the patient may be accessed using a standard or minimally invasive surgical (MIS) technique. The surgery may be performed with the assistance of robotic and/or navigational systems.
[0072] In some embodiments, interchangeable components and/or instrumentation may be provided. This may help to reduce the number of sets required in the operating room and to streamline the technique. Using instrumentation across platforms further reduces the manufacturing burden by reducing the number of new instruments required.
[0073] It will be further understood that various changes in the details, materials, and arrangements of the parts which have been described and illustrated in order to explain the nature of this invention may be made by those skilled in the art without departing from the scope of the invention as expressed in the claims. One skilled in the art will appreciate that the embodiments discussed above are non-limiting. It will also be appreciated that one or more features of one embodiment may be partially or fully incorporated into one or more other embodiments described herein.

Claims

1. An implant comprising: a dowel extending along a central longitudinal axis having a distal tip configured to facilitate insertion into bone and a proximal end configured to be engaged by an instrument, the dowel having a triangular cross-section with three faces and three vertices configured to limit rotational motion about the central longitudinal axis, wherein the dowel includes a solid portion for providing structural integrity and a lattice portion for facilitating bone growth, wherein the solid portion includes an amorphous geometry optimized based on anatomical loading conditions for the implant.
2. The implant of claim 1, wherein the amorphous geometry for the solid portion is developed by finite element analysis.
3. The implant of claim 1, wherein the solid portion includes an inner core.
4. The implant of claim 3, wherein the inner core includes an outer framework with three beams forming the three vertices of the dowel and an inner framework having the amorphous geometry.
5. The implant of claim 4, wherein the amorphous geometry defines a plurality of irregular openings that vary in sizes.
6. The implant of claim 5, wherein the lattice portion surrounds the inner framework and fills in the irregular openings.
7. The implant of claim 1, wherein the distal tip is a self-broaching tip with stepped cutting flutes in the form of concentric rings.
8. The implant of claim 1, wherein the solid portion includes an outer shell.
9. The implant of claim 8, wherein the outer shell includes solid walls with non-uniform windows.
10. The implant of claim 8, wherein the lattice portion is a block sized and dimensioned to fit within the outer shell.
11. The implant of claim 10, wherein the lattice portion is securable to the outer shell with a spring latch.
12. An implant comprising: a structural core extending along a central longitudinal axis having a tapered nose configured to facilitate insertion into bone and a proximal end configured to be engaged by an instrument, the structural core having three fins extending outward from the central longitudinal axis; and three outer insert trays receivable within respective channels defined between adjacent fins of the structural core, thereby forming a triangular outer shape for the implant.
13. The implant of claim 12, wherein the fins are oriented at 120-degree intervals from each other.
14. The implant of claim 12, wherein each fin has a base portion with tapered planar sides and a tip portion with a triangular tip.
15. The implant of claim 14, wherein each insert tray includes a multi-faceted inner surface configured to fit against the base portions of the fins.
16. The implant of claim 12, wherein each insert tray includes an outer surface defining a lattice structure.
17. The implant of claim 16, wherein the lattice structure includes a porous scaffold configured to promote bone growth surrounded by a rim.
18. A method for stabilizing a sacroiliac joint, the method comprising: providing an implant having a triangular cross-section with three faces and three vertices, wherein the implant includes a solid portion for providing structural integrity and a lattice portion for facilitating bone growth, wherein the solid portion includes an amorphous geometry with irregular openings optimized based on anatomical loading conditions for the implant; accessing an ilium of a patient; and inserting the implant across the sacroiliac joint such that once the implant is fully seated, the implant prevents rotational motion of the implant.
19. The method of claim 18 further comprising inserting multiple implants across the sacroiliac joint to better stabilize and prevent movement of the joint.

20. The method of claim 18 further comprising accessing the sacroiliac joint with a robotic and navigational system.